pISSN: 1976-1317 eISSN: 2093-7482

VOLUME 13 | NUMBER 2 | MAY 2019

ASIAN NURSING RESEARCH

Eui Geum Oh, PhD, RN, FAAN
Editor-in-Chief

Korean Society of Nursing Science

Currently Indexed in SCIE, SSCI and SRS
http://www.asian-nursingresearch.com

ELSEVIER

This journal was supported by the Korean Federation of Science and Technology Societies Grant funded by Korean Government (Ministry of Education)

Asian Nursing Research 15 (2021) 157–162

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Invited Review Article

Model Setting and Interpretation of Results in Research Using Structural Equation Modeling: A Checklist with Guiding Questions for Reporting

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ARTICLE INFO

Article history:
Received 16 April 2021
Received in revised form
27 May 2021
Accepted 4 June 2021

Keywords:
Factor analysis
Goodness of fit index
Latent variable
Measurement model
Structural equation model
Structural model

ABSTRACT

Purpose: This study develops a checklist with guidelines for the methods and important factors to consider in research using structural equation modeling (SEM).
Method: The paper discusses the factors to consider in the process across the three stages of 1) model setting, 2) model evaluation and modification, and 3) interpretation and reporting of SEM-based studies.
Results: The authors present a checklist for researchers during the stages of model setting, model evaluation and modification, result analysis, and reporting, along with examples of figures and tables with explanations.
Conclusion: A checklist will help to improve the reporting quality of SEM-based studies.

Introduction

Structural equation modeling (SEM) is a research method that is widely used to verify complex phenomena in the field of nursing, related to various themes such as humans, health, and the environment. It formalizes the structural relationships between cause-and-effect variables in the area of interest into an equation system. Theories or abstract constructs that cannot be directly measured or observed often serve as research topics in the nursing field to not only understand humans in an integrated manner but also identify the relationships between these concepts [1].

SEM is a data analysis method that is widely used in many fields of study as it has many advantages: First, measurement errors can be controlled. Second, mediating variables can be easily utilized. Third, a statistical evaluation of the theoretical model is possible [2]. In other words, the researcher can evaluate how well the theoretical model constructed by himself/herself fits the actual data and either accept the model as valid, or modify it as necessary.

However, it is difficult to show an appropriate consistent form in reporting the research methods, results, and discussions because the SEM data analysis process is complicated [3]. This is because sufficient data on the model's goodness-of-fit, significance of hypothetical relationships, variances in the structural model, and explanations of how the theoretical model fits the actual data must be provided. Due to such difficulties, a considerable number of studies do not effectively utilize the advantages of SEM [4]; moreover, researchers have been criticized for the inappropriate use of SEM and its resulting problems [1].

This paper presents a checklist with the factors that should be taken into consideration when analyzing data using SEM by dividing the process into the following stages: the model setting stage, the model evaluation and modification stage, and the interpretation and reporting stage. It is hoped that the suggestions put forth will be considered by researchers in their attempts to improve research quality and descriptive narratives.

Checklists and guiding questions when conducting an SEM-based study

Table 1 presents a checklist and guiding questions to address during the stages of model setting, model evaluation and

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https://doi.org/10.1016/j.anr.2021.06.001
p1976-1317 e2093-7482/

Table 1 *A Checklist for SEM Model Setting and Evaluation.*

Topic	Item	Guide questions
Model setting	1	Measurement of observed variables – Are the observed variables measured by a valid and reliable measurement tool?
	2	Measurement model setting - Do observed variables represent each latent variable? - Do the observed variables that define each latent variable measure the same concept? - Is each latent variable defined to represent a single concept (or meaning)? - Can the sizes of the latent variables be compared? Or, is it possible to compare the size of the measurements of the latent variable? Or, can you tell the size (large/small) of each latent variable?
	3	Structural model setting - Are there any missing causal relationships or associations between latent variables? - Are causal relationships or associations between latent variables based on theory and empirical facts or results?
Evaluation and modification of the model	4	Do most GFIs show reasonable fitness?
	5	Have all the relatively large modification indices been considered?
	6	Has the parsimony of the model been pursued?
	7	Have the equivalent and alternative models been considered?
	8	Has the relationship between measurement and endogenous error variables been reviewed?
Interpretation and reporting of the model	9	Have all the descriptive statistics and correlation coefficients of the observed variables been reviewed?
	10	Have major GFIs been reported?
	11	Have the main results of the measurement model been presented appropriately?
	12	Were the main results for the structural model adequately presented?
	13	Have the major results of the mediating effect been reported appropriately?

modification, result analysis, and reporting in SEM-based studies. Details on each topic will be explained below.

Model setting

The researcher conducting confirmatory research may have some prior knowledge about the structure of data from existing theories or empirical research results. Thus, he/she may be in a position to state it in a hypothetical form and test the hypothesis through actual data. Such a hypothesis is usually constructed on the basis of specific theories that need to be tested, the given experimental plan, known experimental conditions, and preliminary research results based on big data.

Meanwhile, exploratory research focuses on concisely describing the phenomena of interest, exploring valuable information about the data, and discovering meaningful interpretations, without assuming the aforementioned types of prior knowledge. Of course, the researcher may conduct an exploratory and a confirmatory research concurrently in an actual research situation, rather than clearly distinguishing between the two types of research. However, since SEM is a part of confirmatory research in the sense that it is based on research hypotheses, it is important to establish a valid hypothesis based on theories of and empirical results from the relevant field. For example, determining which variable is the cause and which is the effect in the causal relationship between two variables should be based entirely on the knowledge of the theory and practice in the relevant field. Therefore, sufficient prior research of theories and actual phenomena in the relevant field should be conducted when employing SEM.

In general, SEM includes a number of observed, latent, and error variables. In Figure 1 (A), x_1 and y_1 are observed variables; motivation and satisfaction are latent variables; and δ_1, ε_1, and ζ_1 are error variables. The relationship between these variables is divided into a measurement model and a structural model.

Measurement model

The measurement model defines how latent variables are measured through observed variables. The characteristics of observed variables are of interest because measurement variables construct abstract hypothetical concepts. Here, measurement errors that inevitably occur during the measurement process are also reflected.

The direct analysis targets of SEM are the variance and covariance of the observed variables. Therefore, observed variables should be measured using tools whose validity and reliability have been verified. Tools should be reviewed prior to conducting SEM research because their validity and reliability cannot be evaluated during the course of the research process.

The validity of the measurement model is of primary importance in developing the SEM. Some points to remember are: (1) Observed variables that represent each latent variable must be set. For example, when defining the latent variables of language abilities, we cannot agree whether the observed variables of Korean, English, music, and physical education are selected. If an observed variable that is not valid for a latent variable is selected, SEM results will not be recognized on a logical basis, regardless of their statistical significance. An indirect approach employed in SEM includes latent variables being reflected through the observed variables. From this perspective, the observed variables are called indicators of the latent variables. There are additional considerations when defining latent variables through observed variables [5]. (2) Observed variables that define one latent variable should be able to measure the same concept. (3) A latent variable is not simply a bundle or a description of observed variables. For example, it is meaningless to not only define a latent variable as a "general characteristic" by grouping observed variables such as gender, age, occupation, and education, but also to define a latent variable as a "work characteristic" by grouping them based on wards worked, years of service, positions, and educational background. (4) A latent variable should be defined to represent a single concept. For example, it is not desirable to define a latent variable called a "psychological state" with observed variables of happiness, confidence, depression, and anxiety, since each of these observed variables measures a different concept. (5) Path coefficients should be interpreted with directionality when describing the causal/correlational relationship between latent variables. In other words, they should be able to gauge the size of the latent variables. However, it is difficult to determine whether "general characteristic" or "work characteristic" are large or small.

It is "desirable" to have at least two, but usually "recommended" that there be three to four, observed variables for one latent variable [6,7]. However, inevitably, there are some cases wherein there may be only one observed variable for one latent variable, which means that the observed variable for the latent variable has not been sufficiently secured. In such cases, the theoretical or practical reason should be explained. When a single indicator problem occurs, the method usually employed for model identification involves fixing the variance of the error variable at a specific value. In general, the error variance is fixed at 0. However, it is recommended that it be fixed with "variance of observed variable $\times$ (1-reliability)" if the measurement reliability is known, since this reflects the estimates of the measurement error [8].

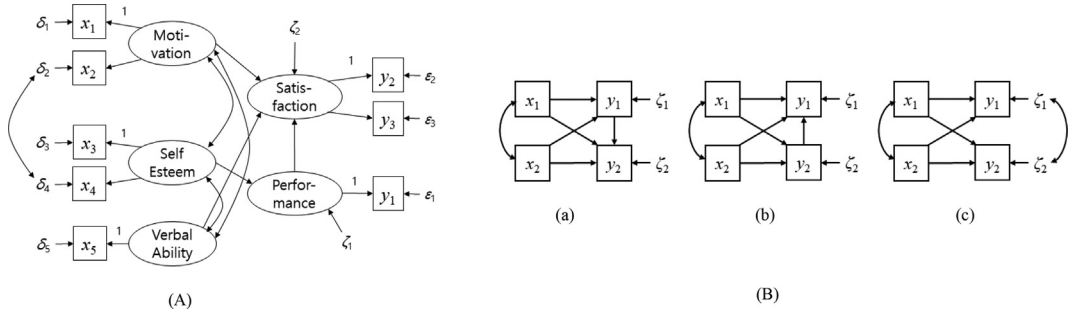

Figure 1. (A). A path diagram of structural equation model. (B). Examples of equivalent models.

Structural model

The structural model defines the causal relationships and associations between latent variables. It also includes a description of error variations that are not explained through the model. Of course, setting an appropriate structural model is important. In the path diagram shown in Figure 1 (A), the one-way arrow refers to the researcher's hypothesis that there is a causal relationship between the variables. However, it is important to remember that the hypothesis is reflected even in paths without arrows. As can be seen, there are no arrows between "motivation" and "performance." This means that the researcher establishes the hypothesis that there is no causal relationship between these two variables. It should also be reiterated that the establishment of this structural model should be based on theories of and empirical results from the relevant field.

Several studies have low goodness-of-fit because they have failed to consider the relationship of exogenous variables [9]. When the relationship between exogenous variables is not established in the structural model, it is the same as assuming independence between them. This will result in a greatly deteriorated goodness-of-fit. Therefore, it is necessary to establish the relationship between exogenous variables when setting up the model, except in cases where there is clear evidence that no relationship exists. Note that the LISREL software automatically establishes the relationship between exogenous variables. AMOS, on the contrary, requires that the user establish these relationships.

Evaluation and modification of model

The primary purpose of SEM is to evaluate how much of the model assumed by the researcher is supported by the data. SEM should be based on the researcher's confirmatory hypothesis as a whole. However, modification is allowed to some extent through actual phenomena.

Goodness-of-fit

Since the goodness-of-fit is an indication of whether the established SEM reflects the data situation well, a poor goodness-of-fit renders the results unreliable. Therefore, model evaluation through the goodness-of-fit indices is a primary process that should be performed when interpreting the results of SEM.

Because there are various goodness-of-fit indices, it is not easy to determine which index to use for an evaluation since each evaluates different aspects of the model fit. The literature recommends the chi-square statistic and degrees of freedom (χ^2/df), goodness-of-fit index (GFI), adjusted goodness of fit index (AGFI), root mean squared error of approximation (RMSEA), and standardized root mean square residual (SRMR) as absolute fit indices; comparative normed fit index (CFI) and Tucker-Lewis index (TLI) as incremental fit indices; parsimony normed fit index (PNFI) as a parsimonious fit index; and expected cross validation index (ECVI) as a predictive fit index [2,6,10,11].

In most cases, the quality of the goodness-of-fit tends to worsen with smaller sample sizes. In such cases, care should be taken when interpreting the goodness-of-fit. In addition, the quality of the goodness-of-fit tends to worsen as the number of observed variables increases. The number of observed variables can be reduced in to simply improve the goodness-of-fit. However, the purpose of the SEM analysis is to verify the hypothetical theory, not to increase the model fit. Attempts to simply increase the goodness-of-fit can lead to incorrect model setting; consequently, the model will not properly reflect reality, and the persuasive power of the researcher's argument will be lost [12].

Goodness-of-fit measures how well the researcher's model reproduces the actual phenomenon presented in the data. However, many researchers often confuse a high degree of fit with a good model. High goodness-of-fit is the most basic of the many necessary requirements for a good model, but is not a necessary and sufficient condition. The evaluation of a good model should be made comprehensively depending on the size of the coefficients, statistical significance, and coefficient of determination (R^2). Even if the goodness-of-fit is high, it is difficult to conclude that a model is good if some coefficient values are much lower than expected or if the coefficient of determination is small.

Another frequently made error arises from confusing the goodness-of-fit with the explanatory power. While the goodness-of-fit is an indication of the appropriateness of the model, the explanatory power represents the strength of the relationship between a specific endogenous variable and explanatory variables. Explanatory power is the degree to which explanatory variables explain the variations of an endogenous variable. In general, the explanatory power of individual endogenous variables in the causal model is measured by the coefficient of determination (R^2).

Model modification

There are two ways by which to modify a model. First, parameters can be added to create a more complex model. A common reason for a poor model fit is that the model is too simple to properly represent the data structure. In such cases, it is necessary to relax the constraints on the model by introducing additional path coefficients or covariances. The modification index can be used to obtain information about which parameters should be added. The criteria for a large modification index are 4 and 10 for a small and a large number of observed variables, respectively. There are cautionary notes when using the modification index: (1) The

modification index only suggests a numerical direction, not parameters that need to be added to the model, which should be determined based on theories or hypotheses in the relevant field. It is not right to add parameters simply because the modification index is large. It also does not mean that the parameters should be added in the order of the large modification index values. (2) Modifying the model by adding some parameters affects the estimation and testing of others. Therefore, even if there are several large modification indices, free parameters should not be added at once.

Second, unnecessary parameters can be deleted to create a simpler model. Given that the goal of constructing a statistical model is to simplify and explain the complex data structure, a model that has not attempted to reduce the number of parameters is less valuable in terms of parsimony. The researcher should explain the structure of the data by using a simple model as far as possible. Statistical hypothesis testing results for parameter estimates can be used.

Equivalent model

A problem that researchers often overlook in the model modification stage is the existence of an equivalent model, which refers to a model that produces the same predicted covariance matrix although the established paths between variables may differ. A model that differs only in the direction of causal relationship but has the same df is likely to be an equivalent model. Figure 1 (B) shows an example of equivalent models. Since they have the same goodness-of-fit and df, the former alone cannot determine which of the models is superior to the other. In addition, there may be alternate models rather than an equivalent model that can explain the same phenomenon. Thus, there is the need to acknowledge the existence of such a model and present a theoretical or logical basis for the model selected by the researcher. A model with a similar-sized df and goodness-of-fit is likely to be an alternative model.

Kim (2015) stated that during the model modification and selection process, 9.8% and 18.0% of the nursing papers published in Korean reporting equivalent and alternative models, respectively, needed to be supplemented [1]. All SEMs must have equivalent models in which the relationship between variables with the same data values is arranged in different ways. Thus, there are bound to be several equivalent models in the model set by the researcher, who should be able to present a reasonable basis for the adoption of the chosen model.

Correlation of error variables

SEM contains several error variables. An error variable is a kind of exogenous variable that is introduced into the model as a cause of variation in the endogenous variable, which cannot be explained by the causal relationships included in the model. It is generally assumed that the error variables are independent of each other. In some cases, they can be assumed to be related to each other. The theoretical basis must be presented to explain the relationship between the error variables.

There are two types of error variables: First, measurement error variables may be attached to each observed variable, reflecting the measurement and observation errors of the latent variables corresponding the observed variables. When two observed variables are measured by similar tools, the association between the error observed variables may be established. In Figure 1 (A), when the observed variables x_2 and x_4 are measured by a measurement tool comprising similar content, there may be an association between the corresponding measurement error variables. It is not advisable to add the correlation of measurement errors only to improve the goodness-of-fit or because the modification index is large. Because the correlation of measurement errors is related to the validity of the measurement model, the reasons should be explained and the results should be interpreted and reported [5].

Second, there may be endogenous error variables attached to endogenous variables, reflecting not only exogenous variables missing from the current theoretical structure but also errors in the functional form of the constructed model. The association between endogenous error variables should be interpreted as a partial correlation between endogenous variables in a situation in which the relevant explanatory variables are controlled [5]. In Figure 1 (B)(c), the association between the two error variables indicates the relationship between endogenous variables y_1 and y_2, in the situation in which explanatory variables x_1 and x_2 are controlled. Many researchers face problems because they do not know the concept of partial correlation, neglect to search for partial correlations, or neglect to report the results.

Confirmatory factor model

When the number of observed and latent variables is large and the model has a complex structure, it is often difficult to determine which part to review first for model modification when the model's fit is poor. A good strategy in this case would be to separate the measurement model from the structural model and review them one by one.

The confirmatory factor model considers all latent variables only as exogenous variables. Thus, it refers to a model that is established with an association between all latent variables. No further increase in the goodness-of-fit can be expected in the structural model since all latent variables are associated with each other in the confirmatory factor model. Therefore, if the confirmatory factor model's goodness-of-fit is poor, the scope of model modification can be narrowed by re-examining the relationship between the latent and observed variables in the measurement model. After sufficiently modifying the problems occurring in the measurement model part, the structural model can be reset to its original state, following which the modification index can be used in to review the problems in the structural model part [9].

Although the strategy of separating the measurement and structural models for review by using the confirmatory factor model is very useful, it is not absolutely necessary. In simple models, model modification can be easily made without performing the aforementioned procedure. In addition, some theoretical models have been established with all associations or causal relationships between latent variables, so that they are equivalent to the confirmatory factor model.

Model interpretation and reporting

Here are examples and commonly recommended formats for reporting observed variables, goodness-of-fit, coefficients and

Table 2 *Correlation Coefficients and Standard Deviations.*

	x_1	x_2	x_3	x_4	x_5	y_1	y_2	y_3
x_1	1							
x_2	.43*	1						
x_3	.34*	.29*	1					
x_4	.25*	.35*	.62*	1				
x_5	−.39*	−.41*	−.33*	−.28*	1			
y_1	.18*	.22*	.63*	.51*	−.28*	1		
y_2	.38*	.35*	.48*	.39*	−.18*	.46*	1	
y_3	.23*	.25*	.51*	.40*	−.09*	.48*	.66*	1
S.D.	.99	.93	1.08	1.08	1.84	1.02	1.77	1.53

*$p < .05$.

Table 3 *Goodness of Fit Indices.*

Model	χ^2	df	GFI	AGFI	RMSEA	SRMR	CFI	TLI	PNFI	ECVI
Hypothetical model	24.5	3	.917	.587	.204	.103	.862	.586	.284	.246
Modified model1	2.0	2	.992	.943	.000	.028	1.000	1.000	.220	.127
Modified model 2	2.2	3	.995	.975	.000	.033	1.000	1.000	.329	.151

Note. AGFI = adjusted goodness of fit index; CFI = comparative normed fit index; df = degree of freedom; ECVI = expected cross validation index; GFI = goodness-of-fit index; PNFI = parsimony normed fit index; RMSEA = root mean squared error of approximation; SRMR = standardized root mean square residual; TLI = Tucker-Lewis index.

mediating effect estimates in measurement models and structural models, in SEM studies.

Descriptive statistics of observed variables

In SEM, the variation and association of observed variables obtained from the given data lead to the inference of causality within the model. In general, the variation is measured by the standard deviation, while the association is measured by the correlation coefficient. Therefore, they should be reviewed in detail before a full-scale analysis. Table 2 provides an example of the correlation coefficients and standard deviations between observed variables.

Care should be taken if the standard deviation is too large, because outliers may exist. However, if the standard deviation is too small, there may not be much information in the observed variables, therefore the reasons for this should be investigated. It is necessary to examine whether the sign and size of the correlation coefficients match the theoretical empirical expectations. If they are different from what is expected, the analysis results based on this data would not be valid. Each observed variable should have a relatively high correlation coefficient with the variable group defining the same latent variables, particularly when establishing a model with latent variables.

Tabachnick (2007) recommended looking at the size of the correlation coefficient based on the criterion of 0.3. [13]. When the correlation coefficient was ±0.3, ±0.4, and ±0.5, Hair (1995) classified the size as “minimal level,” “important,” and “practically significant,” respectively [14]. On the contrary, if the correlation coefficient is too large, it must be checked whether the absolute value is close to 1. If the correlation coefficient of the two measured variables is close to 1, it may mean that the two variables have the same meaning or information.

Evaluating the validity and reliability of the measurement of observed variables, while also reviewing the mean, standard deviation, skewness, kurtosis, and correlation coefficient, should be completed before applying SEM, otherwise errors occurring in the data will make the subsequent analysis meaningless.

Table 4 *Loadings of Measurement Model.*

A. Estimates of loadings

Latent variables	Measurement variables	Loadings	Standardized estimates	*p*-value	SMC
Motivation	x_1	1.00	0.61	–	0.37
	x_2	0.98	0.58	<.001	0.34
Self-esteem	x_3	1.00	0.89	–	0.80
	x_4	0.78	0.71	<.001	0.50
Verbal ability	x_5	1.00	0.92	–	0.85
Performance	y_1	1.00	1.00	–	1.00
Satisfaction	y_2	1.00	0.79	–	0.62
	y_3	0.93	0.84	<.001	0.71

B. Covariances of measurement error

Measurement variables		Covariances	Correlations	*p*-value
x_2	x_4	0.33	0.45	<.001

Goodness-of-fit index

Researchers often report only favorable fit indices. However, the chi-square statistic (χ^2), which is the most basic fit index, should be reported along with at least one absolute fit index and one incremental fit index. When comparing two or more models, it is necessary to report parsimonious fit indices or measures based on the information criteria. Table 3 provides examples of reporting results that mainly use fit indices. For detailed evaluation criteria, refer to [5,11].

Evaluation of the measurement model

Evaluation of the measurement model is crucial as it forms the logical basis for defining latent variables. Kim et al. (2015) pointed out that further extensive reports on the validity of the measurement model in the nursing field are necessary [1].

Table 4 depicts an example of the presentation of main results of the measurement model. Factor loadings, standardized estimates, *p*-values, and squared multiple correlations (SMC) for the measurement model are reported. If an association between measurement error variables is established, this should also be presented. For reference, SMC (R^2) in the measurement model indicates the size of the variation explained by the latent variables for a certain observed variable, and the relationship of ‘measurement error = 1-SMC’.

The convergent validity of the measurement model implies that the observed variables defining the same latent variable should have a relatively high correlation, which is evaluated by the factor loadings. There are several empirical views on the standardized estimate of the factor loadings. Generally, values of at least 0.3 and greater than 0.5 are interpreted as good, while values greater than 0.7 are interpreted as very good.

In addition, it is necessary to review and report whether there is a relatively large modification index for the measurement model part. The discriminant validity of the measurement model implies that there must be a low correlation between the observed variables defining different latent variables. Thus, a relatively large modification index for the measurement model part indicates a problem with discriminant validity.

Table 5 *Estimates of Structural Model.*

A. Regression weights

Endogenous variables	Exploratory variables	Estimate	Standardized estimates	*p*-value	SMC
Performance	Self-esteem	0.74	0.70	<.001	0.49
Satisfaction	Motivation	2.55	1.10	<.001	0.62
	Verbal ability	0.61	0.74	<.001	0.71
	Performance	0.44	0.32	.019	

B. Covariances of exogenous variables

Exogenous variables		Covariances	Correlations	*p*-value
Motivation	Self-esteem	0.38	0.64	<.001
Motivation	Verbal ability	−0.75	−0.73	<.001
Self-esteem	Verbal ability	−0.66	−0.41	<.001

Table 6 *Mediating Effects of Structural Model.*

Endogenous variables	Exploratory variables	Direct effects	Indirect effects	Total effects
Performance	Self-esteem	0.74 (0.70)*	–	0.74 (0.70)*
Satisfaction	Motivation	2.55 (1.10)*	–	2.55 (1.10)*
	Self-esteem	–	0.32 (0.22)*	0.32 (0.22)*
	Verbal ability	0.61 (0.74)*	–	0.61 (0.74)*
	Performance	0.44 (0.32)*	–	0.44 (0.32)*

Note. *$p < .05$; values in parentheses are standardized estimates.

Estimates of structural model

The researcher's main interest is generally in the structural model. Table 5 provides an example of the presentation of the main results of the structural model. Path coefficient estimates, standardized estimates, *p*-values, SMCs, etc. should be reported, as should the details of the associations between exogenous variables. In addition, it is necessary to provide information on the association between endogenous error variables, if any. In the structural model part, it is also necessary to review and report whether there is a relatively large modification index. For reference, SMC (R^2) indicates the size of the variation explained by other explanatory variables for a certain endogenous variable, which can be interpreted as the size of the explanatory power for each endogenous variable.

Mediating effects of structural model

One of the important features of the path analysis model or the SEM, unlike the general statistical model, is that mediating variables can be introduced. It is necessary to report the direct, indirect, and total effects of the mediating variables. Table 6 presents the standardized estimates in parentheses, along with the size of the effect, as an example of presenting the main results for mediating effects.

The Sobel test and bootstrapping are mainly used as statistical tests for mediating effects. However, the methods may differ slightly depending on the software used. Recently, an increasing number of studies have used the bootstrapping method since several software programs provide this feature.

Conclusion

The concept of SEM encompasses a very wide spectrum of models, including the measurement, regression, path analysis, and factor models. Therefore, researchers are required to have a considerable level of statistical knowledge in order to understand and perform SEM properly. However, it is not easy to understand such concepts clearly. This paper aimed to not only provide a guide to help researchers in their research with SEM, but also address possible problems in the actual data analysis process and provide precautions. We recommend that researchers use the suggested a checklist in the future to improve the reporting and research quality of SEM studies. Researchers should be able to answer “yes” to all of the items on Table 1.

Conflict of interest

The authors declared no conflicts of interest to disclose.

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Asian Nursing Research 15 (2021) 163–173

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Review Article

Relationship Between the Exposure to Occupation-related Psychosocial and Physical Exertion and Upper Body Musculoskeletal Diseases in Hospital Nurses: A Systematic Review and Meta-analysis

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ARTICLE INFO

Article history:
Received 23 March 2020
Received in revised form
16 February 2021
Accepted 24 March 2021

Keywords:
Meta-analysis
Musculoskeletal diseases
Physical exertion
Psychology

ABSTRACT

Purpose: Nurses' musculoskeletal diseases (MSDs) are worldwide prevalent and are considered to be a costly occupational injury. This study aims to investigate the relationship between exposure to occupation-related psychosocial factors, physical workload, and upper body musculoskeletal diseases among hospital nurses.

Methods: An electronic search was implemented using nine databases with June 2019 as the latest search date. English and Chinese studies were chosen, and data were independently and separately extracted by two investigators. Pooled odds ratio (OR) and its 95% confidence interval (CI) were estimated for each subset, using the fixed or random-effects model, following heterogeneity between studies for research synthesis. The source of heterogeneity was explored through subgroup, sensitivity, and meta-analyses.

Results: Eighteen studies were included in the meta-analysis. Most participants were women (51.4%–100.0%), aged between 20 and 60. A correlation was found between high job demand and the prevalence of low back pain (OR = 1.41; 95% CI = 1.23-1.62). Total job strain was related to the risk of low back pain (OR = 1.71; 95% CI = 1.15-2.55), neck pain (OR = 1.67; 95% CI = 1.26-2.20), shoulder pain (OR = 1.62; 95% CI = 1.06-2.48) and back pain (OR = 1.45; 95% CI = 1.10-1.91). Furthermore, the physical workload was significantly associated with the prevalence of low back pain (OR = 1.76; 95% CI = 1.32-2.35), neck pain (OR = 1.17; 95% CI = 1.08-1.27), shoulder pain (OR = 1.59; 95% CI = 1.37-1.85) and back pain (OR = 1.66; 95% CI = 1.45-1.90).

Conclusion: There were significant associations between occupational strain, more physical workload and upper body MSDs, but the evidence advocating a growth risk in MSDs due to low levels of social support is quite weak.

Introduction

Musculoskeletal diseases (MSDs) refer to the state of discomfort, disability, damage, or persistent pain in support systems, including the nerves, muscles, bones, joints, ligaments, tendons and blood vessels [1]. Musculoskeletal diseases are widespread worldwide and are considered to be a major occupational injury, both in developed and developing countries [2,3], and the prevalence is especially high among nurses [4,5]. Saberipour B et al. [2] and Habibi E et al. [6] reported a prevalence rate of 84.2% and 87.6% for musculoskeletal diseases among Iranian nurses, respectively. Luan HD et al. reported a prevalence rate of 74.7% for musculoskeletal diseases among nurses in Vietnam [7]. Nutzi M et al. in Switzerland reported a prevalence of MSD of 66% among nurses [8]. Similarly, numerous studies have also been carried out across the other countries such as Bakola H et al. [4]in Greece, Yan P et al. [5] in China and Kasa AS et al. [9] in Africa that respectively reported a prevalence rate of 74.9%, 62.7% and 68.5%, for MSDs among studied nurses.

Musculoskeletal diseases can lead to severe complications such as carpal tunnel inflammation, tendonitis, chest outlet syndrome, etc., and massive economic losses. In work, they are the main reason for sickness absenteeism in the United States and Brazil [10],

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https://doi.org/10.1016/j.anr.2021.03.003
p1976-1317 e2093-7482/

as well as western European countries [11], in which, regardless of productivity losses and social costs, musculoskeletal diseases cost about 2% of its gross domestic product (GDP) [12]. In Japan, work-related MSDs account for more than 62% of the causes of sick leaves longer than four days [13]. In recent years, studies have shown that the prevalence of MSDs in China remains high, including various environments and reaching over 85.7% in some industries, which has caused huge economic losses [14].

According to scientific reports, the significant correlation of MSDs can be attributed to facts that nurses experience greater occupational strain, such as high job demands, low job control or low social support [15,16] and events of the physical work overload that occurred during the patient's transferring activity. These duties, which are exposed to changing clothes, transferring, moving, cleaning, injection postures and handling of patients before and after surgeries, have been recognized to be a significant source of hospital nurses' musculoskeletal diseases [17,18].

Musculoskeletal diseases occur in different parts of the body; however, the upper body areas are more frequently more problematic than the lower extremities [17,19,20]. In other words, nurses are more prone to experience MSD in the upper body than in the lower body [17,21,22]. Although the effect of MSD on the lower-limbs region may be as important as the effect on the upper body area, there is limited research that supports lower-limbs disorders as a symptom [17,22]. Studies reported that discomfort was mostly felt in the shoulders, neck, and lower back [22–24]. For example, recent research conducted by Lin et al. indicated that the greatest prevalence of MSD symptoms among hospital nurses was found in the right shoulder (85.8%), left shoulder (80.9%), neck (62.4%) and lower back (60.4%) [22].

It is obvious that nurses' mental and physical health problems with musculoskeletal diseases and vocational stressors are key factors in reducing the quantity and quality of their work performance, especially patient care. Concomitantly, poor job performance can result in psychosocial and physical problems that could lead to depression [23]. Therefore, the prevalence of MSDs in nurses and their association with some personal and professional factors need to be studied to prevent and treat them in this sensitive group.

Many psychosocial and physical factors play a significant role in the occurrence of musculoskeletal diseases [25–27]. The relationship among occupation-related psychosocial stressors and musculoskeletal diseases, physical workload, and musculoskeletal diseases has been studied in several reviews. However, most of these are narrative reviews rather than systematic, and thus, perhaps not as comprehensive or transparent. Bernal et al. [28] conducted a systematic review and a meta-analysis to examine the relationship between work-related psychosocial factors and musculoskeletal diseases, which identified associations between high psychosocial demands with prevalent and incident low back pain, prevalent shoulder pain, and low social support with incident back pain. However, correlations between work-related low social support and prevalent or incident neck pain, shoulder pain, and low back pain were not revealed. Additionally, Koohpayehzadeh et al. [24] found that low or high psychological workload was not linked to the prevalence of shoulder or neck complaints, although correlation with high physical workload was significant.

The mechanical workload of workers can generate muscular tension, which, in turn, may induce pain or aggravate pre-existing discomfort [29]. Soroush et al. [19] reviewed and analyzed the prevalence of musculoskeletal diseases as common problems among Iranian nurses and found a strong relationship between musculoskeletal diseases and inappropriate body mechanics, such as working while bending or twisting the waist, uncomfortable postures, bending to lift an item from floor level, among others. Because of the close connection between physical workload and musculoskeletal diseases, it has been argued that vocational psychosocial and physical opportunities must be taken into account when analyzing the risk factors of career-oriented musculoskeletal diseases [30]. Although some studies have reported strong associations between physical risk factors in the workplace and musculoskeletal diseases in hospital nurses [24,26,27], to the best of our knowledge, no meta-analysis has specifically addressed the relationship between psychological, physical, and social factors on MSDs.

