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Editorial

A pledge to acknowledge the “post- $p < .05$ ” era

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Although p -values have been used in numerous studies, a longstanding criticism has existed over the misuse and abuse of $p < .05$. For example, in a correlation coefficient test (i.e., test of non-correlations), as a sample size becomes larger, its p -value becomes significant even if the correlation coefficient is small. Conversely, if the sample size is small, no matter how large the correlation coefficient is, the p -value may not be significant. It must be judged instead based on the correlation coefficient, which is the effect size. This is one very obvious example.

In 2015, *Basic and Applied Social Psychology (BASP)* declared the null hypothesis significance testing procedure is invalid and banned the use of p -values (Trafimow & Marks, 2015). Even the prestigious journal *Nature* published a paper in 2019 that asserted “We should never conclude there is ‘no difference’ or ‘no association’ just because a p -value is larger than a threshold such as .05 or, equivalently, because a confidence interval includes zero” (Amrhein, Greenland, & McShane, 2019). When reporting p -values, do not use adornments such as stars or letters to denote statistical significance and use sensitive precision (for example, $p = .021$ or $p = .13$).

Moreover, in 2016, the American Statistical Association (ASA) published the “ASA statement on statistical significance and p -values,” indicating six principles underlying the proper use and interpretation of the p -value and mentioned the use of Bayes factors instead of relying only on p -value (i.e., test of statistical significance) (Wasserstein & Lazar, 2016). Furthermore, in 2019 the assertion was made that, “We conclude, based on our review of the articles in this special issue and the broader literature, that it is time to completely dispense with use of the term ‘statistically significant.’ Nor should variants such as ‘significantly different,’ ‘ $p < .05$,’ and ‘nonsignificant’ survive whether expressed in words, by asterisks in a table, or in some other manner” (Wasserstein, Schirm, & Lazar, 2019).

Since the 6th edition issued in 2009, the “Publication Manual of the American Psychological Association,” which is often used in the nursing field, requires that p -values be expressed as specific numerical values, and that effect size and confidence interval be specified, among others. Under these circumstances, the *Journal of International Nursing Research (JINR)* hereby declares the transition to the “post- $p < .05$ ” era. As a side note, I think I would also like to mention that *JINR* does not necessarily guarantee that papers with statistically significant results are more likely to be accepted.

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Review Article

Assessment of insulin balls: A scoping review

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Abstract

Insulin balls are subcutaneous induration caused by amyloid deposition due to repeated insulin injections to the same site, and subcutaneous injections in this area cause poor glycemic control. Therefore, it is important to assess the site for insulin balls and change the injection site at an early stage, but the assessment method remains unclear. Therefore, we aimed to clarify the available methods for insulin ball assessment. Using the scoping review method, we searched Japanese and English literature from January 1964 to November 2022 using the keywords “insulin ball” and “assessment” and included those that met the selection criteria. Database searches were conducted in Japan Abstracts Society, PubMed, Scopus, and CINAHL. The number of adopted studies regarding insulin ball assessment was 11. Palpation and visual examination were the assessment methods used in all studies. Blood tests and ultrasonography were both performed in nine articles, magnetic resonance imaging (MRI) was performed in five articles, and computed tomography (CT) was performed in four articles. There were two types of insulin balls: palpable and nonpalpable. A paper reporting that nonpalpable insulin balls can be detected by ultrasonography was noted. In addition to palpation and visual examination, imaging tests such as ultrasonography, MRI, and CT are necessary because some insulin balls cannot be palpated. This study suggested that incorporating ultrasonography in addition to palpation and visual examination may be useful as a screening tool for the early detection of insulin balls. We now need to validate the accuracy of the assessment by ultrasonography.

Keywords

assessment, insulin ball, insulin injection, scoping review, subcutaneous induration

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Introduction

In recent years, subcutaneous injections in insulin balls (insulin-derived amyloidosis) have gained attention in the diabetes field as a cause of poor glycemic control (Nagase

et al., 2009). Although patients are instructed to self-inject insulin at 2-3-cm intervals to prevent adipose tissue atrophy or induration (Ohtani, 2013), several cases where patients injected at the same site, resulting in poor glycemic control, have been reported (Hauner et al., 1996; Nagase et al.,

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2014). Injections in the insulin ball tend to be concentrated at the same site because it is less painful than the other sites (Hauner et al., 1996), but this site absorbs insulin poorly, which results in poor glycemic control and leads to increased insulin dosages (Nagase et al., 2014). If the increased dose is injected in a site other than the insulin ball, the insulin formulation will become highly effective and hypoglycemia will occur. Thus, a vicious circle where a patient repeatedly injects insulin at the same site has been reported (Nagase et al., 2009; Hunner et al., 1996). Therefore, we believe that it is essential for healthcare providers to make an early assessment of whether an insulin ball is being formed and to provide guidance on changing the injection site.

However, how insulin ball assessments are performed remains unclear. Scoping reviews are an effective approach when information on a subject has not been comprehensively reviewed (Peters et al., 2015). If we can identify a method by which insulin balls can be assessed, then it may be possible to detect insulin balls and provide interventions at an early stage. We hope to identify a method for insulin ball assessment to help in stabilizing blood glucose levels in patients with hyperglycemia caused by injections in insulin balls. Therefore, this study will review the methods used for insulin ball assessment.

Objective

This scoping review will provide an overview of the following: to clarify what methods for insulin ball assessment are available.

Definition of Terms

An insulin ball (insulin-derived amyloidosis) is defined as subcutaneous induration caused by amyloid deposition due to repeated insulin injections to the same site (Nagase et al., 2009; Ohtani, 2013) (Figure 1).

Methods

The scoping review method was used. Scoping reviews are conducted to determine what research is being conducted in a particular field (Munn et al., 2018). Scoping review was developed by Arksey and O'Malley (2005). Here, we followed the five steps outlined by them: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, and (5) collating, summarizing, and reporting the results.

Identifying the Research Question

The research questions in the Patient/Concept/Context (PCC) framework (Peters et al., 2015) are presented in Table 1, where P, diabetic patients who had insulin injections; C, the



Figure 1. Typical physical appearance of insulin balls (insulin-derived amyloidosis) in two patients: patient A and patient B.

From: Nagase et al. (2014). Insulin-derived amyloidosis and poor glycemic control: a case series. *American Journal of Medicine*, 127(5), 450–454.

Note: Reprinted with permission from Dr. Nagase.

Table 1. PCC framework for creating research questions.

P: Patient	Diabetic patients who had insulin injections
C: Concept	Insulin ball and assessment
C: Context	Domestic and overseas research (Japanese and English), regardless of field

concept is insulin ball and assessment; and C, the context is domestic and overseas research (Japanese and English) regardless of field.

Identifying Relevant Studies

The Japan Medical Abstracts Society was used for the Japanese literature search and PubMed, Scopus, and CINAHL were used for the English literature search for relevant studies from January 1964 to November 2022 (search date: De-

ember 1, 2022).

For the first concept of the PCC framework (#1, insulin ball) mentioned earlier, the keywords used in the Japanese literature search included “insulin ball,” “insulin-derived amyloidosis,” “insulin AND induration,” and “insulin AND mass.” In the English literature search, the keywords included “insulin ball,” “insulin-derived amyloidosis,” and “insulin AND induration.” In English literature, insulin balls are generally described using these keywords. However, in Japanese literature, the terms “mass” and “induration” are used to describe insulin balls, and if “mass” is removed from the keywords, the number of references becomes small and references on insulin balls are omitted.

For the second concept (#2, assessment), the keywords “assessment” and “evaluation” were included in both Japanese and English literature searches.

We combined #1 and #2 with AND as a search formula to answer the following question: “What methods are available for the assessment of insulin balls caused by insulin injection?”

Study Selection

1) The literature selection criteria were the following: (1) the literature must be on insulin balls caused by insulin injections, (2) it must describe methods used for assessing insulin balls, and (3) it must include evaluation indicators for assessment. The articles must be original papers, research reports, and case reports in Japanese or English.

2) The exclusion criteria were the following: no mention of insulin balls or assessment and the absence of meeting minutes.

After adding the references identified from other sources to those retrieved from the database and excluding duplicate references, the first and second authors independently reviewed the article titles and abstracts to exclude articles that did not meet the selection criteria. Full texts of the selected articles were subsequently evaluated to exclude those that did not meet the selection criteria, and the adopted literature was selected. Articles that were difficult to determine were selected through discussion between the two researchers.

Charting the Data

We constructed a study selection flowchart based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews (Tricco et al., 2018). We extracted the following data from the adopted literature: authors, themes, year of publication, country, objectives, subjects, implementers, assessment methods, evaluation indicators, and results. The extracted data were discussed by the first and second authors and tabulated using Microsoft Excel 2019.

Results

Study Selection

The study selection flowchart, which shows the selection process, is shown in Figure 2. A total of 939 articles were selected from database searches and 19 from other sources. Of the 946 articles, excluding duplicates, 11 that met all eligibility criteria were selected. In total, 6 of the 11 studies were conducted in Japanese (Nagase, 2020; Kitano et al., 2019; Kusuki et al., 2015; Yabe et al., 2015; Ohtani, 2013; Yashizaki and Honda, 2012).

Insulin Ball Assessment

The assessment methods for insulin balls are shown in Table 2. Of the 11 studies, it was confirmed that palpation and visual examination were performed in all studies. The next most common assessment methods were both blood tests and ultrasonography in nine articles, magnetic resonance imaging (MRI) in five articles, and computed tomography (CT) in four articles. Insulin balls were assessed using multiple methods, and a definitive diagnosis was made by pathological examination.

Regarding the implementer, as shown in Table 2, one study where a physician was listed as the implementer of the insulin ball assessment was noted (Kikuchi, 2017). No studies where nurses conducted the assessment and summarized the evaluation and results were noted.

Table 3 shows what was evaluated using the assessment method. Additionally, the assessment methods for each included study are summarized in Table 4. The presence of palpation induration, hardness, size, part, skin color, mobility, and tenderness were confirmed by palpation and visual examination. Blood tests confirmed decreased insulin absorption and increased blood glucose levels. Furthermore, it was revealed that blood glucose control was poor in the case of injection in the induration, but the blood glucose level decreased after switching to healthy skin (Nagase et al., 2020; Kikuchi et al., 2017; Yoshizaki, 2012). Ultrasonography revealed echo level, pattern, induration size and depth, skin thickness, and blood flow. In ultrasonography, nonpalpable amyloid deposits were identified from echo levels and blood flow (Nagase et al., 2020; Kikuchi et al., 2017) and their detection was reported to be very high (Kikuchi et al., 2017). Pattern and signal intensity were confirmed by MRI, and the shape, size, and absorption intensity were confirmed by CT.

Discussion

Insulin Ball Assessment

Palpation and visual examination were performed in all references to confirm the site, hardness, and size of the insulin ball. However, there are also nonpalpable insulin balls, and

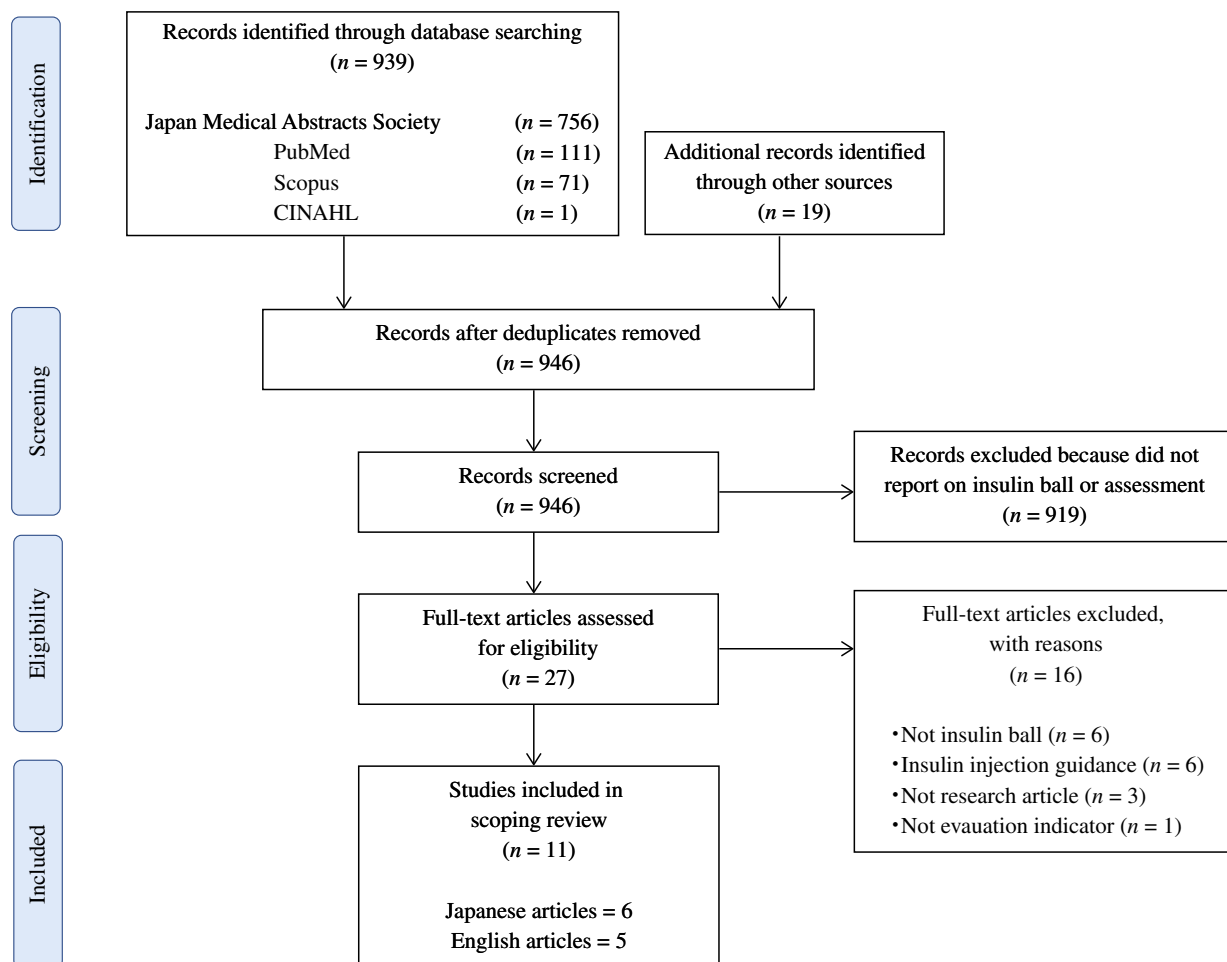


Figure 2. Flowchart of insulin ball assessment.

Table 2. Assessment methods for insulin balls.

Author, Year	Country	Implementer	Assessment					Diagnosis
			Palpation and visual examination (n = 11)	Blood test (n = 9)	Ultrasonography (n = 9)	MRI (n = 5)	CT (n = 4)	Pathological examination (n = 11)
Murao et al. (2022)	Japan	—	○	—	○	—	—	○
Nagase (2020)	Japan	—	○	○	○	○	—	○
Nagase et al. (2020)	Japan	—	○	○	○	○	—	○
Samlaska et al. (2020)	U.S.A.	—	○	—	—	—	—	○
Kitano et al. (2019)	Japan	—	○	○	○	○	○	○
Kikuchi et al. (2017)	Japan	Physician	○	○	○	—	—	○
Hagiwara et al. (2017)	Japan	—	○	○	○	—	○	○
Kusuki et al. (2015)	Japan	—	○	○	○	—	—	○
Yabe et al. (2015)	Japan	—	○	○	○	○	○	○
Ohtani (2013)	Japan	—	○	○	—	—	—	○
Yoshizaki and Honda (2012)	Japan	—	○	○	○	○	○	○

Note: — = Not mentioned.

palpation and visual inspection alone may miss them. Therefore, imaging tests such as ultrasonography, MRI, and CT are necessary to detect nonpalpable insulin balls. As amyloid

deposits without masses were also identified with high power of detection, ultrasonography can be used more extensively than palpation and visual examination alone. Re-

Table 3. Insulin ball evaluation by assessment method.

Assessment methods	Evaluation indicators	Results (total number of cases)
Palpation and visual examination (<i>n</i> = 11)	Presence of palpation induration	Palpable (<i>n</i> = 11) Nonpalpable (<i>n</i> = 2)
	Hardness	Hard (<i>n</i> = 5) Elastic (<i>n</i> = 4) Not mentioned (<i>n</i> = 2)
	Size	1.5 cm (<i>n</i> = 1) 4 cm (<i>n</i> = 1) 5 cm (<i>n</i> = 1) 8 cm (<i>n</i> = 1) 8 × 5 cm (<i>n</i> = 1) 13 cm (<i>n</i> = 1) Chicken-egg size (<i>n</i> = 1) Not mentioned (<i>n</i> = 4)
	Part	Abdomen (<i>n</i> = 5) Upper arm (<i>n</i> = 2) Not mentioned (<i>n</i> = 4)
	Skin color	Brown to purple-red (<i>n</i> = 1) Mild subcutaneous bleeding (<i>n</i> = 1) Not mentioned (<i>n</i> = 9)
	Mobility	Movable (<i>n</i> = 2) Not mentioned (<i>n</i> = 9)
	Tenderness	No tenderness (<i>n</i> = 2) With tenderness (<i>n</i> = 1) Not mentioned (<i>n</i> = 8)
Blood test (<i>n</i> = 9)	Insulin absorption rate [※]	Decreased (<i>n</i> = 6) Not mentioned (<i>n</i> = 3)
	Blood glucose level	Increasing (<i>n</i> = 9)
Ultrasonography (<i>n</i> = 9)	Echo level	Hypoechogenicity (<i>n</i> = 7) Hyperechoicity (<i>n</i> = 2)
	Pattern	Striped (<i>n</i> = 2) Not mentioned (<i>n</i> = 7)
	Size	23 × 8 × 22 mm (<i>n</i> = 1) 27 × 10 × 34 mm (<i>n</i> = 1) 66 × 85 mm (<i>n</i> = 1) Not mentioned (<i>n</i> = 7)
	Depth	20 mm (<i>n</i> = 1) Not mentioned (<i>n</i> = 8)
	Subcutaneous tissue thickness	16 mm (<i>n</i> = 1) Not mentioned (<i>n</i> = 8)
	Blood flow	Poor blood flow (<i>n</i> = 2) No blood flow (<i>n</i> = 2) Not mentioned (<i>n</i> = 5)
MRI (<i>n</i> = 5)	Pattern	Stripes or dots (<i>n</i> = 2) Not mentioned (<i>n</i> = 3)
	Signal	Low intensity (<i>n</i> = 5)
CT (<i>n</i> = 4)	Shape	Indefinite (<i>n</i> = 1) Clear border (<i>n</i> = 1) Irregular margin (<i>n</i> = 1) Not mentioned (<i>n</i> = 1)
	Size	Approximately 60 mm (<i>n</i> = 1) 32 × 25 × 30 mm (<i>n</i> = 1) 47 × 25 × 40 mm (<i>n</i> = 1) Not mentioned (<i>n</i> = 2)
	Absorption	High absorption (<i>n</i> = 1) Isoabsorbed (<i>n</i> = 1) Not mentioned (<i>n</i> = 2)

Note: [※]The insulin absorption rate is calculated from the area under the curve (AUC) of serum insulin values and the ratio of the AUC between the amyloid deposition site and the normal site.

Table 4. Summary of studies included ($n = 11$).

Author, Year	Subjects	Palpation and visual examination	Blood test	Ultrasonography	MRI	CT
Murao et al. (2022)	52 insulin-treated diabetic patients with abnormal findings at the self-injection site (Group1: 36 patients with subcutaneous induration, Group2: 16 patients suspected of having subcutaneous induration)	“In Group1, 36 patients had well-defined subcutaneous induration. Sixteen patients in Group2 had firm skin and subcutaneous tissue but no obvious induration.”	—	<ul style="list-style-type: none"> • Skin and subcutaneous tissue were considerably thicker in the abnormal areas than in the normal areas. • The subcutaneous tissue had a median thickness of 16 mm. • When compared to the normal area, the boundary between the skin and subcutaneous tissue in the abnormal area was indistinct. • Ultrasonography revealed a considerable decrease in echoluminance in cases with amyloid deposition on pathology. 	—	—
Nagase (2020) in Japanese	31 patients with diabetes mellitus	Palpable hard mass with margins	<ul style="list-style-type: none"> • Insulin absorption at the amyloid site was 34% of the normal site. • Poor glycemic control • When he injected the same amount of insulin as before in the normal abdomen, avoiding the mass, he experienced marked hypoglycemia. 	<ul style="list-style-type: none"> • Hyperechoic findings with subcutaneous stripes. • Amyloid deposits without masses can be detected. 	Low-signal findings in the form of stripes or dots in the subcutaneous fat.	—
Nagase et al. (2020)	Two patients with type 2 diabetes mellitus	Case 1. There is no palpable mass. Case 2. Soft enlargement in the right abdomen.	<ul style="list-style-type: none"> • Insulin absorption was reduced to a maximum of 40%. • Inadequate glycemic control 	<ul style="list-style-type: none"> • Hyperechoic streaks with loss of normal subcutaneous fat tissue 	Subcutaneous fat had low-signal findings in the form of stripes or dots.	—
Samlaska et al. (2020)	One patient with type 1 diabetes	Four subcutaneous indurations ranging from 8 (abdomen) to 13 cm (left arm)	—	—	—	—
Kitano et al. (2019) in Japanese	One patient with type 2 diabetes mellitus	Elastic soft skin mass of 8 × 5 cm on the left abdomen	Poor glycemic control	<ul style="list-style-type: none"> • Epidermal thickening • Some uniform low density area 	Low signal in both T1- and T2-weighted images	Localized skin thickening of the left lower abdomen with uniform interior
Kikuchi et al. (2017)	22 patients diagnosed with Insulin-derived amyloidosis by pathological examination	<ul style="list-style-type: none"> • Palpability • 59.1% were palpable and 40.9% were nonpalpable 	<ul style="list-style-type: none"> • The insulin absorption rate of the palpable type was significantly lower than that of the nonpalpable type. • Poor glycemic control • HbA1c levels decreased in 15 of the 20 patients after the injection site was changed. 	<ul style="list-style-type: none"> • The detection ability of IDLA on ultrasonography was 100%. • Amyloidosis was low echoic and had low blood flow. • Blood flow distribution was largely decreased in the palpable type compared with the nonpalpable type. 	—	—
Hagiwara et al. (2017)	One diabetic patient with type 2 diabetes mellitus	<ul style="list-style-type: none"> • Two 50-mm mobile, firm subcutaneous masses in the right and left abdomen • The mass surface is smooth, with some subcutaneous bleeding • Tenderness 	<ul style="list-style-type: none"> • Peak blood glucose levels were 2.23 times higher at the mass site compared to nonaffected regions, and peak blood insulin level were 0.77 times higher. • He was advised to rotate the injection sites, which resulted in frequent hypoglycemia. 	<ul style="list-style-type: none"> • A heterogeneous hypoechoic mass measuring 66 mm high × 85 mm wide × 20 mm deep was found in the subcutaneous fat layer of the left abdomen. A similar mass was also present on the right side. 	—	In the left and right abdomen, a subcutaneous mass with irregular margins of approximately 60 mm was discovered.

