



Original Article

Nurse-led coaching of shared decision-making for wound treatment of pressure injury: A pilot study of a randomized trial

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ABSTRACT

Objectives: International guidelines for managing pressure injury (PI) and ulcers recommend that family members and caregivers should be involved in making decisions for appropriate wound care. However, the effect of shared decision-making (SDM) in the context of PI remains unknown. This study investigated the efficacy of nurse-led medical SDM for PI treatment. **Materials and Methods:** We constructed a patient decision aid (PDA) for PI treatment on the basis of nursing evidence. Subsequently, we conducted a pilot randomized controlled trial to evaluate the efficacy of SDM compared with that of usual care (control group, [CG]) for PI treatment. Participants with stage 3, stage 4, or unstageable PI were included and randomized into two groups. In the SDM group (SDMG), 10 participants received the SDM intervention for PI before treatment. All participants were followed up for 4 weeks. Primary outcomes were measured using the nine-item SDM Questionnaire (SDM-Q-9) and Decisional Conflict Scale (DCS). Secondary outcomes included wound size and cost of wound management. **Results:** The expert validity (medical professors and general population) of the PDA designed for PI was measured, and the content validity index was 0.96–0.97. A total of 20 participants were enrolled (10 received SDM and 10 received usual care). The mean age of the participants was 55.7 ± 8.8 years. No significant difference in baseline characteristics (sex, age, staging, or wound area) was observed between the two groups. The SDMG had higher SDM-Q-9 ($P < 0.001$) and DCS ($P < 0.01$) scores than did the CG. For the secondary outcomes, the SDMG had a decreased change of wound size and lower wound management costs than did the CG; nevertheless, the differences were not statistically significant. **Conclusion:** We constructed a PDA for PI treatment, which can be applied in clinical care. The pilot test results revealed that the participants had a lower cost related wound treatment and decreasing wound size in SDMG than CG after the intervention of SDM-PI for 4 weeks. In the future, clinical studies should conduct large-scale randomized trials based on the results of this pilot study.

KEYWORDS: Decision-making, Nurse-led coaching, Patient decision aid, Pressure injury, Wound treatment

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INTRODUCTION

Pressure injury (PI) is a localized alteration in skin, mucous membranes, and/or underlying tissues caused by prolonged unrelieved pressure, with or without the presence of other contributing factors or predisposing physiologic impairments [1]. About 12% incidence of PI in hospital has been reported from a meta-analysis [2]. Patients with PI have an increased risk of infection, a prolonged hospitalization duration, and high hospitalization costs [3]. A study reported that the medical cost burden for treating patients with \geq stage 3 PI was 1.5 times higher than that for patients with stage 1 or 2 PI; the average medical cost for treating patients


with \geq stage 3 PI was US\$3,616 per month [4]. Moreover, compared with those receiving home-based care, older people hospitalized for PI had higher medical costs, which increased with the stage of PI [5]. Therefore, reducing the wound healing duration, preventing complications, and improving medical and social resources are crucial. Evidence-based

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guidelines are available for the prevention and management of PI [6,7].

A care team involving patients, family members, and caregivers is required for effectively managing PI. Patients with PI should be involved in the development of a care plan for PI [4]. In addition, family members and caregivers should participate in the process of shared decision-making (SDM) [4]. According to the guidelines, \geq stage 3 PI requires not only surgical intervention but also moderate surgical debridement, mechanical debridement, traditional dressing, and autolysis [4-6]. Although various treatment modalities for PI have been suggested, evidence for choice sequences is not available. Therefore, the implementation of SDM for PI care involving the patient and medical staff can aid in achieving the most favorable treatment outcomes.

Studies on PI have yet to examine SDM interventions. Although studies have examined the efficacy of SDM in the treatment of other diseases, they have reported inconsistent results. A systematic review of 39 studies reported improved affective, cognitive, behavioral, and health outcomes in patients after the implementation of SDM; these outcomes were self-reported by patients and assessed by physicians using objective assessment methods. However, because most of these have been observational studies, the relationship between SDM intervention and behavioral and health outcomes could not be demonstrated [8]. Moreover, a review study searched five databases for randomized and nonrandomized trials, controlled before–after studies, and interrupted time series studies including a total of 45,641 patients and 3,113 health care professionals; the study reported that compared with usual nursing care, SDM did not reduce decision regret, improve physical and mental health–related quality of life, or reduce consultation length and costs [9]. Therefore, inconsistent findings have been reported regarding the efficacy of SDM.