The purpose of the current study is to present an up-to-date meta-analysis based on cross-sectional and longitudinal study data on the relationship between occupation-related psychosocial factors, physical workload, and musculoskeletal diseases of the upper body among hospital nurses to comprehensively and systematically evaluate and quantify associations. The results of this study can provide a reference for nursing administrators and policymakers to take measures to reduce musculoskeletal diseases among nurses to promote their health, and thus, boost the quality and performance of patient care.

Methods

Search strategy

An electronic search was implemented using Web of Science, PubMed, PubMed Central, MEDLINE (OVID), Springer link, EBSCO host, CNKI, Wan Fang, SinoMed from June 15 to August 15, 2019. Our information retrieval strategy was similarly applied to all databases and incorporated three main blocks to acquire diverse aspects of our review: exposure, outcome, study population, and June 2019 as the latest search date, exploiting a combination of search criteria. The search words used were: ("Work-related stress" or "Work-related strain" or "job stress" or "work stress" or "occupational stress" or "occupational strain" or "stress at work" or "strain at work" or "effort-reward imbalance" or "psychological strain" or "job strain" or "work strain" or "mental workload" or "psychosocial risk" or "job content" or "workload" or "physical overload") AND ("work-related musculoskeletal diseases" or "back pain*" or "shoulder pain*" or "neck pain*" or "wrist pain*" or "elbow pain*" or "hand pain*" or "arm pain" or "musculoskeletal pain*") AND ("hospital patient care workers" or "nurse").

Study selection and eligibility criteria

Inclusion criteria

Inclusion criteria were (1) cross-sectional, prospective cohort, case-control studies, randomized controlled trials, published in English or Chinese, evaluating the relationship between musculoskeletal diseases and occupationally psychosocial or physical risk factors among hospital nurses; (2) types of interventions, including coaching interventions for coping with work stressors, work-place stress management and prevention programs involving psychological intervention; types of controls, including general physical exercise programs, physical training programs and physiotherapy; types of outcome measures, including incidence and location of pain; (3) nurses' occupational stress and workload, including the number, incidence and prevalence of musculoskeletal diseases with each anatomic site among groups.

Exclusion criteria

(1) Unpublished documents (e.g., dissertation) or studies that lacked detailed instruction for either exposure or outcome, incidence or prevalence of MSDs, odds ratios (OR), and 95% confidence intervals (95% CI) were excluded; (2) along with studies that

considered a wide range of hospital occupation workers, but in which data for hospital nurses were not separately analyzed.

Literature screening was independently undertaken by two researchers according to retrieval strategy and selection criteria. After duplicates were removed, the titles and abstracts were browsed to finish the record screening, then full-text articles assessed for disqualification and irrelevance were eliminated. Accordingly, the required detailed information was collected by two reviewers concerning the full text of the publications. In case of inconsistencies, a consensus meeting is held by a third reviewer or an arbitration panel to resolve conflict. As shown in Figure 1, out of 1,968 potential articles were included through database searching and other sources. A total of 532 articles were screened based on their titles and abstracts and 93 of full-text articles assessed for eligibility. Among the 93 articles, 5 that were not English or Chinese publication, 8 without specific measurement or job strain or MSD, 32 irrelevant, 25 odds ratio absent and 5 of inadequate quality were excluded. Finally, 18 publications [3,15,17,18,20,24–26,31–40] that satisfied the selection criteria were analyzed quantitatively and qualitatively. Figure 1 shows the flowchart of the study selection.

Quality assessment of the included studies

The methodological quality of each study that was included in the synthesis was appraised by an adapted version of the checklist for quality assessment developed by Windt et al. [41] and once utilized in a review of epidemiological literature by Bongers et al. [42]. This checklist is built on preexisting systematic reviews of observational studies of occupational risk factors for musculoskeletal discomfort [43]. The checklist contains the quality assessment of prospective cohort (12 items), cross-sectional (11 items), and case-control studies (15 items), including five dimensions of content: study objective, study population, exposure measurements, assessment of the outcome, analysis, and data presentation. Each item was scored as positive if the information was matched, negative (potential bias) if the information was not matched, or unclear when the paper provided insufficient information on a specific item. For each publication, a quality score was quantified according to the sum of items that were rated as positive. Publications were viewed as high-quality (low risk of bias) when the score was above 80% of the maximum possible score, intermediate quality (intermediate risk of bias) when it was between 70% and 79%, and low quality (high risk of bias) when it was below 70% [28].

Statistical analysis

When at least two studies provided data on the same outcome indicators, we conducted a quantitative synthesis. A pooled OR and its 95% CI were estimated for each subset, using fixed or random-effects models, under heterogeneity between papers for research synthesis. Cochran's Q test of heterogeneity and inverse variance (I–V) method with I^2 was performed to detect heterogeneity among the studies. According to the difference in heterogeneity, the random effect and fixed-effect models were used for the estimate, respectively. The value of I^2 is between 0% and 100%, of which 0%, 25%, 50% and 75% means that there is no, low, medium and high heterogeneity, respectively [44]. A choice for a random effect model occurred if $I^2 \geq 50\%$; otherwise, the fixed-effect model was selected to estimate a pooled OR and its 95% CI. In the fixed effect model, the inverse variance weighted average was used to estimate the effect size, whereas, in the random-effect model, it was the inverse variance heterogeneity method. All results were presented as forest

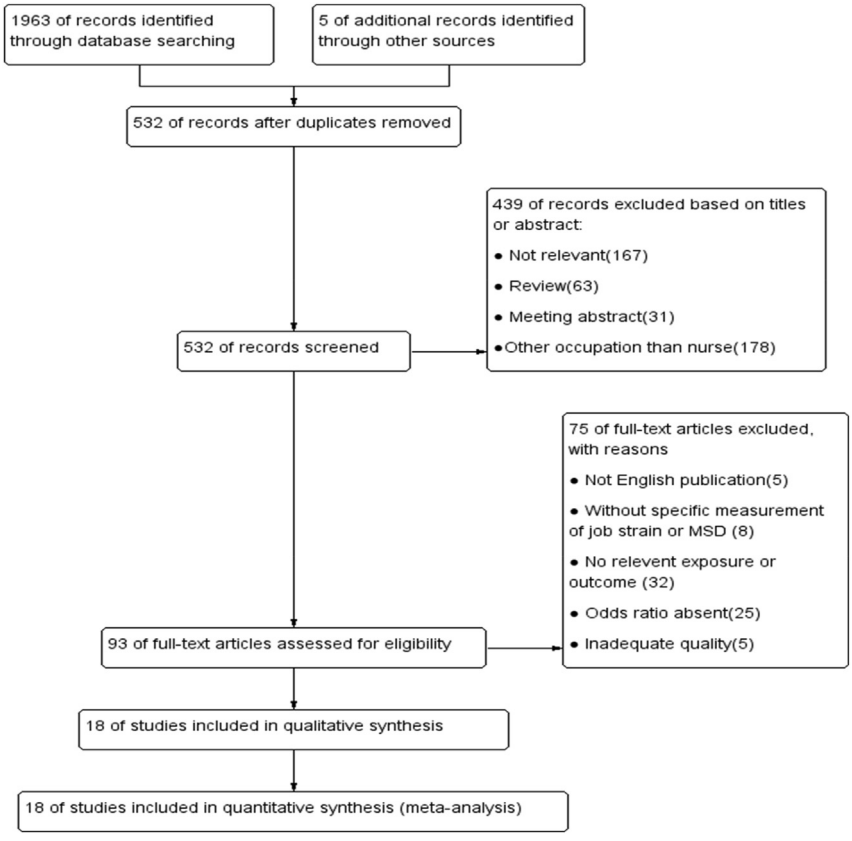

Figure 1. Flow Diagram of study selection.

plots. We explored the source of heterogeneity through subgroup analyses, sensitivity analysis, and meta-regression to check study location, study design, measurement of outcome, measurement of exposure, mean age of subjects, sample sizes and quality of studies as possible sources of heterogeneity among study findings [28]. In the sensitivity analysis, the influence of each study on the pooled effect was evaluated by excluding one study at a time. Publication bias was estimated via a funnel plot, Egger's linear regression, and Begg's rank correlation. When the funnel plot was significantly asymmetric, it was suggested that there was obvious publication bias. All statistical analyses were conducted using Stata software (version 14.0 MP) with packages METAN, METABIAS6, METANINF and METAREG, and $p < .05$ was considered statistically significant.

Results

Characteristics of the included studies

A total of 18 studies were included in our meta-analysis, with the literature consisting of 15 cross-sectional designs, two prospective cohort studies, and one retrospective cohort study. Most volunteers were women (54.1%-100%), between the ages of 20 and 60. The general and methodological information of the included studies are as follows (Table 1): author's name, year of publication, country, research design, response rate, study participants, sample size, mean age, measurement questionnaire, analytical method, adjustment variables and quality evaluation. Furthermore, characteristics of psychosocial risk factors (high job demand, low social support and total job strain) and physical risk factors (physical workload), as well as OR and 95% CI from each study, were collected. The participants were from twelve different countries and areas. Most studies were from Asia (n = 10), seven studies were conducted in Europe, and one in Australia. Fourteen studies investigated the association between psychosocial factors (high job demand, low social support and total job strain) and MSDs, while eleven studies considered physical factors (physical workload). Four anatomic sites (lower back, neck, shoulder and back) were the focus of our included designs. Thirteen studies discussed lower back pain, nine studies considered neck and back pain, and six studies considered shoulder pain. Exposure and outcome were measured using a different questionnaire. Twelve designs used a standardized questionnaire such as the Nordic Questionnaire and Karasek Job Content questionnaire to measure MSDs and psychosocial and physical risk factors, while the other six studies used the other standard scales or questionnaires designed by the researchers.

Methodological Quality

All the included publications were observational studies and were critically appraised using an adapted version of the checklist for quality assessment. Of all the included studies, 10 studies were considered high quality, having a low risk of bias (score ranged between 82.0% and 91.0%), three studies were considered intermediate quality, having an intermediate risk of bias (score ranged between 75.0% and 78.6%), and five studies were considered low quality, having a high risk of bias (score ranged between 63.6% and 69.2%). The results of each study are shown in Table 1, and there is a possibility of risk of bias.

Meta-analysis

Pooled analysis and heterogeneity are summarized in Table 2. In our meta-analysis, psychosocial risk factors were related to high job demand, low social support and total job strain. Positive outcomes were found with the prevalence of low back pain for high job demand (OR = 1.41; 95% CI = 1.23–1.62) and total job strain (OR = 1.71; 95% CI = 1.15–2.55). Exposure to total job strain was also associated with the risk of neck pain (OR = 1.67; 95% CI = 1.26–2.20), shoulder pain (OR = 1.62; 95% CI = 1.06–2.48), and back pain (OR = 1.45; 95% CI = 1.10–1.91). Unexpectedly, no statistically significant results were detected in a subset of low back pain–low social support (OR = 1.23; 95% CI = 0.85–1.78), neck pain (OR = 1.02; 95% CI = 0.97–1.08), shoulder pain (OR = 0.92; 95% CI = 0.53–1.61), and back pain (OR = 1.12; 95% CI = 0.99–1.25). However, the physical workload was significantly associated with the prevalence of low back pain (OR = 1.76; 95% CI = 1.32–2.35), neck pain (OR = 1.17; 95% CI = 1.08–1.27), shoulder pain (OR = 1.59; 95% CI = 1.37–1.85), and back pain (OR = 1.66; 95% CI = 1.45–1.90).

Subgroup analysis

High heterogeneity was found in three subsets of studies (that is, an association between low back pain and low social support; between low back pain and total job strain; and between low back pain and physical workload). Heterogeneous sources were explored via subgroup analysis planned by location, type of design, measurement, mean age, sample size and quality evaluation (Table 3). The subgroup analysis reported that high heterogeneity might stem from the mean age and location in subsets.

Sensitivity analysis

Sensitivity analysis was performed to investigate the possible sources of heterogeneity. Then, two studies created by Feng et al. [20] and Harcombe et al. [26] were ruled out in the subset of low back pain–low social support, and heterogeneity was therefore reduced with the remaining seven studies ($I^2 = 45.2\%$, $p = .090$), while the pooled effect size turned out to become statistically significant (OR = 1.37; 95% CI = 1.09–1.73). High heterogeneity in the subset of low back pain–physical workload was attributed to the study of Harcombe et al. [26] detected by sensitivity analysis. After excluding that paper, heterogeneity remarkably declined ($I^2 = 36.7\%$, $p = .177$), while the association between low back pain and physical workload was still statistically significant with a pooled odds ratio of 1.95 (95% CI = 1.57–2.42). The heterogeneous source of these studies may originate from different study populations, including nursing aides in nursing rooms in the study by Feng et al. [34], while the other investigations only recruited hospital nurses. In the subset of low back pain–total job strain, heterogeneity decreased from 58.8% ($p = .045$) to 48.2% ($p = .122$) after ruling out the study of Smith et al. [33].

Meta-regression

Three subsets with high heterogeneity were also considered for meta-regression. Only variables of "mean age" ($\beta = 0.598$, SE = 0.089, $R^2_{adj} = 100.0\%$, $p = .026$) partially explained the high heterogeneity found in subset low back pain–physical workload (data not shown).

Publication bias

Funnel plot, Begg's and Egger's tests were conducted to evaluate publication bias in the included studies. No significant publication bias was identified according to the funnel plot in this study. Following Begg's test and Egger's test (Table 4), no evidence of publication bias was found for the subsets of high job demand, total strain, and physical workload. However, both studies reported a

Table 1 *Characteristics of Included Studies and Association between Exposure to Psychosocial Factors or Physical Factors at Work and Musculoskeletal Disorders.*

Study	Country	Design, Response rate	Participants, Sample size, Age	Female (%)	Measure	Analysis, Adjustment variables	Quality (%)	Exposure variables	Anatomic site	OR	95% CI
Alexopoulos (2006)	The Netherlands and Greece	Retrospective cohort 64%	Nurses n = 393 38.6 (9.4) 37.1 (7.3)	93 81	Karasek model, Nordic Questionnaire	Logistic regression, adjusted for physical demands	78.6	Physical workload[a] Physical workload[b] Physical workload[a] Physical workload[b]	Shoulder[a] Shoulder[b] Back[a] Back[b]	1.19[a] 2.08[b] 1.93[a] 1.98[b]	0.62–2.30[a] 1.25–3.46[b] 1.23–3.03[a] 1.19–3.31[b]
Arsalani (2014)	Iran	Cross sectional 92%	Nurses n = 520 <40:66.7%	79.4	Copenhagen Psychosocial Questionnaire, Nordic Questionnaire	Logistic regression, adjusted for age and gender	75.0	High job demand, Physical workload, Physical workload,	Low back Low back Neck	1.15 1.18 1.86	0.76–1.73, 0.73–1.88, 1.07–3.23,
Bos (2007)	The Netherlands	Cross sectional 63%	Nurses n = 1977 38 (10)	82	Copenhagen Psychosocial Questionnaire, Nordic Questionnaire	Logistic regression multivariate model, adjusted for physical demands	84.6	Low social support Physical workload Low social support	Neck Neck Back	1.02 0.98 1.10	0.97–1.08 0.75–1.28 0.97–1.24
Choobineh (2006)	Iran	Cross sectional 84%	Nurses n = 641 22–66	84.7	Job Content Questionnaire, Nordic Questionnaire	Logistic regression, adjusted for age, physical demands	63.6	Physical workload Physical workload Physical workload Physical workload	Low back Neck Shoulder Back	2.10 2.09 2.01 2.14	1.50–2.70 1.15–3.80 1.20–3.38 1.24–3.70
Choobineh (2010)	Iran	Cross sectional 80%	Nurses n = 375 19–62	66.4	Job Content Questionnaire, Nordic Questionnaire	Logistic regression, adjusted for age, physical demands	84.6	Physical workload Physical workload Physical workload	Low back Shoulder Back	2.04 3.04 2.25	1.09–5.31 1.65–5.59 1.26–4.01
Dhaini (2016)	Switzerland	Cross sectional 76.6%	Nurses n = 3471 18–50:67% >50:33%	92.4	Health Professions Stress Inventory	Logistic regression, adjusted for facility and care workers characteristics	63.6	Low social support Physical workload	Low back Back	1.25 1.52	0.78–1.99 1.29–1.79
Elfering (2002)	Switzerland	Prospective cohort 75.8%	Nurses n = 186 23.9 (2.2)	-	Instrument for Stress Oriented Task Analysis, Nordic questionnaire	Logistic regressions, adjusted for age, sex, physical workload, problems at baseline, BMI, leisure time sport, smoking, general health	88.9	Low social support	Low back	5.75	1.27–25.97
Feng (2007)	Taipei, Taiwan	Cross sectional 91.3%	Nursing aides n = 244 43.3 (7.9)	100	Job Content Questionnaire, Nordic Questionnaire	Logistic regression, adjusted for smoking, BMI and care workers characteristics	83.3	High job demand Low social support	Low back Low back	1.46 0.62	1.24–1.73 0.42–0.91
Freimann (2013)	Estonia	Cross sectional 57%	Nurses n = 237 23–59	100	Nordic Questionnaire, Copenhagen Psychosocial Questionnaire	Logistic regression, adjusted for age and all risk factors	86.0	Total job strain Total job strain	Neck Shoulder	1.40 0.70	0.70–2.80 0.30–1.70
Golabadi (2013)	Iran	Cross sectional 84.5%	Nurses n = 545 32.1 (7)	79.4	Job Content Questionnaire, Nordic Questionnaire	Logistic regression, adjusted for age,sex, Physical demands	84.6	High job demand Total job strain Total job strain	Low back Low back Back	1.73 2.49 1.82	1.18–2.53 1.46–4.26 1.10–3.001
Gonge (2002)	Denmark	Cross sectional 84%	Nurses n = 200 18–64	100	Whitehall II study, Nordic Questionnaire	Logistic regression, adjusted forage, smoking, neuroticism.	82.0	High job demand Low social support	Low back Low back	1.00 1.20	0.60–1.60 0.70–2.00
Harcombe (2010)	New zealand	Cross sectional 58%	Nurses n = 280 20–59	-	Whitehall II study, Nordic Questionnaire	Logistic regression, adjusted for occupation, age, sex and Body Mass Index	91.0	Low social support Low social support Total job strain Low social support Total job strain Physical workload	Low back Neck Neck Shoulder Shoulder Shoulder	1.25 1.06 3.46 0.75 2.18 1.41	0.78–1.99 0.62–1.81 1.30–9.21 0.43–1.32 0.76–6.24 1.17–1.69
Koohpayehzadh (2016)	Iran	Cross sectional 79%	Nurses n = 405 26–60	51.4	Job Content Questionnaire, Nordic Questionnaire	Logistic regression	63.6	Physical workload	Neck	1.20	1.06–1.30
Smith (2004)	China	Cross sectional 92%		100	Nordic Questionnaire		85.7				

(*continued on next page*)

Table 1 (*continued*)

Study	Country	Design, Response rate	Participants, Sample size, Age	Female (%)	Measure	Analysis, Adjustment variables	Quality (%)	Exposure variables	Anatomic site	OR	95% CI
			Nurses n = 282 34(9.2)			Logistic regression, adjusted for age, total career length and department of employment.		Low social support	Low back	2.30	0.96–6.15
								Total job strain	Low back	1.14	0.68–1.91
								Low social support	Neck	2.52	1.09–6.23
								Total job strain	Neck	1.79	1.06–3.03
								Physical workload	Neck	0.87	0.49–1.54
								Low social support	Shoulder	2.00	0.90–4.59
								Total job strain	Shoulder	1.69	0.99–2.89
								Low social support	Back	1.90	0.85–4.35
								Total job strain	Back	1.24	0.72–2.13
Smith (2006)	Japan	Cross sectional 72.6%	Nurses n = 844 32.9 (8.8)	100	Nordic Questionnaire	Logistic regression adjusted for age, physical demands	90.9	Low social support	Low back	0.92	0.59–1.45
								Total job strain	Low back	1.12	0.72–1.72
								Physical workload	Low back	2.76	1.50–5.13
								Low social support	Neck	1.07	0.71–1.60
								Total job strain	Neck	1.53	1.02–2.31
								Physical workload	Neck	1.58	0.86–2.93
								Low social support	Shoulder	0.68	0.44–1.06
								Total job strain	Shoulder	2.07	1.35–3.17
								Physical workload	Shoulder	2.09	1.11–3.89
								Low social support	Back	1.16	0.77–1.74
								Total job strain	Back	1.37	0.88–2.15
								Physical workload	Back	1.69	0.85–3.58
Warming (2009)	Italy	Cross sectional 100%	Nurses n = 148 21–60	92	Log book instrument	Logistic regression, adjusted for gender, age, physical demands	76.9	Total job strain	Neck	1.16	0.24–5.54
								Total job strain	Back	1.17	0.27–5.01
Yip (2002)	HongKong, China	Prospective cohort 65%	Nurses n = 236 31.3	84.7	General Health Questionnaire	Logistic regression model, adjusted for physical demands	66.7	Low social support	Low back	1.85	1.00–3.42
Yip (2004)	Hong Kong, China	Prospective cohort 64.3%	Nurses n = 144 31.10	85.5	General Health Questionnaire	Multivariate logistic regression, adjusted for age	69.2	Low social support	Low back	2.52	1.03–5.68
								Physical workload	Low back	2.76	1.06–7.22

Note. OR = odds ratio; 95% CI = 95% confidence interval.

[a] Participants are from The Netherlands.

[b] Participants are from Greece.

Table 2 *Association between Work-related Psychosocial Risk Factors or Physical Factors and Musculoskeletal Disorders.*

Anatomic site	Variables		Studies (n)	OR (95% CI)	Test of ES = 1		Heterogeneity		Studies
					z	*p*	I^2	*p*	
Low back	Psychosocial factors	High job demand	4	1.41 (1.23,1.62)	4.91	<.001	26.9	.251	Arsalani (2014), Feng (2007), Golabadi (2013), Gonge (2002).
		Low social support	9	1.23 (0.85,1.78)	0.34	.737	70.8	.001	Dhaini (2016), Elfering (2002), Feng (2007), Gonge (2002), Harcombe (2010), Smith (2004), Smith (2006), Yip (2002), Yip (2004).
		Total job strain	5	1.71 (1.15,2.55)	2.66	.008	58.8	.045	Golabadi (2013), Gonge (2002), Harcombe (2010), Smith (2004), Smith (2006)
	Physical factors	Physical workload	6	1.76 (1.32,2.35)	3.85	<.001	62.0	.022	Arsalani (2014), Choobineh (2006), Choobineh (2010), Harcombe (2010), Smith (2006) , Yip (2004).
Neck	Psychosocial factors	Low social support	4	1.02 (0.97,1.08)	0.90	.367	28.3	.243	Bos (2007), Harcombe (2010), Smith (2004), Smith (2006) .
		Total job strain	5	1.67 (1.26,2.20)	3.63	<.001	0.0	.587	Freiman (2013), Harcombe (2010), Smith (2004), Smith (2006), Warming (2009)
	Physical factors	Physical workload	7	1.17 (1.08,1.27)	3.93	<.001	44.6	.094	Arsalani (2014), Bos (2007), Choobineh (2006), Harcombe (2010), Koohpayehzadeh (2016), Smith (2004) , Smith(2006).
Shoulder	Psychosocial factors	Low social support	3	0.92 (0.53,1.61)	0.29	.772	62.9	.067	Harcombe (2010), Smith (2004) , Smith(2006).
		Total job strain	4	1.62 (1.06,2.48)	3.54	<.001	40.6	.168	Freiman (2013), Harcombe (2010), Smith (2004), Smith (2006)
	Physical factors	Physical workload	6	1.59 (1.37,1.85)	6.11	<.001	46.3	.097	Alexopoulos[a] (2006) ,Alexopoulos[b] (2006) , Choobineh (2006) , Choobineh (2010), Harcombe (2010), Smith (2006).
Back	Psychosocial factors	Low social support	3	1.12 (0.99,1.25)	1.87	.062	0.0	.423	Bos (2007), Smith (2004), Smith (2006).
		Total job strain	4	1.45 (1.10,1.91)	2.60	.009	0.0	.742	Golabadi (2013), Smith (2004), Smith (2006), Warming (2009).
	Physical factors	Physical workload	6	1.66 (1.45,1.90)	7.30	<.001	0.0	.566	Alexopoulos[a] (2006) ,Alexopoulos[b] (2006) , Choobineh (2006), Choobineh (2010), Dhaini (2016), Smith (2006)

Note. OR = odds ratio; 95% CI = 95% confidence interval.
[a] Participants are from The Netherlands.
[b] Participants are from Greece.

Table 3 *Subgroup Analyses to Explore Source of Heterogeneity.*

Sub-group		Low back pain-Low social support				Low back pain-Total strain				Low back pain-Physical workload			
		n	OR (95% CI)	Heterogeneity		n	OR (95% CI)	Heterogeneity		n	OR (95% CI)	Heterogeneity	
				I^2	p			I^2	p			I^2	p
Location	Asia	5	1.31 (0.76,2.28)	77.1	.002	3	1.45 (0.88,2.38)	67.0	.048	5	1.95 (1.57,2.42)	36.7	.177
	Europe	4	1.17 (0.66,2.08)	69.9	.019	1	2.30 (1.33,3.98)	-	-	0	-	-	-
	Australia	0	-	-	-	1	2.85 (1.01,8.04)	-	-	1	1.35 (1.14,1.60)	-	-
Design	Cross-sectional study	6	0.95 (0.68,1.33)	61.1	.025	-	-	-	-	5	1.53 (1.34,1.76)	66.0	.019
	Prospective study	3	2.28 (1.42,3.65)	0.0	.379	-	-	-	-	1	2.76 (1.06,7.20)	-	-
Measurement of outcome	Nonstandard questionnaire	3	0.87 (0.60,1.28)	42.0	.178	2	2.41 (1.48,3.92)	0.0	.720	4	1.63 (1.13,2.37)	58.7	.064
	Standard scale	6	1.62 (0.91,2.87)	77.3	.001	3	1.45 (0.88,2.38)	67.0	.048	2	2.09 (1.59,2.76)	0.0	.946
Measure of exposure	Nonstandard questionnaire	3	0.87 (0.60,1.28)	42.0	.178	4	1.54 (1.00,2.36)	54.0	.089	2	1.81 (0.91,3.61)	79.3	.028
	Standard scale	6	1.62 (0.91,2.87)	77.3	.001	1	2.49 (1.46,4.25)	-	-	4	1.82 (1.28,2.57)	38.9	.178
Mean age	<40	5	1.86 (1.07,3.24)	61.0	.036	3	1.45 (0.88,2.38)	67.0	.048	4	2.22 (1.74,2.84)	0.0	.835
	≥40	4	0.85 (0.57,1.28)	64.8	.036	2	2.41 (1.48,3.92)	0.0	.720	2	1.33 (1.13,1.56)	0.0	.600
Sample (n)	<500	6	1.62 (0.90,2.90)	77.2	.001	2	1.61 (0.81,3.20)	70.0	.068	2	2.31 (1.25,4.25)	0.0	.634
	500–1000	2	0.76 (0.49,1.17)	34.2	.217	3	1.85 (0.98,3.49)	68.6	.041	4	1.67 (1.20,2.33)	73.3	.010
	≥1000	1	1.25 (0.78,1.99)	-	-	-	-	-	-	-	-	-	-
Quality (%)	<70	3	1.61 (1.10,2.35)	15.4	.307	-	-	-	-	2	2.31 (1.25,4.25)	0.0	.634
	70–80	0	-	-	-	-	-	-	-	1	1.18 (0.74,1.89)	-	-
	≥80	6	1.03 (0.66,1.61)	69.9	.005	5	1.71 (1.15,2.55)	58.8	.045	3	1.86 (1.23,2.80)	80.1	.007
Overall		9	1.23 (0.85,1.78)	70.8	.001	5	1.71 (1.15,2.55)	58.8	.045	6	1.76 (1.32,2.35)	62.0	.022

Note. OR = odds ratio; 95% CI = 95% confidence interval.

possible publication bias for the association between low social support and low back pain. Egger's test indicated publication bias in the relationship between physical workload and back pain. This may be explained by the inclusion criteria since exposure to social support consists of coworker and supervisor support, but some studies include two kinds of support, while others include only one. Moreover, when the heterogeneity is unexplainable, regression to test publication bias may lead to false-positive outcomes.

Discussion

Our meta-analysis assessed the pooled effects of 18 studies on work-related risk factors for upper body MSDs. The quality evaluation of most studies was intermediate or high (ranging from 63.6% to 91.0%). Most of the included studies used standard questionnaires (such as the Nordic Questionnaire [45] based on the Karasek model [46] and Job Content Questionnaire [47]) to measure MSDs, occupationally psychosocial factors, and physical environment, while others used questionnaires designed by investigators or published in previous literature. It is conceivable that different measurement criteria may produce confounding variables, and subgroup analysis did display obvious heterogeneity decreases in groups of both measurement of exposure and outcome with standard scales in the subset of low back pain−physical workload (Table 3).

Exposure to both psychosocial factors and the physical workload was correlated with the prevalence of MSDs [29,30]. Most studies revealed statistically significant associations between high job demand, total job strain, and MSDs. These results are similar to those reported by Bernal et al. [28] Nevertheless, comparing to studies in which low social support was related to the risk of suffering low back pain, neck pain, shoulder pain and pain at any anatomical site, the meta-analysis does not suggest any statistically significant association between low social support and low back pain, neck pain, shoulder pain or back pain. However, these findings were consistent with a cohort study [48], which showed no evidence to indicate the correlation between work-related factors (such as low social support) and low back pain. In fact, Bernal's review included nurses and aids and used random-effect models to analyze the effects of exposure factors on outcomes. We should carefully interpret the results because the high degree of heterogeneity between studies may lead to false-positive results. A possible explanation for this might be that different questionnaires and different definitions of MSDs may contribute to deviations [28]. Moreover, further analysis showed that there was a statistically significant connection between low social support and low back pain after two studies were excluded through sensitivity analysis. Subgroup analyses (Table 3) indicated that location and mean age might be the sources of heterogeneity in the subset low back pain−physical workload. A systematic review suggested a difference in the prevalence of low back pain among nurses in different countries, which may be related to occupational factors [19]. These findings recommend attention to the heterogeneous sources and caution.

The correlation between physical workload and upper body MSDs was identified based on our comprehensive evaluation of 11 relational studies [3,15,17,18,20,24,26,32,33,36,39]. Syntheses reported that higher physical workload was associated with a much greater risk of developing low back pain (random OR = 1.76; 95% CI = 1.32−2.35; I^2 = 62.0%), neck pain (fixed OR = 1.17; 95% CI = 1.08−1.27; I^2 = 44.6%), shoulder pain (fixed OR = 1.59; 95% CI = 1.37−1.85; I^2 = 46.3%), back pain (fixed OR = 1.66; 95% CI = 1.45−1.90; I^2 = 0.0%) among hospital nurses. Therefore, the findings of our study were, to a great degree, in line with other evidence serving to an increased risk of musculoskeletal dysfunction stemming from high physical workload [24,26,35].

Table 4 *Egger's linear regression for publication bias.*

Anatomic site	Exposure	Intercept and 95% CI	t	*p*	Publication bias
Low back pain	High job demand	−1.17 (−7.25,4.90)	−0.83	.493	No
	Low social support	4.28 (1.39,7.16)	3.51	.010	Yes
	Total job strain	3.39 (−5.26,12.05)	1.25	.301	No
	Physical workload	1.63 (−1.34,4.61)	1.52	.203	No
Neck	Low social support	0.92 (−1.97,3.82)	1.37	.305	No
	Total job strain	0.48 (−2.91,3.87)	0.45	.681	No
	Physical workload	0.64 (−1.58,2.88)	0.75	.490	No
Shoulder	Low social support	5.40 (−16.81,27.63)	3.09	.199	No
	Total job strain	−1.74 (−10.52,7.02)	−0.86	.482	No
	Physical workload	1.6 9 (−0.75,4.14)	1.92	.127	No
Back	Low social support	1.09 (−6.51,8.70)	1.82	.319	No
	Total job strain	−0.44 (−5.36,4.47)	−0.39	.735	No
	Physical workload	1.33 (0.38,2.28)	3.90	.017	Yes

In a systematic review of Iran, an enhancing prevalence of musculoskeletal complaints among nurses was reported [19], in agreement with Switzerland's [8], Chinese [43], and Vietnam's [7] studies. Our research showed that high levels of physical workload led to an increase in the risk of lower back, upper back, shoulder, and neck pain by 1.76, 1.66, 1.59 and 1.17 times, respectively, indicating that the lower back is more prone to MSDs when exposed to overload physical conditions. This is consistent with most previous studies [15,19,40]. In Japan, having more than four days of sick leave and work-related low back pain accounted for 62% of cases [21]. Low back, upper back, shoulder and neck pain among the nurses might be physically attributed to recurrent transferring/lifting patients or heavyweights, continual bending and standing, frequent long walk, pulling and pushing, and sudden movements in improper posture, inappropriate body postures that nurses experience given the nature of nursing, particularly of some emergencies in hospital wards [1,28,39].