Table 4. Summary of studies included ($n = 11$) (continued).

Author, Year	Subjects	Palpation and visual examination	Blood test	Ultrasonography	MRI	CT
Kusuki et al. (2015) in Japanese	Ten patients with insulin injection-related subcutaneous induration (9 with type 2 diabetes and 1 with type 1 diabetes)	There is subcutaneous mass present	<ul style="list-style-type: none"> • Insulin absorption decreased to $34\% \pm 22\%$ at the amyloid deposition site. • The lesion site had higher mean blood glucose levels. 	<ul style="list-style-type: none"> • There was a significant low echogenic area with poor blood flow and deep attenuation. 	—	—
Yabe et al. (2015) in Japanese	One type 1 diabetic patient	On both the sides of the umbilicus, a smooth, grayish-white subcutaneous induration about 4 cm in size was discovered. The induration was rubbery, hard, movable, and not tender.	The hyperglycemia remained. After changing the site of insulin injection, blood glucose levels were stabilized.	The masses on the left and right were depicted as hypoechoic areas of internal heterogeneity with indistinct borders, measuring approximately $23 \times 8 \times 22$ mm on the right and $27 \times 10 \times 34$ mm on the left, with no blood flow observed.	On T1-weighted images, the mass had a lower signal than the surrounding fat and a slightly higher signal than the surrounding fat on fat-suppressed T2-weighted images.	It was depicted as a subcutaneous indeterminate mass on both the sides of the umbilicus, with high absorption when compared to the surrounding fatty tissue.
Ohtani (2013) in Japanese	One type 1 diabetic patient	A 1.5-cm-large brown-to-purplish-red firm nodule with pale purpura around it was discovered on the right upper arm.	Inadequate glycemic control	—	—	—
Yoshizaki and Honda (2012) in Japanese	One diabetic patient with type 2 diabetes mellitus	<ul style="list-style-type: none"> • Palpable mass, electric and firm, chicken-egg size, good mobility, no tenderness, symmetrically located in the lower abdomen, in line with the site of insulin injection. • There is light subcutaneous bleeding on the epidermis of the mass's surface. 	<ul style="list-style-type: none"> • Insulin absorption was considerably reduced at the site of amyloid deposition compared to normal skin. • Inadequate glycemic control • After the insulin injection site was changed to healthy skin, blood glucose levels dramatically dropped. 	Without blood flow, the induration was extracted as a uniform hypoecho.	T1-weighted images (C) and T2-weighted images (D) revealed a low signal similar to muscle.	It was depicted as an isoabsorbed mass with clear borders on the right, measuring $47 \times 25 \times 40$ mm and $32 \times 25 \times 30$ mm on the left.

Note: — = Not mentioned.

garding MRI and CT, they were performed in less than half of the literature, but these are relatively large-scale examination methods and may not be performed early. Conversely, we believe that the introduction of ultrasonography, which is relatively simple and noninvasive, as an assessment method of insulin balls, can contribute to early detection. Kikuchi et al. (2017) reported that “the detectability of insulin-derived localized amyloidosis on ultrasonography was 100%,” and ultrasonography is expected to be used as a screening tool in clinical practice. It was suggested that if there is decreased insulin absorption or increased blood glucose levels, it is advisable to check for subcutaneous induration by ultrasonography, even if it is not palpable.

No studies where nurses assessed and summarized the evaluation of insulin balls and results were noted. Because insulin injections are often instructed by nurses, we believe that ultrasonography should also be introduced to nurses. It has been reported that patients often inject at the same site

even if the medical provider has instructed them to change the injection site. However, it is expected that patients will more likely change their behavior of injecting at the same site if the presence of an insulin ball is visually confirmed by the medical provider and patient through ultrasound examination (Tanaka et al., 2019).

However, in reality, it has been reported that few nurses utilize ultrasonography to assess the patient's condition and link it to care (Saito and Watanabe, 2018). Nurses are required to be pretrained to use ultrasonography and guide patients in collaboration with physicians.

The literature used in this study did not include nurses among those who identified subcutaneous induration, which may have suggested palpation and visual examination, blood tests, and imaging tests as possible assessment methods. In addition to these, knowledge of the patient's insulin ball, insulin injection technique, and other factors may be used in insulin ball assessment. In the future, it will be necessary to

conduct multifaceted insulin ball assessment from the perspective of nurses and to encourage patients to self-manage. Furthermore, we believe that it is necessary to verify the usefulness of insulin ball assessment by nurses and to consider effective patient education.

Limitations and Tasks for Future Research

The reason for the large number of Japanese references is that studies on insulin balls were pioneered by Nagase and his colleagues in Japan. In this study, only articles written in Japanese and English were included and those written in other languages were excluded. Therefore, the comprehensiveness of insulin ball assessment in Japan and abroad cannot be confirmed. Moreover, we aimed to extract data on insulin ball implementers, but because most of them were not listed, we could not determine the current status of their implementation.

In the current study, we focused on insulin balls because we believe that it is important to identify and intervene early on how to assess insulin balls with more impaired insulin absorption. Lipohypertrophy is another cutaneous complication of insulin injection. Lipohypertrophy is a milder disorder of insulin absorption compared with insulin balls (Nagase et al., 2009), and it is a rubbery texture subcutaneous induration of the skin in which insulin injections cause hypertrophy and hyperplasia of subcutaneous adipose tissue (Hauner et al., 1996). In the future, we are planning to study lipohypertrophy.

Conclusion

It is necessary to incorporate imaging tests because palpation and visual examination alone cannot detect nonpalpable insulin balls. It was suggested that in addition to palpation and visual inspection, the inclusion of relatively simple and noninvasive ultrasonography as a screening method for the early detection of insulin balls may be useful, but its accuracy needs to be verified in the future.

From now on, we believe that nurses will have a role in assessing the presence and extent of insulin balls using ultrasonography and in providing patient education to help patients manage them.

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Author Contributions

Sugama, Yanagita, and Seto contributed to the conception

and design of this study. Nakamura and Kageura searched the literature and performed the screenings and study selection. Nakamura drafted the manuscript. Oe, Matsui, Kageura, Horiguchi, and Ueda critically reviewed the manuscript. Sugama, Yanagita, and Seto oversaw the entire study process. All authors read and approved the final manuscript.

Declaration of Conflicting Interests

The authors declare no conflict of interest.





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Original Research

Health-related quality of life of patients with heart failure using noninvasive telemonitoring systems with and without visiting nursing support: A longitudinal observational study

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Abstract

Objective: This study aims to measure the health-related quality of life (HR-QOL) of patients with heart failure (HF) after using two types of telemonitoring (TM) tools and to evaluate which type of tool contributes to improving patient outcomes. **Methods:** We measured the HR-QOL and psychological status of patients with HF after using two types of TM systems (smartphone application or web-based), and the data from baseline to six months were compared. **Results:** A total of 24 patients with HF completed the study period of six months. The mean age of the participants was 60.58 ± 12.81 years, and 70.8% were male. The major differences between the study groups comprised support and access to home visit services. The physical HR-QOL scores increased significantly from baseline to six months in the web-based group (baseline vs. six months, 4.04 ± 1.02 vs. 4.58 ± 1.18 , $p = .034$), but no significant difference (baseline vs. six months, 5.05 ± 1.00 vs. 5.20 ± 1.24 , $p = .410$) was found in the smartphone application group. The mean scores for anxiety and depression in both groups were not significantly different. **Conclusions:** Using the TM system for patients with HF may improve global HR-QOL and psychological status. In addition, adding nursing support using a TM system may be more effective in improving patient-reported outcomes.

Keywords

heart failure, health-related quality of life, telemonitoring, visiting nursing, self-management

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Introduction

Heart failure (HF) remains a major cause of death worldwide, and it can also significantly reduce the quality of life (QOL) of affected patients (McDonagh et al., 2021; Stretti et al., 2021). Toback et al. proposed that improved self-management might increase treatment adherence, promote patient QOL, improve clinical outcomes, reduce hospital readmissions, and decrease hospitalization costs (Toback & Clark, 2017). Self-management interventions for chronic dis-

eases during home care are effective in decreasing patient-borne costs, the cost of health care, the number of outpatient, and emergency room visits, hospital stays, and health-related QOL (HR-QOL) (Kamei, 2013; Tsutsui et al., 2021).

In recent years, many clinical trials have been carried out worldwide to assess the effectiveness of telemonitoring (TM) systems in HF management. The TM systems used in HF management include various aspects, such as vital sign monitoring, telephone follow-up by nurses, video consultation, communication between healthcare providers, web-

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based telemonitoring, remote hemodynamic monitoring, or combinations of these. Since there are various types and aims of TM systems, different outcome measures have been used in previous studies, and the reported results have been heterogeneous (Nick et al., 2021).

Some studies have shown that noninvasive TM interventions reduce HF-related hospitalization and trends in total mortality, as well as HF-related admissions (Bashi et al., 2017; Carbo et al., 2018; Kotooka et al., 2018; Ware et al., 2020). Moreover, these interventions also promote improvements in HR-QOL, HF knowledge, and self-care behaviors (Inglis et al., 2015; Jeong et al., 2018; Ware et al., 2020). Specifically, well-established TM systems or nurse-led care programs, including educational components, could improve patient compliance, self-management behaviors, and early detection of HF exacerbation (Ding et al., 2020; Mizukawa et al., 2019). However, a systematic review on the topic found that most TM programs demonstrate high methodological heterogeneity and concluded that further research is warranted to identify the effective components of TM systems (Auener et al., 2021).

Therefore, in this study, we implemented two types of TM systems for patients with HF following admission to outpatient HF clinics. This study aimed to measure the HR-QOL of patients with HF after using TM systems and evaluate which system might lead to the highest improvement in patient outcomes. A better understanding of these aspects is crucial for identifying the most effective components of TM systems in the treatment of patients with HF.

Materials and Methods

Study Design

This study is a longitudinal observational study.

Settings and Participants

Eligible participants were recruited from one Japanese academic medical center with cardiovascular outpatient clinic services. HF in this study corresponds to I50 in the International Classification of Disease, Tenth Revision.

The participants for this study were recruited from a Japanese university hospital with HF outpatient clinic services. After obtaining consent, the researcher, or programmer instructed the participants regarding the use of the tool through face-to-face interaction using a manual. Twenty participants were finally recruited for this study. Patients who had a clinical diagnosis of HF were able to understand and speak the Japanese language, operated mobile devices or laptop computers, and were willing to provide informed consent were eligible to participate. We used a targeted sampling procedure in the recruitment of participants, and patients were recruited by their direct care team during scheduled clinic visits.

Ethical Considerations

Ethical approval for this study was obtained from the institutional ethics review board of the university with which the authors are affiliated. The consent form that each eligible patient received in-person provided information regarding the aims, procedures, and potential risks, and benefits of the study. This manuscript adheres to the Strengthening the Reporting of Observational Studies in Epidemiology statement (von Elm et al., 2014).

Measurements

HR-QOL

This study used the MacNew Heart Disease HR-QOL Questionnaire, which assesses, and evaluates patients' QOL from their personal perspective. It is designed to evaluate the impact of treatment, including cardiac rehabilitation, and has been shown to be valid, reliable, and responsive. It is simple to administer and well-accepted by patients, and normative data are available for patients with myocardial infarction, angina pectoris, and HF. This questionnaire consists of 27 items that fall into three domains: a 13-item physical limitations domain scale, a 14-item emotional function domain scale, and a 13-item social function domain scale. The maximum possible score in any domain was 7 (high HR-QOL), and the minimum was 1 (poor HR-QOL) (Dixon et al., 2002).

Anxiety and Depression

The Hospital Anxiety and Depression Scale was developed by Zigmond and Snaith in 1983 to identify the caseness (possible and probable) of anxiety disorders and depression among patients in nonpsychiatric hospital clinics (Zigmond & Snaith, 1983). Each question on this Likert-type scale is scored from 0 to 3. Each survey received a maximum score of 21. Scores ranging from 0 to 8 indicate healthy patients, scores from 8 to < 11 are near the lower threshold, indicating the presence of depression or anxiety, and a value of ≥ 11 indicates the likely presence of a depression or anxiety disorder.

Data Collection

Baseline data were collected from the researchers' electronic medical records. QOL and psychological status, including anxiety, and depression at baseline and six-month follow-up, were collected either directly, or by mail. Participants who provided informed consent received a gift card worth 2,000 yen. Data were collected from April 2020 to December 2021.

Data Analysis

The characteristics between the two study groups were compared using the independent group t-test for continuous vari-

ables and the chi-square test for categorical variables. HR-QOL changes within the group from baseline to six months were compared using a paired t-test. Statistical significance was defined as $p < .05$. All results are presented as mean values and standard deviations. All statistical analyses were performed using IBM SPSS Statistics (version 27.0, IBM, NY, USA).

Description of TM Systems

This study used two types of TM systems for patients with HF. System A was a smartphone application. Using this system, patients could see personal health data such as blood test results, prescriptions, the history and schedule for clinic visits, and previous histories. Healthcare providers in the hospital, such as primary physicians, can access the dedicated website and view patient data at the time of their clinic visit. Thus, during this time, the physician provided lifestyle guidance and prescriptions by referring to the patient's home data. In addition, patients could enter their individual health-related data on a daily basis, including daily blood pressure levels, pulse rate, body temperature, oxygen saturation, and blood glucose levels. There was no alert function in this application.

System B was web-based. Patients with HF accessed the dedicated website and entered their daily data, such as body weight, blood pressure, pulse rate, and subjective symptoms related to HF exacerbation, once daily using an Internet-connected tablet device (if the participants did not own a device, we lent it to them). Healthcare providers, such as physicians (including primary and visiting), nurses (including hospital and visiting), and physical therapists (including hospital and visiting), were able to view graphs and tables based on individual patient data via the dedicated website. Thus, they were able to assess the patient's condition without in-person visits. Therefore, healthcare providers, especially visiting nurses, could contact the patient if there were any signs or symptoms of concern without visitation, share patients' data with other healthcare providers, or consult with their primary physicians. When visiting the patient's home, they viewed their data with the patient and discussed their symptoms and lifestyle. There was no alert function in this system.

Table 1 lists the characteristics of these two systems.

Results

Participants

A total of 24 patients with HF completed the six-month study period. The system A group included 13 participants, and the system B group included 11 participants. The mean age of the 24 participants was 60.58 years (± 12.81), and 70.8% were male. Table 2 summarizes the baseline characteristics of the present study sample. The only significant

Table 1. Characteristics of TM systems.

Types of system		A	B
Specification		Smartphone App	Web-based
User		Hospital, patients	Hospitals, patients, clinics, and home care services
Capability	BP	✓	✓
	P	✓	✓
	BT	✓	
	SpO ₂	✓	
	Height	✓	
	BW	✓	✓
	BS	✓	
	NYHA class		✓
	SOB		✓
	Edema		✓
	Urine volume		✓
	Dyspnea		✓
	Bowels		✓
	Limits of BW		✓
Past history		✓	
Prescription		✓	
Test results		✓	
feedback			✓
History of clinic visit		✓	
Comment field			✓
Patient's goal			✓

Note: BP = blood pressure; P = pulse rate; BT = body temperature; BW = body weight; BS = blood glucose level; NYHA = New York Heart Association classification; SOB = shortness of breath

difference found between the study groups was regarding access to home visit services (72.7% in the system B group vs. 0% in the system A group).

HR-QOL

The HR-QOL scores at baseline did not differ significantly between study groups (Table 2). The physical HR-QOL scores increased significantly from baseline to six months in the system B group (baseline vs. six months, 4.04 ± 1.02 vs. 4.58 ± 1.18 , $p = .034$), but no significant difference (baseline vs. six months, 5.05 ± 1.00 vs. 5.20 ± 1.24 , $p = .410$) was found in the system A group. The global HR-QOL scores in systems A and B from baseline to six months were 4.93 ± 0.94 vs. 5.01 ± 1.08 ($p = .620$) and 4.41 ± 0.75 vs. 4.74 ± 0.94 ($p = .135$), respectively. The emotional HR-QOL scores in systems A and B groups from baseline to six months were 4.72 ± 1.07 vs. 4.72 ± 1.15 ($p = .979$) and 4.89 ± 0.60 vs. 4.91 ± 0.67 ($p = .907$), respectively. The social HR-QOL scores in systems A and B groups from baseline to six months were 4.92 ± 1.17 vs. 5.21 ± 1.37 ($p = .127$) and 3.84 ± 0.96 vs. 4.49 ± 1.61 ($p = .055$), respectively. Global and social (with the exception of emotional)

Table 2. Baseline characteristics of participants according to type of tool.

Characteristics	Total	A (n = 13)	B (n = 11)	p value*
Age (years, mean \pm SD)	60.58 \pm 12.81	56.54 \pm 9.96	65.36 \pm 14.53	.093
Male (%)	17 (70.8)	10 (76.9)	7 (63.6)	.476
LVEF (% , mean \pm SD)	34.88 \pm 8.87	33.82 \pm 9.11	36.41 \pm 8.80	.515
NYHA (%)				
II	17 (70.8)	11 (84.6)	6 (54.5)	.137
III	6 (25.1)	2 (15.4)	4 (36.4)	
IV	1 (4.1)	0	1 (9.1)	
Device therapy				
CRT	6 (25.0)	4 (30.8)	2 (18.2)	.402
ICD	3 (12.5)	2 (15.4)	1 (9.1)	
None	13 (54.2)	7 (53.8)	8 (72.7)	
Visiting Nursing Service	8 (33.3)	0	8 (72.7)	<.001
HR-QOL (mean \pm SD)				
Global	4.88 \pm 0.93	4.92 \pm 0.87	4.53 \pm 0.95	.285
Physical	4.90 \pm 1.11	4.97 \pm 0.95	4.45 \pm 1.18	.239
Emotional	4.84 \pm 0.99	4.79 \pm 1.00	4.64 \pm 0.97	.707
Social	4.80 \pm 1.18	4.91 \pm 1.10	4.31 \pm 1.17	.200
HADS (mean \pm SD)				
Anxiety	5.62 \pm 3.73	6.42 \pm 4.10	4.56 \pm 3.04	.269
Depression	8.24 \pm 3.37	8.33 \pm 3.49	8.11 \pm 3.41	.886

Note: LVEF = left ventricular ejection fraction; NYHA = New York Heart Association classification; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter defibrillator; HR-QOL = health-related quality of life; HADS = hospital anxiety and depression scale

* Chi-square test and t-test

HR-QOL scores tended to increase, although no statistically significant differences were observed between the baseline and six-month follow-up assessments (Figure 1, Table 3).

Anxiety and Depression

Anxiety and depression scores were comparable between the groups at baseline and did not differ significantly (Table 2). The mean anxiety (6.27 \pm 4.29 vs. 6.36 \pm 4.47, p = .940) and depression (8.36 \pm 3.66 vs. 8.00 \pm 3.71, p = .740) scores in the system A group were not significantly different. Anxiety scores in the system A group increased, and depression scores in both groups decreased from baseline to six months. The mean anxiety (4.40 \pm 2.60 vs. 3.00 \pm 2.23, p = .108) and depression (7.80 \pm 3.56 vs. 7.60 \pm 4.72, p = .893) scores in the system B group were not significantly different (Figure 2).

Discussion

In this study, most characteristics of the participants were similar between groups, with the exception that most participants in the system B group but none in the system A group had access to home-visiting nursing services. We compared the changes in HR-QOL, anxiety, and depression in patients with HF using the TM system at baseline and six-month follow-up. In terms of results, HR-QOL, except for physical

HR-QOL in the system B group, was not found to change significantly, while overall, HR-QOL scores tended to increase. In recent studies, a nurse-led home-based HF self-management program or cardiac rehabilitation improved self-efficacy and HR-QOL and lowered depression levels compared with the control group (Arjunan & Trichur, 2020; Mo et al., 2021). Although no significant changes in depression scores were observed, visiting nurses supported patients' daily activities or detected symptoms of HF exacerbation earlier through viewing patient data, which could have improved the physical QOL scores observed in this study. In terms of psychological aspects, emotional QOL scores in both groups showed almost no change, whereas anxiety, and depression scores in both groups tended to decrease. In a recent qualitative study, the experiences of patients with HF using TM systems have been assessed, and it has been found that by simply using a TM tool, patients reported higher feelings of safety (Sano et al., 2022). Thus, the introduction of a monitoring system alone may help ensure the psychological safety of patients with HF. The intervention that combined telephone calls and TM by nurses reduced re-admission rates and improved QOL and self-care behaviors (Jeong et al., 2018; Ong et al., 2016; Mizukawa et al., 2019; Son et al., 2020). Similar to previous studies, the results of this study suggest that using a TM system for patients with HF, in addition to nurse support, has the potential to im-

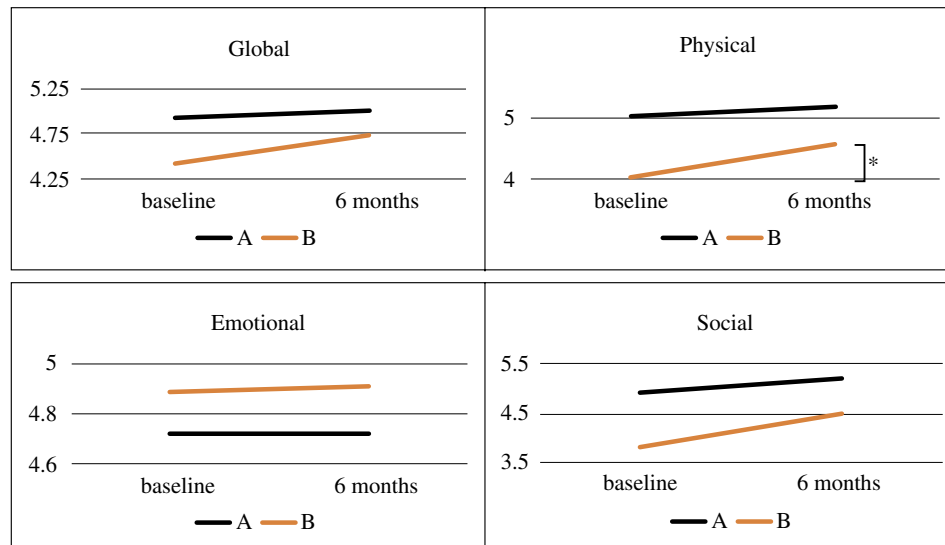


Figure 1. HR-QOL changes at baseline to six months.