A systematic review examined studies on the efficacy of patient decision aids (PDAs) as the intervention; the reviewed studies included a total of 105 PDAs and 31,043 patients. The results revealed that compared with usual nursing care, PDA intervention could improve decision-makers' knowledge [10]. Therefore, the use of appropriate PDAs can increase the efficacy of SDM.

Studies have examined the efficacy of SDM in the intervention of surgery [11], in type 2 diabetes [10], in dementia [12], in obstetrics and gynecology [13], in and breast cancer [14]; however no randomized control trial (RCT) has examined the efficacy of SDM intervention for the treatment of wounds or PI. Although various treatment modalities are available for hospitalized patients with PI, PDAs are not available to guide patients or their caregivers to participate in SDM and select the most favorable treatment method. Accordingly, the present study investigated the efficacy of nurse-led medical SDM for PI.

MATERIALS AND METHODS

In this pilot RCT, we recruited patients with \geq stage 3 or unstageable PI to examine the efficacy of SDM in the treatment of PI.

Participants

Between October 01, 2019, and December 15, 2019, we enrolled participants from a medical center in eastern Taiwan. We included patients who had stage 3, 4, or unstageable PI; were aged older than 20 years; had the ability to read or understand Mandarin; and had made no decision regarding the treatment for PI. The caregivers were enrolled for participant if the patients without ability for decision. We excluded participants who had any critical illness, pregnant, or did not have the ability or a caregiver to discuss medical decisions.

Patient decision aid tool

Based on empirical evidence, the research team constructed a PDA tool for SDM for PI treatment. The PDA tool was developed after two-stage testing and modification and included information regarding SDM for the prevention and care of PI. The PDA tool included a color figure, photos, and QR codes. The content validity of the PDA tool was evaluated by 10 experts in wound care and 10 people with chronic wound in accordance with the first edition of health-related teaching materials provided by Taiwan's Ministry of Health and Welfare. The PDA tool was assessed from seven aspects: content, language, style, organization and editing, numerical reading, visual image and layout, and design. A total of 21 questions related to the seven aspects were reviewed. In the PDA tool, compliance and noncompliance were assigned a score of 1 and 0, respectively. No score was assigned for unsuitable evaluation. For the PDA tool, the content validity index (CVI) calculated by the 10 experts was 0.97, and that calculated by the 10 persons was 0.96.

Allocation concealment

After the completion of baseline interviews, the participants provided informed consent (Research Ethics Committee, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, No. IRB107-251-B); subsequently, the participants were randomized into the SDM group (SDMG, $n = 10$) and control group (CG, $n = 10$). An independent statistician generated a random sequence and allocated a random number to the participants for inclusion in either group.

Interventions and implementation blinding

SDM nursing coaches implemented the SDM intervention. A wound, ostomy, and continence nurse (WOCN) and a senior nurse were included as nursing coaches. For SDM coaching, the PDAs (PDA for PI shown in e-appendix) and a three-talk model based on “team talk,” “option talk,” and “decision talk” were used [15]. The process of SDM was led by nurse and the decision was discussed after team talking including physician, nurse, participant (patients or caregiver).

The participants in the CG received usual care, including medical condition explanation, health education, and health education materials. The patients were assessed and asked to complete questionnaires immediately after the start of this study (T0), at the 2-week follow-up (T1), and at the 4-week follow-up (T2). To reduce the risk of bias, data collection and analysis were performed by research assistants who were not part of the research team or participating teams by using instruments that were not part of the intervention.

Outcomes

Shared decision-making quality

SDM quality was measured using a questionnaire on the effect of the PDA. The questionnaire included 15 items that were rated on a Likert scale from 1 to 5, with higher scores indicating a positive experience about the use of the PDA tool for SDM and the usefulness of the tool for SDM. In addition, two semi-open questions were posed to obtain the participants' opinions about the inclusion of the patient or caregiver in the SDM process [16]. The questionnaire was administered to the participants in the SDMG at T1.

Decisional conflict was evaluated using the SURE test, which is a four-item checklist designed to examine clinically significant decisional conflict in clinical practice. The total score of the SURE test is 4, and a score of <4 indicates that the patient may experience decisional conflict [17]. The participants in both groups were administered the SURE test at T1.