Repetitive abnormal movements impose compression and shear forces on the spinal column, shoulder joints, and cervical vertebrae, causing back, shoulder and neck damage. Therefore, some nurses, such as those of intensive care units, operating rooms, are more prone to MSDs [32].

Based on these findings, clinical nurses should strengthen their awareness of self-protection and improve their self-protection skills and knowledge level. This can be done in their usual work through the principle of labor-saving when lifting heavy objects or patients is necessary to avoid long-term engagement in forced postures or wrong positions for lifting, which cause musculoskeletal injury. By enhancing their musculoskeletal syndrome-related knowledge, nurses can perceive early warning symptoms of MSDs in a timely manner, reasonably arrange rest time, and take effective measures to deal with high work demands, as well as high occupational stress [21,49].

As far as the hospital is concerned, On the one hand, hospitals should strengthen the training of the principles of labor-saving in the work process of nurses and encourage and provide ergonomics lifting devices for transfers and repositioning, which are more effective to control or prevention of MSDs among nurses. Based on other studies, motivating health care staff to use lifting devices was strongly associated with the decreasing percentage of MSD prevalence during a patient's transfer and repositioning [49]. This finding highlights the demand for a plan that allows or encourages nurses to use ergonomic lifting devices when required by ensuring that sufficient lifting devices are available for the number of patients in each ward. The results of other studies corroborate those of the current study; they affirm that more attention is required for preventing and controlling these disorders before they occur [2,9,21]. On the other hand, hospitals need to take all measures to reduce the occupation-related psychosocial pressure on nurses, to promote the health of nurses, and to ensure that nurses can provide high-quality nursing care for patients.

Limitations and prospects

This study had three main limitations: (1) as the data were collected using self-reported techniques, participant responses may be biased as a result of social desirability to provide favored answers instead of real experiences; (2) cultural (participants from 12 countries, and Asia, Europe, and Australia) and language (English, Chinese)differences may have influenced the individuals' understanding and interpretation of the study items; (3) when the study was restricted mainly to female nurses (51.4%–100.0%), a bias for certain gender and preference parameters might have occurred. For instance, in the psychological domain, females are generally found to have lower decision latitude than men in most populations. Future studies could try to use more objective indicators, conduct subgroup analysis based on culture and language, and recruit more male nurses to reduce bias. (4) Because hospitals around the world have diverse medical delivery systems, size, and manpower, specific departments, and severity of patients and the burden of nurses'' work, there is not enough evidence to conduct a subgroup analysis. In the future, in-depth research can be carried out according to different countries or hospitals.

Further limitations can be pointed out. There were 15 cross-sectional studies but only two prospective cohort studies and a retrospective cohort study. More longitudinal research should be conducted to explore the occupational risk factors for upper body MSDs in future work. There was no evidence to indicate the correlation between low social support and low back pain; thus, future studies on this topic are highly recommended. Subgroup analysis, sensitivity analysis and meta-regression were used to explore heterogeneous sources, and a certain degree of heterogeneity may reduce the estimation accuracy. Additionally, using different questionnaires and measurement standards to test the same outcome indicators was unreasonable. Further studies that consider these variables need to be undertaken. Furthermore, our study only focused on psychosocial risk factors and physical workload but ruled out additional interventions that could prevent and reduce the occurrence of MSDs. In future investigations, more theoretical and experimental research could be performed.

Conclusion

To our knowledge, this meta-analysis is the first attempt to comprehensively and systematically identify and critically appraise published studies that explore the relationship between exposure to occupational psychosocial, physical factors, and MSDs in hospital nurses simultaneously; however, most present literature findings

included in this review drew the conclusion that there was a significant association between more physical workload and MSDs, as well as occupational strain among hospital nurses. These findings are correspondingly in step with current scientific knowledge, the demonstration advocating a growth risk in upper body MSDs among nurses due to low levels of social support is statistically insignificant. Executing a longitudinal design to validate our explanation and apply it to national prevention programs for health care workers is strongly recommended.

A high prevalence of chronic MSDs will result in low quality, low-efficiency work performance, high medical costs or even job changes. Providing effective preventive measures to reduce nurses' occurrence of MSDs is necessary. These preventions should consider both occupational physical and psychosocial factors, including ergonomics, appropriate exercises and the improvement of the organizational environment.

Financial support and sponsorship

This research was funded by the Key Project of Health Policy Research in Shandong Province in 2019 (Lu Wei Han [2019] No. 77).

Conflict of interest

None declared.

Acknowledgments

We would like to offer special thanks to the Key Project of Health Policy Research in Shandong Province in 2019 (Lu Wei Han [2019] No. 77) for project funding.

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Asian Nursing Research 15 (2021) 215–221

Contents lists available at ScienceDirect

Asian Nursing Research

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Research Article

Behavioral Responses of Pregnant Women to the Early Stage of COVID-19 Pandemic in the Network Era in China: Online Questionnaire Study

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ARTICLE INFO

Article history:
Received 24 December 2020
Received in revised form
29 May 2021
Accepted 18 June 2021

Keywords:
Behavior
COVID-19
Public health
Pregnant women

ABSTRACT

Purpose: The aim of this study was to examine the behavioral responses of pregnant women during the early stage of Coronavirus Disease 2019 (COVID-19) outbreak.
Methods: We recruited 1,099 women to complete an online questionnaire survey from February 10 to February 25, 2020. The subjects were divided into two groups (the pregnant women group and the control group).
Results: Concerns about infection: most of the participants watched the COVID-19 news at least once a day. Protective behaviors: the utilization rate of pregnant women (often using various measures) was higher than that of nonpregnant women. Exercise: 30.6% of the pregnant women continued to exercise at home, whereas in the control group, this percentage was 8.4%. Spouse relationship: 38.8% of the subjects' relationship improved, whereas only 2.3% thought the relationship was getting worse.
Conclusion: Pregnant women had some unique behavioral responses different from that of nonpregnant women. It is important to understand the behavioral responses of pregnant women in this network era.

Introduction

Coronavirus disease (COVID-19) has spread quickly and evolved into a pandemic since December 2019 when it first emerged in Wuhan, China [1]. The World Health Organization (WHO) declared the coronavirus outbreak to be a public health emergency on January 31, 2020 [2]. As of mid-November 2020, COVID-19 has infected more than 54 million people and resulted in the deaths of more than 1.3 million people.

The concerning features of COVID-19 are its apparent ability to spread readily and its propensity to cause severe disease or even death [3,4], which can cause fear and panic in society [5,6]. Nevertheless, the panic of the pregnant women could be doubled due to worries about the safety of themselves and their fetus.

The COVID-19 outbreak occurred 17 years after the 2003 epidemic of severe acute respiratory syndrome (SARS) in China. Currently, with the popularity of smart phones and the development of the network, in addition to the traditional means of obtaining information, such as television, radio, and newspapers, young people are more likely to use smartphones and tablets. The rapid and timely information dissemination has now become the new normal.

News and information can influence people's behavior [7]. Petrie et al. conducted a cross-sectional telephone survey and found that the public perceptions could influence the members' behavioral responses in Ebola outbreak [8]. A BBC News posited that hearing a lot of information and news about COVID-19 had affected the public on daily life [9]. However, behavioral studies of

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https://doi.org/10.1016/j.anr.2021.06.003
p1976-1317 e2093-7482/

epidemic outbreaks tend to focus on nonpregnant women [10–12]. There have been few studies on pregnant women's behavioral responses during disease outbreaks, including SARS, middle east respiratory syndrome coronavirus (MERS), and Ebola. Recent studies found that pregnant women had changes in behavior including self-isolating, changing their method of transportation, and so on in COVID-19 pandemic [13,14]. However, those studies only focused on pregnant women without a control group of nonpregnant women. We wondered if pregnant women would have some special behavior changes different from nonpregnant women.

Therefore, we aimed to investigate the behavioral responses of COVID-19 on pregnant women in this network era in mainland China. Its related lifestyle and quality of life among pregnant women within 1 month after travel restrictions were imposed by the Chinese government. The results may assist clinicians in considering pregnant women's behavioral changes and offering early supports during the disease outbreaks.

Methods

Study design

This study used a cross-sectional design and convenience sampling.

Setting and samples

Participants were recruited from online consultation according to the following criteria: each individual 1) agreed to participate in the study and gave digital informed consent; 2) ordinarily resided in Hangzhou; 3) was a married woman and living with her husband; 4) first marriage; and 5) had no history of mental diseases.

People can participate in online consultations through WeChat app (one of the most popular apps in China) or another app called the "Mother and Child Health Handbook App," which is popular among pregnant women. People using the two apps were prompted to answer whether they were willing to complete the psychometric evaluation and the questionnaire. If the participants had any questions during the administration of the questionnaire, they could pose these questions online to the investigator.

The subjects were divided into two groups (the pregnant women group and the control group) according to whether they were pregnant or not. We matched the age and parity to select the control participants after we recruited pregnant women. The pregnant women were further divided into three subgroups: first trimester subgroup (0-13^{+6} weeks), second trimester subgroup (14-27^{+6} weeks), and third trimester subgroup ($\geq$28 weeks).

Ethical considerations

All the study procedures were approved by the ethics committee of Hangzhou Women's Hospital (Hangzhou Maternity and Child Health Care Hospital) (Approval no. 202002-16). The participants gave written consent and were informed about the study objectives, the possibility of discontinuing the study at any time without penalty, and the protection of the confidentiality of personal information.

Measurements

The questionnaire was designed to determine the pregnant women's behavioral responses to the early stage of COVID-19 pandemic. Before designing the questionnaire, we used qualitative methods to examine the experiences of pregnant women during the outbreak.

We conducted a descriptive qualitative study and semi-structured individual interviews were conducted at a time convenient for the participants. The Consolidated Criteria for Reporting Qualitative Research (COREQ) were used to report the method used and findings obtained [15]. A purposeful sampling method combined with the maximum variation strategy (for instance, age, trimester, parity, employment status, education level) was used to recruit eligible participants in our hospital. The sample size was determined by data saturation, that is, we stopped data collection at the point where no new themes from participants were emerging [16].

A total of nine women participated in the interviews, which lasted approximately 45 min per person. The audio recordings were transcribed verbatim by two researchers within 24 h of the interviews to ensure the accuracy of the information. The data were analyzed using thematic content analysis. There themes were emerged after data analysis: 1) increasing demand for comprehensive information; 2) more cautious self-protection behavior; and 3) changes in the relationship between spouse.

Based on the themes that were identified, a questionnaire was constructed to be used in the later quantitative survey. The questionnaire included six items in total: a. the frequency of watching the COVID-19 news (single-choice question: "hardly ever," "1-2 times a week," "once a day," or "more than once a day"); b. preferred social media platform (single-choice question: "WeChat," "Weibo (a platform similar to Facebook)," "Video apps (youku etc.)," "Zhihu," "Douban," or "Others"); c. the methods they used for preventing COVID-19 infection (multiple-choice question: "wearing masks," "wearing gloves," "wearing eyewear," "wearing protective clothing," and/or "using disinfectants"); d. the most commonly used means of transportation when going out (single-choice question: "driving a car," "taxi," "public transportation," or "walking or cycling"); e. continuing exercise habits (single-choice question: "keep doing," "reduce," or "hardly ever"); and f. relationship between spouse (single-choice question: "better," "worse," or "same").

Data collection

Data were collected between February 10, 2020 and February 25, 2020 in Hangzhou City, Zhejiang Province. This was a study to explore potential differences between the two groups, and there was no quantifiable hypothesis to test in advance. It seemed impossible to directly estimate the sample size. Thus, we referred to a rough estimation method with 5-10 times the number of variables to calculate the sample size [17]. A total of 14 variables were included in the study; therefore, the required sample size was 70 (14×5). Considering a sample loss of 20.0%, the minimum sample size required for this study was 88 participants. We recruited as many eligible subjects as possible. In total, 1,099 respondents who completed the questionnaires were included in the final analysis (1,099/1,200, 91.6% response rate), including 565 pregnant women and 534 controls.

Data analysis

Continuous data were compared using the independent-sample *t*-test and analysis of variance. Chi-squared analysis was used for categorical variables. A one-sample, Kolmogorov–Smirnov test was used to test nonparametric variables. We used the SAS System for Windows 9.4 software (SAS Institute Inc, Cary, NC), and $p < .05$ was considered to indicate a significant difference. All tests were two-tailed analyses.

Results

Characteristics of the study population

A total of 1,099 participants completed all the procedures in the study. As shown in Table 1, of 565 pregnant women, 146 were in the first trimester, 212 were in the second trimester, and 207 were in the third trimester. Overall, no significant differences were observed between the pregnant women and control groups in terms of mean age, parity, employment status, education level, and time taken to complete the questionnaire. There were also no significant differences in those characteristics among the three subgroups (Table 1). No one was infected with COVID-19 at the end of the study.

Behavioral responses to the COVID-19 pandemic

We used Cronbach' α to determine the reliability of the questionnaire. The value was .76, which indicated that the study questionnaire is reliable.

Response of watching the COVID-19 news

Most of the participants (91.3% in the pregnant women group vs. 92.5% in the control group) watched the COVID-19 news at least once a day. There was no significant difference in the frequency of watching the COVID-19 news between the two groups ($p > .05$) (Table 2).

All of the participants chose smart devices, including smart phones and tablets, as the preferred way of getting news. Therefore, we further investigated their preferred social media platform. As shown in Table 2, WeChat was the most popular platform to acquire information about COVID-19, followed by Weibo. There was no significant difference between the two groups ($p > .05$).

Response of the protection methods selection

To mitigate the risk of infection, 100.0% of the subjects wore masks, and 40.0% of the pregnant women wore gloves, which was higher than the percentage in the control group ($p < .001$). The number of participates who wore eyewear or protective clothing was higher in both the pregnant women group than in the control group ($p < .001$, $p < .05$). Additionally, 53.1% of the pregnant women used disinfectants, which was also a higher portion than that in the control group ($p < .001$) (Table 3).

Response of the transportation means selection

There were 79.5% of the participants used self-driving car to reduce the risk of contracting the virus when going out. The use of cars was higher, while walking or cycling was lower, in the pregnant women group than in the control group. There was significant difference between the two groups ($p < .01$) (Table 4).

Response of exercising

People spent most of their time at home during the outbreak in China, which would affect their exercise. There was significant difference between the two groups ($p < .001$) (Table 4). There were 30.6% of the pregnant women continued to exercise at home, whereas in the control group, this percentage was 8.4%. Among those who hardly ever exercise, the rate in the pregnant women group (about 30%) was lower than that in the control group (about 40%).

Response of the spouse relationship

Staying at home may also affect relationships between the spouse. We found that 38.8% of the subjects' relationship improved, whereas only 2.3% thought the relationship was getting worse. There were no significant differences between the two groups ($p > .05$) (Table 4).

Behavioral responses to the COVID-19 pandemic in different trimesters

Among the three subgroups of the pregnant women, there were no significant differences in all those items showed above (Table 5).

Table 1 *Participants Characteristics.*

	Pregnant women group (n = 565)	Different trimesters			Control group (n = 534)	*t* or χ^2	*p*
		First trimester subgroup (n = 146)	Second trimester subgroup (n = 212)	Third trimester subgroup (n = 207)			
Age (years)	29.96 ± 3.37	30.02 ± 3.31	29.84 ± 3.44	30.05 ± 3.35	29.90 ± 3.38	0.10	.747
Gestational age (weeks)	22.62 ± 10.56	8.12 ± 2.24	21.88 ± 4.11	33.61 ± 3.70			
Parity [n (%)]:							
Nulliparous	372 (65.8)	93 (63.7)	140 (66.0)	139 (67.1)	358 (67.0)	0.18	0.674
Married [n (%)]	565 (100.0)	146 (100.0)	212 (100.0)	207 (100.0)	534 (100.0)	NA	NA
Marriage length (years):						3.89	0.143
<5	440 (77.9)	114 (78.1)	162 (76.4)	164 (79.2)	410 (76.8)		
5 to 9	105 (18.6)	26 (17.8)	46 (21.7)	33 (16.0)	114 (21.3)		
≥10	20 (3.5)	6 (4.1)	4 (1.9)	10 (4.8)	10 (1.9)		
Employment status [n (%)]:						0.84	.657
Full-time	445 (78.8)	116 (79.4)	168 (79.3)	161 (77.8)	430 (80.5)		
Part-time	86 (15.2)	22 (15.1)	31 (14.6)	33 (15.9)	78 (14.6)		
Unemployed	34 (6.0)	8 (5.5)	13 (6.1)	13 (6.3)	26 (4.9)		
Education [n (%)]:						0.60	.897
Less than middle school	28 (5.0)	9 (6.2)	12 (5.7)	12 (5.8)	30 (5.6)		
Middle school	57 (10.1)	13 (8.9)	19 (8.9)	22 (10.7)	49 (9.2)		
Bachelor	451 (79.8)	117 (80.1)	169 (79.7)	163 (78.7)	430 (80.5)		
More than bachelor	29 (5.1)	7 (4.8)	12 (5.7)	10 (4.8)	25 (4.7)		
Time for completing the questionnaire (seconds)	321.02 ± 125.11	311.83 ± 131.59	321.21 ± 127.55	327.33 ± 117.91	330.05 ± 128.03	1.40	.238

The value of *t*, χ^2, and *p:* Pregnant women group versus control group. NA: Not applicable as the percentages are 100.0% for each group.

Discussion

Through the present study, we found that epidemic and pandemics of COVID-19 can have behavioral effects on the population, especially on pregnant women. Our findings could be used as fundamental data for the government to pay close attention to pregnant women (a vulnerable group) in this epidemic and also provide some important information for medical workers to offer early interventions and supports by online manners. To the best of our knowledge, our study was among one of the first studies to investigate behavioral responses of pregnant women to the early stage of COVID-19 pandemic in mainland China.

Studies focus on pregnant women's behavioral state during a disease outbreak has been rare. Lee et al. reported that women in the SARS cohort adopted behavioral strategies, including wearing masks and cleaning hands vigilantly, to mitigate their risk of contracting infection [18]. However, this study compared the changes without a control group of nonpregnant women. A phenomenological research in Hong Kong during the SARS outbreak found that new mothers disrupted daily routines as they tried to eliminate their risk of contracting this disease including information gathering, avoiding places of risk, and washing bags, clothes, and hair after leaving the house [19]. Corbett et al. recruited patients in the second and third trimester of pregnancy and demonstrated that they had major changes in behavior including self-isolating, changing their primary method of transportation, bulk-buying, and so on in COVID-19 pandemic [13]. A cross-sectional, Web-based survey between March 3 and 10, 2020, in China showed that 55.7% of the participants protected themselves from contracting COVID-19 with self-efficacy [14].

However, behavioral studies of epidemic outbreaks still tend to focus on nonpregnant women. A study in Iranian residents demonstrated that social media increase perceived risk and safety behaviors [10]. Zhang et al. investigated the quality of life among local residents in Liaoning Province, China, and found that the participants changed exercising time and relax time in the COVID-19 pandemic [11]. Another study in China showed that the three most commonly used prevention measures were making fewer trips outside and avoiding contact, wearing a mask, and hand hygiene, which was similar to the results of our control group [12]. Among college students, a wide variety of behaviors, including increased phone usage, decreased physical activity, and fewer locations visited, were associated with fluctuations in COVID-19 news reporting in the United States [20]. Similar results were observed in children and adolescents. The data revealed a substantial decrease in physical activity increase in screen time during the COVID-19 pandemic [21]. However, compared with the youngers, older men reported relatively less worry and the fewest total number of behavior changes [22]. The issues related to this emerging global event may evolve into long-lasting health problems, which merits further investigation.

Epidemics and pandemics, such as those of SARS and MERS, have unique characteristics in terms of progression and control measures. The Spring Festival holiday occurred during 24–30 January, 2020, in China. The Chinese government–imposed traffic restrictions and extended the national holidays to control the outbreak during this time. At the time when this study was conducted, our city, Hangzhou, Zhejiang Province was also locked down. As of February 25, the deadline of our study enrollment, Zhejiang Province was one of the second-high epidemic areas in mainland China. Additionally, at that time, there was insufficient understanding of the new coronavirus and the epidemic situation. People were staying at home and self-isolating to avoid contracting or spreading the disease, which inevitably disrupted daily routines and decreased the quality of life. Staying at home with family and reducing recreational activities were considered to be safer ways to prevent virus infection. Our study investigated the changes in exercise and the relationship with spouse. Surprisingly, nearly one-third of pregnant women continued to exercise at home, which was obviously higher than that of nonpregnant women. Currently, using health education and popular science news, doctors suggest that pregnant women exercise properly, which is beneficial to both mothers and fetuses. Therefore, for the sake of fetal health, pregnant women themselves and their families may supervise and urge them to keep exercising. The time couples spent together increased during the epidemic period. The results were similar in the pregnant women and the control group and showed that about 40% of the subjects' relationships became better, whereas only about 3%

Table 2 *Response of Watching the COVID-19 News (single-choice question).*

	Pregnant women group (n = 565)	Control group (n = 534)	χ^2	p
Frequency of watching the COVID-19 news [n (%)]:			5.63	.131
Hardly ever	5 (0.9)	11 (2.1)		
1-2 times a week	44 (7.8)	29 (5.4)		
Once a day	256 (45.3)	258 (48.3)		
More than once a day	260 (46.0)	236 (44.2)		
Preferred social media platform [n (%)]:			1.91	.862
WeChat	425 (75.2)	398 (74.5)		
Weibo	83 (14.7)	84 (15.7)		
Video apps (youku etc.)	48 (8.4)	39 (7.3)		
Zhihu	5 (0.9)	6 (1.1)		
Douban	2 (0.4)	4 (0.8)		
Others	2 (0.4)	3 (0.6)		

Table 3 *Response of the Protection Method Selection (multiple-choice question).*

	Pregnant women group (n = 565)	Control group (n = 534)	χ^2	p
Methods of preventing the COVID-19 infection [n (%)] :				
Wearing masks	565 (100.0)	534 (100.0)	NA	NA
Wearing gloves	226 (40.0)	111 (20.8)	47.67	<.001**
Wearing eyewear	35 (6.2)	11 (2.1)	11.70	<.001**
Wearing protective clothing	8 (1.4)	1 (0.2)	5.10	.024*
Using disinfectants	300 (53.1)	222 (41.6)	14.62	<.001**

*$p < .05$, **$p < .01$.
NA: Not applicable as the percentages are 100.0% for each group.

Table 4 *Response of the Transportation Means Selection, Exercising, and the Spouse Relationship (single-choice question).*

	Pregnant women group (n = 565)	Control group (n = 534)	χ^2	p
Means of transportation [n (%)] :			12.68	.005**
Self-driving car	449 (79.5)	382 (71.5)		
Taxi	48 (8.5)	49 (9.2)		
Public transportation	31 (5.5)	39 (7.3)		
Walking or cycling	37 (6.5)	64 (12.0)		
Exercise [n (%)] :			86.14	<.001**
Keep doing	173 (30.6)	45 (8.4)		
Reduce	228 (40.4)	267 (50.0)		
Hardly ever	164 (29.0)	222 (41.6)		
Relationship between the spouse [n (%)] :			3.98	.136
Better	219 (38.8)	231 (43.2)		
Same as before	333 (58.9)	285 (53.4)		
Worse	13 (2.3)	18 (3.4)		

*$p < .05$, **$p < .01$.

Table 5 *Behavioral Responses to the COVID-19 Pandemic in Different Trimesters.*

	First trimester subgroup (n = 146)	Second trimester subgroup (n = 212)	Third trimester subgroup (n = 207)	χ^2	*p*
Frequency of watching the COVID-19 news [n (%)] : (single-choice question)				5.10	.531
Hardly ever	1 (0.7)	2 (0.9)	2 (1.0)		
1-2 times a week	8 (5.5)	18 (8.5)	18 (8.7)		
Once a day	63 (43.1)	90 (42.5)	103 (49.7)		
More than once a day	74 (50.7)	102 (48.1)	84 (40.6)		
Preferred social media platforms [n (%)] : (single-choice question)				6.17	.801
WeChat	108 (74.0)	160 (75.5)	157 (75.8)		
Weibo	24 (16.4)	34 (16.0)	25 (12.1)		
Video apps (youku etc.)	10 (6.8)	17 (8.0)	21 (10.1)		
Zhihu	2 (1.4)	1 (0.5)	2 (1.0)		
Douban	1 (0.7)	0 (0.0)	1 (0.5)		
Others	1 (0.7)	0 (0.0)	1 (0.5)		
Methods of preventing the COVID-19 infection [n (%)] : (multiple-choice question)					
Wearing masks	146 (100.0)	212 (100.0)	207 (100.0)	NA	NA
Wearing gloves	64 (43.8)	85 (40.1)	77 (37.2)	1.57	.455
Wearing eyewear	8 (5.5)	17 (8.0)	10 (4.8)	2.01	.367
Wearing protective clothing	4 (2.7)	2 (0.9)	2 (1.0)	2.47	.291
Using disinfectants	82 (56.2)	111 (52.4)	107 (51.7)	0.76	.565
Means of transportation [n (%)] : (single-choice question)				3.77	.708
Self-driving car	114 (78.1)	176 (83.0)	159 (76.8)		
Taxi	14 (9.6)	15 (7.1)	19 (9.2)		
Public transportation	8 (5.5)	8 (3.8)	15 (7.2)		
Walking or cycling	10 (6.8)	13 (6.1)	14 (6.8)		
Exercise [n (%)] : (single-choice question)				2.26	.689
Keep doing	45 (30.8)	60 (28.3)	68 (32.8)		
Reduce	54 (37.0)	91 (42.9)	83 (40.1)		
Hardly ever	47 (32.2)	61 (28.8)	56 (27.1)		
Relationship between the spouses [n (%)] : (single-choice question)				1.51	.825
Better	54 (37.0)	81 (38.2)	84 (40.6)		
Same as before	87 (59.6)	127 (59.9)	119 (57.5)		
Worse	5 (3.4)	4 (1.9)	4 (1.9)		

NA: Not applicable as the percentages are 100.0% for each group.

thought their relationships were getting worse. However, Dodgson et al. demonstrated relationship difficulties in the women who became mothers during the SARS outbreak with their spouse [19], which was not consistent with our findings.

Overall, the Internet was currently the first choice for health information acquisition by the general public during the COVID-19 epidemic in China. A retrospective analysis showed that the peak of Internet searches and social media data about the COVID-19 outbreak occurred 10–14 days earlier than the peak of daily incidences, with which Internet searches and social media data had high correlation with daily incidences in China [23]. In our study, more than 90% of the subjects paid close attention to the latest information on the number of cases in the local area, the availability and effectiveness of medicines, the advice on prevention and so on. As something unthinkable, most social media platforms had not yet been born 20 years ago. Now people used social media platforms to gain information about COVID-19 for its convenience, and WeChat has become one of the most popular apps on smartphones in our participants.

The experiences of the SARS epidemic changed the attitude of the general public towards precautionary measures. The official guidance of the Chinese government advises that people should wear masks if they are going out and use disinfectants in a timely manner. People began to care more about their health. Nevertheless, they were more likely to read information from their friends through WeChat or Weibo, instead of using the official webpage [24]. Many people were also unable to discern, which information on social media was true. Research has shown that fake news and misinformation can have detrimental effects on public health [11,25]. In China, the genuine or fake news of “the increasing number of patients and suspected cases nearby,” “the shortage of masks and disinfectants,” etc. influenced people's behavior. The utilization rate of pregnant women (often using various measures) was higher than that of nonpregnant women. One hundred percent of the subjects wore masks. This finding was anticipated because wearing masks is a common practice when people are sick or to counter urban pollution or haze in China [26,27]. In terms of transportation, more than 70% of the participants used cars to minimize their contact with others. Pregnant women seldom walked or rode, possibly because pregnancy made those options inconvenient.

The possible reason for those behavioral responses might have been related to the fear of COVID-19 infection, which may be related to the body's normal protective responses. We also found that pregnant women were most concerned about their fetus being infected, followed by their family members and themselves. In the control group, the trends of worrying were similar (data not shown). Although there was no evidence of in utero transmission [28], pregnant women were naturally concerned about the safety of their fetuses. However, related data on COVID-19 are still rare. We

may infer that if the pregnant women themselves were infected, they would further worry about spreading to the fetus, which would result in more protection responses.

The prevalence of prenatal psychological reaction could be different during the trimesters of pregnancy [29,30], which may lead to different behavioral responses. It is also controversial whether perinatal anxiety or depression is higher in a particular trimester during pregnancy [31,32]. In our study, there were no significant differences in all the behavioral items among the pregnant women in the three trimesters. This finding may be because the impact of epidemic stress on pregnant women exceeds the stress of the trimester itself, although a further study is necessary.

Study limitation

This study also has some limitations. First, the participants who wished to participate in this study were recruited though online consultation manner, which might narrow the recruitment of participants. Second, the questionnaire was designed by our team, and there was no other research to measure the effectiveness of the questionnaire. However, the questionnaire was designed based on a qualitative study and it was a collection of questions on how people react to COVID-19. The questionnaire has contributed to this research and merits use. Third, the study lacks longitudinal follow-up. The arduous situation would gradually improve, and the behavioral state of the pregnant women might also improve. Thus, we will further investigate the of long-term follow-up of the participants, including pregnancy outcomes.

Conclusion

Pregnant women had some unique behavioral responses different form that of nonpregnant women. It is important to understand the behavioral responses of pregnant women in this network era. This will then provide some important information for government and medical workers to provide early interventions and supports by online manners.

Source of funding

This work was supported by National Health Commission Scientific Research Fund—Major Science and Technology Program of Medicine and Health of Zhejiang Province (WKJ-ZJ-1911). General Science and Technology Program of Medicine and Health of Zhejiang Province (2019KY140 & 2019RC096). Social Development Scientific Research Projects of the Science and Technology Bureau of Hangzhou (20180417A02, 20180533B84&20191203B124). Basic public welfare research project of Zhejiang Province (GD20H260003). Natural Science Foundation of Zhejiang Province (LQ21H040001).

Conflict of interest

The authors reported no conflict of interest. All authors have contributed significantly.

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Asian Nursing Research 15 (2021) 174–180

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Development of a Nomogram for Carbapenem-Resistant *Enterobacteriaceae* Acquisition Risk Prediction Among Patients in the Intensive Care Unit of a Secondary Referral Hospital

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ARTICLE INFO

Article history:
Received 11 August 2020
Received in revised form
4 February 2021
Accepted 15 February 2021

Keywords:
Calibration
Carbapenem-resistant *Enterobacteriaceae*
Models, Statistical
Risk factors

ABSTRACT

Purpose: This study aimed to identify the risk factors of carbapenem-resistant *Enterobacteriaceae* (CRE) acquisition to build a nomogram for CRE acquisition risk prediction and evaluate its performance.
Methods: This unmatched case-control study included 352 adult patients (55 patients and 297 controls) admitted to the intensive care unit (ICU) of a 453-bed secondary referral hospital between January 1, 2018, and September 31, 2019, in Busan, South Korea. The nomogram was built with the identified risk factors using multiple logistic regression analysis. Its performance was analyzed using calibration-in-the-large, the slope of the calibration plot, concordance statistic (c-statistic), and the sensitivity and specificity of the training set, subsets, and a new test set.
Results: The risk factors of CRE acquisition among ICU patients at a secondary referral hospital were Acute Physiology and Chronic Health Evaluation II score at the time of admission, use of a central venous catheter and a nasogastric tube, as well as use of cephalosporin antibiotics. At 20.0% of the predicted CRE acquisition risk in the training set, the calibration-in-the-large was 0, slope of the calibration plot was 1, c-statistic was .93, sensitivity was 85.5%, and specificity was 84.8%. The performance was relatively good in the subsets and new test set.
Conclusion: The nomogram can be used to monitor the CRE acquisition risk for ICU patients who have a similar case mix to patients in the study hospitals. Future studies need to involve more rigorous methodology and larger samples.

Introduction

Carbapenem-resistant *Enterobacteriaceae* (CRE) is rapidly spreading globally as the horizontal transmission of antibiotic-resistant genes occurs through plasmids to other strains [1,2]. According to the Centers for Disease Control and Prevention (CDC) report, 13 million people are infected with CRE annually, leading to 1100 deaths per year [3]. In South Korea, CRE cases have increased to 15,369 as of 2019 ever since four cases were initially reported in 2010 under sentinel surveillance [4]. As one of the control measures to CRE transmission, active screening testing (AST) is recommended to identify unrecognized CRE colonization among patients who might not be epidemiologically linked to known CRE patients [1,4]. As clinical cultures alone identify only a fraction of CRE patients [5], the majority of unrecognized CRE patients, a potential source of CRE transmission, might not be following contact precautions [1]. However, as a limited application of AST may increase the risk of missing unrecognized CRE patients, early detection of patients at high risk of CRE acquisition at hospital unit admission has been emphasized [6]. A few studies have identified the risk factors of CRE acquisition or proposed CRE acquisition risk prediction

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https://doi.org/10.1016/j.anr.2021.02.005
p1976-1317 e2093-7482/

model to assess the patients at high risk of CRE acquisition [7–9]. The logistic regression model or Cox's proportional risk model is mainly used to construct predictive models for dichotomous outcome variables such as CRE acquisition, but this statistical prediction model features a complex formula that is difficult to apply in the clinical setting [10].