Table 3. Outcome measures at baseline and six months.

Variables	Tool A Group (<i>n</i> = 13)			Tool B Group (<i>n</i> = 11)		
	Baseline	6 months	Within Group	Baseline	6 months	Within Group
HR-QOL	mean ± SD	mean ± SD	<i>p</i> value *	mean ± SD	mean ± SD	<i>p</i> value *
Global	4.93 ± 0.94	5.01 ± 1.08	.620	4.41 ± 0.75	4.74 ± 0.94	.135
Physical	5.05 ± 1.00	5.20 ± 1.24	.410	4.04 ± 1.02	4.58 ± 1.18	.034
Emotional	4.72 ± 1.07	4.72 ± 1.15	.979	4.89 ± 0.60	4.91 ± 0.67	.907
Social	4.92 ± 1.17	5.21 ± 1.37	.127	3.84 ± 0.96	4.49 ± 1.61	.055
HADS						
Anxiety	6.27 ± 4.29	6.36 ± 4.47	.940	4.40 ± 2.60	3.00 ± 2.23	.108
Depression	8.36 ± 3.66	8.00 ± 3.71	.740	7.80 ± 3.56	7.60 ± 4.72	.893

* Comparisons each group between baseline and 6 months using paired t-test

** HR-QOL, health-related quality of life; HADS, hospital anxiety and depression scale

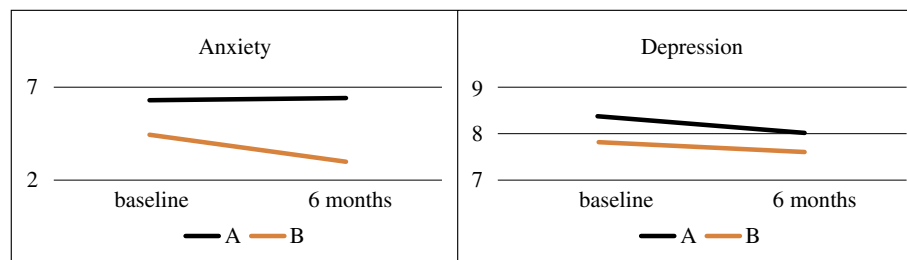


Figure 2. Anxiety and depression changes at baseline to six months.

prove QOL and psychological status in affected patients.

Consequently, this study compared the changes in HR-QOL and psychological status between the two types of TM systems. We believe adding home-visiting nursing supports to the TM system may have contributed to the improvement in HR-QOL and psychological status, which is our study's strength. Our study's results are consistent with previous studies demonstrating that nurse-led HF management is ef-

fective in improving patient outcomes (Cajanding, 2016; Mo et al., 2021).

As a major limitation of the study, the number of participants was small, and strict grouping was not conducted. In system B, which can be used by multiple healthcare providers and facilities, participants who did not use home-visiting nursing services were mixed. In future research, it will be necessary to conduct it with increased rigor so that differ-

ences in characteristics do not occur.

Conclusions

We aimed to measure the HR-QOL and psychological status of patients with HF after using two types of TM systems. We found statistically significant changes in physical HR-QOL in the TM system, including visiting nursing support. Depression tended to improve in both groups. The use of the TM system for HF management might exhibit positive effects on the psychological status of patients with HF. In addition, we suggest a nurse-led support intervention using a TM system to improve the QOL and psychological status of patients with HF.

Author Contributions

MS wrote the manuscript. SO, TM, and YK contributed to the interpretation of the results and reviewed and edited the manuscript. All authors read and approved the final version of the manuscript.

Declaration of Conflicting Interests

We have no conflicts of interest to disclose.

Ethical Approval

This study was approved by the Institutional Ethics Review Board of the Chiba University Graduate School of Nursing [No. R2-3].

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Informed Consent

Informed consent was obtained from all patients or participants involved in this study.






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Original Research

Developing a communication skills scale in the initial oncology nursing consultation after a cancer diagnosis in Japan

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Abstract

Objective: Psychosocial interventions during nursing consultations emotionally support and inform patients undergoing cancer diagnosis. In Japan, certified nurse specialists (CNSs) and certified nurses (CNs) mainly provide nursing consultations. Using communication skills in therapeutic nurse-patient relationships is an effective advanced nursing practice when performed consciously. We developed a scale to measure the frequency of oncology nurses' intentional use of communication skills in the initial oncology nursing consultation after a cancer diagnosis. **Methods:** Based on a literature review, we identified nine initial dimensions and developed a 32-item questionnaire. After the focus group interviews and pilot study between January and March 2018, the final questionnaire was administered to CNSs and CNs who offered nursing consultations to patients with cancer in Japanese hospitals. The properties of all scales and subscales were assessed using item-to-item and mean item-to-item correlations. The reliability was evaluated using Cronbach's alpha. Construct validity was assessed using exploratory factor analysis, correlations between all scales and characteristics, and contrast group comparisons. **Results:** The communication skills scale comprised 29 items across six dimensions of communication skills: Exploring, Listening, Acceptance, Silence, Approval, and Empathy. The scale has good reliability and validity. **Conclusions:** This scale is a valid and reliable item for self-assessing nurses' communication skills in the initial oncology nursing consultation after a cancer diagnosis.

Keywords

communication skills scale, initial nursing consultation, cancer diagnosis, exploratory factor analysis

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Introduction

In Japan, there are more than 1,000,000 new cancer cases each year and 380,000 cancer-related fatalities, making it the leading cause of death, accounting for 30% of total deaths (Cancer Statistics in Japan Editorial Board, 2020). Although the cancer survival rate in Japan has improved, being diagnosed with a life-threatening disease is a shocking and

stressful experience for patients and their families (Suzuki & Komatsu, 2002). Reportedly, 10%-20% of people with cancer experience stress-related mental health problems, such as adjustment disorders and major depression (Akechi, 2018). In particular, suicide rates are high within the first year after cancer diagnosis (Yamauchi et al., 2014). Therefore, psychosocial interventions to improve the quality of life must also focus on mental and psychosocial issues aside from physical

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problems (Gabriel et al., 2020).

While physicians are responsible for making the cancer diagnosis and obtaining informed consent for the treatment plan, nurses, as part of the team of healthcare professionals, provide patient-centered care and are involved in ongoing follow-up after the cancer diagnosis (Kaneko et al., 2013). In the course of their work, nurses collaborate with healthcare teams to offer emotional support to patients through interpersonal counseling and provide information about health education and referrals to team professionals when needed (Kaneko et al., 2013; Warnock et al., 2010). Thus, a therapeutic relationship and effective communication between nurses and patients are essential (Duxbury, 2000; Travelbee, 1971). This communication is designed to understand patients' fears and concerns, identify patients' needs, and achieve nursing goals in meeting these needs (Duxbury, 2000). Furthermore, this communication is backed by oncology nursing expertise and practical skills to support illness-coping behaviors consistent with each patient's values, preferences, and wants (Mazor et al., 2013).

Therapeutic communication has been defined as an "interpersonal exchange, using verbal and nonverbal messages that culminates in the patient being helped" (Van Servellen, 2018). Nurses practice therapeutic communication by encouraging patients to express their feelings and thoughts and conveying acceptance and respect to them (Van Servellen, 2018). In this process, nurses intentionally use specific strategies, such as communicating skillfully, preparing, introducing the communication environment, and providing counseling (Duxbury, 2000; Fukuhara et al., 2004; Van Servellen, 2018). Key skills comprise nonverbal behaviors (eye contact, voice quality, and body language), active listening (verbal tracking, using open and closed questions, encouraging, paraphrasing, focusing, and summarizing), observation, empathy, sharing of hope, humor, and self-disclosure (Fukuhara et al., 2004; Sharma & Gupta, 2022; Sherko et al., 2013). Successful communication allows patients to express themselves and satisfy their basic needs to be heard and understood (Van Servellen, 2018). Further, it helps them gain insight into their true emotions and face their current reality (Sharma & Gupta, 2022). Oncology nurses effectively practice therapeutic communication and provide additional warmth and emotional support (Sinclair et al., 2017). By empathically understanding the patient, the nurse conveys compassion and motivates the patient to act and alleviate their suffering (Katz, 2019; Sinclair et al., 2017).

Recent research on healthcare providers' communication has focused on palliative care conversations, including prognostic discussions (Ikander et al., 2022); however, the focus on communicating cancer diagnosis and relaying bad news is limited (Agnese et al., 2022). Previous intervention studies suggest that improved therapeutic communication by nurses is associated with patients' subjective assessments of

pain improvement (Canivet et al., 2014), wellbeing (Arbour et al., 2022), quality of life (Fukui et al., 2011), self-efficacy (Hochstenbach et al., 2015), and satisfaction with the care received (Lotfi et al., 2019). However, a cancer diagnosis is devastating, and for patients expressing strong emotions, nurses often report communication difficulties, including the inability to convey empathy successfully and poor relationship-building with patients (Banerjee et al., 2016; Sheldon et al., 2006; Warnock et al., 2017). A lack of empathy during patient communication can be stressful enough to cause burnout among nurses (Yu et al., 2016).

Therapeutic communication between nurses and patients has emotional, cognitive, and behavioral aspects, each of which can be assessed using a comprehensive instrument (Moudatsou et al., 2020). However, these scales are intended to assess communication between nursing students and patients for educational purposes (Campbell & Aredes, 2022; Kondo et al., 2020) or between nurses and patients in primary healthcare or critical care, not just patients with cancer (Campbell & Aredes, 2019; González-Cabrera et al., 2020; Granados-Gámez et al., 2022); thus, both scales are often inadequate for assessing the communication skills of oncology nurses specific to the distress of patients with cancer.

Newman and Helft (2015) developed an instrument to assess communication between oncology nurses and patients; however, it only assesses prognosis-related communication at the end-of-life and does not evaluate communication-related emotional support for a cancer diagnosis. Given the negative impact of a cancer diagnosis on patients, families, and nurses and the importance of nurses' roles, oncology nurses must possess and develop strong communication skills that build trust immediately (González-Cabrera et al., 2020). To fulfill their specialized role, oncology nurses devise ways to communicate with patients (Mishelmovich et al., 2016), but knowledge about the actual situation is scant. Although initial oncology nursing consultations are practiced early after a cancer diagnosis in Japan, no validated instrument exists to assess nurses' communication skills. Therefore, this study aimed to develop a valid and reliable scale to assess the intentional use of nurses' communication skills during initial oncology nursing consultations.

Materials and Methods

Design

This study employed a cross-sectional observational design.

Procedure

The original scale was devised using a three-step procedure: item extraction, pilot study, and scale development. The steps are detailed below.

Step 1: Item Extraction

To extract items to assess the frequency of communication

skills used in nursing consultations for patients with cancer, we used PubMed, CINAHL, and ICHUSHI Web databases to perform an extensive literature review. This study aimed to review the development of protocols and communication measures between healthcare professionals and patients with cancer; nurses and patients with cancer; nurses and patients; and between nursing students and patients. This review was based on the concept of the interpersonal aspect of nursing (Duxbury, 2000). Travelbee (1971) described four phases that establish an interpersonal relationship: 1) initial encounter, 2) identification emergence, 3) empathy, and 4) sympathy. Therapeutic communication skills represent the nursing skills used in each phase. Through integrating and synthesizing the findings, we established nine initial dimensions: Listening, Acceptance, Empathy, Reflecting on Emotions, Rephrasing, Summarizing, Questioning, Silence, and Approval. We then discussed the created items to assess communication skills and determined the item pool comprising nine initial dimensions and 32 items. When administering the scale, we asked the participants to recall a previous case in an outpatient setting and rate the frequency of their communication skills used in the patient's initial oncology nursing consultation after a cancer diagnosis on a five-point scale ranging from 1 (*never*) to 5 (*usually*).

We conducted focus group interviews in November 2016 and February 2017 to enhance the content and construct validity of the item pool (Stalmeijer et al., 2014). Interviews were conducted with two groups: One with 15 certified nurse specialists (CNSs) and another with 14 certified nurses (CNs). Participants provided informed consent after receiving explanations about the voluntary nature of their participation and were assured that their anonymity would be preserved. The participants were asked to freely express their opinions about the possible use of the item pool questions in the initial oncology nursing consultation following a cancer diagnosis; they were also asked to recommend modifications and identify any shortcomings. One of the co-authors moderated the session, and the primary researcher documented the meetings. The research team reviewed the results of the interviews, and modifications that were difficult to understand or answer were made into expressions in the item pool. With the help of another four CNSs and two CNs, the validity and response load of the items were rechecked.

Step 2: Pilot Study

Participant Selection

From September to November 2017, the questionnaire was administered to the 26 oncology nurses excluded in the final study to ascertain the content validity and response load. Each participant had been licensed by the Japanese Nursing Association (2017) as either a CNS in Oncology Nursing or a CN in Palliative Care, Cancer Chemotherapy Nursing, Cancer Pain Management Nursing, Breast Cancer Nursing, or Radiation Oncology Nursing.

Procedure

One co-author contacted the nursing directors of the target hospitals in the three regions of Aichi, Mie, and Gifu and asked them if they had provided nursing consultations in outpatient units to patients with cancer. The survey was administered by mail to hospitals providing nursing consultations. The participants were informed about the voluntary nature of participation, anonymity, and data handling, and their consent was obtained. We conducted a primary aggregation of the responses, confirmed no missing values or obvious outliers were present, and completed the questionnaire for the final study.

Step 3: Scale Development

Participant Selection

We conducted a cross-sectional survey in Japan between December 2017 and March 2018. The survey targets were CNSs and CNs providing nursing consultations for patients with cancer in outpatient units of Japanese hospitals. In Japan, CNSs' and CNs' nursing consultations are subject to medical fee calculation. Therefore, using the website of the Japanese Ministry of Health, Labour and Welfare (2017), we determined the hospitals with medical fee calculation, as these hospitals were considered to be ready to conduct or were already conducting nursing consultations. Additionally, the number of nursing consultations for which medical fees were calculated was approximately three times greater for outpatients with cancer than for inpatients with cancer (Japanese Ministry of Health, Labour and Welfare, 2017). Therefore, we recruited nurses who met the inclusion criteria of overseeing individual nursing consultations in an outpatient setting. The inclusion criteria also included being licensed in Japan (JNA, 2017) as CNSs in Oncology Nursing or CNs in Palliative Care, Cancer Chemotherapy Nursing, Cancer Pain Management Nursing, Breast Cancer Nursing, or Radiation Oncology Nursing. Nurses without experience in outpatient nursing consultations were excluded. These participants were identified using the JNA (2017) website. CNSs and CNs are registered nurses who have passed the licensing examination administered by the JNA in Japan (JNA, 2017; Komatsu, 2010).

Procedure

We sent each hospital director and nurse manager a letter explaining the study's purpose and methods. We asked the nurse managers who agreed to participate in distributing one set of letters explaining the study's purpose and methods, the consent form, and the questionnaire to nurses in charge of nursing consultation in the outpatient unit. Additionally, we added a letter explaining that survey participation was voluntary and anonymous and participation could be withdrawn at any time. We limited the participation to a maximum of two participants per site to avoid potential bias. To prevent nurses from being identified, we selected hospitals with at least three eligible nurses. The participants who

agreed were asked to complete the questionnaire and return it with the consent form in a postage-paid envelope within two weeks. A signed informed consent form was required before participating in the study, and responses to the questionnaire were anonymized.

Streiner et al. (2015) recommend a sample size of 5 to 10 times the number of items for exploratory factor analysis (EFA) in medical research; Rouquette and Falissard (2011) recommend a sample size of 300 or more. Accordingly, we set our sample size to between 300 and 320.

Ethical Considerations

This study was approved by the Nagoya University Clinical Research Review Board to which the primary researchers belonged during the survey period approved this survey (Approval number: 17-129). All participants were informed in writing of their anonymity, data security, and the voluntary nature of their participation. All participants signed and returned consent forms. We followed the guidelines of the Declaration of Helsinki.

Statistical Analysis

Data were analyzed using SPSS versions 25 and 28 for Windows (IBM Corp., Armonk, NY, USA). All tests were two-tailed, and the significance level was set at $p < .05$.

Participants' demographic characteristics and communication skills were measured as percentages, means, standard deviations (SD), and medians (interquartile ranges). Average value assignment replaced the randomly occurring missing values (five locations). Samples with numerous missing values were excluded from the analysis as they were considered invalid.

The communication skills' total scale and subscale characteristics were assessed through item-total, interitem, and average interitem correlations. EFA with Promax rotation was used to determine the construct validity (Streiner et al., 2015), and Bartlett's sphericity coefficient and the Kaiser-Meyer-Olkin test were used to confirm the validity of the factor analysis. Internal consistency reliability of the unidimensional scale and subscales were assessed by Cronbach's alpha coefficient. Construct validity was assessed by correlations between communication skills and characteristics and by intersubject comparisons. Based on previous research, we hypothesized that those with high levels of professional education in oncology nursing (Newman & Helft, 2015), more experience (i.e., years of practice) in oncology nursing as a CNS/CN (Malloy et al., 2010, Mishelmovich et al., 2016), and more experience with postprofessional education communication training (Fukui et al., 2008) would use communication skills more frequently. The communication skills scores between groups were compared using *t*-tests.

Results

Focus Group Interviews

We conducted focus group interviews in November 2016 and February 2017. We conducted focus groups to determine the questions/items that should be included on the communication scale we sought to create. Consent was obtained from 15 CNSs and 14 CNs who participated in the collaborative meeting on oncology care in the three districts where study collaboration was requested. The participants were divided into two groups: one with CNSs only and one with CNs only, and one focus group interview was conducted with each group. The interviews lasted 40 and 60 minutes. As a result, many participants agreed that all communication skills items might be used in the initial oncology nursing consultation, suggesting the validity of the content. However, the frequency of use may vary depending on the patient's condition. Based on a review of the results, the research team discussed modifying items that were difficult to understand or answer. Therefore, we modified the names of all items from therapist to nurse and client to patient, making it easier to imagine the communication between nurses and patients. Additionally, there was an opinion regarding difficulty in conveying Reflecting on Emotions concretely; hence, we added an example of how to express this to the patients (No. 15). Finally, it was noted that the Silence items comprised only the skills for nurses to break the silence, hence, a section on how to respond until the patient resumes talking was added to develop a questionnaire (Nos. 24-26).

Another four CNSs and two CNs, members of the research team, informally rechecked the validity and response load of the items. The results indicated that the scores for cases where nurses did not intentionally use communication skills to respond to a patient's condition were unclear and difficult to obtain. Based on this feedback, we added a description of the frequency rating on a five-point scale: 5 (*usually*:80%-100%), 4 (*frequently*:60%-79%), 3 (*occasionally*:40%-59%), 2 (*rarely*:20%-39%), and 1 (*never*:0%-19%).

Pilot Study

The questionnaire was administered between September and November 2017. We sent the questionnaire to 36 eligible hospitals, of which 28 nurses from 20 hospitals agreed to participate; hence, they completed and returned the questionnaire. Of the 28 responses, 26 from 20 hospitals were valid without missing values or apparent outliers and were used in the analysis. There were 20 participants (women = 19; CNS = 8; CN = 12), and the median age of all participants was 46.0 years (IQR 43.0, 49.75). The median duration of working as a CNS/CN was 3.9 years (IQR 2.3, 8.1), and 15 nurses had experience in training communication skills in consultation. By primary aggregation, the Listening, Acceptance, and Approval scores were medians of 5 (IQR 4, 5).

Table 1. Nurses' demographic characteristics ($N = 301$).

	n (%)	Mean (SD) Median (IQR)
Age (years)		44.1 (6.2)
Gender		
Men	6 (2.0)	
Women	295 (98.0)	
Duration of work in nursing (years)		21.3 (6.0)
Professional qualifications related to cancer nursing		
CNS	56 (18.6)	
CN	245 (81.4)	
Duration of work as CNS/CN (years)		6.3 (3.6)
Communication skills training in consultation		
Yes	206 (68.4)	
No	88 (29.2)	
Number of years in charge of consultations		4.4 (2.9)
Number of consultation sessions in the last month		10 (4, 20)
Ways to make time for a consultation session		
Scheduled time	155 (51.5)	
Adjusted nurse's schedule	87 (28.9)	
No scheduled time	52 (17.3)	
Other	7 (2.3)	
Type of room used for consultation		
Private room	99 (32.9)	
Exclusive place	14 (4.7)	
Secure as needed	165 (54.8)	
No room/place	23 (7.6)	
Number of beds available to patients		
≤ 199	11 (3.7)	
200-499	134 (44.5)	
≥ 500	156 (51.8)	
Hospital type		
Cancer medical treatment cooperation-based hospital	208 (69.1)	
Other	93 (30.9)	

Note: SD = standard deviation; IQR = interquartile range; CNS = certified nurse specialist; CN = certified nurse.

for the high items and medians of 4 (IQR 4, 5) for the low items. Empathy, Reflecting on Emotions, Rephrasing, Summarizing, Questioning, and Silence scores were medians of 4 (IQR 3, 5) for high items and medians of 3 (IQR 2.5, 4) for low items.