The nine-item SDM Questionnaire (SDM-Q-9) was used to assess the effect of SDM; the patient and physician versions of the questionnaire were used. The nine items are rated on a 6-point Likert scale ranging from 0 to 5 [18]. The participants in both groups completed the SDM-Q-9 at T1.

Clinical effects

The clinical outcome was evaluated the costs related wound treatment and wound size. The outcomes recorded were those incurred for wound treatment including dressing, surgery, and outpatient follow-up. Information regarding costs was obtained from the hospital database as well as from patients and caregivers for 4 weeks.

The total of cost related wound treatment was from in hospital and home care. The costs related wound in hospital care included the skill of wound care (the skill of wound change dressing, detriment, and surgery), dressing and material for wound care. The cost related wound care at home included home visit by nurse or physician (visit fee and fare) and material for wound care. Furthermore, the number of times for wound change dressing was calculated and compared between two groups.

The size of wound (cm) was measured for the clinical effect and recorded at T0, T1 (week 2) and T2 (week 4).

Statistical analysis

Analyses were based on the intention-to-treat principle. Sociodemographic and clinical characteristics were evaluated using descriptive statistics. Differences in sociodemographic and clinical characteristics between the two groups were examined using the Mann–Whitney *U* test for continuous variables and the Kolmogorov–Smirnov test for categorical variables. A generalized estimating equation (GEE) model was used to examine time and group differences in changes in wound size. If participants had answered at least 80% of the items on a questionnaire, missing items were imputed using the mean value of the completed items. The outcomes were analyzed on the basis of the hypothesis with a two-tailed significance level of 0.05. All analyses were performed using SAS 9.4.

RESULTS

Participant recruitment

We conducted the participant recruitment between October 2019 and December 2019. All measurements were completed in January 2020. A total of 20 participants (10 in the SDMG and 10 in the CG) were included in the trial, and all participants completed the follow-up.

Characteristics

Table 1 lists the participants' characteristics. The average age of the participants was 57 years in the SDMG and 55 years in the CG ($P = 0.481$). Female individuals constituted 50% of the participants in both groups ($P = 1.00$). No difference in the level of education was noted between the groups ($P = 0.400$). Furthermore, 5 participants in the SDMG and 3 in the CG had stage 3 PI, 3 participants in the SDMG and 5 in the CG had stage 4 PI, and 2 participants in the SDMG and 2 in the CG had unstageable PI ($P = 0.356$). After

Table 1: Participant's characteristics (n=20)

	SDMG (n=10)	CG (n=10)	P
Age (years), n (%)	57 (9.8)	55 (6.8)	0.481 ^a
Female, n (%)	5 (50)	5 (50)	1.0 ^b
Education (years), n (%)			
Lower than elementary school (<6)	4 (40)	2 (20)	0.400 ^b
7–12	5 (50)	6 (60)	
>12	1 (10)	2 (20)	
Cause of admission, n (%)			
Pressure injury	0	1 (10)	0.759 ^b
Lung disease	4 (40)	0	
Urinary tract infection	2 (20)	2 (20)	
Kidney disease	1 (10)	3 (30)	
Bone fracture	1 (10)	0	
Cerebral hemorrhage	0	1 (10)	
Liver disease	1 (10)	0	
Cancer	1 (10)	0	
Heart disease	0	1 (10)	
Fever	0	1 (10)	
Sepsis	0	1 (10)	
Site of pressure injury, n (%)			
Sacrum	7 (70)	8 (80)	0.63 ^{sb}
Ischia	0	1 (10)	
Greater trochanter	3 (30)	1 (10)	
Stage of pressure injury			
Stage 3	5 (50)	3 (30)	0.356 ^b
Stage 4	3 (30)	5 (50)	
Unstageable	2 (20)	2 (20)	
Size of wound (cm ²), mean±SD	28.45±43.4	38.4±33.2	0.393 ^a
Duration of wound (days), mean±SD	86.7±76.5	72.9±50.0	0.888 ^a
Duration of hospitalization (days), mean±SD	22.8±16.2	29.6±39.7	0.842 ^a
Care experience of pressure injury, n (%)			
No	8 (80)	8 (80)	1.000
Yes	2 (20)	2 (20)	

^aMann-Whitney *U*-test, ^bKolmogorov-Smirnov test. Duration of wound was from the starting time of wound by participants self-reporting until this admission. SDMG: Shared decision-making group, CG: Control group, SD: Standard deviation

4 weeks, in SDMG, the two unstageable PI changed to stage 4 and stage 3; in CG, one unstageable PI changed to stage 3 and the other one is still unstageable in CG after 4 weeks. The average wound size did not differ between the groups (28.45 [standard deviation (SD) =43.4] cm² in the SDMG and 38.4 [SD = 33.2] cm² in the CG; $P = 0.393$). The average wound duration was 86.7 (SD = 76.5) days in the SDMG and 72.9 (SD = 50.0) days in the CG ($P = 0.888$). Furthermore, the average duration of hospitalization was 22.8 (SD = 16.2) days in the SDMG and 29.6 (SD = 39.7) days in the CG ($P = 0.842$). No difference in caring experience for PI was observed between the groups ($P = 1.000$).