Nomogram is being considered as a good alternative to the conventional risk prediction model [11], and has been used in medical fields to determine the prognosis of cancer patients [11,12] or predict the development of type 2 diabetes [10]. In particular, several advantages of nomogram have been reported in oncology, so, it may assist decision-making of patients and physicians [12]. It could estimate individualized risk based on patient and disease characteristics, incorporate continuous or dichotomous variables into prediction, was easy to use, and showed better estimation than clinician's judgement [11–13]. Nomogram is a graphical expression of the numerical relationship between an event and its risk factors, and is known to help clinicians easily calculate the risk of an event occurring using a scoring system without requiring complex statistical formulae [12,14]. It is composed of graphical lines of points ranging from 0 to 100, each risk factor, total points, and the risk of an event occurring. The length of each risk factor's line reflects the regression coefficient estimated by multiple logistic regression analysis, and the longest line implies the greatest impact on the risk of the event occurring [10,14]. Regardless of the statistical significance, 100 points are assigned to the variable with the highest beta in the model, and the remaining variables have points proportionally to the highest beta [14]. For example, when we assume that three variables such as "admission by direct transfer" ($\beta = 0.50$, $p = .020$), "use of a central venous catheter" ($\beta = 0.30$, $p = .060$), and "use of cephalosporin antibiotics" ($\beta = 1.20$, $p < .001$) are included in the CRE acquisition risk prediction models. The "use of cephalosporin antibiotics" is assigned 100 points first, "admission by direct transfer" gets 41.7 points ($\beta_{\text{admission by direct transfer}}/\beta_{\text{use of cephalosporin antibiotics}}$ multiplied by 100), and "use of a central venous catheter" gets 25 points ($\beta_{\text{use of central venous catheter}}/\beta_{\text{use of cephalosporin antibiotics}}$ multiplied by 100) [14]. Patients who admit by direct transfer use a central venous catheter and cephalosporin antibiotics will get 166.7 points in total, and will have the CRE acquisition risk matching to the total points [12,14]. As in the model performance, the nomogram performance is assessed in terms of calibration, discrimination, and clinical utility [12].

In South Korea, a CRE risk prediction model has been developed for patients admitted to the intensive care units (ICUs) at a large-sized tertiary general hospital with more than 1000 beds, and showed a relatively good level of calibration, discrimination, and clinical utility [9,15]. However, the model showed poor discrimination and clinical utility in an ICU of a secondary referral hospital because of differences in the case-mix in an external validity study, and new CRE risk prediction models for ICUs in secondary referral hospitals have been recommended [16]. Therefore, this study aimed to develop a new CRE risk prediction model for secondary referral hospitals and propose a nomogram based on the new model. The specific objectives are to: (1) identify the risk factors of CRE acquisition for ICU patients in the secondary referral hospital, (2) build a CRE acquisition risk prediction model and a nomogram from the model, and (3) evaluate the performance of the nomogram (calibration, discrimination, and clinical utility).

Methods

Study setting and population

This unmatched case-control study was conducted in a 22-bed medical–surgical ICU at D hospital in Busan, a 453-bed secondary referral hospital. The inclusion criteria were patients admitted to an ICU and who were monitored by active surveillance culture (using rectal swabs) between January 1, 2018, and September 31, 2019. The exclusion criteria were those who were readmitted to the ICU during the same period, did not have a surveillance test at ICU admission and within 7 days of ICU admission, were CRE carriers at ICU admission, and were not confirmed to be CRE acquisition or not.

The sample size of the training set was calculated using Open Source Epidemiologic Statistics for Public Health [17]. We considered a significance level (a) of .05, power (1-β) of .85, percentage of controls exposed of 25.9%, odds ratio (OR) of 2.70 based on a previous study [9], and a case-to-control ratio of 1:5–1:6 [18]. Under the aforementioned condition, a minimum number of 50–52 cases (CRE carriers) and 257–298 controls (non-CRE carriers) are required. Cases refer to patients who were tested negative for CRE in active surveillance culture test on admission, but acquired CRE later during the ICU hospitalization, whereas controls were patients who were tested negative for CRE at admission or on weekly tests until discharge. Cases were retrospectively selected first, whereas controls were selected patients who were hospitalized during the same period. We sorted non-CRE carriers by month, assigned the serial number from 1 to n to the non-CRE carriers, and consecutively generated random numbers using "RAND" function in the Excel version 2016 (Microsoft, Redmond, WA, USA) program. And then, non-CRE carriers with serial numbers corresponding to the first 14 or 15 random numbers were selected as controls.

During the study period, 1031 patients were admitted to the ICU, 483 patients were excluded with the following reasons: readmission (n = 130), no surveillance test at ICU admission (n = 134), no surveillance test within 7 days of ICU admission (n = 195), CRE carriers at ICU admission (n = 14), and were not confirmed to be CRE acquisition or not at the end of the study (n = 10). Of the 548 patients (53.2% of the population) who met the inclusion criteria, 55 patients were CRE carriers and 493 patients were non-CRE carriers. All CRE carriers were selected as cases, and in total, 297 were selected as control (Supplementary Figure 1).

Two types of test sets were established to evaluate the performance of the nomogram for CRE acquisition risk prediction—five subsets of the training set with resampling techniques for internal validation and a new test set with sampling from different but related source populations for external validation [19]. When evaluating the validation by dividing a large sample into a small sample, 10 events per variable is recommended [20]. In this study, 55 cases of the training set were randomly allocated into five groups of 11 people each; the controls were also randomly classified into five groups. The new test set was selected from October 1, 2019, to February 28, 2020, at the same medical center. During this period, a total of 201 patients were admitted to the ICU, of whom 166 subjects (8 CRE carriers and 158 non-CRE carriers) met the selection criteria. All the eight CRE carriers were included as cases and 42 non-CRE carriers were randomly selected as controls.

Study instrument

A structured data collection form was used to extract electronic medical record (EMR) data. The form consisted of the outcome variable (CRE acquisition) and several explanatory variables such as general characteristics, therapeutic procedures, use of indwelling catheters, and use of medication/antibiotics based on previous studies [8,9]. The CRE definition adopted the Korea CDC's recommendation based on the Clinical and Laboratory Standards Institute's recommendation (M100-S27) [21]. Antimicrobial susceptibility to carbapenems was assessed using the disk diffusion and broth diffusion methods. The isolates that were intermediate or resistant to imipenem (≤22 mm, ≥2 μg/mL minimum inhibitory concentration) or ertapenem (≤21 mm, ≥1 μg/mL minimum inhibitory concentration) were considered CRE.

The following general characteristics of the patients were evaluated: age, gender, admission route, length of ICU stay, comorbidities (diabetes and stroke), Charlson comorbidity index (CCI) score, Acute Physiology and Chronic Health Evaluation (APACHE) II score at admission, and multidrug-resistant organisms isolated. Comorbidity was categorized as "Yes" if they were present. Therapeutic procedures included surgery, endoscopy (stomach, bronchial), mechanical ventilation, tracheostomy, and transplantation. Indwelling catheters included a urinary catheter, a central venous catheter, a nasogastric tube, and various drainage tubes. Medications included gastric acid suppressants, immunosuppressants, penicillin, carbapenems, third- or fourth-generation cephalosporins (hereafter cephalosporin), quinolones, vancomycin, tetracyclines, and polymyxin B.

Data collection

For data collection, one author with 3 years of experience in infection control at this study hospital reviewed and extracted EMRs, and verified the accuracy of data extracted from the EMR to the data collection form, using 10 randomly selected cases. Exposure to risk factors was investigated from ICU admission to CRE acquisition for cases and from ICU admission to discharge for controls.

Data analysis

The collected data were analyzed using IBM SPSS Statistics 25.0 for Windows (IBM., Armonk, NY, USA) and R version 3.6.3 (The R Foundation, Vienna, Austria). A two-tailed test was performed with a significance level (α) of .05. The Chi-square (χ^2) test, Fisher exact test, or Mann–Whitney U test was performed to compare the explanatory variables between cases and controls. Variables with $p < .05$ in the aforementioned tests were included in the stepwise multiple logistic regression analysis, and adjusted ORs and 95% confidence intervals (CIs) were calculated. Based on the regression analysis results, a logit model for CRE colonization risk prediction and its nomogram were constructed.

The performance of the logit model and the nomogram were evaluated using a training set, five subsets, and a new test set in terms of calibration, discrimination, and clinical utility. Before the performance analysis, the χ^2 test or Mann–Whitney U test was performed to confirm the homogeneity in the explanatory variables between the training set

Table 1 *Comparison of Groups With and Without CRE Acquisition in the Training Set (N = 352).*

Variables	Total (n = 352)	n (%) or Mean ± SD		X^2 or Z	p
		Case (n = 55)	Control (n = 297)		
General characteristics					
Age (yr)	69.00 ± 13.26	73.02 ± 12.94	68.26 ± 13.21	−2.67	.008§
Women	155 (44.0)	26 (47.3)	129 (43.4)	0.28	.598
Admission by direct transfer†	49 (13.9)	21 (38.2)	28 (9.4)	32.02	<.001
Length of stay in ICU (days)	10.08 ± 10.99	20.02 ± 13.19	8.24 ± 9.48	−7.80	<.001§
Diabetes	118 (33.5)	22 (40.0)	96 (32.3)	1.23	.268
Stroke	68 (19.3)	14 (25.5)	54 (18.2)	1.58	.210
Charlson comorbidity index	3.28 ± 1.86	3.82 ± 1.74	3.18 ± 1.87	−.253	.012§
APACHE II at ICU admission	11.97 ± 5.31	17.76 ± 5.27	10.90 ± 4.58	−8.03	<.001§
MDROs isolated	60 (17.0)	19 (34.5)	41 (13.8)	14.12	<.001
Invasive procedures					
Surgery	97 (27.6)	12 (21.8)	85 (28.6)	1.08	.300
Endoscopy	5 (1.4)	1 (1.8)	4 (1.3)	0.07	.575¶
Bronchoscopy	10 (2.8)	5 (9.1)	5 (1.7)	9.23	.011¶
Indwelling catheters use					
Urinary catheter	346 (98.3)	55 (100.0)	291 (98.0)	1.13	.595¶
Central venous catheter	141 (40.1)	47 (85.5)	94 (31.6)	55.95	<.001
Mechanical ventilator	47 (13.4)	21 (38.2)	26 (8.8)	34.74	<.001
Tracheostomy	13 (3.7)	10 (18.2)	3 (1.0)	38.47	<.001
Nasogastric tube	148 (42.0)	52 (94.5)	96 (32.3)	73.73	<.001
Drainage tube	76 (21.6)	21 (38.2)	55 (18.5)	10.60	.001
Medication use					
Gastric acid suppressant	128 (36.4)	28 (50.9)	100 (33.7)	5.96	.015
Penicillin	115 (32.7)	42 (76.4)	73 (24.6)	56.57	<.001
Carbapenem	92 (26.1)	31 (56.4)	61 (20.5)	30.85	<.001
Cephalosporin‡	160 (45.5)	48 (87.3)	112 (37.7)	45.98	<.001
Aminoglycoside	13 (3.7)	2 (3.6)	11 (3.7)	0.01	1.00¶
Fluoroquinolone	34 (9.7)	3 (5.5)	31 (10.4)	1.32	.250
Vancomycin	45 (12.8)	22 (40.0)	23 (7.7)	43.30	<.001

Note. APACHE = Acute Physiology and Chronic Health Evaluation; CRE = carbapenem-resistant *Enterobacteriaceae*; ICU = intensive care unit; MDROs = multidrug-resistant organisms; SD = standard deviation.

† AAdmitted by direct transfer from acute hospitals or non-acute care facilities.

‡ TThird- or fourth-generation cephalosporins.

§ Mann–Whitney U test.

¶ Fisher exact test.

and the subsets or new test set. The calibration was assessed using the Lemeshow–Hosmer goodness-of-fitness test (L–H test) [22], calibration-in-the-large, and the slope of calibration plot [19,22,23]. When the observed and average predicted risk is perfectly matched, the calibration-in-the-large is 0 and the slope of calibration plot is 1 [19]. To evaluate discrimination, concordance statistic (c-statistic) is the same as the area under the receiver operator characteristic curve and 95% CIs were obtained. The c-statistic has a value of 0.5 (not discriminated) from 1.0 (complete discrimination), and the larger the c-statistic, the better the discrimination [23,24]. To evaluate clinical utility, the sensitivity, specificity, positive and negative predictive values, as well as the correct classification rate were calculated using a 2 × 2 decision table between the actual CRE acquisition and predicted CRE acquisition at a 20% CRE acquisition risk that maximized the sensitivity and specificity of the receiver operator characteristic curve.

Ethical considerations

This study was approved by the Dongeui Hospital Institutional Review Board (Approval no. DEMC–2020–02). The requirement for informed consent was waived because the study involved a retrospective review of de-identified data.

Results

Comparison of explanatory variables between cases and controls

In Table 1, we described the characteristics of the sample. For cases, 47.3% were women with a mean age of 73.02 years and a mean length of stay in ICUs of 20.02 days. The mean APACHE II score was 17.76 points, 85.5% had a central venous catheter, and 56.4% and 87.3% of them have used carbapenem and cephalosporin antibiotics, respectively. For controls, 43.4% were women with a mean age of 68.26 years and a mean length of stay in ICUs of 8.24 days. The mean APACHE II score was 10.90 points, 31.6% had a central venous catheter, and 20.5% and 37.7% of them have used carbapenem and cephalosporin antibiotics, respectively. The cases and controls showed significant differences in all characteristics except gender, comorbidities such as diabetes and stroke, invasive procedures such as surgery and endoscopy, use of urinary catheters, and use of fluoroquinolone antibiotics (Table 1).

The CRE acquisition risk prediction model and nomogram

Compared with other cases, the risk of CRE colonization was 2.47 times (OR = 2.47, 95% CI = 1.02–5.98, $p = .044$) higher in cases that were admitted by direct transfer, 2.95 times (OR = 2.95, 95% CI = 1.16–7.48, $p = .023$) higher in cases in which a central venous catheter was used, 14.20 times (OR = 14.20, 95% CI = 3.93–51.33, $p < .001$) higher in cases in which nasogastric tube was used, 3.93 times (OR = 3.93, 95% CI = 1.51–10.22, $p = .005$) higher in cases in which cephalosporin was used, and 1.16 times (OR = 1.16, 95% CI = 1.07–1.25, $p < .001$) higher in cases in which APACHE II scores increased by 1 point (Table 2). Based on the multiple logistic regression analysis results, the logit model for CRE colonization risk prediction was as follows: E (logit of CRE acquisition) = −7.15 + 0.91 (admission by direct transfer) + 0.15 (APACHE II score at admission) + 1.08 (use of a central venous catheter) + 2.65 (use of nasogastric tube) + 1.368 (use of cephalosporin antibiotics). In the nomogram of the CRE acquisition risk prediction model, points allocated to direct transfer, use of a central venous catheter, use of a nasogastric tube, and use of cephalosporin antibiotics were 0 or 18, 0 or 21, 0 or 51, and 0 or 27, respectively, and 1 point of the APACHE II score at admission was allocated about 2.86 points (range: 0–217 points; Figure 1).

Table 2 *CRE Acquisition Prediction Model Built by Logistic Regression Analysis of the Training Set (N = 352).*

Variables	b	SE	OR (95% CI)	*p*
Admission by direct transfer†	0.91	0.45	2.47 (1.02–5.98)	.044
APACHE score	0.15	0.04	1.16 (1.07–1.25)	<.001
Central venous catheter use	1.08	0.48	2.95 (1.16–7.48)	.023
Nasogastric tube use	2.65	0.66	14.20 (3.93–51.33)	<.001
Cephalosporin antibiotics use‡	1.37	0.49	3.93 (1.51–10.22)	.005
Constant	−7.51	0.98		<.001
(Nagelkerke $R^2 = 0.562$)				

Note. APACHE = Acute Physiology and Chronic Health Evaluation; CI = confidence interval; CRE = carbapenem-resistant *Enterobacteriaceae*; OR = odds ratio; SE = standard error.

† Admitted by direct transfer from acute hospitals or non-acute care facilities.

‡ Third- or fourth-generation cephalosporins.

Performance of the nomogram for the CRE acquisition risk prediction model

Table 3 shows the performance of the nomogram of the CRE acquisition risk prediction model. The nomogram showed good calibration using the L–H test ($p = .969$), and the calibration-in-the-large was 0 and the slope was 1 (Supplementary Figure 2). The C-statistic was .93 (95% CI, .90–.96) in the training set and was .88–.97 in the subsets and new test set (Figure 2). The sensitivity and specificity of the training set were 85.5% and 84.8%, respectively, when the predicted risk of CRE acquisition was 20.0%. For the subsets and new test set, the calibration-in-the-large was −0.55 to 0.34, the slope was 0.81–1.43, and 0 and 1 were included in the 95% CI, the sensitivity was 72.7%–100.0%, and the specificity was 75.0%–93.2%.

The comparison of the characteristics between the subsets, the new test set, and the training set is shown in Supplementary Table 1. Subsets 1 and 3 differed from the training set in surgery, and subset 5 differed from the training set in admission by direct transfer. The new test set differed from the training set in age, CCI score, use of a central venous catheter and a nasogastric tube, as well as use of penicillin and vancomycin antibiotics.

Discussion

This study aimed to identify the risk factors of CRE acquisition, to build a nomogram for CRE acquisition risk, and to evaluate its performance in a 453-bed secondary referral hospital. The risk factors for CRE acquisition in ICU patients were direct transfer, APACHE II score at admission, as well as use of a central venous catheter, a nasogastric tube, and cephalosporins. And, the nomogram composed of the above five factors was shown good calibration, discrimination, and clinical utility in the training set as well as subsets, and a new test set, which means that internal and external validities have been secured. This nomogram constructed in this study makes the healthcare workers easy to calculate the individual CRE acquisition risk, enables them to frequently assess the change in CRE acquisition risk. Therefore, it is expected to contribute to early detection of high-risk CRE patients, to rapid decision making whether the actual surveillance is needed or not in ICUs of secondary referral hospitals.

In this retrospective investigation of ICU patients of a secondary referral hospital over 21 months, about 10% of patients acquired CRE by the end of the study. This figure was lower than 20% CRE acquisition reported in a large-sized tertiary hospital with 1000 beds and more [9], but higher than 5% CRE acquisition reported in a

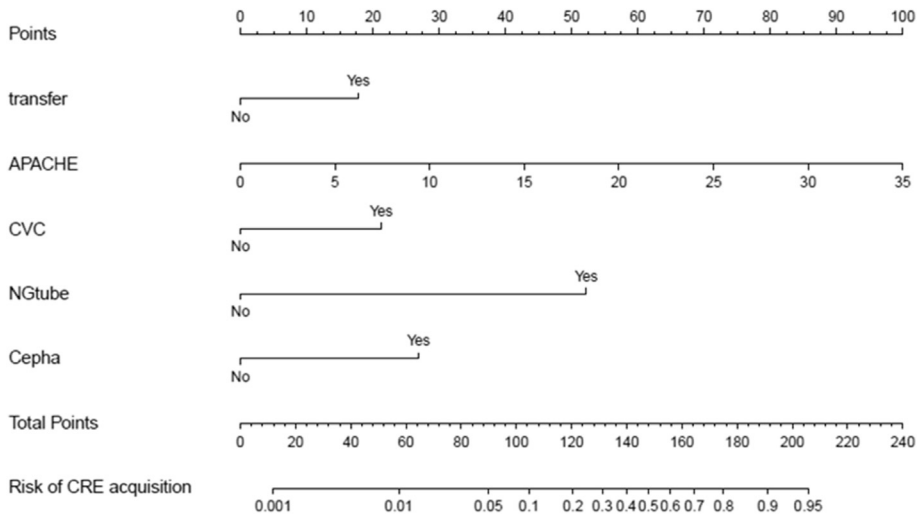

Figure 1. Proposed nomogram for the CRE acquisition prediction model.
Note. APACHE = Acute Physiology and Chronic Health Evaluation; Cepha = use of third- or fourth-generation cephalosporins; CRE = carbapenem-resistant *Enterobacteriaceae*; CVC = central venous catheter; NG tube = nasogastric tube; transfer = admitted by direct transfer from acute hospitals or non-acute care facilities.

similar-sized hospital in Israeli with 550 beds [25]. The difference in the CRE acquisition rate seems to be due to differences in age, subject severity, use of therapeutic procedures or antibiotics, and timing of the investigation.

Considering that the risk factors for CRE acquisition in a previous study in South Korea were the presence of multidrug-resistant organisms, APACHE II scores at admission, as well as use of cephalosporins and carbapenem antibiotics [9], APACHE II scores at admission and use of cephalosporins antibiotics are major risk factors for CRE acquisition, regardless of the size of the hospital and case mix. In particular, the APACHE II score at admission showed the longest line in the nomogram, which implies the greatest impact on the CRE acquisition risk [10,14]. As APACHE II score increases by 1 point, the CRE acquisition increases 1.16 times. Therefore, if other factors are the same, those with an APACHE II score of 20 points have 4.4 times higher in CRE acquisition than those with 10 points. However, age and CCI score were associated with CRE acquisition in the univariate analysis only. This finding may be explained that the correlation between age or CCI score and APACHE II score at admission was not enough to cause multicollinearity but weak (r = .38) or moderate (r = .42) correlation, respectively [26].

The CRE acquisition increases by approximately 4.0 times with use of cephalosporins in this study, which supports the results of previous case–control studies. The use of cephalosporins was increased CRE-induced bloodstream infection by 7.7 times in patients with neutropenia due to hemato-oncologic cancers [27], and the carbapenem-resistant *Klebsiella pneumoniae* (CRKP) infection by 8.0 times [28]. However, the use of aminoglycosides or quinolones has been reported as risk factors for CRKP infection in previous studies [28,29], but not in the present study. This may be because the use of aminoglycosides and quinolones in the control and control groups was too low (<10.0%) to make differences in this study.

In this study, patients who were transferred from acute or non-acute medical centers showed a higher CRE acquisition rate than those who were not. In a study by Goodman et al. [8], the presence of CRO at the time of admission to a general hospital was related to a direct transfer from acute or non-acute medical centers. Other studies have reported previous hospitalization instead of transfer as a risk factor of CRE or CRKP infection [29,30], which may be possible because CRE or CRKP acquisition could have occurred during the previous hospitalization and then developed into an infection during the new hospitalization. However, as we intended to identify the risk factors of CRE acquisition not limited to CRE infection, we excluded the patients detected with CRE at ICU admission using surveillance culture tests and included direct transfer instead of previous hospitalization as an explanatory

Table 3 *Validity Indices of Nomogram of CRE Acquisition Prediction Model in Training Set, Subsets, and a Test Set.*

Data set	Calibration			Discrimination	Clinical usefulness (%) at cut point of 20.0%		
	X^2 (*p*) by L–H test	a (95% CI)	b (95% CI)	c (95% CI)	Sen	Spe	CCR
Training data							
1 (n = 352)	2.34 (.969)	0.00 (−0.38–0.38)	1.00 (0.74–1.26)	.93 (.90- .96)	85.5	84.8	84.9
Subset of training data							
1 (n = 71)	6.04 (.643)	0.00 (−0.85–0.85)	1.00 (0.42–1.58)	.92 (.85–1.00)	81.8	85.0	84.5
2 (n = 71)	3.86 (.870)	0.00 (−0.79–0.79)	1.00 (0.30–1.70)	.88 (.81- .96)	100.0	75.0	78.9
3 (n = 70)	4.95 (.763)	0.00 (−0.98–0.98)	1.00 (0.45–1.55)	.96 (.90–1.00)	81.8	93.2	91.4
4 (n = 70)	2.35 (.968)	0.00 (−0.78–0.78)	1.00 (0.39–1.61)	.91 (.84- .98)	72.7	84.7	82.9
5 (n = 70)	1.84 (.985)	0.00 (−1.03–1.03)	1.00 (0.36–1.64)	.97 (.92–1.00)	90.9	86.4	87.1
New test set							
1 (n = 50)	2.32 (.940)	0.00 (−0.93–0.93)	1.00 (0.30–1.70)	.88 (.75–1.00)	87.5	78.6	80.0

Note. a = calibration in-the-large; b = calibration plot; c = concordance statistic; CCR = correct classification rate; CI = confidence interval; CRE = carbapenem-resistant *Enterobacteriaceae*; L–H test = Lemeshow–Hosmer test; Sen = sensitivity; Spe = specificity.

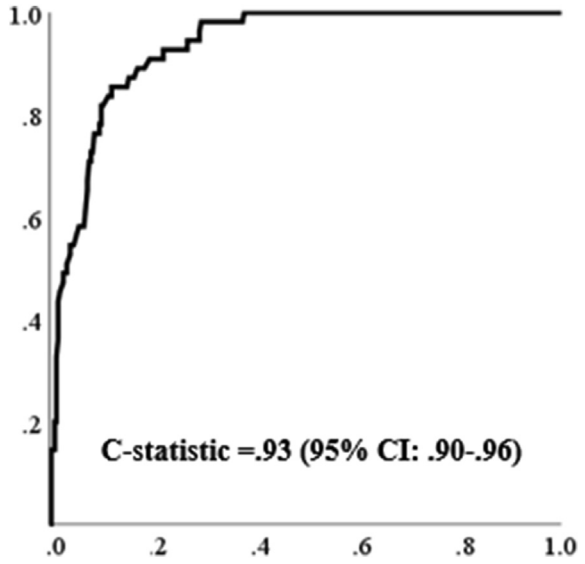

Figure 2. Receiver operating characteristic curve of proposed nomogram for the CRE acquisition prediction model.
Note. C = concordance; CI = confidence interval.

variable of CRE acquisition. The use of a central venous catheter was identified as a risk factor for CRKP infection (OR, 2.30) in a meta-analysis [29]. The risk of acquiring CRE was increased by about 14 times in nasogastric tube users (42%) compared with non-users, which was a key factor influencing CRE acquisition risk in this study. A study of patients in 43 acute and non-acute medical centers in Japan reported a three-fold increase in CRE acquisition risk depending on gastric tube feeding status [31].

In this study, a central venous catheter, a nasogastric tube, or cephalosporin antibiotics was used in more than 40% of the total samples. That is, these can be frequently seen in the ICU settings. Those who have exposure to three factors and an APACHE score of 12 points at admission corresponding to the average score will get 131 points in total and about 30% of CRE acquisition risk. If patients admit by direct transfer, the total points and CRE acquisition risk increase to 149 and more than 50%, respectively. Therefore, nurses working in ICUs need to be aware that the CRE acquisition risk rapidly increases as patients start to use a central venous catheter, a nasogastric tube, and cephalosporin antibiotics without an increase in the APACHE score.

The performance of the nomogram of the CRE acquisition risk prediction model constructed in this study showed good calibration on the L–H test and the calibration plot analysis [19,22] and good discrimination with a c-statistic of >.9 [23,24]. Assuming that 20% risk of CRE acquisition is a cutoff point for deciding CRE acquisition, the correct classification rate, sensitivity, and specificity are about 85%, showing relatively satisfactory clinical utility. However, when we changed 2.86 points to 3 points per 1 point of APACHE II score to facilitate the calculation in the clinical setting, the values of the performance indices of the nomogram were slightly changed, but they still showed good performance (Supplementary Table 2). Therefore, we recommended conversion of the APACHE II score to 3 points for easy use in the clinical setting. In this case, the total points of the nomogram were 0–222. The performance of the nomogram was additionally evaluated using five subsets randomly resampled from the training set and new test set. Although the sets differed significantly in several factors, including direct transfer and use of a central venous catheter and nasogastric tube, they showed relatively good calibration, discrimination, and clinical utility, which implied that the nomogram would have good internal and external validities.

This study is meaningful as it identified the risk factors of CRE acquisition for ICU patients in a secondary referral hospital. Furthermore, we built a nomogram for the CRE acquisition risk prediction model to enable its easy calculation in the clinical setting and evaluated its performance using the training set, subsets, and a new test set to help identify their internal and external validities. However, careful interpretation of the results is required because of the following limitations. First, we adopted an unmatched case–control study design not to exclude demographic characteristics (e.g., gender and age) by matching. However, the case–control study without matching increases the risk of selection bias, so cohort studies or propensity score-matched case–control studies should be considered. Second, the nomogram assumes that the event remains constant over time [12], but the CRE acquisition rate may change over time. Like the event, the distribution of risk factors may change over time. In the nomogram constructed in this study, the APACHE II score at the time of admission was 0–35 points, but some future patients may have scores outside this score range. Hence, the performance of the nomogram may decrease over time, requiring a new nomogram that reflects the change. Third, as this study was performed in a single ICU in a secondary referral hospital, it is difficult to generalize the results to other settings and regions.

Conclusion

The risk factors of CRE acquisition among ICU patients at a secondary referral hospital are APACHE II score at the time of admission, use of a central venous catheter and a nasogastric tube, as well as use of cephalosporin antibiotics. The nomogram for the CRE acquisition risk prediction model was built based on the risk factors, and showed good performance in terms of calibration discrimination and clinical utility for the training set, subsets, and a new test set. Therefore, the nomogram constructed in this study can be used to assess the risk of CRE acquisition and to early detect high-risk CRE patients in secondary referral hospitals. However, considering the limitations of this study, further studies with higher methodological rigor and larger samples in various settings are recommended.

Conflict of interest

The authors declared no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.02.005.

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Asian Nursing Research 15 (2021) 181–188

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Effects of Home-and-Workplace Combined Exercise for Patients with Ankylosing Spondylitis

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ARTICLE INFO

Article history:
Received 10 September 2020
Received in revised form
22 February 2021
Accepted 12 March 2021

Keywords:
Exercise
Physical functional performance
Spondylitis, ankylosing
Workplace

ABSTRACT

Purpose: The purpose of this study was to investigate the effects of home-and-workplace combined exercise on physical function, depression, and work-related disability in patients with ankylosing spondylitis.
Methods: This study adopted a non-randomized quasi-experimental design. Fifty-two patients were recruited: home-and-workplace combined exercise (n = 17), home exercise (n = 18), and control group (n = 17).
Results: The home-and-workplace combined exercise group showed improvement in spinal mobility and pulmonary function and significantly lower absenteeism and overwork impact than the home-exercise group and control group. The home-and-workplace combined exercise and home exercise groups showed a higher level of activity improvement than the control group.
Conclusion: home-and-workplace combined exercise can be recommended to patients with ankylosing spondylitis to enhance their physical function, including spinal mobility and pulmonary function, and reduce work-related disability.

Introduction

Ankylosing spondylitis (AS) is a manifestation of a systemic chronic osteoarticular inflammatory disease characterized by inflammation of the spine (spondylitis) and large joints [1]. The prevalence rate of AS per 10,000 people is 23.8 in Europe, 16.7 in Asia, 31.9 in North America, 10.2 in Latin America, and 7.4 in Africa [2]. In South Korea, the mean prevalence per 100,000 people was estimated at 31.62 in 2010, and it increased sharply to 52.30 in 2015, at an annual rate of 7.7%. The age range of the 20s to 40s showed the highest prevalence rate, and the prevalence among males was 3.6-fold higher than that among females [3]. In particular, the reduced physical function among the economically active population may have a negative effect on their household financial situation, employment, and social activities [4,5]. Thus, the rehabilitation of employed AS patients is a crucial theme.

AS patients usually experience not only articular manifestations in the shoulders, knees, hands, and feet, but also non-articular manifestations in the cardiovascular, nervous, and digestive systems. These symptoms are usually accompanied by pain, stiffness, and fatigue. In addition, the pulmonary function may be reduced due to spinal involvement and decreased thoracic diameter [6]. It also aggravates patients' fear and anxiety regarding the worsening of the disease and subsequent depression and fatigue, which can lead to sleep disorders [7]. Finally, it can reduce their engagement in daily activities and quality of life [8].

Despite recent reports stating that pharmacotherapy, such as tumor necrosis factor-alpha (TNF-α) inhibitors, can improve the quality of patients with AS, non-pharmacological therapies, including exercise, physiotherapy, and education, continue to be used as adjuvant therapies. In particular, exercise is highly recommended [9]. Normally, exercises for patients with AS are designed to enhance their strength, flexibility [10]. Exercises prescribed to patients with AS are effective not only in reducing disease activity, pain, stiffness, and fatigue, but also in enhancing physical function,

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https://doi.org/10.1016/j.anr.2021.03.001
p1976-1317 e2093-7482/

including spinal mobility and pulmonary function, engagement with daily activities, quality of sleep, and mental health [11].