Final Study

Demographic Characteristics

We sent the questionnaire to 649 eligible hospitals; of these, 338 nurses from 236 hospitals agreed to participate and returned the questionnaire. Of the 338 responses, 301 from 216 hospitals were valid and used in the analysis. Table 1 presents the participants' backgrounds. Of the 301 participants, 98% ($n = 295$) were women, and the participants' mean age was 44.1 years ($SD = 6.2$). Further, 18.6% ($n =$

56) were CNSs, and 81.4% ($n = 245$) were CNs. The average duration of working as a CNS/CN was 6.3 years ($SD = 3.6$). There were 206 ($SD = 68.4$) nurses with experience in communication skills training in consultation and 88 ($SD = 29.2$) nurses without experience.

Item Analysis

Table 2 presents the descriptive data on oncology nurses' communication skills. Skewness ranged from $-.21$ to -1.54 and kurtosis from $-.01$ to 2.53 , indicating that most data deviated from a normal distribution. Item analysis was conducted to confirm the Pearson's correlations for the total items ($r = .52-.74$ [$p < .001$]) and interitem correlations ($r = .14-.76$ [$p < .001$]); 87% of the items were positively correlated ($r \geq .3$). However, as items 16, 17, 30, and 31 exhibited strong correlations (interitem correlations of $\geq .7$), we

Table 2. Descriptive data on the communication skills scale in the initial oncology nursing consultation after a cancer diagnosis ($N = 301$).

Item No.	Item	Mean	(SD)	Skewness	Kurtosis	ITC
1	I take care to come down to the patient's eye level and avoid talking down to them.	4.68	(.53)	-1.54	2.22	.51
2	I do not stare at the patient; I try to make eye contact to let them know that I am listening.	4.46	(.62)	-.81	.06	.64
3	If the patient becomes nervous, I break eye contact to make it easier for them to talk.	4.19	(.84)	-.74	-.29	.56
4	I lean forward slightly and assume a relaxed posture and expression, conveying the message to the patient, "Please talk, I'm listening."	4.31	(.78)	-.89	.14	.62
5	I adjust the tone of my voice and speaking speed to suit the patient.	4.45	(.67)	-.95	.31	.64
6	I carefully listen to the patient's story and keep up with what they tell me.	4.41	(.68)	-.99	1.24	.70
7	I am concerned with what the patient feels, what they think, and how they view themselves and their surroundings.	4.27	(.76)	-.63	-.55	.67
8	I actively listen to the patient's stories without my preconceptions or sense of values.	4.33	(.66)	-.62	-.01	.70
9	I encourage the patient to talk about their feelings and thoughts using non-verbal expressions such as nodding, pausing, and smiling.	4.47	(.68)	-1.10	.78	.70
10	I encourage the patient to talk about their feelings and thoughts using verbal expressions such as "I see," "Tell me more," and "What happened next?"	4.18	(.86)	-.92	.70	.72
11	I do not criticize or evaluate the patient's story and emotions with my sense of values. I accept the patient as they really are.	4.37	(.67)	-.73	.02	.68
12	I repeat the patient's story and convey that I have accepted what they have told me.	4.28	(.76)	-.83	.20	.70
13	I try to look at the patient's situation from their point of view. I accept the patient's emotions as my own.	3.73	(.89)	-.45	.09	.66
14	I feel the patient's emotions and this influences my viewpoint. I let the patient know that I understand their emotions and feel the same way.	3.82	(.91)	-.59	.30	.74
15	I adequately express the patient's emotions, perhaps using adjectives (For example, "Is it painful?" and "Were you sad?")	4.23	(.77)	-.89	.86	.66
16	I carefully observe the patient's un verbalized emotions and express those emotions back to the patient.	3.79	(.91)	-.46	-.27	.75
17	Instead of just repeating the patient's words, I feel their feelings and respond with words that seem appropriate.	3.84	(.87)	-.58	.24	.75
18	I clarify the meaning of the patient's story and paraphrase it.	3.65	(.91)	-.21	-.26	.70
19	I do not merely paraphrase the patient's story but also try to understand the background. I confirm with the patient whether my understanding is correct.	3.77	(.88)	-.30	-.18	.71
20	I briefly summarize what the patient tells me and confirm the main point.	3.96	(.85)	-.71	.58	.67
21	I encourage patients to talk freely with open questions and listen to their thoughts and feelings.	4.20	(.77)	-.66	-.14	.68
22	I confirm the facts with the patient using "closed questions" in which the patient answers with "yes" or "no."	3.47	(1.12)	-.23	-.84	.53
23	I try to notice any inconsistencies or changes between the patient's response and facial expressions/attitude and ask them with interest and focus.	3.67	(.98)	-.43	-.25	.72
24	I wait quietly for some time for the patient to respond.	4.05	(.88)	-.98	1.22	.67
25	I watch over the patient for a while until their emotional reactions such as crying subside.	3.87	(1.20)	-1.07	.35	.53
26	If the patient is silent, I will not immediately break the silence. I also try to be as quiet as possible, and I try to think about why the patient is being silent.	3.81	(1.13)	-1.01	.45	.58
27	If I intentionally break the silence, I will focus on the patient's feelings. For example, "Can you tell me how you feel now?"	3.36	(1.35)	-.45	-.96	.56
28	I clearly tell the patient that I understand their feelings.	4.14	(.79)	-.73	.39	.70
29	I appreciate the patient's efforts to cope with the illness while they were worrying. I affirm their feelings.	4.27	(.81)	-1.25	2.23	.66
30	I encourage the patient about the future so that they feel relieved. I pledge to support them and to think about their situation.	4.51	(.66)	-1.28	1.56	.70
31	I clearly tell my patients that I want to support them.	4.43	(.78)	-1.51	2.53	.67
32	I am grateful to the patient for what they have told me.	4.25	(.89)	-1.15	1.02	.54

Note: SD = standard deviation; ITC = Item-Total Correlation.

examined their content. Items 16 and 17 exhibited overlapping content; therefore, item 17 was deleted. Item 31 was deleted because its scope was limited and it could be merged with item 30.

Verification of Validity

An EFA was conducted to verify construct validity. The Kaiser-Meyer-Olkin test of sample validity value was .943, and Bartlett's sphericity value showed statistical significance ($\chi^2[406] = 5382.675$, $p < .001$), thereby confirming that these data were suitable for factor analysis. We employed nonweighted least squares for the EFA as applicable to the analysis of nonnormal distributions. Promax rotation was used because of the assumed interfactor correlations.

Table 3 presents the EFA results. The commonality among the items remained unique at .46-.82, and no items were deleted. Four factors had eigenvalues > 1.0 , accounting for 60.7% of the variance. However, after Promax rotation, the factor matrix comprising four factors had many items for the first factor (ten items) and the second factor, 12 items, making it difficult to interpret the factors. Therefore, we selected a six-factor structure according to the interpretability of the factors. The cumulative response variance explained by the six-factor structure was 67.1%. We extracted the six factors using EFA, selecting items with factor loadings $\geq .35$. Item 32 was deleted (factor loading = .29). We calculated interfactor correlations to ascertain each item's uniqueness. Pearson's correlation coefficients between the factors were moderate or strong ($r = .44-.74$, $p < .05$).

The six extracted factors were named based on the initial dimensions of the concept of this study. Factor 1 (eight items) was named Exploring (Sherko et al., 2013). It included confirming the patient's feelings, paraphrasing what the patient says, asking clarifying questions, and summarizing the patient's fears and concerns. Factor 2 (six items) was named Listening. This factor represented nurses' listening attitude and comprised nonverbal communication skills, such as maintaining eye contact, speaking speed, tone of voice, and conversation content. Factor 3 (six items), named Acceptance (Sherko et al., 2013), represented nurses encouraging their patients to share their stories using minimal encouragement and accepting the stories without value judgment. Factor 4 (four items) was named Silence (Hill et al., 2003). This factor refers to how nurses react to a patient's silence and how they wait for-and observe-the patient's reactions and responses. Factor 5 (three items), named Approval (Hays & Larson, 1963), included nurses assuring the patient that they understand their feelings, affirming the patient's efforts to cope with the illness, encouraging the patient about the future so that they feel relieved, and suggesting collaboration regarding future care. Finally, Factor 6 (two items), named Empathy (Derksen et al., 2015), included nurses considering the situation from the patient's perspective, accepting the patient's emotions as their own, and communicating

in a language appropriate for the patient.

Verification of Reliability

Cronbach's alpha coefficient was calculated to assess the internal consistency of each factor. The coefficient for the total scale was .95, and the dimensional range was .83-.88, confirming a high degree of internal consistency.

Control-Group Comparisons

The results of the control-group comparisons are presented in Table 4. We tested the hypothesis about differences in total communication skills scores between demographic characteristics within this sample. The results showed that the communication skill scores of the CNSs (mean = 125.27, $SD = 14.05$) were significantly higher than those of the CNs (mean = 117.18, $SD = 15.93$). In addition, the scores of nurses with communication skills training in consultation experience (mean = 120.19, $SD = 16.30$) were significantly higher than those of nurses without such training (mean = 115.37, $SD = 14.63$), supporting the hypothesis. Contrary to this hypothesis, the scores of nurses with fewer than 10 years of CNS/CN experience (mean = 118.72, $SD = 15.98$) were not significantly different from those of nurses with more than 10 years of CNS/CN experience (Mean = 120.40, $SD = 15.91$).

Discussion

Three items of the self-rating scale developed in this study were removed from the initial structure based on EFA, thereby reducing the number of factors to six. The decrease in the number of factors is attributable to the initial four dimensions (Reflecting on Emotions, Rephrasing, Summarizing, and Questioning) being combined to form the first factor. The other factors comprised the initial dimensions and items, and we believe that this scale is a satisfactory representation of the preconstructed concepts. However, Factor 5 had a three-item structure, and Factor 6-a two-item structure; since the recommended number of items is at least three per factor, more items should be considered to increase measurement stability (Sato & Tsuchiya, 2022). Regarding reliability, Cronbach's alpha coefficient ($\alpha = .95$ for the total scale and $\alpha = .83-.88$ for all subscales) exceeded the minimum standard value of $\alpha < .7$, suggesting good internal consistency and reliability. However, to ensure reliability, a confirmatory factor analysis should be conducted with a new sample, and the results should be compared to determine reproducibility. Construct validity was also assessed by comparing the communication skill scores of the control group.

Two of the three control-group comparisons supported this hypothesis. Nurses with higher levels of professional education in oncology nursing (Newman & Helft, 2015) and those with experience in communication skills training after a professional education course (Fukui et al., 2008) obtained higher communication skill scores. These results indicate the

Table 3. Exploratory factor analysis of the communication skills scale in the initial oncology nursing consultation after a cancer diagnosis ($N = 301$).

Item No.	Item	Factor loading						Communality
		1	2	3	4	5	6	
Factor 1: Exploring ($\alpha = .88$, Mean = 3.84, SD = 0.67)								
20	I briefly summarize what the patient tells me and confirm the main point.	.94	-.13	.07	-.09	.03	-.13	.67
18	I clarify the meaning of the patient's story and paraphrase it.	.75	-.00	-.14	.03	.02	.13	.59
19	I do not merely paraphrase the patient's story but also try to understand the background. I confirm with the patient whether my understanding is correct.	.75	.01	.13	-.08	-.08	.07	.63
16	I carefully observe the patient's non-verbal emotions and reflect them back.	.55	.06	-.03	.09	.09	.13	.58
22	I confirm the facts with the patient using "closed questions," which the patient answers with "yes" or "no."	.52	.00	.01	-.01	.19	.02	.31
15	I adequately express the patient's emotions, perhaps using adjectives (For example, "Is it painful?" and "Were you sad?")	.48	.29	-.11	-.03	-.10	.04	.46
21	I encourage patients to talk freely with open questions and listen to their thoughts and feelings.	.43	-.01	.39	.12	.02	-.20	.53
23	I try to notice any inconsistencies or changes between the patient's response and facial expressions/attitude and ask them about it with interest and focus.	.43	.18	-.06	.11	.01	.22	.55
Factor 2: Listening ($\alpha = .87$, Mean = 4.42, SD = 0.54)								
2	I do not stare at the patient; I try to make eye contact to let them know that I am listening.	.08	.83	-.02	-.05	.01	-.08	.66
4	I lean forward slightly and assume a relaxed posture and expression, conveying the message to the patient, "Please talk, I am listening."	-.05	.79	.01	-.04	-.06	.12	.61
3	If the patient becomes nervous, I will break eye contact to make it easier for them to talk.	.12	.73	-.00	.04	-.13	-.07	.51
1	I take care to come down to the patient's eye level and avoid talking down to them.	-.13	.66	.01	.04	.19	-.14	.46
5	I adjust the tone of my voice and speaking speed to suit the patient.	.01	.62	.15	.04	.03	-.06	.57
6	I carefully listen to the patient's story and keep up with what they tell me.	-.05	.37	.24	.01	.16	.13	.55
Factor 3: Acceptance ($\alpha = .88$, Mean = 4.32, SD = 0.58)								
8	I actively listen to the patient's stories without my preconceptions or sense of values.	-.07	.09	.86	.05	-.11	-.00	.69
11	I do not criticize or evaluate the patient's story and emotions with my sense of values. I accept the patient as they really are.	.04	-.02	.78	-.02	-.05	.04	.60
7	I am concerned with what the patient feels, what they think, and how they view themselves and their surroundings.	-.03	.08	.59	-.01	-.03	.19	.52
9	I encourage the patient to talk about their feelings and thoughts using non-verbal expressions such as nodding, pausing, and smiling.	.00	.13	.56	-.12	.16	.07	.59
12	I repeat the patient's story and convey that I have accepted what they have told me.	.29	-.04	.44	-.04	.05	.10	.54
10	I encourage the patient to talk about their feelings and thoughts using verbal expressions such as "I see," "Tell me more," and "What happened next?"	.29	.13	.36	-.03	.04	.04	.54
Factor 4: Silence ($\alpha = .84$, Mean = 3.78, SD = 0.95)								
26	If the patient is silent, I will not immediately break the silence. I also try to be as quiet as possible, and I try to think about why the patient is being silent.	-.01	-.04	.09	.96	-.09	-.10	.82
25	I watch over the patient for a while until their emotional reactions, such as crying, subside.	-.20	-.01	-.07	.83	.06	.19	.65
27	If I intentionally break the silence, I will focus on the patient's feelings. For example, "Can you tell me how you feel now?"	.13	.06	-.15	.64	-.02	.10	.50
24	I wait quietly for a little while for the patient to respond.	.15	.03	.20	.54	.07	-.13	.57
Factor 5: Approval ($\alpha = .83$, Mean = 4.31, SD = 0.65)								
29	I appreciate the patient's efforts to cope with the illness while they were worrying. I affirm and approve the patient.	.06	.03	-.07	-.06	.77	.06	.66
28	I clearly tell the patient that I understand their feelings.	.27	-.01	-.11	.03	.71	-.08	.62
30	I encourage the patient about the future so that they feel relieved. I pledge to support them and think about their situation.	-.13	.00	.32	.04	.63	-.01	.60

Table 3. Exploratory factor analysis of the communication skills scale in the initial oncology nursing consultation after a cancer diagnosis ($N = 301$). (continued)

Item No.	Item	Factor loading						Communality
		1	2	3	4	5	6	
Factor 6: Empathy ($\alpha = .85$, Mean = 3.78, SD = .84)								
13	I try to look at the patient's situation from their point of view. I accept the patient's emotions as my own.	.07	−.08	.12	.05	−.03	.78	.73
14	I feel the patient's emotions and this influences my viewpoint. I let the patient know that I understand their emotions and feel the same way.	.23	−.07	.08	.04	.06	.63	.73
Inter-factor correlation								
	Factor 1	-	.62***	.74***	.52***	.67***	.68***	
	Factor 2		-	.72***	.44***	.58***	.48***	
	Factor 3			-	.47***	.69***	.64***	
	Factor 4				-	.44***	.46***	
	Factor 5					-	.55***	

Note: α = Cronbach's coefficient alpha, SD = standard deviation.

Using the least squares method and Promax rotation, *** $p < .001$

Three items (17, 31, 32) were deleted by item analysis.

Table 4. Association between categorical variables related to demographic characteristics and communication skills in the initial oncology nursing consultation after a cancer diagnosis ($N = 301$).

Demographic characteristics	Communication skills scale			
	Total score			
	Mean	(SD)	p	Effect size d
Professional qualifications related to cancer nursing				
CNS ($n = 56$)	125.27	(14.05)	<.001	.52
CN ($n = 245$)	117.18	(15.93)		
Duration of working as CNS/CN (years)				
< 10 years ($n = 243$)	118.72	(15.98)	.51	-.11
> 10 years ($n = 47$)	120.40	(15.91)		
Communication skills training in consultation				
Yes ($n = 206$)	120.19	(16.30)	.02	.31
No ($n = 88$)	115.37	(14.63)		

Note: Groups were compared by the no correspondence t-test. Cohen's d coefficient was used for assessing the effect size. SD = Standard deviation.

validity of the Communication Skills Scale. However, the length of cancer nursing experience (Malloy et al., 2010, Mishelmovich et al., 2016) did not affect communication skills utilization scores. This result may also be related to the differences in the frequency of CNS/CN nursing consultations, suggesting the need for validation studies with larger samples.

This study used therapeutic communication skills to represent each phase of establishing an interpersonal relationship between the nurse and the patient. Therapeutic communication is a counseling technique that has been developed in psychiatric nursing and psychology (Fukuhara, 2004), and this study aimed to apply it to counsel patients exhibiting anxiety following a cancer diagnosis. Thus, the assessment

items are represented in the specific context of the counseling session mentioned in previous studies: Listening, Acceptance, and Exploring through nonverbal and verbal communication skills. Empathy can be received and felt through the intentional use of these skills. The Empathy extracted in this study included observation, sharing hope, and humor, as identified in previous studies. Meanwhile, self-disclosure identified in the previous study was included in item pools 31 and 32 but was excluded from this scale after analysis. This suggested that nurses and patients do not frequently use these skills. Thus, the Listening, Acceptance, Exploring, and Empathy in this study supported the skills identified in previous studies on communication between nurses and patients.

This study found that previous research did not recognize Silence and Approval as independent skills between a nurse and a patient; however, these aspects must be explicitly measured. In other nurse-patient communication skills scales, silence has been vaguely assessed (Ueno, 2005) or has been treated as part of other skills (Campbell & Aredes, 2019; Granados-Gómez et al., 2022; Kondo et al., 2020). However, many sensitive topics that nurses must address with patients in the nursing consultation result in emotional reactions from both patients and their families and sometimes from oncology nurses (Katz, 2019). Therefore, in oncology nursing consultations, each person needs some quiet time to sort through their thoughts and feelings. Hill et al. (2003) suggested that therapists use silence to lend patients a margin for deep thinking and processing their problems during communication. Intentionally including Silence as a communication skill allows the patient to arrange their thoughts, reflect on issues, and introspect about the relevant agenda in the communication. "Silence," as extracted in this study, refers to the oncology nurse's support for the patient's reflective thinking.

Approval, which might also be called assurance or reassurance, has been considered nontherapeutic communication if skills are premature because it has been regarded as arousing suspicion in patients and preventing them from expressing deeper emotions (Hays & Larson, 1963). This concept has also been incorporated into communication scales between nurses and patients (Campbell & Aredes 2019). However, the structure of communication skills extracted in this study was not limited; rather, it encompassed Listening, Acceptance, and Empathy, including deeply Exploring the patient's problems and needs and helping patients to reflect and face them silently. This finding suggests that communication using such skills is therapeutic and involves deep communication. In this study, Approval was identified as a skill to be used in conversations providing positive support for the patient's coping, demonstrating a willingness to work together to solve problems, and reassuring the patient of continued involvement in the future. Such Approval is addressed in communication protocols in difficult conversations (Back et al., 2005) but is not found in nurse-patient or nursing student-patient communication scales. Approval has been considered a warm and caring response from a nurse conveyed through empathy with appropriate communication (Komatsu, 2019; Sinclair et al., 2017). Moreover, such a response from the nurse encourages the patient with cancer to face themselves and motivates appropriate behavior change (Sinclair et al., 2017). Thus, Approval skills are necessary for patients with cancer who are hurt and stressed by their cancer diagnosis and should be considered essential and independent skills for advanced cancer care practice.

In principle, oncology nursing consultations are individual consultations from the viewpoint of privacy protection as

they support patients after a cancer diagnosis, helping them make decisions without causing distress. Therefore, nurses should self-assess their skills after each initial consultation. Recording the assessment history based on the scale helps nurses repeatedly recognize their tendency to use communication skills and consciously improve them. However, communication skills must be intentionally used in the context of a conversation according to the situation; therefore, using every skill during a communication session is not mandatory. It may also be useful in educating nurses unfamiliar with nursing consultations.

This study's target population was outpatient nurses because most initial oncology nursing consultations in Japan are conducted in outpatient settings. Therefore, understanding the true needs of patients when there are few places and times for consultation may be a specific communication skill. Nursing consultation after a cancer diagnosis may also differ from the communication skills used in consultation with inpatients; a notable issue for future research.

Limitations

The primary limitation of this study is that the sample only represents some CNSs and CNs in Japan. However, notably, the survey was administered in hospitals throughout Japan to avoid sample bias. Additionally, the number of participants was a maximum of two nurses from each hospital, regardless of the hospital size. However, the survey may be biased toward the views of selected nurses within the hospital. Further, as data from nurses with multiple missing values were excluded from the analyses, the results may only represent the opinions of some nurses. Next, the number of items for the two communication skills identified in this study was small. Increasing the number of items is necessary to improve measurement stability. Additionally, the validation of the reliability of the six communication skills identified in this study was insufficient because we did not assess reproducibility with different samples. Future research should further refine and validate these skills and assess their replicability. We also recommend that educational interventions be tested for effectiveness and scale validity should be assessed for the six skill-based scales. Future research should develop educational programs using this scale. In Japan, no scale has been developed to assess nurses' communication skills in initial nursing consultations following a cancer diagnosis. Future research should compare the results with theoretically relevant scales and assess the criterion-related validity. Finally, this study was conducted entirely in Japanese translation to reflect communication in clinical oncology. An accurate English translation of the scale items, including comparative cultural studies, would be beneficial in the future.