Shared decision-making quality

In the 2nd week, we examined the SDMG participants' experience of using the PDA tool for SDM and their perceptions of the usefulness of the tool. We used descriptive statistics to determine the participants' experience of SDM. All participants scored more than 4 points in each item, indicating that they had a positive experience of SDM. Moreover, 80% of the participants reported that the PDA tool with pictures and descriptions were easy to understand, and 20% of the participants reported that the word size of the PDA tool could have been larger [Table 2].

Table 3 presents the results for decisional conflict. The total average score for decisional conflict was 4 (SD = 0) in the SDMG and 1 (SD = 1.5) in the CG ($P = 0.001$); scores for each item differed significantly between the groups [Table 3]. Table 4 shows the SDM effects determined using the SDM-Q-9. The SDM-Q-9 scores were higher in the SDMG than in the CG for each item (all $P < 0.001$).

The results of shared decision-making, cost and clinical effect

In the results of decision after SDM, 70% of the participants in the SDMG selected advanced dressings; 30% participants who selected the traditional antibiotics for wound care. In the CG, 80% of the participants selected traditional antibiotics for wound care; two participants who underwent surgery for wound debridement.

Wound dressings were changed for 36 and 48 times per month, on average, in the SDMG and CG, respectively; nevertheless, this difference was not significant between the groups [$P = 0.353$; Figure 1a]. In total of costs related wound care, the SDMG and CG required NT\$8,258 and NT\$14,621, respectively, on average; however, these values did not differ significantly between the groups [$P = 0.247$; Figure 1b]. In hospital, the mean of costs included skill of wound care (NT\$2,988 in SDMG and NT\$8,043 in CG), dressing (NT\$1,883 in SDMG and NT\$3,009 in CG), and material for wound change dressing (NT\$1,201 in SDMG and NT\$1,504 in CG). After discharge, the average of cost about wound care at home included home visit by nurse and physician (NT\$1,668 in SDMG and NT\$1,346 in CG), material for wound change dressing (NT\$ 652 in SDMG and NT\$721 in CG).

Figure 1c illustrates changes in wound size. The average wound sizes assessed at T0, T1, and T2 were 28.45, 26.9,

Table 2: Participant's experience of shared decision making (n=10)

Items; n (%) This decision aid tool can...	Much, n (%)	Very much, n (%)
1. Help me realize that I must make decisions	2 (20)	8 (80)
2. Prepare me to make a better decision	2 (20)	8 (80)
3. Help me weigh the advantages and disadvantages of each option	2 (20)	8 (80)
4. Help me decide which advantages and disadvantages matter the most to me	2 (20)	8 (80)
5. Help me clarify what about a decision matters the most to me	0	10 (100)
6. Help me organize my thoughts on decisions	1 (10)	9 (90)
7. Help me determine how much I can involve myself into making a decision	2 (20)	8 (80)
8. Help me identify what I want to consult medical professionals about	3 (30)	7 (70)
9. Prepare me to tell my doctor what I care about the most	3 (30)	7 (70)
10. Prepare me for follow-ups with medical professionals	2 (20)	8 (80)
11. Is there any description, image, presentation, or question in this decision aid tool that makes it difficult for you to understand or answer the questions?	The images and descriptions are specific, clear, and easy to understand (n=8; 80%). The text size should be larger (n=2; 20)	
12. Does this decision aid tool miss anything that you would like to know and is critical to decision-making?	The descriptions are clear (n=10; 100)	

Items; n (%) I think shared decision-making can...	Agree, n (%)	Strongly agree, n (%)
1. Inform me of treatment options available to me	1 (10)	9 (90)
2. Provide me with an opportunity to express my doubts to medical professionals	2 (20)	8 (80)
3. Promote my participation in medical treatments	2 (20)	8 (80)
4. Promote my communication with medical professionals	2 (20)	8 (80)
5. Enhance my trust in medical treatments prescribed by medical professionals to me	2 (20)	8 (80)

and 19.4 cm², respectively, in the SDMG and 38.4, 38.4, and 46.9 cm², respectively, in the CG. At T2, the average wound size decreased by 9.05 cm² in the SDMG and increased by 8.50 cm² in the CG with $P = 0.05$ by GEE model examination.