In many cases, AS tends to have an early age of onset, and most patients have vocational jobs, so there is a strong need for exercises that are not limited to place and time [10]. Unfortunately, there are no specific instructions on exercise methods and intensities for office workers [12]. In many previous studies, home-based exercises have been recommended for patients with AS, as it allows patients to perform exercises in an autonomous and independent manner without space and time constraints, but the risk of low exercise adherence is high because of disability, fatigue, and worsening of symptoms [13].

Employed AS patients have three-fold higher risks of work-related disability, decreased work productivity, absenteeism, etc., because of physical and structural changes and dysfunction. The High Spondylitis Disease Activity Index and decreased function due to physical damage are the main indicators of unintended retirement [14]. Additionally, work efficiency decreases because of physical discomfort, pain, and fatigue [15]. In order to prevent social and economic burden and loss caused by AS, measures should be taken to prevent the occurrence of disability in the workplace, decrease in productivity, and work instability in the early stage through appropriate clinical measures and mediation at the workplace [5].

Exercise plays a crucial role in preventing and controlling chronic diseases, and it has been reported that regular exercise has a positive effect on the reduction of sickness presenteeism and health-related productivity loss [16]. The effectiveness of exercise (hospital- or home-based) in improving the physical and mental state of AS patients has been proven in previous research [17]. Workers with AS tend to be weaker, both physically and psychologically, and experience more work disabilities than workers without AS [4].

Health-enhancing exercises during office hours at the workplace are effective for disease prevention and rehabilitation [18]. In addition, customized exercise programs that consider the individual characteristics of the workers are effective in enhancing the exercise implementation rate [12]. Thus, home and workplace combined exercises that consider the characteristics of employed AS patients are expected to help delay physical deformation and sustain healthy work-life balance through high exercise compliance. However, very few studies have validated the effect of exercise intervention at the workplace, especially for AS patients.

Although workers are aware of the need to exercise, they find it difficult to adhere to regular exercise at the workplace because of their irregular work schedules and lack of time. Hence, they need some spare time to engage in exercise and relieve discomfort. This research aimed to develop an exercise program that combines a house-based program and additional methods that can be incorporated at the workplace to maximize the effectiveness of exercises. Thus, this study developed and applied a home-and-workplace combined exercise program for AS patients and evaluated its impact on physical function, depression, and work-related disability.

Methods

Sample and setting

The patients were recruited from among AS patients who visited the rheumatology outpatient ward of a university hospital in South Korea. The inclusion criteria were as follows: (1) age above 18 years; (2) full-time employment; (3) no progression of the bamboo spine on radiographical scans, which is caused by the development of marginal syndesmophytes leading to fusion of vertebral bodies [19]; (4) AS diagnosis in the last 15 years, considering evidence indicating that exercise has a remarkable effect on patients at a young age or in the early stages of diagnosis [20]; (5) Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of 4.0 points or lower, considering evidence that exercises are clinically effective in a state of stable physical symptoms [21]; (6) lack of regular exercise for the last 6 months; (7) use of medication for the last 6 months; and 8) inability to exercise more than 5 days per week at home and the workplace. Those with uncontrolled chronic diseases or psychiatric history and currently on psychiatric medication were excluded.

G*power statistical software (Heinrich Heine University, Düsseldorf, Germany) was used to determine the sample size for a repeated-measures analysis of variance at 95.0% power, an effect size of 0.30 [22], and a 5.0% level of significance. As a result, the minimum number of patients required in the HWE group (home-and-workplace combined exercise program), HE group (home-based exercise program), and control group (use of pamphlets with information on the disease, exercise, and usual care) was estimated to be at least 16 patients. Considering the dropout rate, 22 patients were recruited and assigned to each group. In the HE group, four patients were excluded for the following reasons: exercise compliance for 4 or fewer days weekly ($n = 3$) and worsening of symptoms ($n = 1$). In the control group, five patients were excluded because they refused to participate in follow-up surveys due to personal reasons. The final participant count was 17 in the HWE group, 18 in the HE group, and 17 in the control group (Figure 1).

Development of Home-and-Workplace combined exercise program

The program was developed in three stages: (1) in-depth literature review, (2) survey of patients' needs, and (3) designing of the exercise program [10,11]. The first step was to identify related research articles published between January 2005 and May 2017. Various institutions and studies have recommended general exercise instructions for patients with AS. However, there are no official instructions for vocational workers at the workplace. Thus, we aimed to identify exercise instructions for this patient population. The purpose, form, place, duration, and number of exercises were examined through an in-depth literature review. In the second stage, the need for exercise programs for patients with AS was identified. A focused group interview was conducted. The disease duration was classified into three categories: less than 10 years, 10–19 years, and 20 years or more. Each category included two patients (a total of six patients) and the duration of each interview was 90 minutes. Their physical discomfort and demand for exercise in the presence of symptoms were determined through these interviews. As per the focused interview, the main obstacles to exercise were lack of time, lack of assurance about the effect of exercise, and lack of knowledge about exercise. In addition, the patients wanted individually tailored exercises that could be carried out in their spare time and ease physical discomfort during work.

In the third stage, a home-and-workplace combined exercise program was designed. Based on the results of the first and second stages, the exercise program was modified and supplemented with five sessions of consultation with two physical therapists. The intensity and duration of the exercise program developed in this study were based on evidence from previous studies [10–12,22–26]. The home-based exercise program consisted of stretching and muscle strengthening, walking, and deep breathing exercises using an incentive spirometer. The workplace-based exercise program comprised stretching and muscle-strengthening exercises. During the 8 weeks, the HWE group was prescribed home-based (5 days/week, 70 min/day) and workplace-based

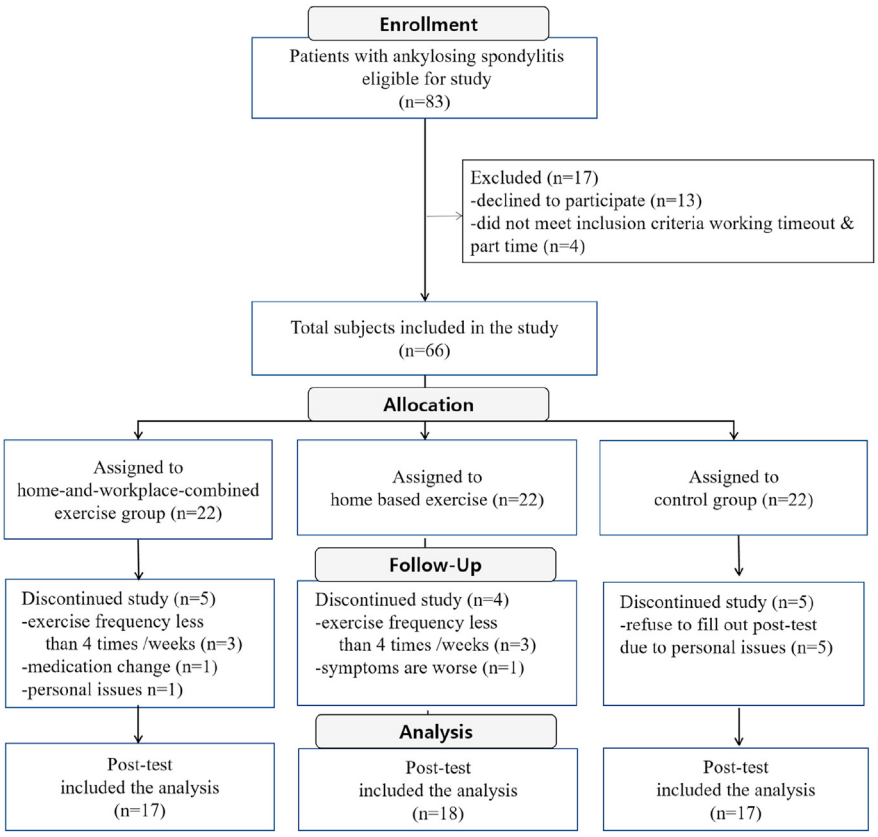

Figure 1. Flow diagram of the study design.

(5 days/week, 20 min/day) exercise, the HE group was prescribed only home-based exercise, and the control group was prescribed routine treatment and nursing consultation, i.e., health education for 90 minutes, including the need for regular medical checkups, information about the disease, management of daily life activities, and basic exercise methods (Appendix 1).

Stretching and muscle strengthening exercises were based on the recommendations of the Ankylosing Spondylitis Society in the United States of America for enhancing patients' flexibility and strengthening their muscles [27]. The 10-minute warm-up exercises comprised five movements to relax whole-body muscles and ensure safe exercise.

The walking exercise was based on the criteria proposed by the American College of Sports Medicine [23]: speed of 5 km/h (exercise intensity of 40–50%), a gradient of 15%, frequency of 5 times/week, and duration of 30 min per session. Since none of the patients had a bamboo spine, the exercise intensity was applied without modification.

The recommendation of deep breathing exercise using the incentive spirometer was based on evidence on the effectiveness of incentive spirometry for patients with AS [24]. For the regular deep breathing exercise, the flow-oriented incentive spirometer (DHD 22-4000; Vol.4,000 mL, disposable, Munmun Trading) was used.

To improve the exercise compliance rate, workout videos, training materials, and exercise notebooks were prepared and distributed. The exercise regimen was reviewed by one rheumatologist, one rehabilitation specialist, one preventive medicine specialist, two nurses who had doctoral degrees with more than 10 years of clinical experience, and one physical therapist all of whom did not participate in the design of the program. Expert content validity was indexed for all measurement items, including the composition, method, intensity and time, intervention period, and safety. The usability of the program was scored at 0.82–1.00 points.

Instruments

Physical function

Spinal mobility. Spinal mobility was measured using the Bath Ankylosing Spondylitis Metrology Index (BASMI) developed by Jones et al. [28]. The BASMI comprises five test items related to physical function: tragus-to-wall distance (TWD), lumbar flexion (modified Schober's test, MST), intermalleolar distance (IMD), cervical rotation (CR), and lumbar side flexion (LSF).

The measurements were repeated three times, and the highest value was selected. Each measurement was scored on a 3-point scale: 0 points for mild disease involvement, 1, for moderate disease involvement, and 2, for severe disease involvement; the total accumulated score would be 0–10 points. Scoring was based on the findings of a previous study [28], with higher scores indicating worse spinal mobility.

Pulmonary function

Chest expansion. The degree of chest expansion was evaluated by measuring the chest circumference around the fourth intercostal space using a tape (MK Distribution, Korea) with the patient inhaling as much as possible. After three measurements, the highest value was selected. If the difference between the maximum

inhalation and exhalation was 5 cm or more, it was evaluated as "normal."

Lung capacity index. The lung capacity index was measured using the Spirometer HI-801 (CHEST, Japan), and the largest value was selected after repeated measurements. Forced vital capacity (FVC), forced expiratory volume in 1 second (FEV_1), forced expiratory volume in 1 second/forced vital capacity (FEV_1/FVC), and peak expiratory flow (PEF) were measured. The lung capacity measurement equipment was calibrated once per week to ensure the accuracy of the measured data.

Depression

Depression was measured using the Korean version of the Beck Depression Inventory (BDI) [29]. The BDI comprised 21 questions, and the response to each question was scored on a scale of 0–3 points. The total accumulated scores ranged from 0 to 63 points: 0–9 points for normal depression, 10–18 points for mild depression, 19–29 points for moderate depression, and 30–36 points for severe depression. In this study, the reliability of the tool as per Cronbachs's α was .90.

Work disability

Work disability was measured using the Work Productivity and Impairment Questionnaire [30]. This tool's validity and reliability for AS patients have been verified in previous research. The Korean version of this tool can be downloaded from the official website of Reilly Associates. The Work Productivity and Activity Impairment – Ankylosing Spondylitis (WPAI-SpA) consists of six questions designed to evaluate the impact of the exercise regimen on the work productivity and daily activities of AS patients over the last week. Absenteeism (%), presenteeism (%), activity impairment (%), and overall work impairment (%) were quantified. Presenteeism is the opposite of absenteeism and refers to the degree of productivity of workers with health problems [31]. A higher score indicated a greater degree of work disability due to the disease.

Data collection

This study obtained approval (Approval no. EMC 2017-08-003-001) from the Institutional Bioethics Committee of the hospital. The purpose, procedures, and expected effects of the study were explained to the patients, and they were asked to provide informed consent. All the patients were informed that they could quit at any point in the program even after they have provided written consent.

Data were collected after obtaining consent from the physician in charge and head nurses at the hospital. To prevent the exercise regimen from being assigned to an unintended group, the control group (routine treatment) participated in the prescribed program from November 2017 to January 2018, while the HWE and HE groups participated in their respective prescribed exercise program from February to May 2018. The patients were allocated to the HWE and HE groups in the order of their outpatient visits.

Prior to the intervention, the HWE, HE, and control groups completed the physical function test and questionnaire survey. Spinal mobility and lung capacity tests were conducted by a single research assistant, who was a clinical technologist with 10 years of experience in conducting lung capacity tests and was trained in spinal mobility evaluation. To increase the reliability of the process, the researchers did not participate in the data collection process, and the data were measured by one research assistant. Additionally, the measurements were conducted in a single-blind manner so that the assistant did not know the group to which the participants belonged.

The HWE and HE groups were individually informed of the details and process of the exercise program. The duration of patient education was 60 minutes: the researchers demonstrated the exercises, and the patients were instructed to follow the demonstration, read the leaflets, and watch the videos. The researchers checked the exercise postures and corrected any improper postures. For the deep breathing exercises using the incentive spirometer, the researchers demonstrated how to perform the exercise using a leaflet. After the patients practiced the exercise, the researchers educated them on the proper technique and on maintaining the incentive spirometer in good condition. The patients were educated about the speed and method of the walking exercise. When the HWE and HE groups visited the outpatient clinic in the fourth week of the experiment, their exercise notebooks were reviewed to check their compliance and to motivate them to continue the exercise. The compliance was reported by telephone or through social network services (SNS) weekly (15–20 minutes per session), and the patients were provided feedback on symptom management. Stability was ensured by limiting the intensity of the exercise to a degree that did not cause pain through 8 weeks of continuous monitoring. The patients were encouraged to carry out the planned schedule more than five times a week.

At the end of the intervention (eighth week), the HWE, HE, and control groups underwent the same physical function tests and survey as at the pretest and the same data were collected, excluding the general characteristics. After the posttest survey, the HE and control groups were provided information about the exercise regimens prescribed to the HWE and HE groups, and the patients who wanted to engage in the exercise program were instructed accordingly.

Statistical methods and analysis

All collected data were analyzed using SPSS WIN 24.0 (IBM Corp., Armonk, NY, USA). The general characteristics were presented as numbers, percentages, means, and standard deviations, and the homogeneity test was performed using the -χ^2 test, Fisher's exact test, and independent t test. The effect of the program was validated using repeated measured ANCOVA. A post-hoc test was performed using the paired samples t test ($p < .05$) and the Bonferroni method ($p < .01$).

Results

Homogeneity test of general characteristics

Prior to the intervention, the homogeneity of the general characteristics of the HWE, HE, and control groups was tested, and the results showed no significant differences among the groups (Table 1).

Effect on physical function

Spinal mobility

No statistically significant differences were observed between the groups regarding the total score for spinal mobility ($F = 1.07$, $p = .353$). No significant changes in the total spinal mobility score were observed within the groups over time ($F = 0.66$, $p = .421$). No significant interactions between group and time for the total spinal mobility score were observed ($F = 2.30$, $p = .112$). The HWE group showed an enhancement in spinal mobility after the intervention compared to before ($t = 3.77$, $p = .002$), and the HE and control groups did not show significant changes.

Table 1 *Homogeneity Test for General Characteristics between Groups (N = 52).*

Characteristics	Categories	Total n(%) or M ± SD	HWE (n = 17) n(%) or M ± SD	HE (n = 18) n(%) or M ± SD	Cont. (n = 17) n(%) or M ± SD	F/χ^2	*p*
Age (years)		37.1 ± 6.7	38.4 ± 5.1	37.2 ± 8.0	35.6 ± 6.7	0.74	.480
Gender	Men	48 (92.3)	15 (88.2)	17 (94.4)	16 (94.1)	0.59	.744
	Women	4 (7.7)	2 (11.8)	1 (5.6)	1 (5.9)		
Marital status	Single	16 (30.8)	3 (17.6)	9 (50.0)	4 (23.5)	4.91	.086
	Married	36 (69.2)	14 (82.4)	9 (50.0)	13 (76.5)		
Educational level	High school	11 (21.2)	2 (11.8)	2 (11.1)	7 (41.2)	6.07	.048
	≥College	41 (78.8)	15 (88.2)	16 (88.9)	10 (58.8)		
Occupation	Self-employment	5 (9.6)	1 (5.9)	3 (16.7)	1 (5.9)	3.73	.444
	Office job	40 (76.9)	14 (82.4)	14 (77.8)	12 (70.6)		
	Production work	7 (13.5)	2 (11.8)	1 (5.6)	4 (23.5)		
Monthly income (10,000 KRW)	<250	13 (25.0)	2 (11.8)	6 (33.3)	5 (29.4)	2.43	.297
	≥250	39 (75.0)	15 (88.2)	12 (66.7)	12 (70.6)		
Period after diagnosis (month)	≤60	16 (30.7)	5 (29.4)	7 (38.9)	4 (23.5)	1.58	.812
	61~120	12 (23.1)	3 (17.6)	4 (22.2)	5 (29.4)		
	≥121	24 (46.2)	9 (52.9)	7 (38.9)	8 (47.1)		
BASDAI			3.32 ± 1.45	3.08 ± 1.21	3.01 ± 1.66		
Use of TNF-α inhibitor	Yes	41 (78.8)	13 (76.5)	15 (83.3)	13 (76.5)	0.33	.847
	No	11 (21.2)	4 (23.5)	3 (16.7)	4 (23.5)		

Note. BASDAI = Bath Ankylosing Spondylitis Disease Activity Index; Cont. = control group; HE = Home-based Exercise group; HWE = Home- and- Workplace combined Exercise group; KRW = Korean Won; M = mean; SD = standard deviation; TNF = Tumor Necrosis Factor.

In terms of lumbar flexion (MST score), intermalleolar distance (IMD), and cervical rotation (CR) in the subdomain, there were no statistically significant differences between the groups (F = 0.42, p = .661; F = 0.74, p = .483; F = 1.31, p = .279) or within groups (F = 0.36, p = .551; F = 2.07, p = .157; F = 0.03, p = .872). However, the MST score, IMD, and CR showed statistically significant differences in the group-time interaction (F = 3.35, p = .043; F = 6.45, p = .003; F = 5.34, p = .008) (Table 2).

Pulmonary function

In terms of chest expansion, one of the items used to test pulmonary function, there was no significant change between groups (F = 0.40, p = .672) or within groups over time (F = 0.02, p = .902). However, statistically significant differences were observed in the group-time interaction (F = 6.36, p = .004). In terms of peak efficiency flow (PEF), used to determine lung capacity, there was no significant change between the groups (F = 0.05, p = .953) or within groups over time (F = 2.44, p = .125); however, statistically significant differences were observed in group-time interactions (F = 3.42, p = .041) (Table 3).

Effect on depression

Regarding depression scores, there were no statistically significant differences between the groups (F = 1.09, p = .346), within groups over time (F = 0.11, p = .739), and in the group-time interaction (F = 0.61, p = .547) (Table 4).

Effect on work disability

Regarding work disability, all groups showed an absenteeism rate of 0% during the experiment period. Because there was no absenteeism, the rates of presenteeism and overall work impairment were similar. In terms of presenteeism, activity impairment, and overall work impairment, there were no statistically significant differences between the groups (F = 2.73, p = .076; F = 2.17, p = .125; F = 2.73, p = .076) or within the groups (F = 0.45, p = .507; F = 0.93, p = .341; F = 0.45, p = .507). However, statistically significant differences were observed in the group-time interaction for presenteeism, activity impairment, and overall work impairment (F = 4.67, p = .014; F = 3.90, p = .027; F = 4.67, p = .014) (Table 4).

Table 2 *Comparison of Spinal Mobility between Groups (N = 52).*

Variable	Group	Pretest M ± SD	Posttest M ± SD	Difference (pre-post) M ± SD	t	*p*	Sources	(N = 52)	
								F	*p*
Total	HWE	1.59 ± 0.62	1.12 ± 0.49	0.47 ± 0.51	3.77	.002	Group	1.07	.353
	HE	1.56 ± 0.86	1.39 ± 0.78	0.17 ± 0.62	1.14	.269	Time	0.66	.421
	Cont.	1.71 ± 1.05	1.65 ± 1.00	0.06 ± 0.43	0.57	.579	G*T	2.30	.112
MST (cm)	HWE	5.12 ± 0.94	5.54 ± 0.68	−0.41 ± 0.75	−2.25	.039	Group	0.42	.661
	HE	5.21 ± 1.31	5.21 ± 1.20	0.00 ± 0.82	0.00	1.000	Time	0.36	.551
	Cont.	5.18 ± 0.95	5.07 ± 0.88	0.11 ± 0.26	1.78	.095	G*T	3.35	.043
IMD (cm)	HWE	106.17 ± 12.83	110.06 ± 12.14	−3.89 ± 6.99	−2.36	.030	Group	0.74	.483
	HE	105.44 ± 11.84	111.24 ± 13.01	−5.79 ± 4.61	−5.18	.000	Time	2.07	.157
	Cont.	107.00 ± 18.08	105.12 ± 18.56	1.88 ± 5.36	1.45	.167	G*T	6.45	.003
CR (°)	HWE	48.47 ± 9.76	53.12 ± 7.82	−4.65 ± 5.45	−3.51	.003	Group	1.31	.279
	HE	51.39 ± 7.85	53.56 ± 9.76	−2.17 ± 5.02	−1.83	.085	Time	0.03	.872
	Cont.	47.76 ± 10.97	47.35 ± 10.75	0.41 ± 1.97	0.86	.402	G*T	5.34	.008

Note. HWE=Home-and-Workplace combined Exercise group (n = 17), HE=Home-based Exercise group (n = 18), Cont. = control group (n = 17); FVC = Forced Vital Capacity; FEV_1 = Forced Expiratory Volume in 1 second; PEF = Peak expiratory flow.
MST = modified Schober test; IMD=Intermalleolar distance; CR=Cervical rotation.

Table 3 *Comparison of Pulmonary Function between Groups (N = 52).*

Variable	Group	Pretest M ± SD	Posttest M ± SD	Difference (prepost) M ± SD	t	p	Sources	(N = 52)	
								F	p
Chest expansion (cm)	HWE	4.56 ± 1.19	5.16 ± 1.17	−0.61 ± 0.86	−2.89	.011	Group	0.40	.672
	HE	4.92 ± 1.19	5.61 ± 1.09	−0.69 ± 1.06	−2.75	.014	Time	0.02	.902
	Cont.	5.39 ± 1.59	5.13 ± 1.23	0.26 ± 0.54	1.98	.066	G*T	6.36	.004
Lung capacity									
FVC (liters)	HWE	3.81 ± 0.45	3.87 ± 0.42	−0.06 ± 0.12	−2.06	.056	Group	1.70	.194
	HE	4.26 ± 0.55	4.29 ± 0.46	−0.03 ± 0.14	−0.89	.388	Time	0.96	.333
	Cont.	4.18 ± 0.80	4.13 ± 0.76	0.05 ± 0.17	1.23	.237	G*T	2.25	.117
FEV_1 (liters)	HWE	3.17 ± 0.44	3.27 ± 0.38	−0.09 ± 0.14	−2.79	.013	Group	1.06	.356
	HE	3.50 ± 0.57	3.55 ± 0.44	−0.05 ± 0.25	−0.91	.375	Time	0.03	.859
	Cont.	3.42 ± 0.69	3.41 ± 0.68	0.01 ± 0.15	0.33	.747	G*T	2.09	.135
FVC/FEV_1 (%)	HWE	82.88 ± 3.67	84.00 ± 2.55	−1.12 ± 2.09	−2.21	.042	Group	0.44	.648
	HE	81.50 ± 5.77	82.50 ± 4.40	−1.00 ± 3.53	−1.20	.246	Time	0.20	.657
	Cont.	81.41 ± 3.36	82.12 ± 3.84	−0.71 ± 2.62	−1.11	.282	G*T	0.37	.690
PEF (liters/s)	HWE	8.40 ± 1.12	8.73 ± 1.01	−0.32 ± 0.62	−2.15	.048	Group	0.05	.953
	HE	8.96 ± 1.16	8.48 ± 1.63	0.48 ± 1.30	1.57	.135	Time	2.44	.125
	Cont.	8.85 ± 1.30	8.76 ± 1.23	0.09 ± 0.59	0.66	.519	G*T	3.42	.041

Note. Cont. = control group; FEV1 = Forced Expiratory Volume in 1 second; FVC = Forced Vital Capacity; HE = Home-based Exercise group; HWE = Home- and- Workplace combined Exercise group; PEF = Peak expiratory flow.

Discussion

After the 8-week HWE regimen, AS patients showed enhanced physical function, such as enhanced spinal mobility and pulmonary function and improvement in work capability. According to the results of this study, only the HWE group showed improvements in lumbar flexion and cervical rotation, while both the HWE and HE groups showed improvements in the intermalleolar distance.

The home-and-workplace combined exercise program was effective in improving some aspects of spinal mobility to some degree; in particular, the patients who adhered to the exercise regimen showed improvement in relaxation and flexibility of the lumbar and cervical vertebrae. However, because our study period was relatively short (8 weeks), we were unable to observe long-term improvements in physical function (i.e., spinal mobility). Thus, it is necessary to verify the long-term effects of exercise through longitudinal research.

For employed AS patients who were generally healthy, the exercises did not show any visible level of improvement, and they experienced difficulties in adhering to the exercise program because of the lack of information. Thus, a new strategy should be developed to motivate and enhance self-efficacy and improve the compliance of patients who are newly diagnosed and those who do not have any structural damages [32].

Exercise is prescribed to patients with AS to prevent mobility restriction and disease progression. However, if AS affects the lungs, the pulmonary function is compromised because of weakened inspiratory muscles [25]. According to the results for chest expansion in the lower domain of the postintervention pulmonary function test, the HWE and HE groups showed a higher level of improvement than the control group. In terms of peak expansion flow (PEF), which is a lung capacity index, the HWE group showed a higher level of improvement after the intervention than the HE and control groups.

These results are consistent with those of a previous study, which reported significant improvement in chest expansion after a 6-week intensive home-based exercise regimen [33], and of another previous study that reported similar results after a combination of home-based exercise and incentive spirometer exercise [22,24]. In this study, the HWE group showed improvement in chest expansion and peak expiratory flow, leading to the assumption that increased frequency of exercise helps improve pulmonary function. Therefore, including exercises for improving respiratory function in the rehabilitation treatment before further degradation of the pulmonary function will help enhance the quality of life.

After the intervention, the average depression level of the HWE and HE groups was lower than that of the control group, but not a significant level, possibly because the depression scores of the patients were all below 9 in the “normal” category. However, since previous studies have reported that exercise has a positive impact on decreasing the psychological stress of AS patients [26], this finding must be verified with studies involving larger samples and longer intervention periods than those used in this study.

AS-induced pain and structural changes in the skeletal system may pose a heavy burden on individuals and affect their social activities [34]. The combined exercise program that AS patients could perform at home and at work significantly reduced the work disability.

A period of 15 years or less had elapsed since the diagnosis of AS in our patients, and their disease activity was at a stable level, and all three groups had an absence rate of 0%. In terms of absenteeism and overwork impact, the HWE group showed a significant decrease after the intervention compared to the HE and control groups. In terms of activity impairment, the HWE and HE groups showed a higher level of improvement after the intervention than the control group. A previous study reported that workers with various occupations in Denmark showed improvement in muscle strength, reduction in body mass index, and an increase in workplace productivity after exercising for more than an hour per week for a period of approximately one year [18].

This finding is also similar to the results of a study that reported positive improvements in quality of life, depression, and work disability after 18 weeks of nutrition management programs for multi-agency workers in the United States [35]. Muscle-strengthening or endurance exercise regimes are usually prescribed for the management of pain in the neck and shoulder that office workers often develop. Although is no evidence showing the specific types of exercises that have a pain-relieving effect, stretching has a proven effect in reducing muscle rigidity and improving flexibility [36].

It is assumed that because the HWE group was actively addressing their physical discomfort at the workplace by performing exercises at home and work, they showed a reduction in work-related disability. However, as this study did not identify any direct association between exercise and work disability,

Table 4 *Comparison of Depression and Work Disability between Groups (N = 52).*

Variables	Group	Pretest M ± SD	Posttest M ± SD	Difference (prepost) M ± SD	t	*p*	Sources	(N = 52)	
								F	*p*
Depression	HWE	5.00 ± 4.11	2.53 ± 3.20	2.47 ± 2.43	4.20	.001	Group	1.09	.346
	HE	7.33 ± 8.22	4.72 ± 5.37	2.61 ± 4.72	2.35	.031	Time	0.11	.739
	Cont.	6.88 ± 5.77	5.53 ± 4.67	1.35 ± 2.89	1.93	.072	G*T	0.61	.547
Work Disability[a]									
Absenteeism (%)	HWE	0.00	0.00	–	–	–	–	–	–
	HE	0.00	0.00	–	–	–	–	–	–
	Cont.	0.00	0.00	–	–	–	–	–	–
Presenteeism (%)	HWE	18.82 ± 14.09	11.76 ± 9.51	7.06 ± 7.72	3.77	.002	Group	2.73	.076
	HE	20.00 ± 14.55	19.44 ± 13.92	0.56 ± 9.38	0.25	.805	Time	0.45	.507
	Cont.	24.71 ± 17.00	27.06 ± 16.59	−2.35 ± 8.86	−1.10	.290	G*T	4.67	.014
Activity impairment (%)	HWE	18.82 ± 10.54	13.24 ± 10.15	5.59 ± 7.05	3.27	.005	Group	2.17	.125
	HE	30.56 ± 22.35	22.22 ± 16.65	8.33 ± 13.83	2.56	.020	Time	0.93	.341
	Cont.	24.12 ± 16.22	25.88 ± 15.93	−1.76 ± 8.28	−0.88	.393	G*T	3.90	.027
Overall work impairment (%)	HWE	18.82 ± 14.09	11.76 ± 9.51	7.06 ± 7.72	3.77	.002	Group	2.73	.076
	HE	20.00 ± 14.55	19.44 ± 13.92	0.56 ± 9.38	0.25	.805	Time	0.45	.507
	Cont.	24.71 ± 17.00	27.06 ± 16.59	−2.35 ± 8.86	−1.10	.290	G*T	4.67	.014

Note. Cont. = control group; HE = Home-based Exercise group; HWE = Home- and- Workplace combined Exercise group.
[a] The three groups showed an absenteeism rate of 0% during the experiment. Because there was no absenteeism, presenteeism, and overall work.

qualitative and longitudinal studies should be conducted in the future. For patients with AS who have difficulty adhering to recommended exercises, multidisciplinary efforts are required to maintain physical function and improve work productivity. Because health improvement activities for workers are difficult to practice without systematic support (policy development, employer education, use of workplace health-promotion programs, etc.) [37], these aspects should not be ignored.

The dropout rate was 22.7% (5 persons) in the HWE group and 18.2% (4 persons) in the HE group, slightly higher than the 17.5% (14/80 persons) in a previous study [11] that implemented home exercise programs, and the reason for dropping out was not specified. In this study, the reason was the relatively strict regimen of more than five times a week. In the two exercise groups, the reason for dropping out was usually the inability to carry out the prescribed regimen of $\geq$5 times/week. According to the exercise records, the reasons for not exercising were because they "were too tired," "forgot to do it," and "had no time." Therefore, to continue the implementation of the exercise regimen, it is necessary to propose a flexible exercise method that can be adjusted to the individual situation of the patients, their willingness to exercise, and their health condition.

Rehabilitation nurses can recommend exercise programs at home and at work to improve the daily life activities and productivity at work of AS patients. Patients with AS can maintain a vibrant work-life by managing symptoms through exercise not only at home but also at work. In addition, the present study highlights the importance of customized exercise programs that consider the characteristics of AS patients and their effects. A specific approach was established by using various methods to motivate AS patients to self-manage and adhere to the exercise program.

However, this study has some limitations. First, the convenience sample increased the risk of sampling bias, which can limit the generalizability of the results of this study. Second, this study was a quasi-experimental study in which the variables were not controlled. Third, because of the relatively short duration and small sample size of our study, we did not include follow-up measures after the post-test, and it was not clear whether the gains from the intervention were maintained. We were unable to identify the workplace environments and situations that could affect the implementation and maintenance of the exercise and approach in the HWE group. In addition, this study failed to regulate the exercise that the patients individually performed at the workplace. The intervention duration should be longer than 8 weeks, and the effectiveness of the exercise should be validated using various factors. Additionally, the intensity of the effect of exercise depending on the stage of the disease should be evaluated. Systematic training programs should be developed, considering the severity of the disease, to reinforce motivation.