Conclusions

The communication skills scale developed in this study, comprising six subscales, is useful and reliable for oncology nurses, and a future refined version may be a tool that can be introduced in clinical oncology settings. Further, this tool will enable the sharing of accumulated data and provide useful information for developing educational programs for nurses who are new to nursing consultations or want to become experts in oncology nursing.

Author Contributions

Takako Mitsuyuki designed and conducted the study, analyzed and interpreted the data, and prepared the manuscript. Shyoko Ando coordinated the research, data interpretation, and critically reviewed the manuscript. Kazuki Sato, Ayumi Sugimura, and Shigeyoshi Maki interpreted the findings and critically reviewed the manuscript.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

This study was approved by the Ethics Review Committee of Nagoya University Graduate School of Medicine in July 2017 (No.17-129).

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Informed Consent

Informed consent was obtained from all participants involved in this study.

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Original Research

Risk of developing postpartum type 2 diabetes in women with a history of gestational diabetes who did not undergo postpartum glucose tolerance testing

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Abstract

Objective: This study aimed to examine the presence of high-risk women developing type 2 diabetes mellitus among women with a history of gestational diabetes mellitus (GDM) who had not undergone a postpartum oral glucose tolerance test (OGTT). **Methods:** This was a retrospective observational study. The participants were Japanese women diagnosed with GDM and were managed at two perinatal medical centers. We compared the risk factors for developing type 2 diabetes between women who had undergone a postpartum OGTT (examinees) and those who had not had it (nonexaminees). In addition, we divided the participants with a history of GDM into high- and low-risk groups and examined the presence of high-risk women developing type 2 diabetes mellitus. **Results:** Of the 117 participants, 77 (65.8%) underwent a postpartum OGTT and 40 (34.2%) did not. There were no significant differences in the risk factors for developing type 2 diabetes between the two groups, except for the premature birth rate. We divided the 80 participants into two groups, including 30 nonexaminees and 50 examinees, and 34 high- and 46 low-risk women. Although there was no significant difference in the percentage of high-risk women who had undergone a postpartum OGTT, 10 (33.3%) of the 30 nonexaminees were assessed as high-risk. **Conclusions:** Our results indicate that 10 (12.5%) of 80 women with a history of GDM did not undergo a postpartum OGTT despite being in the high-risk group and improving the rate of postpartum OGTT may contribute to the prevention and early detection of type 2 diabetes.

Keywords

developing type 2 diabetes mellitus, gestational diabetes, glucose tolerance test, Japanese, postpartum period

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Introduction

Gestational diabetes mellitus (GDM) is a risk factor for the development of type 2 diabetes mellitus. In a recent study, the relative risk of developing type 2 diabetes mellitus in women with a history of GDM was found to be 9.5-fold higher than that in women who exhibited normal glucose tolerance during pregnancy (Vounzoulaki et al., 2020). According to the Hyperglycemia and Adverse Pregnancy Out-

come follow-up study, after 11.4 years, the incidence of diabetes among women with GDM diagnosed according to the new International Association of Diabetes and Pregnancy Study Groups (IADPSG) diagnostic criteria (revised in 2010) was 5.4 times that in pregnant women who did not have GDM (Lowe et al., 2018). Therefore, the international recommendation is to evaluate glucose tolerance in women with a history of GDM using a 75 g oral glucose tolerance test (OGTT) within 12 weeks of delivery (American Diabe-

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tes Association Professional Practice et al., 2022; Feig et al., 2018). However, the examination rates of postpartum OGTT have remained low because of mothers experiencing a sense of security from the temporary normalization of glucose metabolism after childbirth and being busy with childcare and unaware of the risk of developing diabetes (Bernstein et al., 2016; Van Ryswyk et al., 2016). Studies in several countries, including those in Asia, have also shown that the examination rates of postpartum OGTT among women with a history of GDM are low (18.5%-61.0%) (Pastore et al., 2018). Therefore, increasing these examination rates is of urgent importance.

The postpartum OGTT rate among Japanese women is reportedly 67.6% (Kawasaki et al., 2020), which is higher than that in other countries (Pastore et al., 2018). However, because Asian women with a history of GDM are at a higher risk of developing type 2 diabetes mellitus than Caucasian women (Lee et al., 2007), the current examination rate among Japanese women is insufficient for follow-up on the potential development of type 2 diabetes mellitus in the future. Japan has postpartum support systems for women with a history of GDM, but a postpartum OGTT is not compulsory. Therefore, high-risk women with a history of GDM who need follow-up for type 2 diabetes mellitus may be overlooked. However, previous studies (Masuko et al., 2022; Phaloprakarn & Tangjitgamol, 2022) on the risk factors for developing type 2 diabetes mellitus in women with a history of GDM after delivery only enrolled women who underwent a postpartum OGTT, and a study including women who did not undergo a postpartum OGTT was considered important. If, as a result, a large number of high-risk women are included among the women who did not undergo a postpartum OGTT, the postpartum check-up system for women with a history of GDM needs to be revised.

In the present study, we examined the presence of risk factors for developing type 2 diabetes mellitus in women with a history of GDM who had not undergone a postpartum OGTT.

Materials and Methods

Study Design

This was a retrospective observational study. The participants were Japanese women who were diagnosed with GDM based on the IADPSG criteria (at least one of fasting plasma glucose \geq 92 mg/dL, OGTT 1-h plasma glucose \geq 180 mg/dL, or OGTT 2-h plasma glucose \geq 153 mg/dL is positive), which are the globally unified diagnostic criteria for GDM. The deliveries were managed at one of two perinatal medical centers from January 2015 to December 2017. Cases of multiple pregnancy and overt diabetes during pregnancy were excluded. The sample size was calculated using a study that compared the risk factor for developing type 2

diabetes mellitus and the use of insulin in pregnancy between women who had undergone a postpartum OGTT (examinees) and those who had not undergone a postpartum OGTT (nonexaminees) (Cabizuca et al., 2018), and 16 of 21 (76.1%) examinees and 52 of 131 (34.4%) nonexaminees had used insulin during pregnancy. Therefore, the effect size was 0.28, and the combined sample size was 98.

Data from January 2015 to December 2017 were collected from medical records. The data collection period was from August 2018 to December 2019.

Risk of Developing Type 2 Diabetes Mellitus in Women Who Did Not Undergo a Postpartum OGTT

Using the risk factors for type 2 diabetes mellitus reported by Rayanagoudar et al. (2016), we compared the risk factors of women who had and had not undergone a postpartum OGTT. This review focused on 39 papers, mainly from western countries, and included 95,750 women with a history of GDM. Individual risk factors for developing type 2 diabetes mellitus in women with a history of GDM included advanced maternal age, maternal obesity, family history of diabetes, and nonwhite ethnicity. Pregnancy-related risk factors include multiparity, hypertension disorder in pregnancy, use of insulin in pregnancy, preterm delivery, an early diagnosis of GDM, and the fasting, 1-h, and 2-h plasma glucose levels in the OGTT performed at the time of GDM diagnosis.

The review by Rayanagoudar et al. (2016) did not include studies on Japanese participants. Risk factors for developing type 2 diabetes mellitus among women with a history of GDM have been recently reported in papers investigating Japanese women (Nishikawa et al., 2017; Inoue et al., 2018; Kawasaki et al., 2020; Masuko et al., 2022) and a review targeting Asian women (Nouhjah et al., 2017). Although risk factors have been examined in various papers, there have been insufficient comparisons of risk factors between Asian and Caucasian women. Asians are at a higher risk of developing diabetes, even with a slight weight gain, than Westerners (Caleyachetty et al., 2021). It has been reported that Asian women with a history of GDM have a higher risk of developing type 2 diabetes mellitus as compared to Caucasian women (Lee et al., 2007).

Therefore, we thought that it is necessary to investigate the risk factors for developing type 2 diabetes mellitus in Japanese women with a history of GDM. We used risk factors for type 2 diabetes mellitus for Japanese women with a history of GDM, as recently reported by Kugishima et al. (2018), and these included 75 g OGTT 2-h plasma glucose \geq 183 mg/dL and HbA1c \geq 5.6% at the time of GDM diagnosis.

Data Analysis

Descriptive statistics were calculated for the participants' attributes, 75 g OGTT results in pregnancy, and use of insulin

Table 1. Maternal characteristics and 75g OGTT results in pregnancy.

Characteristics	All subjects <i>N</i> = 117	Nonexaminees <i>n</i> = 40	Examinees <i>n</i> = 77
	<i>n</i> (%) or Mean \pm SD		
Age (years)	34.4 \pm 5.2	33.4 \pm 5.4	34.9 \pm 5.9
Ethnicity, Japanese	117 (100.0)	40 (100.0)	77 (100.0)
Previous BMI (kg/m ²)	25.1 \pm 5.7	24.5 \pm 4.6	25.5 \pm 6.1
Previous BMI \geq 25 (kg/m ²)	51 (43.6)	16 (40.0)	35 (45.5)
Multiparous	66 (56.4)	25 (62.5)	41 (53.2)
Family history of type 2 diabetes	50 (42.7)	18 (45.0)	32 (41.6)
75 g OGTT results during pregnancy			
Fasting plasma glucose (mg/dL)	84.8 \pm 12.1	83.7 \pm 11.4	85.4 \pm 12.5
1-h plasma glucose (mg/dL)	181.5 \pm 29.3	181.6 \pm 24.7	181.5 \pm 31.7
2-h plasma glucose (mg/dL)	162.9 \pm 35.6	159.1 \pm 31.4	164.9 \pm 37.6
Use of insulin in pregnancy	45 (38.5)	11 (24.4)	37 (44.2)

Note: BMI = body mass index; OGTT = oral glucose tolerance test; SD = standard deviation.

in pregnancy. Using the risk factors for developing type 2 diabetes mellitus reported by Rayanagoudar et al. (2016), the risk status was compared between women who did and did not undergo an OGTT using a Pearson's chi-square test, Fisher's exact test, and unpaired t-test. Moreover, the type 2 diabetes mellitus risk factors reported by Kugishima et al. (2018) were used to divide Japanese women with a history of GDM into a high-risk group (75 g OGTT 2-h plasma glucose \geq 183 mg/dL or HbA1c \geq 5.6%) and a low-risk group (75 g OGTT 2-h plasma glucose < 183 mg/dL and HbA1c < 5.6%), which were analyzed using Pearson's chi-square test (Kugishima et al., 2018).

All statistical analyses were performed using SPSS for Windows version 27 (IBM Inc., Armonk, NY, USA), and the significance level was set at 5%.

Ethical Considerations

This study was approved by the ethical review board of the Osaka Prefecture University Graduate School of Nursing (approval number 30-42). Informed consent was obtained in the form of an opt-out procedure, and we ensured that their anonymity was preserved. This research conformed to the provisions of the Declaration of Helsinki.

Results

From January 2015 to December 2017, there were 1,944 and 2,498 deliveries at the two participating institutions and 101 and 52 women were diagnosed with GDM (incidence rates of 5.1% and 2.1%, respectively).

From these 153 women, we excluded 7 with a history of twin pregnancy, 4 foreign women, 11 with missing data, and 14 who had been referred to other institutions for an OGTT, and 117 women were included in the analysis (Table 1). Of the women with a history of GDM, 40 (34.2%) had not un-

dergone an OGTT and 77 (65.8%) had undergone testing (Table 2). The timing of the OGTT in the 77 participants was \leq 5 weeks after delivery for 19 (24.7%), after 6-12 weeks for 40 (51.9%), and \geq 13 weeks for 18 (23.4%) women. After excluding 4 cases with missing data, the OGTT result for the 73 participants was normal in 55 (75.3%), was borderline in 14 (19.2%), and indicated diabetes in 4 (5.5%) women.

We compared the risk factors for type 2 diabetes mellitus reported by Rayanagoudar et al. (2016) between 40 nonexaminees and 77 examinees (Table 2). There was a significantly higher rate of preterm deliveries in examinees (18/77, 23.4%) than in nonexaminees (3/40, 7.5%) ($p = .034$). There were no significant group differences in the other parameters, including advanced maternal age, maternal obesity, family history of diabetes, multiparity, hypertension disorders in pregnancy, an early diagnosis of GDM, 75 g OGTT values during pregnancy, and use of insulin in pregnancy.

After excluding 37 women with missing data of the 75 g OGTT 2-h plasma glucose and HbA1c values, we examined the relationship between the risk level and postpartum OGTT examination status in 80 patients (30 nonexaminees and 50 examinees), but no significant relationships were observed with any risk level criteria (Table 3). However, 10 (33.3%) of the 30 nonexaminees were assessed as high-risk according to the Kugishima et al. (2018) criteria, suggesting that 10 (12.5%) of 80 women with a history of GDM did not undergo a postpartum OGTT despite being in the high-risk group.

Discussion

The GDM incidence rates in the two institutions in the present study were 2.1% and 5.1%, and the overall GDM incidence in Japan was 5.5% (Morikawa et al., 2017). Further,

Table 2. Comparison of risk factors for developing postpartum type 2 diabetes mellitus among nonexaminees and examinees.

Risk factors for developing postpartum type 2 diabetes mellitus	Nonexaminees (<i>n</i> = 40)	Examinees (<i>n</i> = 77)	<i>p</i> value
	<i>n</i> (%) or Mean ± SD		
Maternal characteristics			
Advanced maternal age ≥ 35	20 (50.0)	46 (59.7)	.31 ^a
Maternal obesity (BMI ≥ 25 kg/m ²)	16 (40.0)	35 (45.5)	.57 ^a
Family history of type 2 diabetes	18 (45.0)	32 (41.6)	.72 ^a
Pregnancy factors			
Multiparous	25 (62.5)	41 (53.2)	.33 ^a
Hypertension in pregnancy	2 (5.0)	8 (10.4)	.49 ^b
Preterm delivery	3 (7.5)	18 (23.4)	.03 ^b
Early diagnosis of GDM (weeks)	22.4 ± 7.3	21.3 ± 7.0	.43 ^c
75 g OGTT results during pregnancy			
Fasting plasma glucose (mg/dL)	83.7 ± 11.4	85.4 ± 12.5	.46 ^c
1-h plasma glucose (mg/dL)	181.6 ± 24.7	181.5 ± 31.7	.98 ^c
2-h plasma glucose (mg/dL)	159.1 ± 31.4	164.9 ± 37.6	.40 ^c
Use of insulin in pregnancy	11 (24.4)	37 (44.2)	.07 ^a

Note: BMI = body mass index; GDM = gestational diabetes mellitus; OGTT = oral glucose tolerance test; SD = standard deviation.

Notes: ^a Chi-square test; ^b Fisher's exact test; ^c Student t-test.

Table 3. Relationship between risk level and postpartum OGTT examination status.

Risk factors for developing postpartum type 2 diabetes mellitus	Nonexaminees <i>n</i> = 30	Examinees <i>n</i> = 50	<i>p</i> value
	<i>n</i> (%)		
High risk group (2hPG ≥ 183 or HbA1c ≥ 5.6)	10 (33.3%)	24 (48.0%)	.19 ^a
Low risk group (2hPG < 183 and HbA1c < 5.6)	20 (66.7%)	26 (52.0%)	

Note: OGTT = oral glucose tolerance test; PG = plasma glucose.

^a Chi-square test.

34.2% (40 of 117) of women with a history of GDM did not undergo a postpartum OGTT, which was similar to the postpartum OGTT of 32.4% in a previous study in Japan (Kawasaki et al., 2020).

We compared the presence of risk factors for developing postpartum type 2 diabetes mellitus between nonexaminees and examinees using risk factors reported in a systematic review of mostly European and American studies (Rayanagoudar et al., 2016). Risk factors, except premature delivery, did not significantly differ between them in this study, suggesting that nonexaminees were just as likely to develop type 2 diabetes mellitus as examinees in Japan. Linnenkamp et al. (2022) discussed that women's low health awareness generally influenced postpartum screening behavior because smoking during pregnancy and obesity before pregnancy were significantly more frequent among nonexaminees than examinees. Moreover, high levels of health literacy were associated with good postpartum screening (Jones et al., 2019), indicating that postpartum screening behavior is in-

fluenced by general health awareness. However, women with a history of GDM tended to underestimate their risk of developing type 2 diabetes, thinking that they were healthy once their pregnancy ended (Hamel & Werner, 2017). Therefore, postpartum health awareness among women with GDM should be increased, and a system where all women with a history of GDM can conveniently receive postpartum glucose tolerance testing be established.

We divided the participants into the high-risk and low-risk groups for developing type 2 diabetes mellitus using risk factors for Japanese women and examined the relationship between risk levels and the presence of postpartum OGTT. The results showed no significant difference between the two groups, and 10 (12.5%) of 80 women with a history of GDM had not undergone a postpartum OGTT despite being in the high-risk group. A high-risk group assessed using the same criteria as this study showed a higher incidence of diabetes mellitus within five years after delivery, with a 7.02-fold increase in incidence among women with a history of

GDM and 75 g OGTT 2-h plasma glucose ≥ 183 mg/dL, and a 4.67-fold increase in incidence among women with a history of GDM and HbA1c $\geq 5.6\%$ (Kugishima et al., 2018). In summary, women who did not undergo an OGTT despite being in the high-risk group in this study missed an opportunity to detect glucose intolerance, which means that they were unable to initiate appropriate interventions to prevent progression to type 2 diabetes.

In Japan, 12.1% of people suffer from diabetes (Ministry of Health, Labour and Welfare, 2016), and the percentage is continuously increasing as in other developed countries (Zhou et al., 2016). Medical spending on diabetes has also increased in Japan, exceeding 1.1 trillion yen per year (Ministry of Health, Labour and Welfare, 2020). The number of live births in 2017 was approximately 980,000 (Ministry of Health, Labour and Welfare, 2019), and the GDM incidence was 5.5% (Morikawa et al., 2017), resulting in an estimated number of 54,000 women with GDM. On the basis of our results, the overlooked rate of the high-risk group in the current postpartum check-up system for GDM was 12.5%, and the number of overlooked women in the high-risk group was estimated at 6,800 per year. Follow-up immediately after delivery on high-risk women with a history of GDM may aid in the prevention and early detection of type 2 diabetes mellitus and is important because the incidence of diabetic complications is higher in cases of type 2 diabetes mellitus that develop before age 40 than at a later onset (Huo et al., 2016). As a result, if we would not overlook such high-risk women, we could reduce medical spending.

Furthermore, a review by Michael et al. reported that 1.3%-10.8% of women with a history of GDM developed diabetes within 12 weeks of delivery (Carson et al., 2013). Continuous follow-up of women with a history of GDM through better postpartum OGTT examination rates may have great social benefits. Therefore, it is necessary to consider methods to encourage women with a history of GDM to undergo a postpartum OGTT within 12 weeks after delivery. Although Japanese guidelines recommend that women with a history of GDM need to undergo a 75 g OGTT by 6-12 weeks after delivery when the effects of pregnancy on glucose metabolism disappear, only 40 women (51.9%) in this study underwent a postpartum OGTT during this period. Meanwhile, 24.7% of women with a history of GDM underwent a postpartum OGTT within five weeks after delivery. This may be because their doctor scheduled the OGTT along with the standard postpartum maternal check-up 4-5 weeks after delivery for mothers' convenience. Such a situation is not only in Japan; a German study reported that only 51.6% of women with a history of GDM underwent the recommended postpartum OGTT 6-12 weeks after delivery (Linnenkamp et al., 2022). Recently, the American Diabetes Association (ADA) changed the timing of postpartum OGTT from 6-12 weeks to 4-12 weeks postpartum (Ameri-

can Diabetes Association Professional Practice et al., 2022). To improve the postpartum OGTT rate, it may be necessary to reconsider the current Japanese guidelines and adopt the ADA standard. If the OGTT is taken at 4-12 weeks postpartum, which is considered less affected by pregnancy-related insulin resistance, it could be conducted together with the general postpartum maternal check-up at 4-5 weeks postpartum and it may increase the number of women who will undergo a postpartum OGTT. Furthermore, nursing professionals should educate women regarding the need for a postpartum OGTT during pregnancy to raise health awareness. Moreover, even if the first examination is missed, the number of women who will receive the examination can be increased if the examination is offered along with the general infant check-up (4-month, 7-month, and 1-year-old child check-up) in Japan to women who wish to receive the examination.

The prevention and early detection of type 2 diabetes mellitus require continuous follow-up after the initial postpartum OGTT. Numerous attempts to improve the continuous follow-up of women with a history of GDM have been reported. Methods to improve the follow-up rate included reminders to patients and doctors (Cosson et al., 2015; Halperin et al., 2015) and education and counseling during pregnancy (Bounds et al., 2021; Soffer et al., 2017). In addition, continuous follow-up helps in maintaining good health in women after delivery by preventing the onset of type 2 diabetes mellitus (Aroda et al., 2015). In other words, although support for lifestyle habits by medical professionals is necessary, continuous follow-up will not be effective unless women with a history of GDM make a conscious effort to improve their lifestyles. The initial postpartum OGTT is important as the first motivational factor to promote this change, and it is thought to be the cornerstone for continuous follow-up. In addition, preterm delivery, which is a known risk factor for the development of type 2 diabetes mellitus, carries a risk of recurrence (Spong et al., 2007), with a recurrence rate of 22.3% among Japanese women (Seyama et al., 2022). Furthermore, a history of GDM and obesity are both risk factors for GDM during subsequent pregnancies (Schwartz et al., 2015). Therefore, it is considered important that nursing professionals must provide ongoing follow-up to women with a history of GDM and assume a role in preconception care for the health of the next child. The initial postpartum OGTT is a good opportunity, and the time spent waiting for the examination should be used by nursing professionals to discuss future examination schedules, next pregnancy, and weight control with women with a history of GDM.

This study had three limitations. First, the percentage of participants who took the postpartum OGTT in this study was low (65.8%). In Japan, the management of women with GDM is centrally performed at the perinatal medical centers

where obstetricians and diabetologists work together to provide reliable GDM diagnosis and blood sugar management during pregnancy. However, a referral system (Yamada et al., 2018) and multidisciplinary cooperation (Matsunaga et al., 2021) in postpartum follow-up examination remain not well developed. In the future, these issues need to be improved to increase the percentage of women with a history of GDM who will receive the OGTT.