DISCUSSION

This study constructed a PDA tool for PI treatment and examined the efficacy of nurse-led medical SDM for PI treatment. The study findings reveal that the participants had a positive experience of using the PDA for SDM and positive perceptions of the helpfulness of the tool for SDM after the intervention; this finding is consistent with those of previous studies [10,14,19]. In this study, the SDMG participants' overall agreement regarding the experience and perceptions of medical SDM was 96%; among the items, "The PDA tool can help me understand that this decision depends on things that are most important to me" had the highest score (100%), followed by "The PDA tool can help me organize my own

Table 3: Decisional conflict for pressure injury treatment (n=20)

Sure questionnaire	Items	SDMG (n=10)		CG (n=10)		P ^a
		Yes (score 1), n (%)	No (score 0), n (%)	Yes (score 1), n (%)	No (score 0), n (%)	
1. Sure of myself	Do you feel sure about the best choice for you?	10 (100)	0	2 (20)	80 (80)	0.003
2. Understand information	Do you know the benefits and risks of each option?	10 (100)	0	1 (10)	90 (90)	0.001
3. Risk-to-benefit ratio	Are you clear about which benefits and risks matter the most to you?	10 (100)	0	1 (10)	90 (90)	0.001
4. Encouragement	Do you have adequate support and advice to make a choice?	10 (100)	0	1 (10)	90 (90)	0.001
Total score, mean±SD		4±0		1±1.5		0.001

^aFisher's exact test. SDMG: Shared decision-making group, CG: Control group, SD: Standard deviation

Table 4: Effects of shared decision-making between shared decision-making group and control group (n=20)

SDM-Q-9	SDMG (n=10), mean	CG (n=10), mean	P ^a
1. My doctor made it clear that a decision must be made	4.8	1.8	<0.001
2. My doctor wanted to know exactly how I wanted to be involved in making the decision	4.8	1.4	<0.001
3. My doctor wanted to know exactly how I wanted to be involved in making the decision	4.8	1	<0.001
4. My doctor precisely explained the advantages and disadvantages of the treatment options	4.7	0.8	<0.001
5. My doctor helped me understand the entirety of the information	4.6	1.1	<0.001
6. My doctor asked me which treatment option I preferred	4.6	0.8	<0.001
7. My doctor and I thoroughly weighed different treatment options	4.6	0.5	<0.001
8. My doctor and I selected a treatment option together	4.5	0.5	<0.001
9. My doctor and I reached an agreement on how to proceed	4.6	0.9	<0.001

^aMann-Whitney U-test. Likert scales: 0=Completely disagree, 1=Strongly disagree, 2=Somewhat disagree, 3=Somewhat agree, 4=Strongly agree, 5=Completely agree. SDMG: Shared decision-making group, CG: Control group, SDM-Q-9: Nine-item Shared Decision-Making Questionnaire