Conclusion

Based on the above results, the home-and-workplace combined exercise program for AS patients was effective as an intervention program to enhance their physical function, including spinal mobility (CR, IMD) and pulmonary function (chest expansion, PEF), and reduce work disability. This study produced meaningful outcomes and successfully developed and validated the effect of an exercise program for AS patients considering their work activities, allowing them to efficiently maximize their time and space. To enhance the exercise effect for employed AS patients, a program that can be performed at home and work is highly recommended.

Author contributions

The conception, design, data collection, analysis and interpretation of data, writing, and revising the manuscript critically were undertaken by Jong Mi Lim and Ok-Hee Cho.

Funding

None.

Conflict of interest

The authors declared no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Acknowledgments

This article is based on a part of the first author's doctoral thesis from Kongju National University.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2021.03.001.

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Asian Nursing Research 15 (2021) 189–196

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Effects of Virtual Reality Simulation Program Regarding High-risk Neonatal Infection Control on Nursing Students

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ARTICLE INFO

Article history:
Received 9 December 2020
Received in revised form
1 March 2021
Accepted 24 March 2021

Keywords:
Infection control
Neonatal nursing
Simulation training
Virtual reality

ABSTRACT

Purpose: Virtual reality simulation can give nursing students a safe clinical experience involving high-risk infants where access to neonatal intensive care units is limited. This study aimed to examine the effects of a virtual reality simulation program on Korean nursing students' knowledge, performance self-efficacy and learner satisfaction.

Methods: A nonequivalent control group design was applied. Senior nursing students were divided into an experimental group (n = 25) experiencing virtual reality simulation and routine neonatal intensive care unit practice and a control group (n = 25) having routine neonatal intensive care unit practice. The program consisted of three scenarios: basic care, feeding management and skin care and environmental management for prevention of neonatal infection. The total execution time for the three scenarios was 40 minutes. The simulation created immersive virtual reality experiences using a head-mounted display with hand-tracking technology. Data were collected from December 9, 2019, to January 17, 2020, and were analyzed using descriptive statistics and the t-test, paired t-tests, Mann-Whitney test and Wilcoxon signed-ranks test.

Results: Compared to the control group, the experimental group showed significantly greater improvements in high-risk neonatal infection control performance self-efficacy ($t = -2.16$, $p = .018$) and learner satisfaction ($t = -5.59$, $p < .001$).

Conclusion: The virtual reality simulation program can expand the nursing students' practice experience in safe virtual spaces and enhance their performance self-efficacy and learning satisfaction.

Introduction

The goal of practical clinical education in nursing is to improve the clinical abilities of nursing students by giving them first-hand experience in applying their skills to patients under complex, real-world conditions. However, South Korea lacks legal protections against liability for nursing students' actions, and the health rights of medical consumers and the importance of patient safety management must be considered [1]. Thus, students' practical training focuses more on observation and ancillary tasks than on direct skill application to patients, and many obstacles must be overcome to enhance students' clinical practice abilities. In compensating for these constraints, several forms of simulation education have been developed. These include use of the following scenarios: peer-to-peer learning; partial task trainer models; standardized and simulated patients; computerized task trainers and mannequins; screen-based computer simulations; and more recently, virtual reality (VR) and haptic systems [2,3]. Simulation involves mimicking the reality of clinical environments to demonstrate procedures to students and develop their decision-making and critical thinking skills; specific simulation techniques include role-playing and the use of devices, such as interactive videos or mannequins [4]. Among the simulation learning methods introduced within the past few years, VR simulation involves the creation of an artificial environment experienced through sensory stimuli (such as sights and sounds) provided by a computer, and with high-level VR simulation, the user's actions partially determine changes in the environment [5,6].

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https://doi.org/10.1016/j.anr.2021.03.002

Although existing high-fidelity simulations have been proven effective, the VR approach is a user-oriented learning method that is not restricted by limited faculty preparation time, staff or schedules and that allows students to practice clinical techniques in a safe environment [3]. Furthermore, VR simulation is a practical means of circumventing the restrictions imposed by the Coronavirus disease 2019 (COVID-19) pandemic on face-to-face interaction or clinical education and practice in hospitals. Therefore, VR simulation may prove beneficial in circumstances where student access to mannequin-based training or clinical practice is limited [7].

In the neonatal intensive care unit (NICU) setting, providing nursing students with practical clinical education is particularly challenging due to the restrictions on their activities in that environment. Nonetheless, nursing students require extensive practical training for this environment, particularly in the domain of infection control. All newborn infants are prone to nosocomial infections because of their intrinsic susceptibility to infection and the invasive procedures they are subjected to. This is particularly the case for infants born prematurely or with low birth weight [8,9]. Therefore, infection control is the most important issue in caring for infants during their first week after birth, when their immunity is limited, and protecting infants from infection is a major responsibility of the nurses who care for them [10]. Therefore, to prepare for clinical practice in the NICU, nursing students require thorough and accurate training in neonatal infection management. However, particularly in South Korea, the number of hospitals that have reduced NICU access for students is increasing due to rising rates of premature birth and stricter management policies [11,12]. Due to the infection-related deaths of four infants in a NICU in South Korea in 2017, institutional policies for infection control have grown stricter, and thus, nursing students' ability to develop their clinical skills and gain practice experience with newborns in NICUs is severely limited.

Previous studies have reported on the positive effects of simulation education on nursing and other students' confidence, decision-making ability, communication skills and clinical judgment [2,13–15]; clinical knowledge and performance [16,17]; and self-efficacy or self-confidence, as well as ability to manage anxiety and stress [18]. Insofar as VR simulation is a new learning method, however, the literature around it is limited [5]. According to a recent systematic review of VR simulation programs in nursing education [19], VR studies for nursing students have been conducted in the United States, Canada, Israel, Kuwait and South Korea. These involved VR skill training for urinary catheterization and phlebotomy [20–22], children's postoperative care and medication administration using virtual gaming simulation [23,24], and an intravenous simulator incorporating VR and a haptics device [25]. Furthermore, Williams et al. [3] studied a VR program addressing neonatal resuscitation for midwifery students in Australia. However, no studies that we are aware of have yet examined the effectiveness of a VR simulation program for infection control in the NICU.

Therefore, the objective of this study was to apply a VR simulation program for high-risk neonatal infection control (HirNIC) to evaluate its effects on nursing students' knowledge of neonatal infection control, self-efficacy for infection control performance, and satisfaction with the learning process. The study hypotheses were as follows:

Hypothesis 1. Participants experiencing the VR simulation program (experimental group) will have a higher level of HirNIC knowledge than the control group who only participated in clinical practice in a NICU (control group).

Hypothesis 2. The experimental group will have a higher level of self-efficacy for infection control performance than the control group.

Hypothesis 3. The experimental group will have a higher level of learner satisfaction than the control group.

Methods

Study design

This study used a nonequivalent control group design to evaluate the effectiveness of a HirNIC VR simulation program.

Sample and setting

The target population was Korean senior nursing students, and the study was conducted at a nursing college in J city, Korea. The sample size was calculated using a t-test (one-tailed) and the G * power 3.1 program [26]. Considering that the effect sizes in two previous studies of a similar nature [1,27] were 0.40 and 0.80, we employed a significance level of .05, a power of 0.85, and an effect size of 0.80 for the calculation. A sample size of 48 participants was calculated to be sufficient for this study. In accounting for a potential dropout rate of approximately 5%, 51 participants were recruited from a cohort of 71 senior nursing students by means of convenience sampling.

Procedure

Framework for simulation education

The conceptual framework for the simulation program was based on the National League for Nursing (NLN)/Jeffries Simulation Framework [28]. This model identifies five essential concepts of simulation design that support desired student outcomes, including (a) teacher, (b) student, (c) educational practices, (d) simulation design characteristics and (e) outcomes. The central proposition of this model is that student outcomes are influenced by the incorporation of best education practices into the design and implementation of the simulation experience. Furthermore, the model posits that learning depends on the teacher and student interactions, expectations and roles; hence, when the model's teacher, student and educational practices concept variables are considered in simulation design, student satisfaction and performance improve [4]. In the current study, the "teacher" developed a HirNIC VR simulation program based on her more than 10 years of simulation education experience and her clinical practice career in the NICU environment; the teacher then served as facilitator and evaluator during program operation and provided feedback to students. Each "student" was a senior nearing graduation, and the "educational practices" included 4 hours of lecture on neonatal infection control and 45 hours of clinical practice in the NICU. The "simulation design characteristics" included the HirNIC VR simulation consisting of three scenarios and a short prebriefing and debriefing before and after the scenarios. The "outcomes" included HirNIC knowledge, HirNIC performance self-efficacy and learner satisfaction (see Figure 1).

VR simulation program application

The HirNIC VR simulation program employed in this study was developed by Yu and Mann [29]. It consisted of three scenarios representing basic nursing situations related to infection control—basic care, feeding management and skin care and environmental management—that could be easily understood by nursing students (see Table 1). The program user has to perform enteric precautions, skin care, proper disposal of waste (including the gown and soiled diaper) and incubator disinfection following contact precaution guidelines.

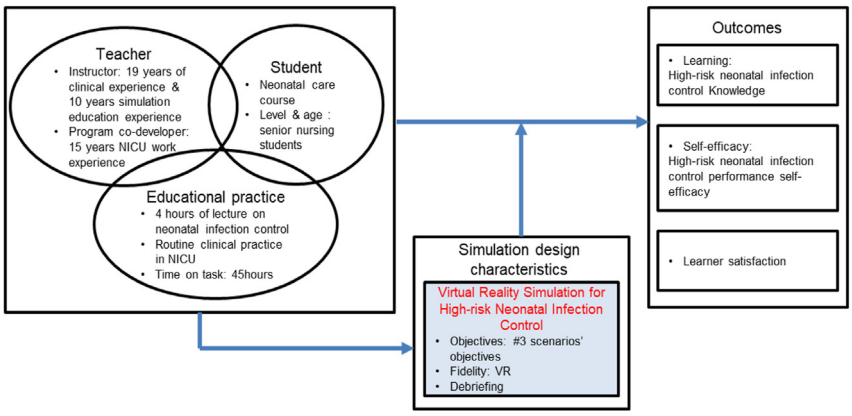

Figure 1. Conceptual framework modified from NLN/Jeffries simulation framework.
Note. NICU = neonatal intensive care unit.

The VR program, with its three scenarios, was produced using VR simulation program software developed by SAMWOOimmersion Co., Ltd., of South Korea. The program employed a Vive Pro Full-Kit Head Mounted Display and sensor (HTC VIVETM, USA), a Leap Motion Controller™ (Ultraleap, USA) hand-tracking device with a VR Developer Mount, and a VR kit containing an EliteDesk 800 G4 laptop computer. In the program, the user wearing the HMD enters the VR world and performs the applicable nursing procedures. The controller attached to the HMD is capable of tracking the user's hands within a 3D interactive zone. The user experiences the three VR scenarios consecutively on a single day, and the total execution time is 40 minutes.

During the study, the student participants received a team-based, 30-minute prebriefing, which included an introduction to the scenarios and use of VR before completing the scenarios. They also received a 20-minute debriefing after scenario completion.

Instruments and measures

General characteristics

Information on students' gender, age and previous semester grade was collected using a questionnaire created by the first author.

HirNIC knowledge

Student knowledge regarding HirNIC was assessed using the High-Risk Neonatal Infection Control Competency Scale Knowledge (HirNICCS_K) developed by Yu et al. [30]. The HirNICCS_K consists of five subdomains: basic care, skin care, feeding management, medication and invasive procedure management, and environmental management. In this study, we condensed this scale to include 10 items for basic care, 8 items for feeding management and 10 items for skin care and environmental management according to the scenario topics. The possible item responses were "Yes," "No," and "I don't know. " Each correct answer received 1 point, while incorrect answers received 0 points. The total possible score was 28 points, including 10 points for basic care, 8 points for feeding management and 10 points for skin care and environmental management; the higher the total score, the higher the knowledge level. The reliability for the overall scale was KR-20 = .67 in a previous study [30] and .61 in this study.

HirNIC performance self-efficacy

In the education context, self-efficacy refers to "perceived capabilities for learning or performing behaviors in designated levels" [31]. HirNIC performance self-efficacy was assessed using a modified version of a self-efficacy measure employed in a previous nursing student simulation study [32]; the instrument was modified based on the High-Risk Neonatal Infection Control Competency Scale_Performance by Yu et al. (2020) [30]. The original instrument consisted of 17 items addressing self-confidence in caring for patients with gastrointestinal bleeding or acute myocardial infarction. The HirNIC performance self-efficacy scale consisted of 21 items

Table 1 *Virtual Reality Simulation Scenario Contents.*

Procedure	Topic/Scenario	Contents and Situation	Time expended (minutes)
Prebriefing	Introduction of scenarios	Simulation scenarios are briefly explained, including learning objectives and principles of high-risk neonatal care and infection control.	20
	Use of VR and precautions	The simulation lab environment is overviewed, including use of VR equipment such as the HMD and Leap Motion Controller, as well as disposable eye masks for the headset to prevent cross-contamination.	10
VR Simulation	Basic care	A premature infant (34 weeks, 2,750 grams) is transferred from the delivery room to the neonatal intensive care unit. For preventing neonatal infection, initial nursing care is performed.	10
	Feeding management	A premature infant (30 weeks, 1,250 grams) needs to breastfeed through a gastric tube. Frozen breastmilk preparation, gastric tube feeding and actions to prevent aspiration are performed.	15
	Skin care and environmental management	A full-term newborn (3,010 grams) with diarrhea is transferred from another hospital due to rotavirus infection and diarrhea. The baby is isolated in an incubator. Enteric precautions, skincare, waste disposal and environmental disinfection are performed according to contact precaution guidelines.	15
Debriefing	Discussion	Students reflect on the simulation experience and exchange feedback with the instructor.	20

Note. HMD = Head mounted display; VR = virtual reality.

covering three domains: basic care (7 items), feeding management (9 items) and skin care and environmental management (5 items). Each item was rated on a 10-point scale ranging from 0 = "not confident at all" to 10 = "maximum confidence," with higher scores indicating higher levels of confidence. As to reliability, the original instrument showed a Cronbach's α of .91 in the previous study [32]. In the present study, the modified instrument had a Cronbach's α of .96, and the Cronbach's α values for the basic care, feeding management, and skin care and environmental management domains were .89, .93 and .89, respectively.

Learner satisfaction

Learner satisfaction was measured using three items developed by Cho [33] to examine nursing students' satisfaction with a root cause analysis education program intended to improve patient safety competencies and modified by the researcher. In the present study, the first item differed for the experimental and control groups: for the experimental group, it was The HirNIC VR simulation program after clinical practice will help me work as a nurse in clinical practice, and for the control group, it was Clinical practice in the NICU will help me work as a nurse in clinical practice." The second and third items were I want to recommend this program to other nursing students and I think this training is necessary as part of the nursing college curriculum. Each item was rated on a five-point Likert scale ranging from "very unsatisfied" (1 point) to "very satisfied" (5 point). Higher total scores indicated higher levels of satisfaction. The Cronbach's α for this instrument was .81 in Cho's study [33] and was .81 in the present study.

Data collection

Data were collected from December 9, 2019, to January 17, 2020. Under the study inclusion criteria, study participants had to be senior nursing students with prior clinical experience and prior high-fidelity simulation training who were willing to volunteer to participate. The 51 participants were divided into six teams, each containing 8 or 9 participants, based on their clinical practice schedules. The three teams that first had clinical practice in the NICU were assigned to the control group, and the next three teams to have clinical practice were assigned to the experimental group. Finally, a total of 25 participants were in the control group and 26 in the experimental group. For both groups, a pretest was administered after lectures related to neonatal infection control. For preventing diffusion of the experiment, the posttest for the control group was administered first, after they completed routine clinical practice in a NICU. After data collection for the control group was completed, the experimental group was enrolled in the VR simulation program performed in the simulation lab, and posttest data were collected immediately after the intervention. The control and experimental groups experienced the same lectures and performed their clinical practice in the NICU. All but one participant completed the study; the single exception in the experimental group did not submit the posttest.

Data analysis

Data were analyzed using the SPSS Statistics 25.0 program (IBM Corp., Armonk, NY, USA). Participants' general characteristics, HirNIC knowledge and HirNIC performance self-efficacy were analyzed using frequencies, percentages, means and standard deviations. A Chi-square test, independent t-test and Mann-Whitney test were used to verify pretest homogeneity between the two groups. A Shapiro-Wilk test was performed to ensure normal distributions of knowledge and performance self-efficacy data. A paired t-test and Wilcoxon signed-ranks test were used to determine differences in HirNIC performance self-efficacy and HirNIC knowledge between the pretest and posttest within the groups. For determining differences between the groups, an independent t-test was used for HirNIC performance self-efficacy and learner satisfaction, and a Mann-Whitney test was used for HirNIC knowledge.

Ethical considerations

This study was approved by the institutional review board (IRB) of the researcher's university (Approval no. GIRB-A19-Y0077). The participants were provided with a thorough explanation of the study's purpose and procedures and were informed that they could refuse to participate without any impact on their grades. Each participant then provided written informed consent. Additionally, participants were informed that the research data would be used only for the stated research purpose, would be coded to ensure their confidentiality and anonymity, and would be disposed of after completion of the study. A research assistant distributed and collected the presurvey and postsurveys, which took participants 10 to 15 minutes to complete, and after data collection, each participant was compensated with a gift card worth about 10 USD. The collected data were encrypted using an identification code, and all data were stored in a locked cabinet. The data will be stored for no more than 3 years and will then be securely disposed off.

Results

General characteristics and homogeneity of study variables

Through homogeneity tests for gender, age and previous semester grade, HirNIC knowledge and performance self-efficacy of the experimental and control groups were determined to be homogeneous (Table 2).

Virtual reality simulation program effects

Table 3 shows the results of the effect verification tests for the HirNIC VR simulation program.

Hypothesis 1

There was no significant difference between the experimental and control groups (U =272.00, $p = .213$) in terms of HirNIC knowledge. Furthermore, there were no significant differences between the groups in the three subdomains of HirNIC knowledge, namely basic care (U =292.50, $p = .335$), feeding management (U =311.00, $p = .488$), and skin care and environmental management (U =271.50, $p = .205$). Therefore, Hypothesis 1 was rejected.

Hypothesis 2

Based on the pretest and posttest results, HirNIC performance self-efficacy significantly increased in both the experimental ($t = 10.03$, $p < .001$) and control ($t = 7.48$, $p < .001$) groups. The experimental group showed a greater self-efficacy increase than the control group, indicating that the VR program was effective in improving self-efficacy ($t = -2.16$, $p = .018$). In the domains of basic care ($t = -2.73$, $p = .005$) and skin care and environmental management ($t = -2.28$, $p = .013$), the experimental group had significantly higher self-efficacy scores than the control group. The experimental group also showed a higher score in the feeding management domain, but the difference from the control group was not significant ($t = -1.28$, $p = .103$). Therefore, Hypothesis 2 was partially accepted.

Table 2 *Participants' Characteristics and Homogeneity of Two Groups (N=50).*

Characteristics	Categories	Total n(%)	Group		t/χ^2/U	p
			Control group (n = 25)	Experimental group (n = 25)		
Gender	Women	46(92.0)	23(92.0)	23(92.0)	—	>.999
	Men	4(8.0)	2(8.0)	2(8.0)	—	—
Age (years)	21–22	31(62.0)	14(56.0)	17(68.0)	0.76	.329
	23–25	19(38.0)	11(44.0)	8(32.0)		
	Mean ± SD	22.40 ± 1.05	22.36 ± 1.22	22.44 ± .87	−0.27	.791
Previous semester grade[a]	Under 3.0	3(6.0)	1(4.0)	2(8.0)	0.48	>.999
	3.0–4.0	33(66.0)	17(68.0)	16(64.0)	—	—
	Over 4.0	14(28.0)	7(28.0)	7(28.0)	—	—
HirNIC Knowledge[†]	Basic care	8.58 ± 1.11	8.40 ± 1.32	8.76 ± 0.83	275.00	.217
	Feeding management	7.64 ± 1.48	7.36 ± 1.66	7.92 ± 1.26	261.00	.153
	Skin care and environmental management	6.44 ± 1.28	6.48 ± 1.36	6.40 ± 1.22	291.50	.337
	Overall	22.42 ± 2.84	22.05 ± 3.31	22.79 ± 2.28	284.00	.288
HirNIC performance self-efficacy	Basic care	5.03 ± 1.60	5.19 ± 1.56	4.86 ± 1.65	0.72	.239
	Feeding management	5.32 ± 1.67	5.30 ± 1.54	5.33 ± 1.83	−0.06	.478
	Skin care and environmental management	6.13 ± 1.70	6.15 ± 1.54	6.10 ± 1.88	0.10	.461
	Overall	5.41 ± 1.56	5.47 ± 1.47	5.36 ± 1.68	0.24	.404

Note. HirNIC = High-risk neonatal infection control; SD = Standard deviation.
[a] Fisher's exact test.
[†] Mann-Whitney test.

Hypothesis 3

The experimental group showed a significantly higher learner satisfaction score (4.79 ± 0.35 points) than the control group (4.13 ± 0.47 points) (t = −5.59, p < .001). In addition, for all three items measuring learner satisfaction, the experimental group had significantly higher scores than the control group. Therefore, Hypothesis 3 was accepted.

Discussion

In all healthcare settings, the infection control practices used during patient care are intended to prevent and control the transmission of microorganisms. Particularly in an environment such as the NICU, pathogenic organisms can easily spread. This study applied a VR simulation program that we designed to help nursing students learn infection control processes, as well as to compensate for the inadequate clinical experience they receive due to practical restrictions placed on nursing students in the NICU.

In simulation teaching methods, role-playing and simulation using a mannequin have the disadvantage that the content delivered depends on the instructor's teaching methods and can vary with each learning session [5,34]. In addition, long operating hours and preparation times are required for each session, so more team than individual training often occurs, offering fewer opportunities for students to practice their skills. Compared to screen-based virtual simulation programs such as SecondLife and vSim, the HirNIC VR program applied in this study provides a more immersive virtual experience using the HMD and mobilizes vision, hearing and touch in ways similar to reality. Furthermore, this form of simulation allows the repeated practice of techniques without

Table 3 *Differences in Variables between Groups (N = 50).*

Variables	Categories	Group	Pretest	Posttest	Difference between time		Program effect	
			Mean ± SD	Mean ± SD	t/z	p	t/U	p
HirNIC knowledge[a]	Basic care	Cont.	8.40 ± 1.32	8.84 ± 0.90	−1.43	.076	292.50	.335
		Exp.	8.76 ± 0.83	8.84 ± 0.99	−0.58	.282	—	
	Feeding management	Cont.	7.36 ± 1.66	8.28 ± 1.46	−2.28	.011	311.00	.488
		Exp.	7.92 ± 1.26	8.72 ± 1.10	−2.12	.017	—	
	Skin care and environmental management	Cont.	6.48 ± 1.36	6.36 ± 0.70	−0.81	.208	271.50	.205
		Exp.	6.40 ± 1.22	6.40 ± 1.04	−0.08	.467	—	
	Overall	Cont.	22.05 ± 3.31	23.29 ± 1.92	−2.12	.017	272.00	.213
		Exp.	22.79 ± 2.28	23.44 ± 2.15	−1.45	.074	—	
HirNIC performance self-efficacy	Basic care	Cont.	5.19 ± 1.56	7.46 ± 1.34	7.91	<.001	−2.73	.005
		Exp.	4.86 ± 1.65	8.36 ± 1.05	10.05	<.001		
	Feeding management	Cont.	5.30 ± 1.54	7.71 ± 1.54	7.17	<.001	−1.28	.103
		Exp.	5.33 ± 1.83	8.35 ± 1.21	8.87	<.001		
	Skin care and environmental management	Cont.	6.15 ± 1.54	8.12 ± 1.56	5.62	<.001	−2.28	.013
		Exp.	6.10 ± 1.88	9.24 ± 0.88	8.35	<.001		
	Overall	Cont.	5.47 ± 1.47	7.72 ± 1.37	7.48	<.001	−2.16	.018
		Exp.	5.36 ± 1.68	8.57 ± 0.98	10.03	<.001		
Learner satisfaction	This program will help me work as a nurse in clinical practice	Cont.	—	4.04 ± 0.45	—	—	−5.12	<.001
		Exp.	—	4.76 ± 0.44	—	—		
	This training is necessary as part of the nursing college curriculum	Cont.	—	4.28 ± 0.74	—	—	−2.54	.008
		Exp.	—	4.72 ± 0.46	—	—		
	I want to recommend this program to other nursing students	Cont.	—	4.08 ± 0.57	—	—	−6.05	<.001
		Exp.	—	4.88 ± 0.33	—	—		
	Overall	Cont.	—	4.13 ± 0.47	—	—	−5.59	<.001
		Exp.	—	4.79 ± 0.35	—	—		

[a] Mann-Whitney test. *Note.* Cont. = Control group; Exp. = Experimental group; HirNIC = High-risk neonatal infection control; SD = standard deviation.

being greatly affected by the instructor's time limitations and teaching methods.

The results of the study showed that nursing students' performance self-efficacy regarding infection control and their satisfaction with the program increased significantly after participating in the HirNIC VR simulation program. However, no significant difference was observed between the experimental and control groups in terms of HirNIC knowledge.

During the application of our VR simulation program, performance self-efficacy levels in the experimental group increased significantly, from a mean score of 5.36 to 8.57 (of 10), and this increase was greater than that observed in the control group. In particular, the experimental group's mean scores for basic care and skin care, and environmental management increased significantly. These results are similar to those of three previous studies of a high-fidelity patient simulation's effect on nurses' self-efficacy [35] and a computer (or screen)-based resuscitation simulation's effects on nursing students' self-efficacy [36,37]. Another previous study [23] examined a Canadian VR program related to child care after appendectomies and also observed increased self-efficacy in nursing students due to the program. We know that simulation as a learning method improves cognitive, emotional and psychological abilities in a safe and realistic environment by forming a bridge between theoretical knowledge and practical skills [38]. In particular, the theoretical core of simulation learning is that learning takes place through experience, and thus, simulation helps students to think like nurses by giving them experiences similar to real-life clinical conditions. As this approach allows nursing students to acquire theoretical and practical knowledge while also verifying and integrating previous learning experiences [39], it is not surprising that simulation employing a VR environment increased nursing students' performance self-efficacy.

The experimental group's satisfaction with the HirNIC VR program was much higher than the learner satisfaction exhibited by the control group. This result is supported by previous studies. For example, the learning satisfaction of new nurses participating in high-fidelity simulation-based high-risk neonatal care education was higher than that of a nonsimulation group [40]. In another study, participation in a computer-based resuscitation simulation was a significant predictor of learner satisfaction in an emergency nursing clinical course [41]. In the present study, the control group's satisfaction level after practice averaged 4.13 points (of 5), while the experimental group had an average satisfaction score of 4.79, a significant difference. In particular, among the items, the mean score for "It helped to acquire infection control capability" was 4.04 in the control group and 4.76 in the experimental group. For the item "I want to recommend it to others," the control group's mean score was 4.08 points compared to the experimental group's 4.88 points. Clearly, students who received only clinical practice in the NICU were less satisfied as learners than those in the experimental group, who had the opportunity to further practice their techniques through the VR simulation. In the debriefing following the VR simulation program, students described the program as "fun" and helpful in allowing them to practice nursing skills that they were denied to opportunity to use in the NICU. Many also asserted that other students should experience this program too.

Importantly, however, our posttest results showed no significant difference in HirNIC knowledge between the two groups, although both groups did show a slight increase. This finding differs from Verkuyl et al.'s [23] study results, which indicated a significant difference in the knowledge of nursing students after the application of a screen-based virtual gaming program. Moreover, Dubovi et al. [24] found that their experimental group's medication knowledge increased after the application of a screen-based VR program. However, Verkuyl et al. [23] used only posttest measures, while Dubovi et al. [24] employed only a single group of nursing students who used a nonimmersive, screen-based virtual simulation program instead of receiving a full VR experience. Therefore, it is difficult to directly compare the results of those studies with our own. Nevertheless, no significant differences in posttest HirNIC knowledge were visible between our two groups, presumably because both had increased their knowledge through basic clinical practice. Additionally, the debriefing time provided after the VR simulation program may have been inadequate. Debriefing is an important component of the learning process, and it has been found to reduce the learning gap between observers and participants [42]. Therefore, in employing the VR simulation program, it will be necessary to allocate more time for debriefing so that learners can discuss their experiences and further expand their knowledge.

Although nursing knowledge is essential, it alone cannot improve novice nurses' or nursing students' competence. It has to be reinforced by the practice of requisite procedures. Few studies have directly compared clinical practice in the NICU environment to simulation in terms of skill performance. However, considering that simulation observation and effective debriefing have shown benefits similar to scenario participation [42], it is reasonable to assume that nursing students would benefit from closely observing nurses' behavior in clinical practice and engaging in self-reflection similar to a debriefing afterward.

The VR simulation program applied in our study offered nursing students repeated practice in performing such procedures. As nurses play a major role in infection control in all intensive care settings, practical educational programs rooted in simulation theory and nursing knowledge are needed to ensure control of infection and reduce morbidity and mortality in neonates cared for in the NICU [43]. Therefore, in addition to knowledge transfer, VR simulation technology should be exploited to support the accurate application of knowledge related to infection control.

Implications and Limitations

This study has significant implications for nursing education and nursing theory. First, it is noteworthy that our VR simulation program was the first to be applied to neonatal infection management. With the growing popularity of VR simulation, it is inevitable that this technology will become more prominent in neonatal health education, training and research [3], particularly at a time when the COVID-19 pandemic makes in-person instruction problematic. Second, our study was guided by the NLN/Jeffries Simulation Framework, and Lafond and Van Hulle Vincent [44] pointed out that rigorous research is needed to test the relationships among this model's concepts and the associated concept variables. Given that the validation of the concepts of a theory is empirically important to the overall development of nursing theory, this study is also significant in its application and partial verification of the NLN/Jeffries Simulation Framework within nursing education; that is, this study confirmed that VR simulation program can improve learners' self-efficacy, knowledge and satisfaction to a degree similar to other simulations.

This study's limitations should be noted. First, within the NLN/Jeffries Simulation Framework, the effectiveness of learning is posited to be dependent on teacher-student interactions. During VR simulation, however, students solve problems and practice skills without direct interaction with the instructor. Hence, there are some limitations in applying the concept of teacher-student interactions in VR programs. However, in our approach, the prebriefing and debriefing do provide opportunities for instructor-student discussion of questions and observations associated with the simulation scenarios; hence, teacher-student interactions are,

in fact, present. Second, the debriefing after the VR simulation was limited to a single 20-minute session addressing all three scenarios. This limited timeframe for sharing of knowledge without repetitive practice may have affected study findings. Third, as the study only involved nursing students at one university, the results may differ with other groups of VR simulation program users. Finally, due to time constraints imposed by the university schedule, the VR simulation program could not be implemented with the control group, which could be considered an ethical limitation.

Conclusion

This study implemented a VR simulation program among nursing students that focused on high-risk neonatal infection control, and we observed improvements in students' performance self-efficacy, as well as greater learner satisfaction compared to nonusers of the program. We demonstrated that VR simulation can help nursing students learn how to solve problems in virtual situations that mimic the real world and can expand their practice of skills in a realistic environment. We also showed that VR simulation facilitates repetitive learning by minimizing environmental constraints such as instructor capacity. In the future, studies will undoubtedly continue to confirm various benefits of VR simulation programs in comparison to traditional simulations. However, one area of need is to develop VR simulation programs and scenarios that build problem-solving skills by means of communication and cooperation between multiple learners in the same virtual space.

Funding

This work was supported by the Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science, and Technology [NRF-2018R1D1A3B07045408].

Conflict of interest

The author declared no conflicts of interest.

Acknowledgments

Tthe authors would like to express thanks to SAMWOOimmersion Co., Ltd., South Korea.

We also thank Ms. Yeon Seon Jung of Gyeongsang National University for her statistical advice with this article.

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Asian Nursing Research 15 (2021) 197–202

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

A Five-step Systematic Therapy for Treating Plugged Ducts and Mastitis in Breastfeeding Women: A Case–Control Study

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ARTICLE INFO

Article history:
Received 23 October 2020
Received in revised form
27 February 2021
Accepted 27 April 2021

Keywords:
Breast feeding
Massage
Mastitis
Therapeutics

ABSTRACT

Purpose: This study aimed to describe the clinical response to five-step systematic therapy (FSST) in the management of plugged ducts and mastitis. FSST was a comprehensive milk stasis dredging treatment, which contained five steps to make the milk out of the plugged duct.

Methods: This retrospective study included 922 breastfeeding women, 714 with plugged ducts, and 208 with mastitis who received FSST from June to September 2017. The breast pain score, swelling degree, and range of breast induration were recorded pre-FSST and post-FSST.