Second, the data on HbA1c at the time of GDM diagnosis were sometimes deficient in the study because HbA1c was not included in the screening test for GDM in Japan. Although 75 g OGTT 2-h plasma glucose and HbA1c values at diagnosis had been reported as risk factors for developing type 2 diabetes mellitus in Japanese women (Kugishima et al., 2018), measurement of HbA1c is not required at the time of diagnosis of GDM. A Swedish study (Ekelund et al., 2010) also reported that the HbA1c value at diagnosis was an independent factor for developing type 2 diabetes mellitus within 5 years postpartum, with an HbA1c level of $\geq 5.7\%$ reported to increase the risk of developing postpartum type 2 diabetes mellitus by 4.8-fold. In the future, it should be mandatory to measure HbA1c values at the time of GDM diagnosis. Postpartum follow-up of GDM has become difficult because the number of women with GDM has increased since the adoption of the IADPSG criteria. Therefore, we believe that it is important to examine the risk of developing postpartum type 2 diabetes based on data at the time of GDM diagnosis.

Third, in the present study, we used OGTT 2-h plasma glucose levels and HbA1c during pregnancy to classify patients according to their risk of developing type 2 diabetes mellitus. However, as the standard for the OGTT 2-h plasma glucose level is 153 mg/dL or higher, our definition of the OGTT 2-h plasma glucose level of <183 mg/dL as a “low-risk group” was limited. Several studies published in the literature have previously investigated the risk factors for the development of type 2 diabetes mellitus (Rayanagoudar et al., 2016; Kugishima et al., 2018), and if the risk classification is clarified in the future by scoring risk factors, then it will be possible to conduct continuous follow-up according to the severity of the classification.

In conclusion, the low rate of postpartum OGTT among women with a history of GDM is a global issue. In the present study, 34.2% of women with a history of GDM did not undergo a postpartum OGTT. There was no difference in the risk factors for developing type 2 diabetes mellitus between women who had and had not undergone a postpartum OGTT, except for the preterm birth rate. In addition, 12.5% of women with a history of GDM did not undergo a postpartum OGTT despite being in the high-risk group for developing type 2 diabetes mellitus. For high-risk women with a history of GDM, the prevention of diabetes from the early postpartum period and that of complications through early

detection are mandatory, so it is necessary to increase the rate of initial postpartum OGTT. As such, it is necessary to reconsider the timing of postpartum OGTT, to conduct a postpartum OGTT as a part of regular medical tests, and to support continuous follow-up. In addition, according to a review of factors that promote postpartum OGTT (Dennison et al., 2020), it has been reported that the establishment of a protocol for sharing the history of GDM among medical professionals and the ability of women to receive medical care together with their children are important promotion factors. These can be achieved by utilizing the maternal and child health handbook and regular health checkups for children, such as health checkups for infants. Writing “GDM” in the maternal and child health handbook by the medical institution that diagnosed GDM allows sharing of information among medical professionals even after childbirth. It is thought that women with a history of GDM can continue to receive support from medical professionals, such as recommendations for postpartum OGTT, advice on lifestyle habits, and blood glucose measurements during regular checkups for their children.

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Author Contributions

Study design: K.Y. and K.O.

Data Collection: K.Y.

Data analysis: K.Y. and K.O.

Manuscript writing: K.Y. and K.O.

All authors have read and agreed to the published version of the manuscript.

Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

Ethical Approval

This research was approved by the ethical review board of the Graduate School of Nursing Osaka Prefecture University (approval number 30-42).

(Osaka Prefecture University changed its name to Osaka Metropolitan University in 2022.)

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Brief Report

Current state of advance care planning for patients with hematologic malignancies in Japan: A nationwide survey

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Abstract

Advance care planning (ACP) has various potential benefits. However, patients with hematologic malignancies (HMs) have fewer chances of accessing ACP compared with patients with solid tumors. It has been reported that one of the main factors is the characteristics of the disease, such as its complex and uncertain trajectories. This study aims to clarify the actual conditions of ACP for patients with HMs in Japan. A nationwide, cross-sectional, self-questionnaire was administered to 346 hematology nurses in government-designated cancer hospitals in Japan. Consequently, 209 valid questionnaires were returned (response rate: 58.5%). All respondents answered that ACP is important in patients with HMs. However, approximately 80% experienced difficulties with ACP. The topics “Surrogate decision-makers,” “Understanding of their illness and prognosis,” and “Place of care” were identified as the most difficult. Notably, respondents recognized that most ACP topics tended to be discussed with family members rather than with patients. Additionally, between 60% and 70% of nurses reported that “Improvement of healthcare professionals’ knowledge and skills” and “Education for healthcare professionals” were the challenges of ACP. Further research to explore the reasons related to the current state of ACP is needed.

Keywords

advance care planning, decision making, end-of-life discussion, hematologic malignancies

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Introduction

Since 1981, cancer has been the leading cause of death in Japan (Ministry of Health, Labour and Welfare, 2018), and as such, Japanese authorities have pushed for palliative care for cancer patients to maintain their quality of life (Ministry of Health, Labour and Welfare, 2018). However, patients with hematologic malignancies (HMs) are less likely to access advance care planning (ACP), palliative care and other related services and interventions, that would help maintain and improve their quality of life (El-Jawahri et al., 2020;

Suthumpong et al., 2021; Tricou et al., 2019). Compared with other cancers, HMs have unique characteristics, such as complex and unpredictable trajectories and continued intensive treatment even in the end-of-life stage (Gray et al., 2021; LeBlanc et al., 2015; Wedding, 2021). Moreover, hospital death is twice as likely to occur in patients with HMs compared with patients with solid tumors (Howell et al., 2010; McCaughan et al., 2018).

ACP is defined in Japanese context as “an individual’s thinking and discussing with his or her family and other people close to them with the support as necessary of

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healthcare providers who have established a trusting relationship with the individual concerning preparations for the future.” (Miyashita et al., 2022). Some potential benefits of ACP for cancer patients are reported. For instance, increased communication of end-of-life wishes with a physician, concordance between preferences and medical care at the end of life, and improvement of the mental well-being of the bereaved families. (Johnson et al., 2018; Paladino et al., 2019).

On the other hand, healthcare professionals have identified different kinds of barriers to the participation of patients and healthcare providers in ACP, such as a lack of time and insufficient staff (Barnes et al., 2007; Durall et al., 2012; Houben et al., 2014), difficulty identifying when to have conversations with patients and families (Barnes et al., 2007; Durall et al., 2012), and a lack of communication skills (McCaughan et al., 2018; Prod’homme et al., 2018). Furthermore, healthcare providers have expressed various concerns about ACP, such as the possibility of diminishing the patients’ motivation for treatment, especially if remission is likely (Barnes et al., 2007; Gray et al., 2021; Prod’homme et al., 2018; Wedding, 2021), and causing patient stress (Prod’homme et al., 2018).

In terms of ACP for patients with HMs, hematologists have been reported to avoid ACP if there is even a remote possibility of remission (Gray et al., 2021; Prod’homme et al., 2018; Wedding, 2021). Nurses and other healthcare professionals have also confronted difficulties in ACP (Kasuga & Uruno, 2008; McCaughan et al., 2018; Wedding, 2021). However, ACP in patients with HMs is still unclear. Therefore, this study sought to clarify the current state of ACP in the Japanese context.

Methods

Study Design

A survey using a cross-sectional, self-administered questionnaire was conducted. The questionnaire items consist of characteristics of the participant, the importance and difficulty of ACP for patients with HMs, difficult ACP topics, actors who engage in conversations with each ACP topic, documentation related to ACP, and challenges in ACP. The items were assessed using a 4- or 6-point Likert scale: very important, important, slightly important, not very important, not important, and not at all important in the importance scale; and very difficult, difficult, slightly difficult, not very difficult, not difficult, and not at all difficult in the difficulty scale.

Setting and Respondents

The surveys were delivered to 346 units that have patients with HMs and one nurse for each unit. Finally 216 nurses responded (a 58.5% response rate). It took place between August and September of 2019.

Data were provided by National Cancer Centre Japan (National Cancer Centre Japan, 2019). Since there is a concern that the nurses who are passionate about ACP in the unit would be selected to answer the questionnaire, we chose the vice-head nurses with a minimum of 5 years’ experience as hematology nurses who work in government-designated cancer hospitals in Japan to avoid selection bias.

Ethical Approval

This study was approved by the Human Research Ethics Committee of Kwansei Gakuin University (No. 2019-17).

Results

Characteristics of the Respondents

A total of 216 participants responded, representing a 58.5% response rate. However, we excluded data from 7 respondents (3%) due to missing data. In total, there were 209 valid responses (see Table 1).

Importance and Difficulty in ACP for Patients with HMs

Regarding the perceived importance of ACP, 209 (100%) of respondents indicated that they viewed ACP as very important, important, or slightly important. No respondent implied that it was not very important, not important, or not at all important.

Furthermore, the distribution of ACP difficulty was as follows: 26 (12.5%) of the respondents indicated that it was very difficult; 69 (33.2%) indicated that it was difficult; 75 (36.1%) indicated that it was slightly difficult; 24 (11.5%) indicated that it was not very difficult; 12 (5.8%) indicated that it was not difficult; and 2 (1.0%) indicated that it was not at all difficult.

Difficult ACP Topics

Table 2 shows that 60% to 70% of respondents answered difficult or slightly difficult on the topics “Surrogate decision-makers,” “Place of care,” and “Understanding of their illness and prognosis.” Conversely, nearly half of them reported that “Specific preferences for types of care or treatment” and “Individual concerns” were not difficult to address with patients.

Actors Who Engage in the Conversation of Each ACP Topic

All other topics, except for “Individual’s concerns” and “Important values or personal goals for care,” were discussed with family members rather than with patients (See Table 3). Moreover, almost 90% of nurses reported that physicians engage in conversations about “Understanding of their illness and prognosis”, whereas “Important values or personal goals for care” was reported as being discussed by less than 60% of nurses.

Table 1. Characteristics of the participants ($n = 209$).

Variables	<i>n</i>	%
Sex		
Female	201	96.2
Male	8	3.8
Status		
Vice-head nurse	136	65.1
Staff	46	22.0
Certified Nurse ^a	27	12.9
Head nurse	8	2.9
Certified Nurse Specialist ^b	6	1.4
No response	3	3.8
Education		
Nursing school	137	65.6
Junior college	32	15.3
University	29	13.9
Graduate school	7	3.3
Non-degree graduate nursing program	3	1.4
No response	1	0.5
Age, y		
≤29	12	5.7
30–39	49	23.4
40–49	91	43.5
≥50	46	22.0
No response	11	5.3
Years of clinical experience, y		
≥5	2	1.0
5–9	2	9.6
10–14	33	15.8
15–19	41	19.6
≤20	113	54.1
Years of clinical experience as a hematology nurse		
1–3	17	8.1
4–6	66	31.6
7–9	63	30.1
≥10	63	30.1

^a Certified Nurse (CN): a registered nurse who has a minimum of 5 years clinical experience and graduated from a special vocational school approved by the Japanese Nursing Association, who engages in clinical practice, training, and consultation.

^b Certified Nurse Specialist (CNS): a registered nurse who has a minimum of 5 years clinical experience and completed a master's degree; has various roles, such as clinical practice, consultation, coordination among health and social care professionals, ethical management, education, and research.

Documentation Related to ACP

A total of 103 respondents (49.3%) did not use documentation to ensure the family's and patient's preferences for medical care. For those nurses that reported using documentation to record ACP discussions, 63 (30.1%) reported that they updated documentation content as needed, yet 35 (16.7%) have not updated documentation regularly. The

most common content of the document was "Individual's concerns." Other contents included the patient's symptoms, family preferences, patient background, details of the care that they received (see Table 4).

Challenges on ACP

Several challenges were reported by respondents, with the most common being "Improvement of healthcare professionals' knowledge and skills" (73.7%) and "Cooperation with physicians" (70.8%), whereas "Financial Support" was only reported as a challenge by 23 (11%) respondents (see Table 5).

Discussion

To the best of our knowledge, this is the first study to clarify the current state of ACP for patients with HMs using a nationwide survey in Japan, which is the strength of this research. First, responses were received from 216 participants, representing a 60% response rate. This result, which was higher than the 41.9% in a similar survey on general nursing difficulties for patients with HMs (Furukawa, 2016), can be said to indicate that nurses were aware of the importance of ACP for patients with HMs.

The most significant finding is that all participants answered very important, important, and slightly important on a single scale of importance for ACP; more than 80% of participants indicated very difficult, difficult, or slightly difficult on a single scale of difficulty for ACP. The difficulties encountered with ACP for patients with HMs reported by healthcare professionals in this study were similar to those found in previous research (Kasuga & Uruno, 2008; McCaughan et al., 2018; Wedding, 2021). However, further research is still required to better understand why these challenges occur and how they can be mitigated to better support professionals with the ACP for this group of patients.

The second important finding is that "Surrogate decision-makers," "Understanding of their illness and prognosis," and "Place of care" were recognized as difficult ACP topics when compared with others.

Discussions regarding "Surrogate decision-makers" are essential in ACP since family members tend to be required to make decisions as surrogate decision-makers on behalf of patients who are unable to make their own decisions (Rietjens et al., 2017), placing a huge burden on families (Sanders et al., 2018). Family caregivers are often worried about whether they would make the "right decision" for patients (Combes et al., 2021), which could be one reason why this topic can be difficult to discuss; it is a common finding regardless of the type of disease (Combes et al., 2021).

The difficulties in discussing "Understanding of their illness and prognosis" and "Place of care" could be related to the unique characteristics of HMs. Patients with HMs often

Table 2. Difficult ACP^a topics (*n* = 209)^b.

ACP topics	Difficult		Slightly difficult		Not really difficult		Not difficult	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Surrogate decision-makers	49	23.6	99	47.6	46	22.1	14	6.7
Understanding of their illness and prognosis	33	15.8	108	51.7	55	26.3	13	6.2
Place of care	27	12.9	97	46.4	65	31.1	20	9.6
Important values or personal goals for care ^c	24	11.5	81	38.8	75	35.9	29	13.9
Particular preferences for types of care or treatment ^c	21	10.1	73	35.1	87	41.8	27	13.0
Individual's concerns	17	8.1	55	26.3	94	45.0	43	20.6

Note: ^a Advance care planning; ^b Multiple answers allowed; ^c *n* = 208 due to missing values.

Table 3. Actors who engage in the conversation of each ACP^a topic (*n* = 209)^b.

Actors who engage	Nurse		Physician		Patient		Family		Others	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Individual's concerns	119	95.7	143	68.4	177	84.7	147	70.3	36	17.2
Place of care	189	92.2	168	80.4	162	77.5	175	83.7	55	26.3
Understanding of their illness and prognosis	189	91.3	182	87.1	151	72.2	162	77.5	23	11.0
Important values or personal goals for care	183	88.4	120	57.4	173	82.8	130	62.2	25	12.0
Particular preferences for types of care or treatment	174	84.5	180	86.1	134	64.1	147	70.3	15	7.2
Surrogate decision-makers	141	68.4	142	67.9	111	53.1	143	68.4	17	8.1

Note: ^a Advance care planning; ^b Multiple answers allowed.

Table 4. Contents of documents related to ACP^a (*n* = 209)^b.

Contents of documents	<i>n</i>	%
Individual's concerns	71	34.0
Understanding of their illness and prognosis	63	30.1
Particular preferences for types of care or treatment	44	21.1
Important values or personal goals for care	43	20.6
Place of care	37	17.7
Surrogate decision-makers	27	12.9
Others	6	2.9

Note: ^a Advance care planning; ^b Multiple answers allowed.

Table 5. Challenges on ACP^a that nurses recognized (*n* = 209)^b.

Challenges on ACP	<i>n</i>	%
Improvement of healthcare professionals' knowledge and skills	154	73.7
Cooperation with physicians	148	70.8
Secure personnel and time	146	69.9
Education for healthcare professionals	131	62.7
Reduction of healthcare professional burden	112	53.6
ACP at a healthy stage	110	52.6
Improvement of organizational system of care	92	44.0
Reduction of the psychological burden on healthcare professionals	91	43.5
Cooperation with Multidisciplinary teams	82	39.2
Increase staff motivation	79	37.8
Raising patient's awareness	77	36.8
Cooperation with regional resource	36	17.2
Financial support	23	11.0
Others	3	1.4

Note: ^a Advance care planning; ^b Multiple answers allowed.

experience an unpredictable illness course that even health-care providers cannot anticipate (Gray et al., 2021; LeBlanc et al., 2015; Wedding, 2021), which can create difficulties for patients. Indeed, more than 80% of patients with HMs have a different understanding of their prognosis in comparison with that of their hematologists (Gray et al., 2021; LeBlanc et al., 2015). Moreover, patients with HMs tend to stay in hospitals and have intensive treatment until the end-of-life stage (Cooper & Dains, 2021; El-Jawahri et al., 2020; Freeman et al., 2018). There are fewer opportunities for them to choose their place of care, which could be what makes this topic more difficult to discuss.

Of note, in this study, there was a tendency for ACP topics to be discussed with family members rather than with patients; however, the reasons for this were not investigated,

therefore further research would be needed. Johnson et al. (2016) claimed that ACP is a relational, family-centered, and social process rather than an isolated set of individual directives. Therefore, it can be stated that the responders were

aware of the value of family involvement, which is a fundamental aspect of achieving patients' preferences and wishes.

Concerning the challenges of ACP, between 60% and 70% of nurses recognized "Improvement of healthcare professionals' knowledge and skills" and "Education for healthcare professionals" as two of the challenges. As ACP has both benefits and risks (Johnson et al., 2016), healthcare providers are concerned that the conversation might cause stress in patients (Prod'homme et al., 2018), and finding the timing to discuss it is difficult (Barnes et al., 2007; Durall et al., 2012). Importantly, a lack of communication skills is one of the biggest barriers to ACP for healthcare professionals (McCaughan et al., 2018; Prod'homme et al., 2018). Therefore, the majority of participants chose further training regarding ACP to gain knowledge and skills regarding these topics.

Regarding limitations, even though HMs encompass various kinds of diseases, such as leukemia, lymphoma, and myeloma, these were classed together as "HMs" in this study. Thus, it was not possible to reflect the detailed characteristics of each disease. Following that, since the target of this study were vice-head nurses in government-designated cancer hospitals in Japan, there might have been a bias in the responses. Additionally, the current state of ACP was not compared between HMs and solid tumors. However, the results of this study as a nationwide survey can be utilized to develop a training program about ACP for patients with HMs that would represent the training needs of nurses across Japan. Finally, this survey was conducted before the COVID-19 pandemic; hence, the situation might have changed in light of the pandemic. Therefore, it would be beneficial to conduct further research to compare the difficulties in ACP before and after the pandemic.

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Author Contributions

Miki Fujimoto conceived the project, conducted the survey, and drafted the paper. Miki Fujimoto and Yoshiyasu Ito analyzed the data. Yoshiyasu Ito also provided feedback on subsequent drafts of the paper. Yukihiro Sakaguchi oversaw the project and provided feedback at each step of the study. All authors reviewed and approved the final manuscript.

Declaration of Conflicting Interests

We have no conflict of interest to disclose.

Ethical Approval

This study was approved by the Committee on Regulations

for Behavioral Research with Human Participants [No. 2019-17].

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Informed Consent

Informed consent was obtained from all participants involved in this study.






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Brief Report

Learning outcomes from preventive home visits practicum in an undergraduate nursing program: A qualitative study

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Abstract

Japan is a super-aging society, so nurses are expected to hold increasingly essential roles in both hospital- and community-based settings in the future. To strengthen community-oriented geriatric and community health nursing competencies among undergraduate nursing students, we implemented an undergraduate nursing practicum called the Preventive Home Visits Practicum (PHVP). In the PHVP, students are grouped into teams of four (a freshman, sophomore, junior, and senior) before visiting healthy community-dwelling older adults to discuss life, health, and activities of daily living. A qualitative descriptive focus group design was used to examine student learning outcomes across 4 years of participation in the PHVP. The data obtained in focus group interviews were descriptively analyzed. Students deepened their understanding of *health and aging lives in an aging population* and developed *interpersonal relationships and communication* through the practicum across the 4-year period. Additionally, we found that a team composed of students from all different grades achieved very effective learning through *interactions among team members*. These findings suggest that nursing practicums that require nursing students to visit community-dwelling older adults longitudinally, such as the PHVP, may have an important educational impact and may address the needs of the aging population.

Keywords

home visit practicum, community-dwelling older adults, nursing education, super-aging society, Japan

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Introduction

Japan has long been known as a super-aging society. According to the Annual Report on Aging Society 2021 announced by the Cabinet Office of Japan, in 2020, the percentages of the population aged between 65 and 74 years, and 75 years and over were 13.9% and 14.9%, respectively, with the latter surpassing the population aged 65-74 years

(Cabinet Office of Japan, 2021). The Japanese government recently initiated a community-based integrated care system that was designed to support older adults in living their lives in their own way in environments familiar to them even if they require long-term care (Ministry of Health, Labour and Welfare of Japan, 2013). In the future, nurses are expected to play an increasingly essential role in both hospital- and community-based settings as the Japanese Nursing Associa-

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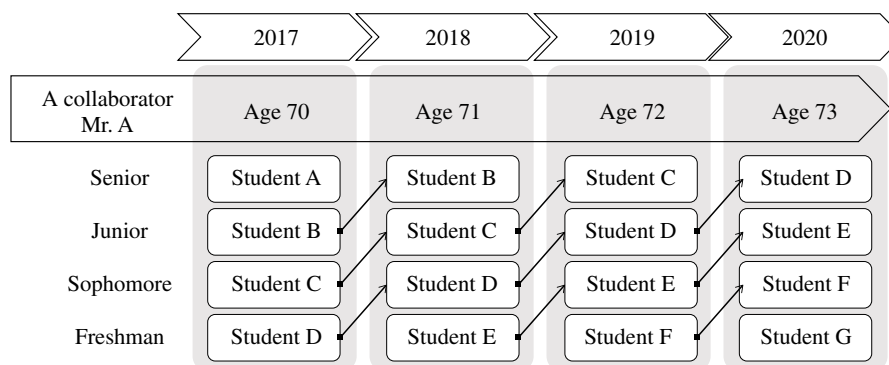


Figure 1. An image of a collaborator and students in a team.