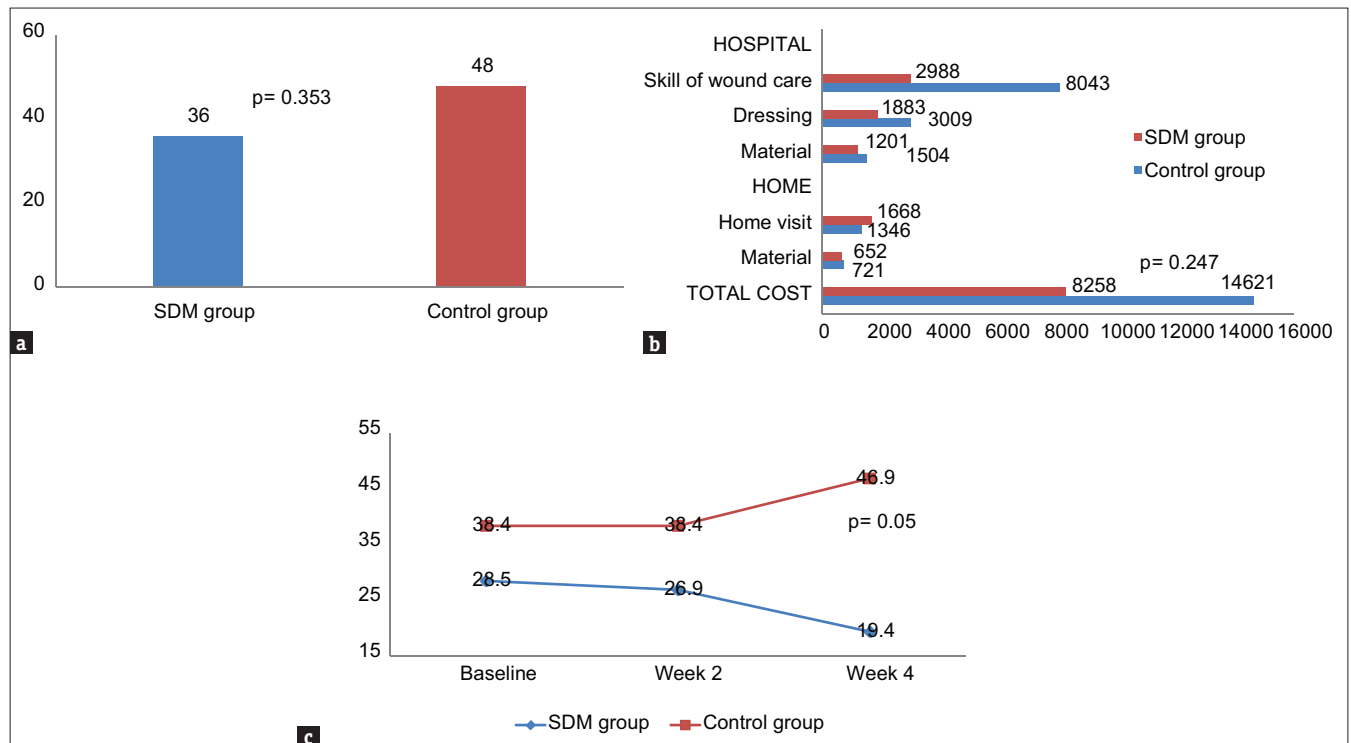


Figure 1: (a) Number of time for change wound dressing (average times/month). (b) Average of cost related wound treatment between two groups (TWD). (c) Change of wound size between two groups during 4 weeks (cm²)

thoughts on these decisions,” which had a score of 90%. A survey study including 38 patients with hemorrhoids and breast cancer reported that the patients’ overall agreement regarding the experience and perceptions of medical SDM was

73%, indicating a moderate degree of agreement; the study also revealed that the effect of SDM on the breast cancer group was significantly higher than that on the hemorrhoid group [20]. The experience of SDM and PDAs depends on

the target population, PDA design, and outcome measurement method.

In this study, the PDA development process involved two parts. First, we designed the PDA based on patients' needs and the results of a cognitive debriefing that indicated that a longer time was required to explain the PDA content to elderly participants with chronic diseases or relatively low health latency. Patients with relatively low health latency have complex communication difficulties, including those related to oral communication and written text, and they get confused about new information [21].

We found that even after SDM intervention, the participants or caregivers encountered difficulties in making decisions if they did not have knowledge regarding PI care. A study reported that if participants cannot understand their disease status or the available choices, they cannot participate in the SDM process [22]. In addition, if patients cannot understand their disease condition or the available treatment choices, they may not make a decision [22]. In this study, we found that if patients or caregivers participated in the SDM process without having knowledge about PI care, they could not make satisfactory treatment choices.

Accordingly, we modified the PDA by considering patients' perceptions along with their health latency. The modified PDA was designed in a handbook format that contained color photos and figures and included two parts: Introduction and prevention of PI and steps of SDM for PI care. We observed that 90% of the participants ($n = 10$, 70% had PI for the first time) reported that the designed PDA was clear and easy to understand. Furthermore, the time required to complete the PDA decreased from 70 to 59.3 min after the modification. A PDA providing detailed information and explaining the standard process can be beneficial for patients to make a medical decision [23]. A meta-analysis study examining barriers and facilitators to SDM implementation in clinical practice also reported that the time required for the SDM procedure is a major barrier to the promotion of SDM [17]. In this study, we found that reviewing the SDM process to develop an easy-to-understand PDA and providing the background knowledge before the SDM process could reduce the time required for the SDM intervention. Therefore, PDAs should be constructed considering the aspect of time required.