Results: After a single FSST, pain score and swelling degree were significantly improved (both $p < .001$) in all cases. After FSST, the mean breast pain relief score was 1.69 ± 0.70, whereas the mean swelling fade away degree was 1.61 ± 0.62. In the subgroup analysis, pain score and swelling degree were significantly improved (both $p < .001$) in the plugged ducts group and the mastitis group. The score of pain relief in the plugged ducts group was less than that in the mastitis group (1.63 ± 0.68 vs. 1.91 ± 0.70, $t = 5.30$; $p < .001$), whereas improvement of swelling fade away was greater in the plugged ducts group than the mastitis group (1.65 ± 0.64 vs. 1.48 ± 0.56, $t = 3.49$; $p = .001$). The composition ratio of changes in induration range between the two groups was statistically different (Pearson $\chi^2 = 137.87$, $p < .001$), of which more obvious improvement in the plugged ducts group than the mastitis group ($\chi^2 = 25.65$, $p < .001$).

Conclusion: FSST can relieve pain, reduce breast swelling and range of induration, and for plugged ducts or mastitis varied degree differently.

Introduction

Because of the benefits to both infants and mothers, breastfeeding is recommended by the World Health Organization (WHO) [1–4]. Furthermore, exclusive breastfeeding is recommended for infants from birth to 6 months [5]. Inflammatory breast diseases, such as plugged ducts and acute mastitis, are common conditions that afflict women during lactation, causing breast pain and discomfort. Studies have shown that breast inflammation during lactation is one of the most important iatrogenic causes of weaning [6,7]. Therefore, the efficient management of plugged ducts and acute mastitis during lactation is key to ensure successful breastfeeding [8].

According to WHO guidelines, plugged ducts and mastitis are different stages of breast inflammation during lactation caused by the blockage of lactiferous ducts as the initial factor [9]. There is no clear boundary between the two conditions, but mastitis is accompanied by more serious local and/or systemic inflammation manifestation. Significant fever, especially when associated with breast erythema and systemic symptoms such as myalgias, suggests the diagnosis of mastitis [10,11]. Both conditions may develop into a mammary abscess if they are not treated promptly and properly [12]. As such, effective treatment of plugged ducts and acute mastitis is particularly important in the management of lactation. The common pathogenesis of both plugged ducts and acute mastitis is inefficient milk emptying. It has been reported that

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https://doi.org/10.1016/j.anr.2021.04.001

timely and effective breast emptying is important to prevent and manage plugged ducts and acute mastitis [8,9].

A number of measures to stimulate efficient breast emptying have been explored, including massage, milk expression, breast pumping, cold and hot compression, acupuncture, auricular therapy, Gua-Sha therapy, ultrasonic treatment, and laser therapy [13–21]. When a single measure proves effective, combination of multiple measures should yield better results. Based on the aforementioned information, we combined five measures and developed a therapy called five-step systematic therapy (FSST). The Breast Surgery Department of our hospital has been performing FSST for patients with inflammatory conditions during lactation since 2015. Until now, more than 10,000 patients received this therapy and achieved good results. We found the symptoms improvement of the patients varied by different inflammatory stages. Commonly used evaluation indicators include ratings of pain, swelling, and hardness [7,22]. The purpose of this study was to describe the clinical response of lactating women with plugged ducts and/or acute mastitis treated with FSST from June to September 2017.

Methods

Study design

This study was a retrospective analysis of lactating women with plugged ducts and acute mastitis women treated with FSST. Case–control study was performed to observed the differences in clinical response between plugged ducts and acute mastitis after a single FSST.

Setting and sample

This study was performed at Guangzhou Women and Children's Medical Center, the largest Women and Children specialized hospital in south China. This hospital is a third-level Grade A hospital, which is the first public hospital certified by the Joint Commission International (JCI) in China. All pregnant women receive breastfeeding education according to the Chinese Baby-Friendly Hospital Standards.

The study included a convenience sample of all lactating women who received FSST from June to September 2017. The symptoms of lactating women with plugged ducts and/or acute mastitis did not relieve after frequently breastfeeding for 48 hours. These women who were referred to our department and received FSST were brought into our analysis. Exclusion criteria were patients who received FSST for other reasons, for example, hypogalactia or breast abscess. Patients who did not complete treatment were also excluded. In fact, all patients should be evaluated and prescribed by a breast specialist before treatment. Suspected benign or malignant tumor excluded from this study should enter the corresponding treatment process.

During the study period, 1,078 patients completed FSST. Of these, 156 (14.5%) were excluded: 100 patients with hypogalactia and 56 with breast abscesses. A total of 922 patients met the criteria and were included in this study and were divided into plugged ducts group (PDG; n = 714) and mastitis group (MG; n = 208).

Ethical consideration

The study was approved by the Ethics Committee of G Medical Center (Approval no. [2020] 30501). Because of the retrospective nature of the study, the requirement of informed patient consent was waived.

Measurements

Five-step systematic therapy

FSST is performed by breast specialist outpatient nurses. The five steps of FSST are as follows.

1) Laser therapy [19,20]. With the patient in the sitting position, the breast skin is fully exposed and irradiated by a SUNDOM-300 IB/233 LCD-type semiconductor laser therapy unit (Beijing SUNDOM Medical Equipment Co. Ltd., China). This semiconductor laser instrument adopts multiwavelength composite output (650/810 mm). According to the instruction of the machine, the composite wavelength laser has the characteristics of noninjury and strong penetration, which can induce the local biological stimulation effect manifested in local blood circulation promotion, tissue edema reduction, inflammatory relief, and analgesic effects. The procedure of laser therapy is 1200 milliwatts of power for 10 minutes, irradiation area of 8800 mm^2, and irradiation distance of 10–15 cm. If both breasts are affected, both should be irradiated at the same time. The nipple/areola is covered with gauze during irradiation.
2) Electric breast pumping [7–9]. A Medela Swing medical breast pump (Medela AG, Switzerland) is used for bilateral breast pumping. Beginning at zero, the negative pressure increases until the patient's maximum discomfort level is reached. Pumping is continued for 10–15 minutes. The medical-grade pump is more efficient and provides better pumping effect.
3) Breast massage [13,16,18,22]. Breast massage is to better promote the discharge of milk stasis, especially when breast pumping still cannot empty the breast. Patients are placed in the supine position with two dry towels under their body. After the comprehensive evaluation of both breasts, the massage is started from the contralateral breast. The root of the nipple is softly massaged for 30 seconds for the milk ejection reflex. The areola is pressed from different directions to open the milk ducts. The breast is pushed and kneaded from the base toward the areola to excrete the milk, and then the nipple and areola are squeezed again to discharge the milk. Hard knots are gently massaged with the thumb or hypothenar muscles until softened. Unilateral breast massage is performed for no more than 15 minutes.
4) Cold wet compress [14,18]. Gauze soaked in a 33% magnesium sulfate solution is applied to both sides of the breast for 10–15 minutes. According to the drug instruction, the external application of 33% magnesium sulfate, which is a hypertonic solution at room temperature, has the effect of cold and wet compress that can reduce swelling and relieve pain after milk discharge confirmed by previous studies.
5) Patient education [8,9,14]. Patients are given individualized guidance for breastfeeding based on their existing problems. Latch-on and breastfeeding position are the most common problem that the breastfeeding mother faced. Tell the mothers how to latch on the nipple–areolar complex to form a long teat, but not only the nipple tip. Teach the mothers to choose a suitable position when feeding. The position of mother semi-reclining and infant semiprone is helpful, especially for a mother who has had a cesarean delivery. Use reverse pressure softening if the areola is edematous. It is very important to insist on breastfeeding. More frequent feeding is helpful to promote milk excretion. The benefits of breastfeeding are reinforced, and they are encouraged to increase their self-confidence for breastfeeding.

According to the work rationale of each step, comprehensive schemes such as FSST can promote milk excretion, reduce tissue

edema, and relieve pain. Individualized guidance can better maintain the therapeutic effect in the out-of-hospital period.

Outcome measures

Pain score, degree of breast swelling, and range of induration were recorded before and after treatment by the breast specialist outpatient nurses who were trained to make sure to keep the measurement consistency. Pain was graded on a numerical rating scale: 0 points for no pain; 1–3 points for mild pain, 4–6 points for moderate pain, and 7–10 points for severe pain. The pain score before treatment minus that after treatment was defined as the pain relief score; the higher the score, the greater the pain relief.

The degree of swelling was assessed using the scale developed by Humenick et al [23]. The scale is as follows: 1°, the breast is soft, no changes; 2°, slight breast swelling; 3°, breast swelling is present, no pain (0 points); 4°, breast distension, mild pain (1-3 points); 5°, breast distension, moderate pain (4–6 points); and 6°, the breast is very swollen, and there is severe pain (7–10 points). Swelling degree was recorded before and after treatment. The swelling degree before treatment minus that after treatment was defined as the swelling fade away degree; the higher the score, the greater the improvement.

The range of induration was recorded before and after treatment. The changes in the range of induration were recorded by modified quantitative grades [22]. The grades are as follows: disappearance (2): the range of the hard lump was reduced by more than 80% after treatment; reduction (1): the range was reduced by 10–80% after treatment; no change (0): the range was between −10% and 10% after treatment; aggravation (−1): the range increased by more than 10% after treatment. The higher the score, the greater the improvement.

Data collection

Data were collected from June to September 2017 by the breast specialist outpatient nurses who performed the treatments. To ensure the accuracy and consistency of the data collection process, a training session was provided to all the breast specialist outpatient nurses involved in this study. Patient demographic information and the time of onset of the condition were recorded before treatment, and pain score, swelling degree, and range of induration were recorded before and after treatment. The data of each patient were recorded separately in an individual form. Data were entered periodically into IBM Statistical Package for the Social Sciences 22.0 (SPSS) software for subsequent analysis (IBM Corp., Armonk, NY, USA).

Data analysis

Descriptive statistics, including median, range, and frequency, were calculated. Items were first summed to create a score for age, onset time, pain level, swelling degree, and changes in the range of induration. Single sample *t* test, two independent samples test, and Pearson Chi-square test were used to assess the variables. For all analyses, a value of $p < .050$ was considered to indicate statistical significance.

Results

Patient basic information

The mean age of all patients was 30.37 ± 3.88 years. The oldest patient was 43 years, and the youngest was 17 years. The most common onset time of all patients was during the first to the third month postpartum, accounting for 41.6%, and the incidence rate within the third month postpartum was as high as 80.7%. According to PDG and MG, the characteristics of the two groups are summarized in Table 1.

Pain

The overall mean pain score before treatment was 3.79 ± 1.54, with a maximum of 7 and a minimum of 0. The mean pain score pre-FSST in the PDG was 3.22 ± 1.23, with a maximum of 7 and a minimum of 0. In the MG, the mean pain score pre-FSST was 5.73 ± 0.72, with a maximum of 7 and a minimum of 4. The pain score pre-FSST of the MG was higher than that of the PDG, and the difference was statistically significant ($t = 28.13$, $p < .001$).

The overall mean breast pain relief score was 1.69 ± 0.70. All patients had statistically significant difference in pain relief score after treatment ($t = 73.54$, $p < .001$). In the PDG, the mean pain relief score was 1.63 ± 0.68, with a maximum pain relief score of 4. No patient experienced pain aggravation after treatment, but some patients did not experience pain relief. In the MG, the mean pain relief score was 1.91 ± 0.70, and the maximum pain relief score was 3. One patient experienced the aggravation of pain after the treatment, with a score of −1. There was a statistically significant difference in pain relief score between the two groups ($t = 5.30$, $p < .001$), with greater pain relief in the MG (Figure 1).

Swelling

The mean swelling degree of all patients before treatment was 3.85 ± 1.21, with a maximum of 6 and a minimum of 1. The mean swelling degree pre-FSST in the PDG was 3.48 ± 1.07, with a maximum of 6 and a minimum of 1. The mean swelling degree pre-FSST in the MG was 5.15 ± 0.59, with a maximum of 6 and a minimum of 4. The swelling degree pre-FSST of the MG was higher than that of the PDG, and the difference between the two groups was statistically significant ($t = 21.66$, $p < .001$).

In the whole population, the mean swelling fade away degree was 1.61 ± 0.62. All patients had a statistically significant difference in swelling fade away degree after treatment ($t = 78.46$, $p < .001$). In the PDG, the mean swelling fade away degree was 1.65 ± 0.64, with a maximum of 3 and with a minimum of 0. In the MG, the mean swelling fade away degree was 1.48 ± 0.56, with a maximum of 3 and with a minimum of 0. There was a statistically significant difference in the swelling fade away degree between the two

Table 1 *Clinical Characteristics of PDG and MG (N = 922).*

Group	No.	Age (years)	Onset time		
			Within the first month, *n* (%)	During the first to third month, *n* (%)	Beyond the third month, *n* (%)
PDG	714	30.38 ± 3.89	300 (42.0)	277 (38.8)	137 (19.2)
MG	208	30.35 ± 3.83	60 (28.9)	107 (51.4)	41 (19.7)
Test value		$t = 0.11$	Pearson $\chi^2 = 13.37$		
p value		$p = .909$	$p = .001$		

Note. MG = mastitis group; PDG = plugged ducts group.

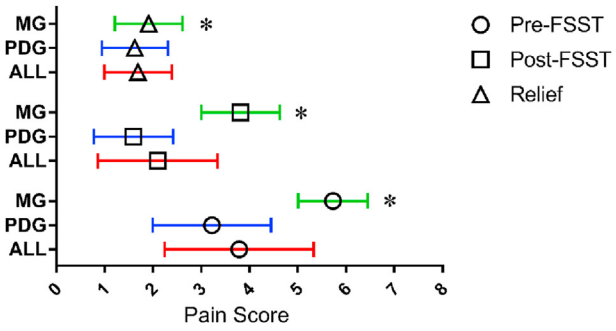

Figure 1. Separated symbols plots of pain scores in ALL, PDG, and MG.
Note. FSST = five-step systematic therapy; MG = mastitis group; PDG = plugged ducts group. *Compared with PDG, pain score in MG was statistically different in subgroup ($p < .050$).

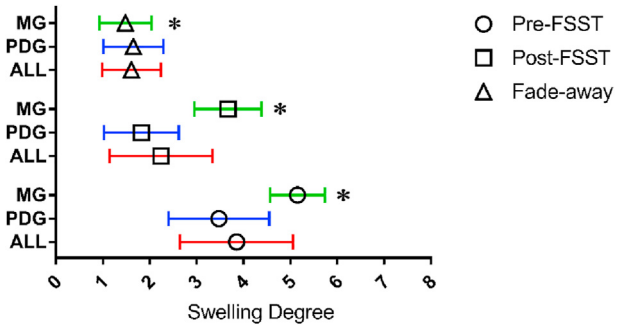

Figure 2. Separated symbols plots of swelling degree in ALL, PDG, and MG.
Note. FSST = 5-step systematic therapy; MG = mastitis group; PDG = plugged ducts group. *Compared with PDG, swelling degree in MG was statistically different in subgroup ($p < .050$).

groups ($t = 3.49$, $p = .001$), with the swelling fade away greater in patients with plugged ducts (Figure 2).

Range of breast induration

All breast induration in all patients could be evaluated. Based on the scoring system, in the overall population, the frequency of a score of 2 (disappearance) was 31.7% (292/922), 1 (reduction) was 63.9% (589/922), 0 (no change) was 4.4% (41/922), and −1 (aggravation) was 0 (0/922). Change score of induration range in PDG and MG could be seen in Table 2. The effective rate of treatment (the frequency of 1 and 2) was 97.5% in the PDG, whereas 88.9% in the MG. According to the effective rate, the range of breast induration was improved more obviously in the PDG than the MG ($\chi^2 = 25.65$, $p < .001$).

Table 2 *Change Score of Induration Range in PDG and MG (N = 922).*

Group	No.	Change score of induration range		
		0, *n* (%)	1, *n* (%)	2, *n* (%)
PDG	714	18 (2.5)	404 (56.6)	292 (40.9)
MG	208	23 (11.1)	185 (88.9)	0 (0)
Test value		Pearson $\chi^2 = 137.87$		
p value		$p < .001$		

Note. MG = mastitis group; PDG = plugged ducts group.

Discussion

Plugged ducts, acute mastitis, and mammary abscesses are collectively called inflammatory breast diseases during lactation. Plugged ducts often occur 2–3 weeks after delivery [24] because of injury to the nipple, ineffective milk removal, poor breastfeeding technique, irregular lactation, superficial pressure on the breast, and an overabundant milk supply [9,25]. Because of the delayed resolution, plugged ducts may lead to more severe symptoms, such as mastitis and mammary abscess [24]. Acute mastitis can happen at any time during lactation, but mostly seen in the first 6 weeks postpartum [8,26]. Whatever plugged ducts or mastitis, the discomfort and pain can affect the mother's confidence in breastfeeding, cause anxiety, and can lead to early weaning [6]. In our study, plugged ducts occurred more frequently within the first month of postpartum, whereas mastitis occurred in the first to the third month of postpartum. No matter the onset time of plugged ducts or mastitis was similar in the previous study.

Plugged ducts and mastitis can be effectively relieved with enough breast emptying. A baby feeding is the most effective way to empty the breast. However, because of the separation of maternal and infant diseases, nipple injury, congenital malformation, or the blocked milk tube hard to be recanalized by infant sucking, some mothers must seek medical help. Our hospital developed a comprehensive milk stasis treatment called FSST, which can effectively increase stasis milk excretion to relieve the symptoms of patients with plugged ducts and mastitis. Previous studies have used similar comprehensive treatments and obtained similar positive results [27].

In our study, the symptoms of the patients, including pain and swelling, were significantly improved after receiving FSST, which to some extent indicated that the FSST scheme had certain curative effects on these patients. Previous studies had shown that the clinical symptoms at different stages of lactation could be effectively alleviated after treatment [28]. Laser therapy adopted composite output (650/810 mm) could relieve pain and reduce tissue edema. According to the instruction of the machine and the results of the previous study, the composite wavelength laser was the golden wavelength of the human body, which can stimulate the biological effect of anti-inflammation and detumescence at the irradiated site [20]. The laser treatment had the characteristics of high efficiency, noninjury, and safety, as long as it worked in the recommended irradiation mode. No adverse effects caused by laser treatment had been seen in our hospital in clinical practice. The second and third steps were to directly promote milk excretion through different ways, whereas the excretion of stasis milk removed the cause of disease and significantly improved the symptoms such as pain, swelling, and induration formation caused by it. The fourth step was through the hyperosmotic liquid cold compress so that breast swelling and pain might further relief. External application of 33% magnesium sulfate solution was safe because of minimal absorption on intact skin and limited duration. Magnesium poisoning caused by topical magnesium sulfate had not been reported before. But there were no prior data to show whether the clinical response on different symptoms varied at different stages after effective treatment. We focused on the clinical response to FSST on patients with plugged ducts and those with mastitis, and an interesting phenomenon was found. FSST provided better pain relief in the MG, whereas breast swelling fade away and reduction of hard lumps were greater in the PDG. Breast swelling fade away and hard lumps reduction both reflected the objective situation of the disease change, indicating the degree of milk excretion, the results of both should be consistent, and statistical analysis also supported this conclusion. In theory, the breast swelling fade away, and the lumps reduction was better in the PDG, suggesting greater pain relief, but the opposite was observed. There may be two reasons for this finding. The pretreatment pain score of the MG was higher than that of the PDG. The higher the score, the more obvious it falls. Patients had a strong feeling about the

improvement of pain. Second, breast pain is not only caused by the mechanical expansion of milk ducts caused by plugged ducts but also by an increase in inflammatory factors, such as prostaglandins, bradykinin, and substance P [29]. In animal studies, extracellular matrix (ECM) increases during the mastitis stage, and the increased ECM such as prostaglandins can cause more serious pain [30,31]. Human study has shown there are considerable differences in the concentrations of many components of human milk before and after breast massage [32]. FSST can stimulate stasis milk excretion, and milk excretion may affect the concentration of ECM. We hypothesized that pain relief in mastitis after FSST is, on the one hand, because of the physical effect of stasis milk excretion and, on the other hand, because of the chemical effect of milk excretion causing a decrease in the concentration of pain-related factors. Further research is needed to confirm the hypothesis. Changes in induration range could be observed that the lumps could vanish completely in quite a number of patients in PDG (40.9%) after treatment, but none of the patients in MG.

Since 2015, more than 10,000 patients have been treated with FSST at our hospital. FSST was simple and easy to implement and could be applied in the clinical treatment of lactating women with plugged ducts and/or mastitis. Because of the variation of clinical response at different stages, therapeutic scheme required optimization to achieve the best effect, such as more times FSST, medicine, and so on. The detailed operation steps of FSST could refer to the introduction mentioned previously. Breast massage techniques needed to be practiced to find effective drainage skills and needed to be individualized because of the variation of strength tolerance for different patients. Our goal was not to completely clear the breast induration in one FSST, and the scheme was not just a step as breast massage. The specialist nurses had played an important role in this treatment process. Higher requirements were put forward for the nurses. They not only needed to master the process of FSST but also master the professional knowledge of breast and breastfeeding. They needed to have knowledge of the breast anatomy to dredge along the direction of the plugged duct to the nipple because the induration was drained rather than crushed. Breast massage step is needed to avoid violence. Meanwhile, they needed to master rich professional knowledge of breastfeeding to give the individualized guidance to the patients according to the different breastfeeding problems. At the end of each treatment, the efficacy should be evaluated by the nurses, and the cases with poor effect should be referred to the clinician again to exclude the tumor or abscess. The safety and effectiveness of FSST were based on the cooperation of medical and nursing care. Professional guidance, adequate evaluation, and multidisciplinary collaboration were essential to carry out this treatment program.

There are some shortcomings in the study. FSST is a complex therapeutic protocol, and the most effective scheme should be explored. In addition, the difference of clinical response to FSST between the two groups is still in observation research. There is lack of pathophysiological evidence, such as the hypothesis that treatment can reduce the concentration of pain-related factors in ECM, and the analysis of milk is still to be further studied in the next stage.

Conclusion

FSST relieved breast pain and reduced breast swelling and range of induration. An interesting phenomenon was found that clinical response was different between the two groups. However, the FSST scheme requires optimization, and the mechanisms of difference in clinical response need to be further studied.

Funding

The authors disclosed no receipt of the financial support for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Acknowledgments

The authors would like to give their special thanks to our patients who participated in the project.

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Asian Nursing Research 15 (2021) 203–209

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

The Work Experience of Newly Recruited Male Nurses during COVID-19: A Qualitative Study

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ARTICLE INFO

Article history:
Received 18 July 2020
Received in revised form
2 May 2021
Accepted 5 May 2021

Keywords:
COVID-19
Male
Nurses
Pneumovirus infections
Qualitative research

ABSTRACT

Purpose: This study was to investigate the work experience of newly recruited male nurses during the COVID-19 pandemic.
Methods: With a phenomenological approach, this qualitative study was adopted semistructured interviews by phone or video calls. A total of 9 male nurses newly recruited for the COVID-19 wards in Chinese hospitals were interviewed for this study. And Colaizzi's method was applied for evaluation in the data analysis.
Results: Based on our findings, three themes were extracted. First, the newly recruited male nurses showed negative emotions at the beginning of COVID-19 epidemic, which was caused by changes in working conditions and content, but also prompted the nurses to change the way of coping with the crisis. Second, they gradually mastered the working skills and psychological training to cope with COVID-19 and developed a positive attitude toward life and a high sense of professional responsibility. Finally, we learned about their needs to respond to public health emergencies such as the COVID-19 pandemic.
Conclusion: COVID-19 is a disaster for all of humanity. The newly recruited male nurses are an important force in emergency rescue. Although they suffered from short-term negative emotions, they quickly adapted to the crisis. In order to better prepare for future emergencies, the disaster response capacity of newly recruited male nurses needs to be further improved. In addition, newly recruited male nurses have a strong demand for timely and personalized career development guidance.

Introduction

According to the World Health Organization (WHO), the coronavirus disease 2019 (COVID-19) has been identified as a disease caused by a novel coronavirus [1,2], and the first case was reported in Wuhan, China on December 12, 2019 [3]. As of May 1, 2021, there were 150,989,419 confirmed cases of COVID-19 worldwide, including 3,173,576 deaths [4]. And male nurses were considered essential for the care and treatment of COVID-19 patients in response to such a serious public health event. In the face of emergencies, male nurses had strong adaptability and antipressure ability [5], strong physical quality, decisive character, and can undertake heavy physical work to relieve patients' tension and anxiety [6,7]. These qualities could make male nurses indispensable in the healthcare workplace, especially when dealing with medical emergencies [8].

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https://doi.org/10.1016/j.anr.2021.05.001
p1976-1317 e2093-7482/

In the early stage of clinical work, these new male nurses were full of curiosity and had a strong thirst for knowledge when they encountered new knowledge or problems at work. In addition, they had strong plasticity and adaptability and often showed high enthusiasm for their work [5]. However, in Asian culture, due to insufficient training, lack of clinical experience, weak safety awareness, and social prejudice [9,10], they were often vulnerable to physical and mental trauma [11–13].

The COVID-19 pandemic with high rates of infection, which leads to heavy work, has put pressure on inexperienced nurses in particular. And nurses, as a line of defense for healthcare, should be considered as people who also need support and attention. Previous studies on male nurses' response to public emergencies were mostly quantitative studies [14,15], which often failed to reflect the psychological experience of new male nurses in the outbreak of infectious diseases.

There have been quantitative studies examining nurses' response to public crisis events. However, most of them were evaluation studies designed to investigate the effects of educational interventions in simulated environments on crisis event prevention, response, and post-disaster management. While these studies may be helpful in identifying key factors in crisis response, they could not provide detailed information about the nurses' experience [16]. As recently observed, quantitative studies often failed to assess the perspectives, intentions, and role awareness of nurses in response to the COVID-19 pandemic [17]. At the same time, the influence of environment, law, and organizational culture on nurses' crisis response ability could not be fully clarified [18]. And qualitative research was considered necessary to advance the understanding of care and public health emergencies. As a commonly used qualitative research method, Colaizzi's phenomenological approach mainly focuses on the experience and feelings of participants and finds common patterns among the research subjects rather than individual characteristics. Therefore, it ensures the authenticity of participants' experience and follows scientific standards, which has been verified in various qualitative nursing studies [19].

In this study, Researchers aimed to understand the work experience of newly recruited male nurses during the COVID-19 pandemic through a well-designed interview and to further reveal the problems and challenges they might encounter in the process of their work. In addition, the identified experience could broaden the information available in the current literature on how nurses respond to public crisis events [20]. Therefore, by exploring the real experience of male nurses in coping with COVID-19, as well as the challenges and problems they faced, this study could provide information for further improving the comprehensive nursing management strategy and enhancing the ability of male nurses to cope with public health emergencies such as COVID-19.

Methods

Study design

This is a qualitative exploratory descriptive study, conducted using semistructured interviews, based on phenomenological research methods and Colaizzi's seven-step method. The interview explored the experience of newly recruited male nurses during the COVID-19 pandemic. This study is consistent with the unified standard of qualitative survey [21].

Setting and participants

The study started in March and recruited nursing staff who participated in the fight against COVID-19 in tertiary hospitals in Wuhan and Zhengzhou from January to February 2020. These hospitals were chosen because of their commitment to treating patients with COVID-19. Voluntary participation in this study was carried out by the method of objective sampling. Demographic information included age, educational level, years of nursing experience, and marital status. In order to determine the number of nurses in the sample, data saturation was considered in the qualitative study. A total of 9 nurses were determined to be required to achieve data saturation. The average age of these 9 interviewees was 25 ± 2.0 years old, all of them had a bachelor's degree, and the average time of participating in anti-epidemic work was 17.5 ± 3.1 days.

Ethical consideration

When collecting and storing participant information, researchers paid close attention to confidentiality principles. Therefore, all personnel information was anonymized by using codes (N1, N2 …) during the transcription process. Transcribed text was then fed back to the participants for their approval. Audio recordings, videos, and other interview materials were stored on a password-protected computer. At the end of the study, all acquired data would be deleted. This study was approved by the Ethics Committee of Zhengzhou University (Approval no. 2020-18).

Data collection

Previous relevant reports were studied in this study to formulate an interview outline [22]. The questions were reviewed by a nursing team (including two professors and a research fellow) with expertise in qualitative methodology. In order to adjust the interview outline and complete the interview guidance, three male nurses were selected for pre-interview, followed by a comprehensive survey using the improved interview guidance. The final interview guide consisted of five open-ended questions to explore various aspects of the nurses' experiences in isolation wards: (a) What came to your mind when you learned that you would be working in the COVID-19 patient isolation ward? (b) What has been your previous experience in caring for COVID-19 patients? (c) In your opinion, what are the advantages and disadvantages of male nurses in fighting the epidemic? (d) How do you view your career after this experience? (e) As a newly recruited male nurse, what do you expect from hospital training?

The interview started after the participants were informed of the purpose and significance of the study. Since these interviewees were mostly college classmates or friends of the researcher, the two sides maintained a good trust relationship, which laid the foundation for the smooth conduct of the interview. The interviewer has a master's degree in nursing and experiences in qualitative interview and psychological counseling. Additionally, the interviewer has obtained a Third-Level Psychological Consultant Certificate issued by the Ministry of Human Resources and Social Security of China. Hence, the researcher was qualified to conduct this study independently.

Considering the government's initiative in reducing the risk of infection, the interviews were conducted via video communication (using WeChat program). All interviews were recorded with the consent of the interviewees. Information was recorded simultaneously during the one-on-one interview. Through WeChat video interview, interviewers could clearly see the interviewees' facial expressions and body movements during the interview. Interviewers mainly listened to what the participants were talking about while paying attention to their movements, facial expressions and body language. Each interview lasted about 20 to 40 minutes.

Data analysis

Colaizzi's seven-step analysis was used to analyze the interview data: (1) transcribing recorded interviews verbatim into text and reading the participants' descriptions multiple times; (2) extracting significant statements from each description; (3) formulating meanings from those significant statements; (4) organizing those formulated meanings into themes; (5) integrating the results of the data; analysis into a description of the phenomenon under study; (6) returning the results to the participants for validation; and (7) incorporating any new, relevant data into the fundamental structure of the phenomenon [23]. The interview recordings were transcribed within 24 hours after the interview. The transcripts had been carefully checked and reviewed. Previous study from Lincoln and Guba [24] suggested that member checking was essential to ensure the credibility of qualitative data. In this study, the researchers gave feedback on emerging explanations, then reached a consensus within the group, and finally formed written materials. Finally, the written materials were emailed to the interviewees for verification. In this study, the interviewees had no disagreement about the completeness and accuracy of the written materials. After a careful reading of the transcript, the key information was highlighted and then properly encoded and subject optimized (Table 1).

Findings

This study conceptualized the attitudes and perspectives of newly recruited male nurses in dealing with COVID-19 based on their work experience. Three themes and several subthemes emerged from the analysis, which are described as below in detail.

I. Impact of the epidemic

COVID-19 is a disaster that threatens people's health and safety, leaving people in fear. Newly recruited male nurses also have negative emotions in the early stages. In order to mitigate the detrimental effects, newly recruited male nurses have to adopt coping strategies to reduce the impact of negative experiences.

Early negative experiences

The COVID-19 outbreak was sudden and highly infectious, with a large number of people infected initially. Under the condition of insufficient medical staff and lack of medical resources, the newly hired male nurses need to wear protective gear to carry out a lot of treatment work. On the other hand, the newly recruited male nurses need to work longer hours in order to address the shortage of medical staff. The physical discomfort caused by the closed protective equipment and the extended work load therefore caused the nurses to have serious physical and psychological fatigue.

> *Hospital was crowded with early patients. We had to distinguish between the infected and the uninfected (patients) and adopt different treatment methods. One has to do several things at once. We were on the go from morning till night. (Nurse 4)*

The overwhelming number of untreated patients in hospital has also increased the mental fatigue of newly recruited male nurses.

> *Sometimes at the end of a busy day, we could find that we had even more patients than when we took over. Faced with these circumstances and my mental exhaustion, I really thought my work was futile and probably hopeless. (Nurse 7)*

In addition, witnessing how patients were infected, and in some cases the inevitable death, made newly recruited male nurses worry about their health and safety, as well as their families, increasing their psychological burden and fear of death.

> *The condition of a severely infected patient was both complicated and serious. Although as a nurse with expertise in respiratory diseases, I felt that my knowledge and experience were insufficient at this time. The rapid change of (patient)'s condition made me unable to determine whether I was doing the right thing and sometimes suspects that I really was not. (Nurse 3)*

> *I saw news reports about thousands of medical staffs being infected, which made me worry about my health. At first, infected people were not treated successfully. I could adjust my emotions quickly, but many people die every day and the grief recurs without waiting for you to return. The rescue treatment was good but there was no good result. No mood to eat anything. (Nurse 5)*

Temporary response strategy

In order to alleviate the negative experience caused by the clinical management of COVID-19, the newly recruited male nurses adopted an abstinence attitude, refused to pay attention to their own experiences and avoided expressing their feelings and emotions.