Students were grouped in teams of four (a freshman, sophomore, junior and senior), with two faculty members for support. Teams are consolidated every year by replacing graduating seniors with freshmen.

tion (2017) declared that nursing services are in demand essentially everywhere, not only in hospitals.

In 2013, we developed an experimental practicum for the undergraduate nursing curriculum called the Preventive Home Visits Practicum (PHVP). The purpose of the PHVP was to strengthen community-oriented geriatric and community health nursing competencies among undergraduate nursing students. In the PHVP, small groups of undergraduate students regularly visit healthy community-dwelling older adults to discuss life, health, and activities of daily living to gain a better understanding of their lives and health status. After an initial 2-year trial period, in 2015, the PHVP was expanded as a required yearly practicum for all undergraduate students.

In 2018, students who had participated in the PHVP in all 4 years of their undergraduate nursing program graduated. We conducted focus group interviews with senior students to examine learning outcomes across 4 years of participation in the PHVP.

Description of the Preventive Home Visits Practicum (PHVP)

1. Overview

Students were grouped in teams of four (a freshman, sophomore, junior and senior), with two faculty members for support. Teams are consolidated every year by replacing graduating seniors with freshmen (Figure 1).

Each team makes monthly or bimonthly visits to an assigned community-dwelling older adult (these participants are referred to as “collaborators”). Students and collaborators then discuss lifestyle and health, and blood pressure, weight, and grip strength are measured as needed. In consultation with their assigned faculty, the students provide advice regarding physical or cognitive exercises and diet to promote a healthy lifestyle. No medical treatment or clinical care is provided during the visits. Each visit takes approxi-

mately 1 h, and two members or more in a team visit together. Four visits or more in a year are necessary for a student. Therefore, the students in a team take turns to visit their collaborator. The collaborators live in neighborhoods or villages in the communities around the university, so students walk, drive, or take a taxi to visit their collaborator. The students can observe the environment and services nearby in transit.

Four main goals were identified to guide the students during their PHVP: 1) to understand health and living among community-dwelling older adults, 2) to contribute to the prevention of dysfunction by discussing appropriate health and wellness measures with them, 3) to comprehend community systems to support home-dwelling older adults, and 4) to learn teamwork with students of different academic grades and generations. After each home visit, the students submit a brief report to their team’s assigned faculty members. Faculty members then provide feedback to enlighten their perspectives or support their thinking and facilitate the students in accomplishing their goals. An important role of the faculty members is to encourage the students to develop their abilities and critical thinking skills during the home visits.

2. Collaborators and Visiting Area

We have administered the PHVP with the cooperation of community residents’ association leaders, officials, local governments, and public health nurses in two areas near the university, namely, areas A and B. As of December 2018, the population of area A, a residential area developed in the 1970s, was 7,278, with 39.9% aged 65 years or over, and that of area B, a mountainous rural region, was 4,315, with 44.3% aged 65 years or over.

Older residents in these two areas near the university who were aged 70 years or above were eligible to volunteer to be a collaborator in this practicum. Officials in each area initially suggested candidates as collaborators. Although collaborators are asked to commit to long-term participation,

when necessary, local leaders may also assist in seeking replacement collaborators.

Methods

This study applied a qualitative descriptive design with focus group interviews to describe longitudinal experiences and perceived outcomes for students who had completed the 4-year undergraduate nursing curriculum (Rabiee, 2004). We recruited 79 seniors (10 males and 69 females) who had participated in the PHVP throughout their undergraduate education. Eight students who had applied for the study were organized into two groups of four students each. Audio-recorded focus group interviews were conducted by the second author as a facilitator and the first author as an observer on December 2018. The two researchers who led the interviews have been managing the PHVP since 2018, and they had previously participated in the practicum as team faculty members assigned to three teams each.

All eight student participants provided written informed consent to participate in the study after receiving an explanation of the study objectives, confidentiality, and ethical considerations. Permission was also granted for the audio recording of the group interviews.

Data Generation and Analysis

Each focus group session lasted for approximately 60 min. The interviews consisted of a set of open-ended questions matching the purposes of the study. The participants were asked regarding a scene in which they felt their own growth while visiting their collaborator and what experience came for that growth. The same questions were given to each group, but the interviewers allowed the participants to expand on their answers and discuss the questions with each other. With consent from the participants, the interviews were audio-recorded and transcribed for data collection purposes.

The focus group data were then subjected to qualitative descriptive analysis. Students' narratives were read and re-read to identify the essential content. Similar ideas and underlying meanings were coded and analyzed further to develop subcategories. Subcategories were further grouped into the three categories. These categories corresponded with the original aim of the study. Thus, the quotations in the table illustrated these findings. The findings were reviewed by other faculty members who were involved in managing the PHVP to check whether the descriptions appeared consistent with the students' experiences. Bold italic font was used to indicate categories, and italic font was used to indicate subcategories.

Ethical Considerations

The study protocol was approved by the authors' university

ethics review board (authorization No.: Educational research 18-2).

Results

All participants were female. Seven participants were the same age, and one participant was older. Three participants visited a collaborator living in area A, and two participants visited a collaborator living in area B. The remaining three visited both areas as they were assigned multiple collaborators in the 4 years because of attrition.

We extracted 3 categories and 11 subcategories that describe student learning resulting from the PHVP experience. We have illustrated the results using the description by a student (students are identified as A to H) in Table 1.

Health and Aging Lives in an Aging Population

The first category describes how students developed an understanding of the health and life experiences in an aging population through their collaborators.

1. Observing Changes in the Environment

Students were able to identify changes from previous home visits as they continuously visited the same collaborator's home and developed knowledge year by year. Identifying such changes helped the students gain confidence in observing the living environment.

2. Consideration for Support Tailored to Individual Living

As students gained knowledge and built up their experiences, they developed the perspective to see both the physical and mental health or life experience of their collaborators. Thus, students contemplated what support they could offer regarding their collaborators' conditions.

3. Comprehension of Living after Hospital Discharge

Some students experienced their collaborators' hospitalization during the period of their continuous visits. Students could then witness their collaborators' physical and psychological changes after discharge, which allowed them to learn how an illness or injury affected an older person's life. This perspective is not often possible solely from practice in an in-patient setting, so these students develop a sense of patients' posthospital life.

4. Differences in Lives and Perspectives of Health

Some students' collaborators were replaced several times because of health issues or the need for family nursing care. Although we had requested longitudinal participation from the collaborators, this was not always possible. However, students expressed their gratitude for all of their collaborators and the valuable experience that they had gained during the 4 years. They felt that the more collaborators they had, the more knowledge and experience they gained.

5. Aging and Participation in Society

Because of their continuous visits, students observed the physical and mental changes of their collaborators due to

Table 1. Categories of what students learned through the preventive home visits practicum (PHVP) across 4 years.

Categories	Subcategories	Student descriptions
Health and aging lives in an aging population	1. Observing changes in the environment	<i>I could find a changed picture on a hanging scroll and the growth of flowers and vegetables that my collaborator had planted in her garden. I felt my own growth by noticing such changes. (Student B)</i>
	2. Consideration for support tailored to individual living	<ul style="list-style-type: none"> <i>I knew that my viewpoints of my collaborator changed after continuous home visits. I tried to understand my collaborator's physical and mental health, and his life. (Student C)</i> <i>I am now able to contemplate the person's lives and consider support tailored to that person's needs. (Student H)</i>
	3. Comprehension of living after hospital discharge	<i>My collaborator was hospitalized for lower back fracture. I think that I can imagine how the lives of older adults change after discharge because I learned about changes in her mind and way of life. (Student A)</i>
	4. Differences in lives and perspectives of health	<ul style="list-style-type: none"> <i>I was given the opportunity to learn about the lives and thoughts of the older people living in the community and what concerns they have about their lives through four years. (Student C)</i> <i>I learned different lifestyles and various perspectives on health through each of my collaborators. I believe that these experiences will help me in my career as a nurse. I really appreciated (this practicum). (Student E)</i>
	5. Aging and participation in society	<i>As my collaborator grew older, I learned that his way to relate to society differed from before...Only this practicum allowed us to learn that. (Student B)</i>
Interactions among team members	1. Roles on a team according to their level in their nursing educational program	<i>The more I visited my collaborators with younger members, the more I began thinking about what my role was on a team. (Student F)</i>
	2. Growth with interactions among team members	<i>I knew (recognized) my development because I could do things that a senior student (had done) for us before. (Student B)</i>
	3. Importance of discussion with team members	<ul style="list-style-type: none"> <i>I think that it was great experience to discuss what we could do with team members for our collaborator, especially the time she expressed heartache after her daughter had passed away. (Student F)</i> <i>Sharing information about a collaborator allowed us to work together as a team. (Student H)</i>
	4. Self-confidence in their nursing practice	<i>My collaborator often told me that I was able to communicate well with him and measure blood pressure properly, although I could not do any of that before. At the end, he told me that I had grown into a very fine student. (Student C)</i>
Interpersonal relationships and communication	1. Enhancing communication skills	<i>My collaborator often told us that she did not want to get older, but I did not know what to say to her at first. I gradually learned that listening closely while showing my understanding about her feelings was enough for her. (Student A)</i>
	2. Interpersonal relationships as a community member	<i>My collaborator told me about nearby shops and gave me details about the surroundings. He also asked me what I had learned at school. I think I learned how to talk to (community-) dwelling older adults who were not (in an in-patient) nursing setting through this practicum. (Student G)</i>

the aging process. Furthermore, they considered how such changes affected the participation of older adults in society.

Interactions among Team Members

The second category concerned student-to-student interactions as they served as members of multigrade level teams. Although students participate in extracurricular activities with others, they rarely work together on teams in clinical courses or settings.

1. Roles on a Team according to Their Level in Their Nursing Educational Program

Each student visited their collaborator with one or more team members from a different grade. They gradually became aware of what would be expected when they became the senior member of a team. Therefore, leadership skills developed naturally.

2. Growth with Interactions among Team Members

Students recognized their growth as they matured in the program and found that their skills had been nurtured by other team members. They understood that they had gained confidence through this process.

3. Importance of Discussion with Team Members

After each home visit, we encouraged the students to share the observations they had made with their team members and to discuss what they had learned and thought regarding the time spent with the collaborator. As a result, they acquired differing points of view from their team members.

4. Self-confidence in Their Nursing Practice

The collaborators were found to serve in a support role to facilitate their students' growth and improvement. Their words encouraged students and gave them confidence.

Interpersonal Relationships and Communication

A third category reflected building communication skills through formed relationships. Interpersonal relationships were stressed during the practicum team meetings and discussions. The group discussions strengthened the students' communication skills with peers, faculty, and collaborators.

1. Enhancing Communication Skills

Students described feeling too nervous to communicate with their collaborator at first. However, over time, they learned the importance of listening closely and empathizing. Subsequently, they became more comfortable and developed better communication with their collaborator and other older people.

2. Interpersonal Relationships as a Community Member

Collaborators taught students a lot regarding their community and surroundings. Over the period of the visits, they demonstrated that in their words, "their hearts went out to these students." In turn, this atmosphere encouraged students to learn how to relate to community-dwelling older adults.

Discussion

In the present study, we verified that visits to community-dwelling older adults provided students with essential learning considered necessary for their future nursing practice. A review by Hsieh and Chen (2018) reported that geriatric and long-term care contents in undergraduate nursing curricula can effectively enhance students' nursing competence. In the present study, we found that collaborators' physical and mental changes over continuous visits broadened students' views on aging and caring for older adults (Redfield et al., 2016). We assume that continuous visits across time deepened student knowledge of the aging process, health, and environment because they could witness changes and hear regarding lived experiences and feelings from their collaborators.

Furthermore, in contrast to in-patient or acute care clinical setting practicums, older adults can take the lead in conversations in the PHVP. As described by Walton and Blossom (2013), students experience the welcoming presence and hospitality of older adults as they gradually engage with their collaborator, gaining confidence along the way. As Reitmaier et al. (2015) concluded, a practicum involving community-dwelling older adults as partners in student learning enhanced intergenerational understanding. This intergenerational exchange in the PHVP helps students develop not only as nurses but also as human beings. The wide range of topics that students discuss with their collaborators can lead them to reflect on their own lives and, as mentioned by Eaton (2015), to provide motivation for their nursing studies.

The present evaluation study revealed that interactions

with other students in different grade levels in nursing education improved student learning and work effectiveness. This finding is in agreement with the research reported by Pålsson et al. (2017), where peer learning was found to be a useful method for improving nursing students' self-efficacy. Senior students could begin to serve as mentors on a team, which, in turn, might stimulate their motivation. We presume that interactions among team members have the same effect as the findings reported by Gonzalez et al. (1999), where collaborative alliances with faculty and registered nurse preceptors in home health enabled students to view the new practicum environment as a meaningful learning experience. As teamwork is an essential competency in health care, we believe that the PHVP and faculty mentoring can have a positive influence on students' later development as graduate nurses working on multidisciplinary teams.

According to the results of previous research on the PHVP conducted at the early stage of introduction, students acquired multiple perspectives for understanding older adults, such as wellness, prevention, community life, and team practicums (Iwasaki et al., 2019). In the present study, we observed enriched student learning and were able to describe ways in which students further developed their perspectives on community-dwelling older adults. The long-term perspective gained from graduating students who had experienced the practicum over time clarifies the relationship with the achievements of the purposes of the practicum.

This study had two major limitations. First, as we only interviewed a small number of students, our findings may not fully reflect the learning that occurred through the PHVP or its potential difficulties. Second, the students might have been prompted to provide socially adequate responses because of the face-to-face nature of the interviews conducted by the faculty. We propose further educational evaluation research with larger sample sizes and different designs to identify additional outcomes and possible pitfalls of the PHVP regarding nursing students, community-dwelling older adults, and undergraduate nursing education. Despite this limitation, it should be noted that continuous visits to community-dwelling older adults enabled students to increase their knowledge and develop their perspectives. It remains highly likely that the role of nursing will continue to expand in community settings, so nurse educators must be prepared to take a leading role in the development of educational strategies.

Conclusion

The results of the present research suggest that visiting community-dwelling older adults during a nursing practicum may make an important educational impact on nursing students as future nurses. This study is a part of a series of investigations into the PHVP that may have implications for

improving undergraduate nursing education and equipping future nurses to anticipate and address a super-aging society.

Author Contributions

Conceptualization, A.S., A.O., T.K., J.K.M, and S.M.; methodology, A.S. and A.O.; formal analysis, A.S. and A.O.; investigation, A.S. and A.O.; data curation, A.S., A.O., and T.K.; writing-original draft preparation, A.S.; writing-review and editing, A.S., A.O., T.K., J.K.M, and S.M.; supervision, T.K., J.K.M, and S.M.; funding acquisition, T.K. All authors have read and agreed to the published version of the manuscript.

Declaration of Conflicting Interests

The authors declare that they have no competing interests.

Ethical Approval

The study protocol was approved by the Committee on Research Ethics and Safety of Oita University of Nursing and Sciences. Authorization number: Educational research 18-2.

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Brief Report

The relationship between sense of coherence, occupational stress, organizational climate, identity, and mental health of newly graduated nurses in a specified functional hospital (secondary publication)

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Abstract

Objectives: The purpose of this study is to examine the sense of coherence (SOC), occupational stress, organizational climate, and identity of new graduate nurses in a specified functional hospital to identify factors related to mental health. It will also identify the relationship between SOC and generalized resilience resources. **Methods:** This study employed a self-completion questionnaire on SOC (29 items), an identity scale (20 items), a job content questionnaire (22 items), an organizational climate scale (12 items), and a general health questionnaire (GHQ; 12 items) among 105 new graduate nurses in specialized hospitals. **Results:** A multiple regression analysis was performed with each subscale of the GHQ-12 and SOC-29 as dependent variables. The mental health of new graduate nurses was found to be strongly associated with their SOC. Furthermore, the organizational environment and basis of identity contributed to a sense of comprehensibility, which is a factor in SOC. A sense of manageability and meaningfulness is also related to the basis and establishment of identity. **Conclusions:** Increasing SOC as a mental health measure for new graduate nurses is pivotal. Thus, creating an organizational environment may strengthen SOC.

Keywords

sense of coherence, mental health, occupational stress, organizational climate, new graduate nurses

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Introduction

New graduate nurses often face stressors such as reality shock and transition shock (Al Awaisi et al., 2015; Labrague & McEnroe-Petitte, 2018), which can lead to mental health problems and early turnover (Rudman et al., 2014). Mental health problems are particularly serious for new graduate nurses who join hospitals that provide highly ad-

vanced medical care (Satoshi Ikeda, 2020). The effects of stress on mental health are determined by an individual's stress tolerance and other factors. SOC (Antonovsky et al., 2001), the perception of coherence around an individual, has been shown to positively impact an individual's ability to cope with stress. Early adulthood, which applies to most new graduate nurses, is a critical period in which job characteristics and the work environment play an important role

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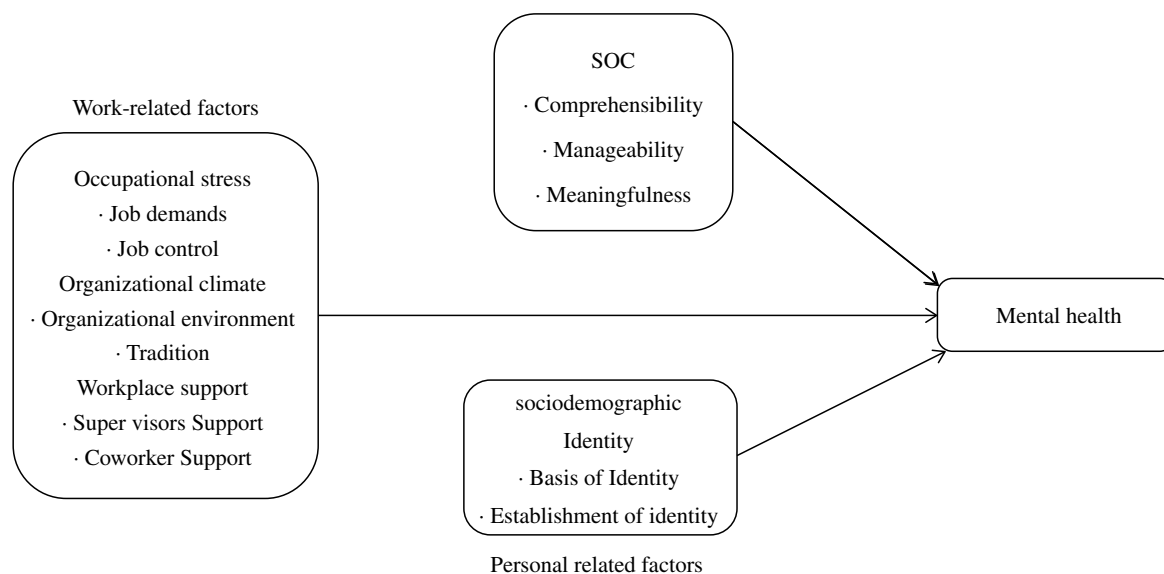


Figure 1. Factors associated with mental health (conceptual framework).

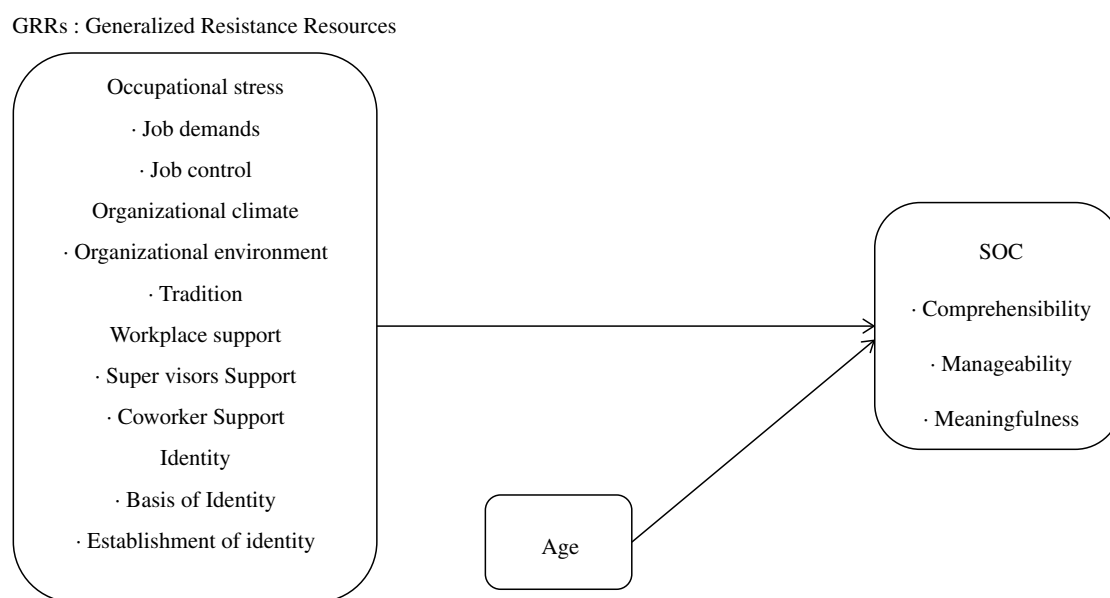


Figure 2. Factors related to SOC (conceptual framework).

in the development of SOC (Antonovsky et al., 2001). Thus, mental health interventions in nursing should address workplace and individual stressors and create healthy work environments that promote SOC (Langius et al., 1992).

Previous research on SOC among nurses has shown that it is strongly associated with mental health, including stress, depression, burnout, and PTSD, including work-related and personal factors (Michele Masanotti et al., 2020). Only a few studies have examined the factors that influence each dimension of SOC (comprehensibility, manageability, and meaningfulness); however, it has been suggested that a communicative organizational climate, adequate workload, and opportunities for participation and career advancement in-

crease SOC (Kretowicz & Bieniaszewski, 2015). Most existing studies on SOC have focused on nurses in general, with only a handful focusing on new graduate nurses. A prior study has found that SOC in early adulthood, during which nursing students graduate, is thought to be influenced by the identity developed in childhood and adolescence (Antonovsky et al., 2001), and a favorable organizational climate may enhance SOC (Feldt et al., 2000). This study focuses on SOC, its relationship with mental health, and the factors affecting SOC among new graduate nurses.