Successful SDM depends on guidance provided by trained personnel and the application of a suitable PDA [24]. In a medical team, a nurse is the spokesperson of patients; in particular, a specialist or advanced nurse should effectively understand patients' disease condition and patients' and family members' attitudes. Patients' willingness to participate in SDM affects the SDM process. Accordingly, nurses with specialized knowledge and skills and a positive attitude toward SDM can collaborate with other medical personnel to promote the SDM process. Our preliminary research results demonstrated that the participants in the SDMG, who participated in WOCN-led SDM for PI care, had a higher degree of agreement in the medical-patient SDM process than did the participants in the CG. In addition, the SDMG exhibited significantly fewer

decisional conflicts. This result is consistent with those of a previous study [14].

Lack of knowledge and uncertainty regarding treatment options are crucial factors affecting decisional conflicts [25]. Decision-making guidance by trained nurses can increase patients' knowledge and overcome decision-making conflicts and obstacles, such as those related to time limitation and the power relationship between patients and doctors [26]. In Taiwan, a quasi-experimental study including patients with end-stage renal disease examined the efficacy of SDM for different renal replacement therapies; the study demonstrated that patients in the SDMG had higher self-efficacy and lower decision-making conflicts than did those in the usual-care group [25]. Therefore, future studies should investigate the relationships among self-efficacy, knowledge about wound care, and SDM in patients with wounds.

The SDM intervention showed clinical efficacy for stage 3, 4, or unstageable PI. This pilot study revealed that the participants in the SDMG had a larger reduction in wound size and a decreased average cost for wound care after 4 weeks; however, these findings did not differ significantly between the two groups. Future studies with a large sample size can verify these findings.

In the 2nd week, we found a decrease in the wound size in SDMG and no change in CG. In the 4th week, the wound size decreased by 32% in the SDMG but increased by 22% in the CG. Moreover, the duration of hospitalization in SDMG (mean = 22. Days) is less than CG (29.6 days). The shorter duration of hospitalized may increase the cost of home care for home visit by nurse or physician, but no significant difference in total cost related wound treatment between two groups. Furthermore, in the result of decision after SDM, 30% of the participants in the SDMG and 80% of the participants in the CG selected traditional antibiotics for wound care. Traditional wound care increases the times of wound care such as frequency wound wet dressing and caregiver need to learn how to wound care for discharge that may cause increasing cost of wound care and prolong duration of hospitalization. The participants were followed for 4 weeks included care in hospital and at home and the total costs related wound care was lower in the SDMG (8258TWD) than in the CG (14621 TWD). However, the average wound healing period for PI is 626 days [27], we could not examine longitudinal effects in this study because we included a follow-up period of only 4 weeks.

There are some limitations in this study. This pilot RCT was conducted in a single institution and included a small sample size. The patient with critical illness were excluded and the average age is younger than the international average age. Therefore, we obtained limited evidence regarding SDM intervention efficacy; hence, the generalizability of our findings to other settings or situations is limited. Furthermore, wound size should be measured using more objective measurement tools. Because of the short follow-up period, the outcomes of wound care could not be examined longitudinally. In clinical, there are various factor to affect the wound healing and medical cost including nutrition and causes of PI, however, in this study, no more information to analysis the topic.

In terms of clinical SDM promotion, medical PDAs should be constructed on the basis of empirical evidence, and health-related teaching materials should include both images and videos rather than only textual information. For new PI cases, SDM and health education processes should integrate patients' wound and disease histories to improve the SDM efficacy and reduce its clinical implementation time. Few studies have examined SDM for PI management. On the basis of the aforementioned results, we suggest that future studies develop nurse-led SDM processes for PI care. Moreover, acute and chronic disease conditions should be considered during the development of PDAs and design of SDM processes for PI care. To measure outcomes, patients' medical decision-making experience, decisional conflicts, knowledge, and self-efficacy should be considered. The long-term effect and costs incurred, including labor costs, should also be considered.

CONCLUSIONS

We constructed a PDA tool (CVI of 0.96-0.97) for PI treatment and investigated the efficacy of nurse-led medical SDM for PI treatment. The pilot study showed that the intervention of SDM guided by trained nurses can decrease costs related wound care and improve wound healing size.

Data availability statement

All data generated or analyzed during this study are included in this published article.

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Conflicts of interest

There are no conflicts of interest.

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