> *I will play my favorite online games after work, which can relieve my pressure and no longer think about my work experience. (Nurse 1)*

Table 1 *Extrapolation of Themes from Qualitative Data, Illustrating How Relevant Phrases Are Condensed to Codes and Extrapolated to Themes.*

Quotations	Theme	Subtheme
• *One person had to do several tasks at the same time. We were busy from morning till night, without rest. I really thought my work was futile and there might be no hope.*	I. Impact of the epidemic	Early negative experiences
• *I will play my favorite online games after work, which can relieve me of stress and no longer think about the work experience.*		Temporary response strategy
• *I found being a nurse can save many lives in the first place, especially patient's gratitude to me for treating them makes me proud of my profession and feels that everything is worth it.*	II. Gain experience and growth in the fight against the epidemic	Positive life perception
• *I am proud to be able to come forward when our country and people are in distress. I feel that I have done a great thing. In this particular moment, I feel like a hero.*		Improve professional recognition and enhance work responsibility
• *Managers should strengthen the training of emergency rescue content so that we can respond to unexpected accidents in the future.*	III. Need for nurses in the epidemic	Need for more emergency knowledge training
• *We don't know the coping strategies...I think it would be easier if there are psychologists who can provide psychological counselling...*		Need for psychosocial supports
• *Everyone should abandon traditional ideas in the future, respect us in the hospital and not discriminate against male nurse.*		Hope to get professional care

Some psychological cues could help nurses strengthen their mental resilience and stress capacity.

I often tell myself that I am doing a great thing, so I will try to protect myself and save others. It is necessary and meaningful. (Nurse 7)

II. Gain experience and growth in the fight against the epidemic

With the great achievement in the fight against COVID-19, the newly recruited male nurses obtained a positive outlook on life. The healing and rehabilitation of patients also make them feel the greatness of professionalism, and at the same time improve their professional recognition and enhance their sense of responsibility.

Positive life perception

There is no denying that newly recruited male nurses play an important role in the care of COVID-19 patients. The support and warmth they receive from society and family reassures them and in turn expresses gratitude to those who support them.

The whole society is praising us and supporting us. The whole country is our backing. We only need to treat patients wholeheartedly. (Nurse 6)

Improve professional recognition and enhance work responsibility

In the early days of the COVID-19 outbreak, there was a shortage of medical supplies, which quickly overwhelmed Wuhan's medical system. The rescue conditions in hospitals were rapidly exhausted, and nurses were faced with high workload and psychological pressure. In this case, the newly recruited male nurses had outstanding physical and psychological advantages in this rescue work.

After the outbreak of the epidemic, I found that being a nurse could save many lives in the first place. Especially, the gratitude of patients for my treatment made me proud of my profession and feel that everything was worthwhile. (Nurse 6)

I am proud to be able to come forward when our country and people are in distress. I feel that I have done a great thing. In this particular moment, I feel like a hero. (Nurse 8)

The newly recruited male nurses felt the appreciation and care from the whole society and were grateful for it.

We were from different departments. At the beginning, I was worried about getting along with everyone, but everyone was enthusiastic, helped each other at work, and cared for each other. I felt warm in the team, and everyone was working together to fight against the disease. (Nurse 3)

III. Need for nurses in the epidemic

Through the fight against COVID-19, newly recruited male nurses have found themselves lacking in professional knowledge and are eager for psychosocial support and professional guidance in their career development.

Need for more emergency knowledge training

Newly recruited male nurses find themselves lacking in treating COVID-19 patients and wish to improve their knowledge and skills in the future.

Managers should strengthen the training of emergency rescue content in order to respond to unexpected accidents in the future. (Nurse 2)

Improve my expertise and master more advanced professional operations. (Nurse 6)

Need for psychosocial support

The COVID-19 outbreak had led to a rapid increase in the number of infections, and new male nurses faced greater work pressure and psychological burden. Therefore, the way to alleviate this situation was to give them the material and psychological spiritual support they need from all walks of life.

We don't know how to deal with it … I think it would be easier if there are psychologists who can provide psychological counseling … We do need some kind of support from family members or social groups because we are facing high risks. (Nurse 2)

Hope to get professional care

During the COVID-19 pandemic, society discovered that nurses were prone to burnout from overloaded care. In times like this, however, newly recruited male nurses expressed that social support has been a powerful source of motivation.

Everyone should abandon the traditional ideas in the future, respect us in the hospital and do not discriminate against male nurses. (Nurse 4)

Discussion

Under the threat of the epidemic, people often feel afraid of their own health and helpless psychologically due to lack of knowledge, which only leads to the aggravation of negative emotions such as fear, exhaustion, and anxiety. COVID-19 is clearly a serious disease of international concern. It was more infectious than SARS, and more people were infected and killed than SARS [25,26]. Like others, newly recruited male nurses were concerned about their lives, health, and job safety in the face of a COVID-19 pandemic. Studies have shown [19] a sharp increase in the number of infections due to the COVID-19 outbreak, a 1.5-2 times increase in nurses' normal working hours and workload, and widespread fatigue. However, in the interview, it was found that the main reason for the fatigue of newly recruited male nurses was not the extension of working hours or the increase of workload, but the change in working conditions and content. Because this is a highly contagious disease, all treatment takes place in isolation wards. Frontline nurses without infectious disease expertise faced many challenges in adapting to a new work environment [27]. In addition, the management of COVID-19 patients needs to be both comprehensive and specific. Many newly recruited male nurses have little clinical experience in infectious intensive care [28]. When the health department is not prepared to deal with outbreaks of infectious diseases, there is an urgent shortage of medical staff. Therefore, there is an urgent need to train and educate newly recruited nurses. The rapid change in work content has also caused newly recruited male nurses to become more stressed and anxious on the job. We found that newly recruited male nurses showed significant anxiety during their first week on the job when they first entered the isolation ward. As working hours lengthen, most nurses experience an increase in fatigue and awareness of their own safety. Therefore, in the early stage of the epidemic, it is particularly important to carry out early psychological intervention for nurses. This could include immediate stress assessment and professional,

continuous psychological interventions [29,30] to promote emotional relief and improve the mental health of nurses [31]. In addition, an early support system should be established for newly recruited male nurses working in isolation wards for a long time to ensure adequate supplies and reasonable staffing. Managers should also introduce flexible shift schedules and fixed allocations based on infections, illness, workload, and the number of nursing staff in order to provide a productive working environment for newly recruited male nurses. They should also ensure that nurses have enough time to recuperate to improve the quality of medical care [32].

Previous studies, such as those conducted during SARS, have found that infectious diseases have brought great pain to medical staff, affecting more nurses than doctors [33]. This is due to the nature of their work and their long-term close contact with infected patients. In addition, due to the shortage of staff, nurses also have to handle some of the daily work of the hospital. Therefore, it is interesting to see how nurses respond to the challenges of care and treatment during the COVID-19 outbreak. In the face of a variety of challenges, the newly recruited male nurses have shown great strength and resilience. They actively seek multiple support systems and self-regulation skills to relieve stress because they know that in order to save more lives and protect themselves, they need to take care of themselves and focus on their responsibilities. In terms of psychology, they often gave themselves positive psychological affirmation, defining fighting COVID-19 as a process that supports positive experiences and growth, which was consistent with Sun's findings [19]. Male nurses tend to adopt a certain abstinence attitude, refuse to pay close attention to their own experiences and further avoid expressing their feelings and emotions. For example, they will play online games, watch movies, and listen to music to adjust the unhappy mood at work. Similar to previous studies [19,34], some nurses record their emotions and cognition through electronic diaries or letters, and interact closely with the outside world to obtain social and family information and psychosocial support. Unlike previous research results, newly recruited male nurses did not mind paying attention to the news about COVID-19. They just do not want to recall their experiences in the ward but are still keen on social report on COVID-19. This may be because they come from different regions, hoping to get more information about their hometowns.

Like other medical staffs, male nurses had negative experiences in the early stage of the COVID-19 fight, but they were able to quickly adjust and adapt to working in the isolation zone and continued to develop positive emotions during their work. Overall, respondents were more optimistic and could feel their own peace of mind. They were proud to participate in the epidemic prevention and control work and were full of confidence and expectations for the future work. Newly recruited male nurses have several reasons to be particularly optimistic: (a) they are enthusiastic about their work and are willing to accept challenging things; (b) they believe that participating in the fight against the epidemic has given them a sense of self-worth and accomplishment; (c) team support, social care, and compliments from patients can alleviate their mental stress of patients and reduce the impact of some negative emotions; and (d) in terms of crisis management, men are more likely to choose to tackle impersonal problems that cause specific difficulties and are less likely to focus on emotional issues.Therefore, when dealing with stress, they rarely use emotion-centric coping methods [35].

COVID-19 has been a disaster, creating huge challenges for newly recruited male nurses. However, despite the stress of the epidemic, they had to use their medical and psychological knowledge to make psychological adjustments. At the same time, they were in emergency rescue and infectious disease prevention. The physical and mental recovery and control of the injured after the disaster also gave them good experience in responding to public health crises in the future. Based on our findings, we were able to determine that the majority of newly recruited male nurses grew psychologically and cognitively under stress. They actively reflected on their cognitive thinking and found positive forces, such as greater respect for health and life, increased professional identity and responsibility, and gratitude for social and family support, which was consistent with the findings of Shih *et al.* [36]. Notably, the newly recruited male nurses showed positive altruism and greater solidarity in the face of disaster. The sense of responsibility that comes with a career encouraged them to take an active part in related work, which improved their professionalism and self-esteem [37]. In addition, the collaborative work of nurses from different regions and positions also enabled newly recruited male nurses to participate in a multidisciplinary teamwork. Therefore, during the COVID-19 epidemic, actively guiding and inspiring newly recruited male nurses to realize their own growth, adjusting cognitive evaluation, guiding positive coping styles, and stimulating positive emotions might play a positive role in psychological adaptation and career development.

Our findings indicated that newly recruited male nurses responding to the COVID-19 pandemic need more training in emergency preparedness, psychosocial support, and specialized care. Respondents showed that although they had received training on disaster knowledge during their employment, they mainly focused on emergency drills such as earthquakes and fire. These trainings mainly include first aid techniques, trauma treatment and injury, disposal, and classification of the wounded [38]. However, in the prevention and control of infectious diseases, the newly hired male nurses are still inadequate, such as lack of experience in response. Based on these findings, newly hired male nurses should also play a more important role in the leadership, such as resource allocation, patient transport, and health support for survivors and vulnerable groups [39]. In the future, leaders should pay attention to the construction of the disaster relief team, improve the relevant rules and regulations, and ensure the team construction and talent reserve [40].

Previous studies have shown that [41] lack of psychosocial support is a significant risk factor for negative psychological experiences in all types of disasters. At the same time, positive emotions are related to the support of patients, family members, team members, government, and the whole society. Therefore, psychosocial support is also anessential resource for newly recruited male nurses to fight the epidemic. This study also identified that good psychological adaptability and sufficient social support could ensure that newly hired male nurses could quickly acquire the mental recovery ability under severe stress. Therefore, encouraging various social supports and strengthening the psychological treatment of nurses fighting COVID-19 in the initial phase of the COVID-19 response is critical to ensure the mental health of newly hired male nurses in the aftermath of disasters.

Although we found a further increase in the professional identity and responsibility of newly hired male nurses to participate in the COVID-19 outbreak, there were still many who were not involved in the treatment of COVID-19 patients and might require more professional guidance and care. Men were relatively underrepresented at different levels of employment in most countries, and male nurses were in a minority category [42]. Male nurses with less than 4 years of work experience have a higher turnover rate [43], which is not conducive to maintaining the diversity of the nursing team.

Male nurses tend to be enthusiastic at the beginning of their work and have high expectations for the development of their nursing career, but often their positions do not match their own conditions, which can only lead to major setbacks for male nurses

[44]. The training of male nurses mainly includes professional training, continuing education, further training, promotion teaching, and scientific research [45]. During the interview, respondents mostly wish to receive more professional and scientific research training. According to the professional ability demand of male nurses, specialized training groups such as pressure ulcer care group and nutrition care group should be set up. Group training should be conducted once a week; furthermore, long-term planning arrangements should be made. Moreover, managers need to take full account of gender differences in the profession and make use of "person-job matching" [46], which could help them make full use of their own advantages and meet their career expectations according to their personal situation, professional ability, and personality characteristics of male nurses.

At present, nursing is still a highly gendered occupation. It is deeply influenced by traditional gender discrimination, regional development level, and other factors. In some regions, especially in developing countries, nursing recognition is low, nurses generally have a low social status, and men's participation in nursing is often disingenuously accepted [47]. Respondents believe that improving their social status is of far-reaching significance for future career development. Therefore, it is suggested that nursing managers and educators should carry out the concept of "gender neutrality" in nursing work, so as to promote the dedication of male nurses, establish the image of male nurses in society in the new era, and change the public prejudice against male nurses. At the same time, gender-sensitive nursing policy should be made consciously, so that gender-sensitive nursing policy should run through the whole education, practice, supervision, and leadership functions.

Although the newly recruited male nurses were well adapted to this incident, we could not ignore the physical and mental damage they suffered. We called on the family members and the community to provide full support and care to the male nurses in their prevention work. Psychologists should play a greater role in the diagnosis and treatment of male nurses who had completed rescue work.

Limitations

This study has limitations. Our study examined the working experiences of newly recruited male nurses working in major hospitals in several Chinese cities, including the previous epicenter Wuhan city. As a result, we still lack information about male nurses working in other countries and in different cultural contexts. Besides, our findings were based on data from participants who had shared educational experience at undergraduate institutions. Thus, it is necessary to expand the sample size and further study in combination with the investigation.

Conclusion

The COVID-19 outbreak has become a disaster that affects all of humanity. Compared with female nurses, male nurses were more adaptable to COVID-19 (able to make rapid psychological and cognitive adjustments to improve vocational skills and career planning level), but negative emotions were evident in the short term. Therefore, the integration of appropriate medical resources and social support and the establishment of supporting systems are crucial to alleviate the severe physical and mental stress of new male nurses in dealing with COVID-19 in its early stages. Based on these results, nursing managers should further strengthen the disaster rescue ability of newly recruited male nurses and make timely career development guidance to promote the career growth of new male nurses.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

This work was supported by the National Natural Science Foundation of China (No.81773175), China Postdoctoral Science Foundation in 2018: (2018M630839) and the Science and Technology Research Project in Henan Province (192102310299). The authors appreciate all participants for their generous participation.

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Asian Nursing Research 15 (2021) 210–214

Contents lists available at ScienceDirect

Asian Nursing Research

journal homepage: www.asian-nursingresearch.com

Research Article

Factors Associated with the Need for Breastfeeding Information Among Women with Gestational Diabetes Mellitus: A Cross-sectional Study

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ARTICLE INFO

Article history:
Received 21 December 2020
Received in revised form
10 May 2021
Accepted 16 May 2021

Keywords:
Breast feeding
Diabetes, gestational
Information services
Quality of life

ABSTRACT

Purpose: Analyzing information based on individual needs can maximize the effectiveness of education, leading to changes in personal health behaviors. This cross-sectional descriptive survey study aimed to identify the characteristics of mothers who experienced gestational diabetes mellitus and correlate the factors associated with their information needs.
Methods: The participants were 298 women between the ages of 20 and 49 years who were pregnant and diagnosed with gestational diabetes at the time of the study, or who were diagnosed with gestational diabetes mellitus within five years after delivery. The average age of the participants was 34.28 years. After comparing participants' demographics, diabetes, and breastfeeding-related characteristics according to their need for information on breastfeeding, a multiple logistic regression analysis was performed.
Results: Factors associated with participants' need for information on breastfeeding were economic conditions, usual body mass index, current pregnancy, and experience of breastfeeding.
Conclusion: The findings can be used to implement programs that meet the needs of these women and help improve maternal and pediatric health and quality of life.

Introduction

In 2019, the International Diabetes Federation (IDF) estimated that 20.4 million pregnant women had hyperglycemia. In 83.6% of these cases, the underlying reason was gestational diabetes mellitus (GDM). The prevalence of GDM increases with age, resulting in a 37% occurrence in the 45–49 age group and a 50.1% occurrence in women under the age of 30 years [1]. In the 1990s, the prevalence of GDM in Korea ranged from 1.7% to 3.9%; however, a systematic review from 2000 to 2016 revealed that its prevalence in Korea increased to approximately 7.2% [2,3].

The risk of type 2 diabetes and obesity in both mothers and newborns increases if pregnant women with GDM do not receive timely treatment; thus, diabetes-related knowledge and management skills are essential for this population [4]. Of the various methods to decrease the risk of diabetes, breastfeeding has been found to be one of the most beneficial since it can also reduce the incidence of other diseases and improve women's health [5–7]. Being breastfed as a newborn also plays a role in adult life. Specifically, in a population-based birth cohort study of 3493 newborns in Pelotas, Brazil in 1982, breastfeeding was linked to an increase in intelligence quotient 30 years later, which helped influence educational performance and income growth during adulthood [8].

However, there are a number of factors that lead to early breastfeeding cessation, including problems with breastfeeding at home, early return to work after childbirth (i.e., within three months), inadequate breastfeeding support, cesarean section

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https://doi.org/10.1016/j.anr.2021.05.002
p1976-1317 e2093-7482/

delivery, low socioeconomic status, and increased body mass index (BMI) [9]. Only a few studies have investigated the need for information on breastfeeding or beliefs related to it among women with GDM, which is important since some diabetes medications taken by mothers can affect the children being breastfed [10]. Technological advancements, the abundance of available resources (i.e., information overload), and information targeting pregnant women do not always accurately reflect the needs of those with GDM [9]. Furthermore, anecdotal information by grandmothers has been found to negatively affect proper breastfeeding [11].

Knowledge, attitudes, and interest can influence the duration a mother breastfeeds; thus, education regarding the benefits and methods of breastfeeding is not only helpful but imperative [12,13]. Information based on an individual's needs that is provided in a timely manner can lead to changes in personal health behaviors [14]. The present study, therefore, aimed to identify the characteristics of mothers who experienced GDM and correlate their information needs. This information will serve as the basis for programs that can be potentially effective and aid mothers with GDM and their children lead healthy lives.

Materials and methods

Participants

Potential participants were recruited through an online forum for pregnant women with diabetes in May 2020 and were required to provide information regarding their GDM diagnosis in the form. Participants were then selected based on their self-reports. The inclusion criteria were: (1) women aged 20–49 years who were (2) currently pregnant and diagnosed with GDM or (3) diagnosed with GDM within five years after delivery. Women who were diagnosed with GDM and had type 2 diabetes after delivery were excluded. The data were collected anonymously, and the questionnaire was identified by a serial number, placed in an anonymous envelope, and delivered to individual participants.

The sample size for logistic regression was calculated using G* Power, version 3.14. We considered an odds ratio (OR) of 1.62, Pr of 0.43, significance level of 0.05, alpha of 5%, and two-tailed test with 95% confidence interval (CI) based on self-efficacy. The minimum sample size was determined to be 248; accounting for a potential dropout rate of 20%, a total of 298 women were surveyed.

Variables

Need for breastfeeding information

The need for breastfeeding information was assessed by one question: “Do you want to receive information about a breastfeeding program for mothers with GDM?” Participants were then divided into two groups based on their responses (yes or no).

Demographic characteristics

Demographic characteristics included age (26–30 years, 31–35 years, 36–40 years, and ≥41 years), educational level (high school or college/university and above), economic condition (low or above medium), employment status (employed or unemployed), weight (in kg), and height (in cm). Weight and height were used to calculate BMI, which was included in the final analysis. Current pregnancy was classified as “yes” if they were pregnant at the time of the survey and were diagnosed with GDM.

Diabetes-related and breastfeeding experience characteristics

For diabetes-related characteristics, participants provided information on previous illnesses other than diabetes (if any, the number of such diseases), current diabetes medication/s (if any, medication name/s, and type of management), and diabetes duration. The instrument used to assess GDM-related knowledge was developed based on the “Knowledge and Health Beliefs about Gestational Diabetes and Healthy Pregnancy's Breastfeeding Intention” [13]. This tool comprised 15 questions: four on GDM's definition, signs, and symptoms; four on GDM management; five on the adverse outcomes of GDM; and two concerning breastfeeding. The content validity was confirmed by two obstetric-gynecologists and two maternity nursing professors. Fifteen items with a content validity index of 0.8 or higher were extracted, and in a previous study, Kuder-Richardson 20 ranged from .75 to .77 [13,15]. Each question was answered as “Yes,” “No,” or “Don't know”; correct answers received 1 point while wrong answers or “Don't know” responses earned 0 points. The knowledge score was converted to a percentile correct answer rate (%), with higher scores indicating greater knowledge. The Kuder-Richardson Formula 20 was .607. The breastfeeding experience was divided into full breastfeeding, mixed breastfeeding, and artificial breastfeeding.

Data analysis

Survey data were processed with SPSS, version 24.0 (IBM Corp., Armonk, NY, USA). The differences in demographics, diabetes-related characteristics, and breastfeeding-related characteristics were analyzed using t-tests and chi-square tests. The correlates of breastfeeding information needs were analyzed through multiple logistic regression.

Ethical considerations

The participants understood the study's purpose, that participation was voluntary, and that the collected data would be used only for research purposes. All participants provided written informed consent. The study was approved by the concerned institutional review board (KBUIRB-202004-SB-003-01).

Results

Demographic characteristics

The data of 298 women with GDM were analyzed. Among them, 123 (41%) had information needs, and there was no significant age difference between the groups with and without information needs (mean = 34.28 years). The difference between the two groups concerned economic condition; when the economic level was low, information needs were about 10% higher ($\chi^2 = 4.42$, $p = .036$). Furthermore, the usual BMI in the group with information needs was 25.30 kg/m^2, indicating greater obesity (about 2 kg/m^2) compared to the group without information needs ($t = -4.20$, $p < .001$). In those with information needs, there were approximately 15% more women who were currently pregnant than in the group without ($\chi^2 = 12.79$, $p < .001$). However, there was no significant difference between the groups in terms of educational level and employment status (Table 1).

Diabetes-related and breastfeeding experience characteristics

Table 2 presents the characteristics of diabetes and other diseases in terms of participants' information needs. The group with information needs had an average of 0.40 diseases other than diabetes, which was statistically higher than those without information needs, with an average of 0.26 ($t = 7.23$, $p = .007$). In other words, 36.6% of the participants with information needs had more than one disease, apart from diabetes. In the groups with and without information needs, the prevalence of use of diabetes

Table 1 *Demographic Characteristics of Women with Gestational Diabetes Mellitus.*

Variables	Total	Need for information		Difference
	(N = 298)	Yes (n = 123)	No (n = 175)	
	n (%)/M±SD	n (%)/M±SD	n (%)/M±SD	χ^2 or t (p)
Age (years)	34.28 ± 3.73	34.17 ± 3.62	34.35 ± 23.37	0.40 (.686)
26–30	54 (18.1)	22 (17.9)	32 (18.3)	
31–35	136 (45.6)	60 (48.8)	76 (43.4)	
36–40	93 (31.2)	37 (30.1)	56 (32.0)	
≥41	15 (5.1)	4 (3.2)	11 (6.3)	
Educational level				2.61 (.106)
High school	65 (21.8)	33 (26.8)	32 (18.3)	
≥College/university	233 (78.2)	90 (73.2)	143 (81.7)	
Economic condition				4.42 (.036)
Low	44 (14.8)	25 (20.3)	19 (10.9)	
≥Medium	254 (85.2)	98 (79.7)	156 (89.1)	
Employment status				1.12 (.735)
Employed	131 (44.0)	56 (45.5)	75 (42.9)	
Unemployed	167 (56.0)	67 (54.5)	100 (57.1)	
Usual BMI (kg/m^2)	24.19 ± 3.96	25.32 ± 3.89	23.37 ± 3.82	−4.20 (<.001)
Current pregnancy				12.79 (<.001)
Yes	53 (17.8)	34 (27.6)	19 (10.9)	
No	245 (82.2)	89 (72.4)	156 (89.1)	

Note. BMI = body mass index; M = mean; SD = standard deviation.

medications was 30.1% and 26.3%, respectively, with insulin being the most commonly used drug (24.4% and 13.7%, respectively). However, differences between the groups in use of diabetes medication, duration of diabetes, GDM-related knowledge, and breastfeeding experience were not statistically significant (Table 2).

Factors affecting information needs in participants

To identify the factors influencing information needs in the participants, a logistic regression analysis was performed using demographic, diabetes-related, and pregnancy and breastfeeding experience characteristics as independent variables. The predictors were economic condition (OR = 2.60, 95% CI = 1.14–5.92), usual BMI (OR = 1.11, 95% CI = 1.03–1.20), current pregnancy (OR = 3.57, 95% CI = 1.14–11.11), and breastfeeding experience (OR = 2.38, 95% CI = 1.04–5.45). Thus, the group with a low economic level had 2.60 times higher information needs than the groups with middle or high economic levels; additionally, the higher the usual BMI, the greater the need for information (by 1.11 times). Furthermore, women who were pregnant at the time of the study had a 3.60 times greater need for breastfeeding information than those who were not. The need for breastfeeding information was 2.38 times greater among women who experienced mixed breastfeeding than among those who did not (Table 3).

Discussion

This study aimed to identify factors associated with breastfeeding information needs among pregnant women with GDM. In this study, about 41% of participants had information needs. This result is difficult to collate accurately due to a lack of prior studies on the information needs of mothers with GDM; however, in a previous study of 21 patients who experienced psychological impairment after ICU treatment, 75% of patients had information needs [16]. Among these ICU survivors, only 33% were satisfied with the information provided by the hospital; thus, it can be

Table 2 *Diabetes-Related and Breastfeeding Experience Characteristics of Women with Gestational Diabetes Mellitus.*

Variables	Total	Need for information		Difference
	(N = 298)	Yes (n = 123)	No (n = 175)	
	n (%)/M±SD	n (%)/M±SD	n (%)/M±SD	χ^2 or t (p)
Previous illness (except DM)	0.32 ± 0.54	0.40 ± 0.55	0.26 ± 0.52	7.23 (.007)
No	215 (72.1)	78 (63.4)	137 (78.3)	
Yes	83 (27.9)	45 (36.6)	38 (21.7)	
1	72 (24.2)	41 (33.3)	31 (17.7)	
≥2	11 (3.7)	4 (3.3)	7 (4.0)	
Diabetes medication				0.35 (.556)
No	215 (72.1)	86 (69.9)	129 (73.7)	
Diet and exercise	213 (71.5)	85 (69.1)	128 (73.1)	
Observation	2 (0.6)	1 (0.8)	1 (0.6)	
Yes	83 (27.9)	37 (30.1)	46 (26.3)	
Insulin + OHA	12 (4.1)	2 (1.6)	10 (5.7)	
Insulin only	17 (5.7)	30 (24.4)	24 (13.7)	
OHA only	54 (18.1)	5 (4.1)	12 (6.9)	
Disease period (months)	28.13 ± 21.96	27.67 ± 25.61	28.47 ± 19.03	0.31 (.758)
GDM-related knowledge	11.38 ± 2.51	11.28 ± 2.20	11.44 ± 2.72	0.55 (.586)
Experience of breastfeeding (n = 254)*				2.20 (.333)
Artificial feeding	44 (14.8)	14 (11.4)	30 (17.1)	
Mixed breastfeeding	145 (48.7)	63 (51.2)	82 (46.9)	
Complete breastfeeding	65 (21.8)	24 (19.5)	41 (23.4)	

Note. M = mean; SD = standard deviation; DM = diabetes mellitus; OHA = oral hypoglycemic agents; GDM = gestational diabetes mellitus.
* n = 44: No delivery experience.

Table 3 *Factors Associated with Information Needs in Women with Gestational Diabetes Mellitus.*

Variable	Odds ratio	95% CI	p-value
Age (years) (ref: 26–30)			
31–35	1.12	0.48–2.64	.790
36–40	0.87	0.35–2.15	.762
≥41	0.44	0.10–1.99	.287
Educational level (Ref: ≥College/University)			
High school	1.20	0.56–2.57	.633
Economic condition (Ref: ≥Medium)			
Low	2.60	1.14–5.92	.023
Employment status (Ref: Unemployed)			
Yes	1.18	0.67–2.08	.578
Usual BMI	1.11	1.03–1.20	.007
Previous illness (Ref: No)			
1	1.70	0.88–3.30	.115
≥2	0.64	0.13–3.25	.591
Diabetes medication (Ref: No)			
Yes	1.15	0.61–2.17	.671
Disease period (Months)	1.00	0.99–1.01	.976
GDM-related knowledge	0.99	0.88–1.11	.811
Current pregnancy (Ref: No)			
Yes	3.57	1.14–11.11	.028
Experience of breastfeeding (Ref: Artificial)			
Mixed	2.38	1.04–5.45	.041
Complete	1.80	0.70–4.58	.222

Note. CI = confidence interval; BMI = body mass index; GDM = gestational diabetes mellitus.

assumed that 42% still required more information. In another study, a Swedish survey of 542 patients with chronic obstructive pulmonary disease requiring ongoing self-care, reported that further information on self-care and diet was needed in 68% of moderate and 32% of severe grade patients [17]. Another study involving 458 patients diagnosed with hematologic cancer reported a perceived need for information among 40–70% of the patients [18]. As compared to these studies, the participants in the current study had lower medical severity, but similar information needs. However, although the present study investigated the specific information needs of mothers with GDM, follow-up studies are needed to corroborate the information needs among this target population.

Factors associated with the need for breastfeeding information were low economic levels, increased BMI, current pregnancy status, and mixed breastfeeding experiences. Unlike in previous studies [3,8], GDM-related knowledge, complications, and diabetes drug use levels were not correlated with the need for breastfeeding information in the current study. Demographic data, pregnancy status, and breastfeeding experience were found to be more important than diabetes-related characteristics. Low economic levels and increased BMI have previously been known to influence early breastfeeding cessation in mothers with GDM [9]. Therefore, providing adequate breastfeeding information to mothers with GDM, especially among those with the aforementioned risk factors, can help prevent early breastfeeding cessation.

According to the 2018 National Health and Nutrition Survey, approximately 55% of women had breastfeeding experience of over one month; the average breastfeeding duration was about 17 months [19]. The present results indicate that 70.5% of the women who engaged in mixed and complete breastfeeding had a better breastfeeding experience than the domestic average. Furthermore, the group that engaged in mixed breastfeeding had higher information needs than the group that engaged exclusively in artificial feeding.

The first possible reason for these findings is that the participants may have had experiences with GDM and failed to complete breastfeeding for a previous child. In a study among 1323 healthy mothers investigating the reasons for the cessation of breastfeeding within one year, three main factors were found: that the baby began to bite, the baby lost interest in breast milk, and the mother was unable to produce enough milk [20]. To date, few studies have investigated whether there is a difference between breast milk in healthy women and in women with GDM; however, some research indicates that GDM causes elevated sodium levels in breast milk [21], which are associated with insufficient milk supply and malnutrition in infants [22]. Therefore, the possibility that GDM influences breastfeeding cannot be excluded. Moreover, insufficient breast milk production is a concern not only for the mother but also for healthcare providers [23,24]. Hence, prenatal education on topics such as breast massage and maternal health status is necessary to increase breast milk production.

The second possible reason for the findings is that mothers who already have GDM are aware that breastfeeding has many benefits, but the information given to them while they breastfeed may not be what they need or want. Many studies have focused on motivating breastfeeding mothers by investigating the factors that affect the presence or absence of breastfeeding [9,25]. However, there is a lack of research on breastfeeding-related problems among mothers with GDM and their solutions. Throughout the breastfeeding period, it is necessary to ensure that mothers with GDM can have their doubts clarified by experts, receive corrective feedback, and benefit from supportive programs.

In 2015, a qualitative study of 14 African American mothers found that most were using at least one mobile application to obtain breastfeeding information through social media [26], confirming that pregnant women have a high need for information. Therefore, providing information using social media or mobile applications can help those who are currently pregnant and who will be breastfeeding in the near future, to communicate with experts on related topics.

Despite its strengths, this study has the following limitations. First, although social support, such as support from family members, is very important for continued breastfeeding [9,12], this study did not confirm whether it is associated with information needs. Second, in conducting an online survey, we did not consider potential differences in the information needs of mothers with GDM who do not have access to the internet. Third, interactions between variables, such as economic level and BMI, were not confirmed. Finally, research on the information needs of women with GDM is currently limited. Therefore, knowledge on women

who refuse to receive breastfeeding information is scarce. This study also did not investigate why these women did not want to receive this information. Further, a qualitative study on the experience of breastfeeding preparation in women with GDM is necessary. In addition, according to previous studies, mothers with GDM who have high self-efficacy are more likely to breastfeed [15]. Therefore, it would be helpful for health care providers to offer information programs to increase self-efficacy.

Conclusions

We identified the correlates of breastfeeding information needs among women with GDM. Healthcare providers should offer information needs–based programs to increase breastfeeding self-efficacy among women with GDM.

Funding

This work was supported by the Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education (NRF-2019R1I1A3A01059963).

Conflict of interest

The authors declare that they have no competing interests.

Acknowledgments

S. P., I. S., and D. M. conceived and designed the study, performed the data analysis, and wrote the manuscript. All authors have read and approved the final manuscript.

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