This study examined the relationship between work-related factors, personal factors, SOC, and the mental health of new graduate nurses in hospitals. To examine the rela-

relationship between SOC and mental health, a model that included personal and work-related SOC as independent variables was constructed. The hypothesis for this study objective is that SOC is most strongly related to mental health and that the higher the SOC, the better the mental health (Figure 1). The second objective was to determine the relationship between work-related and personal factors and SOC development. The framework used was a salutogenesis model (Antonovsky et al., 2001), which posits that generalized resistance resources (GRRs), such as individual identity, occupational stress, organizational climate, and job support, are related to SOC development. The hypothesis for this study objective is that individual identity is strongly related to SOC and that occupational stress, organizational climate, and job support also play a role in SOC development (Figure 2).

Materials and Methods

Participants

A convenience sample of 320 new graduate nurses from five Japanese hospitals with specific functions was used. Survey forms were sent to these facilities and distributed by nursing managers who requested anonymous completion. The survey instrument comprised 101 items and took 20-30 min to complete, and the completed survey form was returned. Data was collected from October 2013 to November 2013.

Measurement Tools

The General Health Questionnaire-12 (GHQ-12)

The GHQ measures depression- and nervousness-related illnesses using a 12-item scale (Goldberg et al., 2013). Developed in the UK by Goldberg (1978), it uses the Likert method (0-1-2-3) for scoring. The total score evaluates mental health, with higher scores indicating poorer mental health.

Identity Scale

The identity scale, developed by Shimoyama (1992), measures one's identity through two subscales: establishment of identity and basis of identity. The basis of identity reflects insecurity and loneliness, whereas the establishment of identity expresses independence and confidence. The four-case method was used to ask the questions. The total score was used as the score for each subscale. The reliability and validity of the scale were evaluated.

SOC-29

The SOC-29 was developed by Antonovsky (1987/2001) and validated for reliability and validity in Japanese by Yamazaki (2001). It comprises three subscales: comprehensibility, manageability, and meaningfulness. Scores were calculated by adding the rate (1-7) of the responses to each item.

Job Content Questionnaire-22 (JCQ-22)

Developed by Karasek (1985), the JCQ-22 was evaluated for

reliability and validity by Kawakami and Fujigaki (1996). It comprises 22 items scored on a 1-4 scale, measuring job demands, job control, supervisor support, and coworker support. Higher scores indicated greater job demands, job control, supervisor support, and coworker support.

The 12-Item Organizational Climate Scale (OCS-12)

The 12OCS-12 (Fukui et al., 2004) measures an organization's climate and comprises two subscales: tradition and organizational environment. An organizational environment refers to a climate in which the rules and norms outlined in the organization are clear and rational, and organizational management is conducted with a high degree of staff participation. Higher scores indicate a higher level of tradition or a more favorable organizational environment.

Sociodemographic Factors

The six sociodemographic information items were sex, age, basic nursing curriculum, hospital department, workplace, and night shifts.

Statistical Analysis

Descriptive statistical tables were prepared for the sociodemographic information of the participants. The mean, standard deviation, minimum and maximum values, and Pearson's correlation coefficients for each scale and subscale were calculated. Cronbach's alpha was calculated for the internal consistency of each scale, and only values greater than 0.6 were used in multiple regression analysis: (1) for hierarchical multiple regression analysis with GHQ-12 as the dependent variable, with the total SOC score as the main independent variable and other factors such as sex, education, work location, and identity as additional independent variables; and (2) for multiple regression analysis, each SOC-29 subscale was used as the dependent variable, considering variables that showed significant correlation with the subscales and the effect of age as an independent variable. The IBM SPSS statistics software for Windows (version 24; IBM Corp.) was used to conduct the statistical analyses. Statistical significance was set at $p < .05$.

Ethical Considerations

Approval was obtained from the Research Ethics Committee of Fukuoka Prefectural University and the director of the collaborating institution for the study using a survey form (approval date: July 12, 2013, no approval number provided).

Results

Sociodemographic Factors

Data from 107 participants were collected (collection rate: 33.4%), out of which, 105 were included in the analysis with a mean age of 22.9 ± 1.8 years; 102 (97.1%) were females, and 92 (87.6%) were college graduates. Table 1

Table 1. Participants' sociodemographic factors ($n = 105$).

		<i>n</i>	%	<i>M</i>	<i>SD</i>
Gender	Male	3	2.9		
	Female	102	97.1		
Age				22.9	1.8
Basic Nursing Curriculum	High School (Hygiene and Nursing)	4	3.8		
	Vocational school	9	8.6		
	University	92	87.6		
Department	Internal medicine department	17	16.2		
	Surgical department	39	37.1		
	Mixed (Internal medicine/surgical)	30	28.6		
	Psychiatry department	4	3.8		
	Other departments	15	14.3		
Workplace	Hospital ward	99	94.3		
	Other	6	5.7		
Night shift	Two-shift	80	76.2		
	Three-shift	22	21.0		
	No night shift	3	2.9		

shows other sociodemographic factors.

Mean, Standard Deviation, Minimum and Maximum Values, Pearson's Correlation Coefficient, and Cronbach's α for Each Scale and Subscale

Table 2 shows the mean, standard deviation, minimum and maximum scores, Pearson's correlation coefficient and Cronbach's α for each scale and subscale.

SOC-29, Scores for Comprehensibility, Manageability, and Meaningfulness

The SOC-29 mean score was 120.3 ± 6.5 , with mean scores of 40.2 ± 8.7 for comprehensibility, 44.1 ± 8.7 for manageability, and 36.4 ± 8.1 for meaningfulness.

Correlation between GHQ-12 and Each Scale

The GHQ-12 had strong negative correlations with SOC-29 ($-.68$), manageability ($-.63$), meaningfulness ($-.61$), basis of identity ($-.57$), and comprehensibility ($-.55$), in order of increasing correlation coefficients ($p < .001$ for all).

SOC-29, Comprehensibility, Manageability, Meaningfulness, and Correlations among the Scales

The strongest positive correlation with SOC-29 was found to be with the basis of identity ($r = .81$, $p < .001$), followed by the establishment of identity ($r = .59$, $p < .001$). For the SOC-29 comprehensibility subscale, coworker support ($r = .36$, $p < .001$) and organizational environment ($r = .34$, $p < .001$) had moderately positive correlations. Regarding manageability, job control ($r = .45$, $p < .001$) and coworkers' support ($r = .42$, $p < .001$) showed moderately positive correlations. For

meaningfulness, job control ($r = .49$, $p < .001$), coworker support ($r = .38$, $p < .001$), and supervisor support ($r = .31$, $p = .002$) had moderately positive correlations with increasing correlation coefficients.

Cronbach's α for Each Scale and Subscale

Cronbach's α for job control was low (0.47), so it was excluded from the regression analysis. Organizational environment (0.67) and tradition (0.63) were acceptable as independent variables. All other variables had a Cronbach's α greater than 0.7.

Hierarchical Multiple Regression Analysis with the GHQ-12 as the Dependent Variable

A hierarchical multiple regression analysis was conducted to examine the relationship between the GHQ-12 and various independent variables, including those that showed a significant correlation with the GHQ-12. In Step 1, sociodemographic factors and significant variables were used, except for SOC-29. In Step 2, the SOC-29 was added to the equation (forced entry method), resulting in a higher goodness of fit (adjusted $R^2 = .532$). The results showed that SOC-29, establishment of identity, and three-night shifts (compared with two-night shifts) were associated with the participants' mental health. There was no multicollinearity, and the residuals were normal (Durbin-Watson ratio = 2.092). Table 3 shows more detailed results.

Multiple Regression Analysis with Comprehensibility, Manageability, and Meaningfulness as Dependent Variables

Table 4 shows the detailed results of a multiple regression

Table 2. Mean, standard deviation, minimum and maximum values, Pearson's correlation coefficient, and Cronbach's α for each scale and subscale.

	1	2	3	4	5	6	7	8	9	10	11	12	M	SD	min.	max.	Cronbach's α
1. GHQ-12													20.0	22.3	4.0	34.0	.85
2. Basis of Identity	-.57***												22.8	4.9	11.0	35.0	.83
3. Establishment of identity	-.49***	.53***											25.9	4.5	11.0	39.0	.87
4. SOC-29	-.68***	.81***	.59***										120.3	6.5	76.0	182.0	.92
5. Comprehensibility	-.55***	.72***	.38***	.84***									40.2	8.7	21.0	65.0	.79
6. Manageability	-.63***	.74***	.54***	.95***	.72***								44.1	8.7	25.0	62.0	.82
7. Meaningfulness	-.61***	.67***	.64***	.85***	.49***	.77***							36.4	8.1	14.0	55.0	.85
8. Job demands	.35***	-.19*	-.10	-.22*	-.24*	-.20*	-.16						38.8	5.1	24.0	48.0	.71
9. Job control	-.41***	.34***	.38***	.46***	.29**	.45***	.49***	-.18					69.4	8.1	48.0	90.0	.47
10. Supervisor support	-.40***	.24*	.17	.33**	.25*	.31**	.31**	-.33**	.39***				12.7	2.4	4.0	16.0	.92
11. Coworker support	-.48***	.33**	.24*	.44***	.36***	.42***	.38***	-.25*	.45***	.66***			12.6	2.1	7.0	16.0	.78
12. Organizational environment	-.31**	.20*	.21*	.33**	.34***	.30**	.22*	-.17	.23*	.33**	.30**		10.8	1.5	6.0	12.0	.67
13. Tradition	.34***	-.16	.03	-.18	-.21*	-.18	-.10	.43***	-.34**	-.51**	-.47**	-.06	8.4	1.5	6.0	11.0	.63

* $p < .05$, ** $p < .01$, *** $p < .001$

analysis. The dependent variables are comprehensibility, manageability, and meaningfulness.

Factors Related to Comprehensibility

A multiple regression analysis was conducted, with comprehensibility as the dependent variable; and age and seven significant variables (Basis of Identity, Establishment of identity, Job demands, Supervisor support, Coworker support, Organizational environment, and Tradition) as independent variables. Basis of identity ($\beta = .654$, $p < .001$) and organizational environment ($\beta = .184$, $p = .014$) were associated with comprehensibility. The fit of the regression equation was satisfactory ($R^2 = .574$, adjusted $R^2 = .539$), no multicollinearity was observed, and the Durbin-Watson ratio was 1.924.

Factors Related to Manageability

A multiple regression analysis was conducted, with age and six variables significantly correlated with manageability (Basis of Identity, Establishment of identity, Job demands, Supervisor support, Coworker support, and Organizational environment) as independent variables. The results showed that the basis ($\beta = .584$, $p < .001$) and establishment of identity ($\beta = .164$, $p = .029$) were associated with manageability, and the goodness of fit was high ($R^2 = .630$, adjusted $R^2 = .603$). No multicollinearity was found, and the Durbin-Watson ratio was 2.076, indicating no issues with the residuals.

Factors Related to Meaningfulness

A multiple regression analysis was conducted, with age and five variables significantly correlated with meaningfulness (Basis of Identity, Establishment of identity, Supervisor support, Coworker support, and Organizational environment) as independent variables. The results showed that both the basis of identity ($\beta = .422$, $p < .001$) and the establishment of identity ($\beta = .372$, $p < .001$) were significantly related to meaningfulness. The model had a high goodness of fit, with an R^2 value of .591 and an adjusted R^2 of .566. Additionally, there was no evidence of multicollinearity among the independent variables. A Durbin-Watson ratio of 2.155 also confirmed the absence of unusual patterns in the residuals.

Discussion

This study found that SOC, the establishment of identity, and working three shifts are related to mental health, and that mental health and SOC have a strong relationship. Identity is strongly related to SOC factors. Additionally, a strong organizational environment is related to high levels of comprehensibility. These results support part of Antonovsky's salutogenesis model (Antonovsky et al., 2001).

Table 3. Hierarchical multiple regression analysis with GHQ-12 as a dependent variable.

		GHQ-12			
		Step 1		Step 2	
		β	VIF	β	VIF
Personal related factors	Gender*1	.068	1.131	.080	1.136
	Age	.048	1.718	.075	1.744
	High School (Hygiene and Nursing) * ²	.002	1.058	.024	1.074
	Vocational school* ²	-.008	1.418	.020	1.445
	Internal medicine* ³	-.085	1.369	-.060	1.453
	Mixed (Internal medicine/surgical) * ³	-.036	1.429	.025	1.641
	Psychiatry* ³	.019	1.286	.019	1.293
	Other department* ³	-.121	1.830	-.090	1.868
	Workplace* ⁴	.233*	2.694	.195	2.747
	Three-shift* ⁵	.199*	1.119	.167*	1.153
	No night shift* ⁵	-.140	2.676	-.134	2.677
	Basis of Identity	-.315**	1.650	-.093	3.376
Establishment of identity	-.236**	1.544	-.179*	1.659	
Work-related factors	Job demands	.163	1.453	.152	1.458
	Supervisor support	-.018	2.185	-.015	2.186
	Coworker support	-.199*	2.044	-.144	2.151
	Organizational environment	-.041	1.401	-.017	1.421
	Tradition	.081	1.969	.086	1.970
	SOC-29			-.348*	4.228
R^2		.589***		.617***	
Adjusted R^2		.503***		.532***	
Δ adjusted R^2		.029			

* $p < .05$, ** $p < .01$, *** $p < .001$ β : standard partial regression coefficients, R^2 : coefficient of determination, VIF: Variance Inflation Factor

*1 Gender (0 = Male, 1 = Female)

*2 Reference category is University

*3 Reference category is Surgical

*4 Workplace (Ward = 0, Other = 1)

*5 Reference category is two shifts

Table 4. Multiple regression analysis with comprehensibility, manageability, and meaningfulness as dependent variables.

	Comprehensibility		Manageability		Meaningfulness	
	β	VIF	β	VIF	β	VIF
Age	.082	1.084	.098	1.050	.074	1.040
Basis of Identity	.654***	1.508	.584***	1.502	.422***	1.482
Establishment of identity	-.025	1.487	.164*	1.440	.372***	1.438
Job demands	-.046	1.323	-.001	1.154		
Supervisor support	-.092	2.071	.003	1.911	.070	1.821
Coworker support	.121	1.989	.165	1.884	.118	1.884
Organizational environment	.184*	1.207	.092	1.179	-.012	1.177
Tradition	-.077	1.764				
R^2	.574***		.630***		.591***	
Adjusted R^2	.539***		.603***		.566***	

* $p < .05$, *** $p < .001$ β : standard partial regression coefficients, R^2 : coefficient of determination, VIF: Variance Inflation Factor

Characteristics of the SOC of the Study Participants

The mean SOC-29 score (120.3 ± 6.5) of the study participants was lower than that of the general adult population but close to the mean scores of junior college students and college students (Togari et al., 2008; Tsuno & Yamazaki, 2007).

Factors Related to the Level of Mental Health

Mental health was associated with factors such as SOC, the establishment of identity, and three shifts. The SOC showed the strongest relationship with mental health, suggesting that a higher SOC could improve mental health. Although previous studies have shown a relationship between occupational identity and mental health (Inaba et al., 2017), the establishment of identity in this study reflects the degree of self-initiative and self-confidence and is not limited to occupational identity. Compared with two-shift work, three-shift work is associated with higher cumulative fatigue and mental fatigue (Sato et al., 2002; Nakayama & Sato, 2004). In addition, shift work with a strong sense of job strain leads to sleep disturbance (Karhula et al., 2013). Shift work is an important factor in the mental health of new graduate nurses.

Factors Related to the Development of a Sense of Comprehensibility

This study suggests that the organizational environment and basis of identity play a crucial role in the development of a sense of comprehensibility in new graduate nurses. A stable sense of self and workplace with clear rules, goals, and a rational management style leads to higher comprehensibility. Consistency and appropriate feedback from coworkers and management are thus important for a sense of comprehensibility, and specific feedback on work and progress toward goals and objectives set by the organization are key evaluation items (Antonovsky et al., 2001). The study also showed a strong relationship between SOC and a good organizational environment, highlighting the significance of the relationship between SOC and a sense of comprehensibility.

Factors Related to the Development of a Sense of Manageability

These results suggest that the basis and establishment of identity are related to a sense of manageability. A balanced workload and the use of GRRs, such as knowledge, skills, and support from coworkers, can lead to a sense of manageability (Antonovsky et al., 2001). The degree of job control may also play a role in the sense of manageability, as it allows employees to adjust their workload balance; however, the relationship between job control and the sense of manageability needs further investigation.

Factors Related to the Development of a Sense of Meaningfulness

The higher the basis and establishment of identity, the higher the sense of meaningfulness. A prior study found that only a sense of meaningfulness is related to identity (Dobeta, 2020), and Antonovsky's salutogenesis model suggests that participation in decision-making is important for the development of a sense of meaningfulness (Antonovsky et al., 2001). Therefore, a work environment that allows employees to participate in decision-making is believed to increase their sense of meaningfulness. Job control has been suggested to be associated with the development of meaningfulness (Takeuchi et al., 2009), but it could not be implemented in this study. Further studies are needed to examine the relationship between a sense of meaningfulness and job control.

Limitations and Problems of the Study

This study has three main limitations: a small sample size, a limited target area, and outdated data. These limitations limit the generalizability of the results. Additionally, as this was a cross-sectional study, the influence of the results could not be accurately determined. Job control, an important factor in mental health and SOC, could not be used as an independent variable because of the low reliability of the scale. To improve the results, it is thus necessary to increase the sample size, conduct longitudinal studies, and consider the number of questions and scale selections.

Conclusions

The SOC was strongly related to the mental health of new graduate nurses working in hospitals with specific functions, and the factors related to the development of the SOC were largely due to the individual identity that developed from infancy to adolescence, while a high organizational environment was related to the development of a sense of comprehensibility.

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Author Contributions

SI conceived the study, designed the study, collected the data, analyzed and interpreted the data, drafted the manuscript, and critically revised important intellectual content.

Declaration of Conflicting Interests

There are no conflicts of interest related to this study.

Ethical Approval

This study was approved by the Ethics Review Committee of Fukuoka Prefectural University [approval date: July 12, 2013, without an individual approval number].

Informed Consent

Informed consent was obtained from all participants involved in this study.

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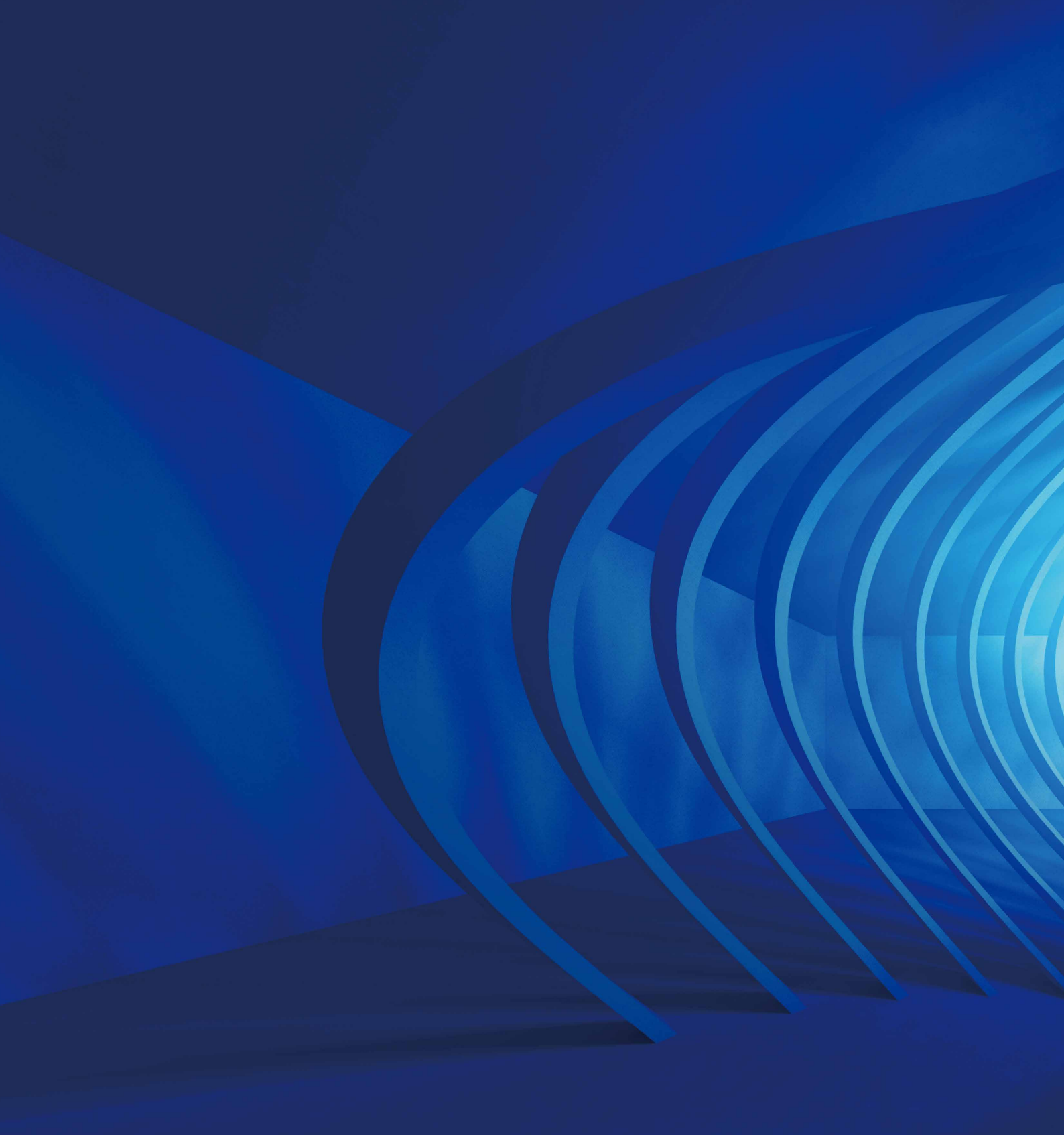
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