

Impact of structured educational interventions on the prevention of pressure ulcers in immobile orthopedic patients in India: A pragmatic randomized controlled trial

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ABSTRACT

Background: Pressure ulcer (PU) is one of the common, neglected and avoidable complications among bedridden patients. Despite the potential to reduce PU incidence, the evidence on the effect of patient/caregiver education is low. This pragmatic randomized controlled trial (CTRI/2011/07/001862) compared the impact of two structured educational interventions to patients and caregivers on prevention of PU in immobile orthopaedic patients. **Methodology:** Ninety-two orthopedically immobile patients (Braden score ≤ 12 or stage I PU) and their caregivers were (block) randomized into two equal groups. One group was offered Prevention Package 1 (PP1), i.e., self-instruction manual (SIM), one to one training and counselling on PU care practices. The second group (PP2) was given SIM only. Patients were followed equally at the hospital and home after discharge. Intention to treat analysis was conducted. **Results:** The cumulative incidence of PU was 8.7% in PP1 and 21.7% in PP2 for the entire study period. PU incidence rate in PP1 and PP2 was 0.9 and 2.41 per 1000 person-days, respectively. Incidence rate ratio was 2.67 (95% CI: 0.89, 8.02, $p=0.04$). The Kaplan-Meier survival curves of PP1 and PP2 were statistically significantly different ($p=0.043$). PP1 also showed statistically significant improvement in knowledge on the prevention and management of PU compared to PP2 at post-intervention ($p < 0.001$). **Conclusion:** Individualized, structured education of patients and caregiver is effective in improving the knowledge and preventing the PU in immobile orthopaedic patients. A comprehensive approach involving hospital administrators, health care professionals, patients and caregivers may be further researched upon for a sustainable reduction in PU.

Keywords: Immobile patients, orthopaedic patients, pragmatic trial, pressure ulcer, prevention

Introduction

Pressure ulcer (PU), “a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear”, is still a neglected condition in low-and middle-income countries.^[1] The reported burden of PUs in major hospitals, long-term facilities and home care setting was 0.4–38%, 2.2–23.9%, and 0–17%

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respectively. Intensive care unit (3–23.9%), neuro-trauma (3.1–13.3%), and orthopaedic (8.4–34.2%) patients are more prone to develop PUs compared to other patients.^[2–7] The development of PUs prolongs nursing time and duration of hospitalization. This ultimately increases the workload of health personnel and also the economic burden to the patients' family and the hospital.^[8,9]

Prevention of PUs is an important indicator to be considered while assessing the quality of care provided by any healthcare facility and is more cost-effective than treatment of PUs.^[6,10,11] The interventional studies on prevention of PUs were primarily reported from developed countries and mostly used specialized pressure-relieving devices (PRDs) and nutritional supplementation with or without educational interventions.^[3,12,13] Although these interventions were cost-effective compared to treatment of PUs, the cost incurred to prevent each PU was also high in the context of developing countries. Similarly, specialist nurses like clinical staff nurses, wound ostomy/continence nurses, advanced practice nurses and patient care technicians and comprehensive, multidisciplinary wound management teams are not available in developing countries like India. Alternative types of healthcare facilities such as long-term care and home care are also not routinely available, and the family caregivers are the primary caregivers of immobile patients in India.^[11,14,15]

In resource-constrained setup, appropriate risk assessment and interventions addressing the risks could reduce the PU incidence. Health education of patients and their caregivers could be one of the cost-effective and risk reduction strategies.^[11,16] Though the literature on educational interventions among patients/caregivers to reduce the PU has been reported from various countries, none is from India.^[17–20] Mostly, these studies reported among patients with spinal cord injury or degenerative neurological diseases.^[21,22] The evidence on the effect of educational interventions in reducing PU incidence is also low.^[23]

With this background, we have conducted this study to compare the impact of two structured educational interventions for patients and caregivers on a) improving their knowledge on PU care practices and b) reducing the incidence of PU among orthopaedically immobile patients of a tertiary care hospital in India.

Methodology

Study design

A parallel, two-arm, pragmatic randomized controlled trial (RCT) design.

Study setting

We have conducted this study at orthopaedic wards of a tertiary care teaching hospital situated in northern India. This is a ~ 2000 bedded hospital and delivers healthcare services to patients from 5-6 states in and around Chandigarh union territory.

Study participants

Inclusion criteria

Patients (≥ 18 years) from Chandigarh tri-city (Chandigarh, Panchkula and Sahibzada Ajit Singh Nagar) admitted to orthopaedic wards were screened for presence of PU on the day of admission using the National Pressure Ulcer Advisory Panel (NPUAP) staging system and the Braden PU risk assessment scale (Braden Scale).^[24,25] Immobile patients with stage one PU or a Braden scale score ≤ 12 (high risk and very high risk) were recruited after informed written consent. Immobile patients are patients expected to be confined to bed for \geq seven days for 90% of the time during the day; and unable to get out of the bed without assistance. The Katz index of independence in activities of daily living was used to evaluate the level of functional dependence of patients.^[26] A caregiver is a person who is primarily responsible for the care of the patient; either a family member or a friend or hired (trained/untrained) personnel.

Exclusion criteria

Patients younger than 18 years, and patients/caregivers who were not able to read English/Hindi were excluded.

Interventions

PU prevention through structured education of the patient and caregivers using a self-instruction manual (SIM) was tested. The SIM included the definition of PUs, how it develops, the risk factors, common sites, early warning signs, and different stages of PUs. Importantly, it included the detailed information on how to prevent PUs, i.e., proper positioning, type and frequency of patient repositioning, skincare, type and duration of active and passive exercises, diet, hydration, and methods to prevent friction injury and contractures. It also included how to take care of hemiplegic, paraplegic or quadriplegic and wheelchair-bound patients, and information on PU healing processes and when to report to a doctor. The SIM was developed by the investigators both in English and Hindi languages.

Two types of educational interventions (arms) were tested since there was no formal educational protocol/program is available in the study hospital namely Prevention Package 1 (PP1) and Prevention Package 2 (PP2).

Prevention package 1

The SIM was divided into three chapters, and each chapter was distributed daily to patients and caregivers over a period of three days. The researcher explained the SIM in detail and demonstrated the preventive PU care practices. The various components involved in the education and demonstration were: proper positioning; changing the posture, bed sheets and clothes; active and passive exercises; feeding; skincare; maintaining hydration and hygienic practices. Counselling was also given to motivate the patients and caregivers to practice the taught skills regularly. On average, 45–60 minutes/day was taken to explain

and demonstrate the PU preventive care practices to patients and caregivers allocated in this group.

Prevention package 2

Distribution of SIM-only for self-reading and was distributed to patients and caregivers like PP1. One to one demonstration and explanation of the SIM was not provided to this group.

Outcome measures

The prevention of new PU (PU incidence) was the primary outcome and improvement in knowledge and practice on prevention and management of PU was the secondary outcome. A patient who moved from high and very high-risk Braden score (≤ 12) to stage one PU and above or from stage one PU to stage two PU or above is considered as the occurrence of PU event. Patients who developed more than one PU (in a different anatomical site) after seven days of the first PU were counted for a recurrent (second) event of PU to calculate the incidence rate.

Sample size and randomization

It was assumed that the incidence of PU would be three times more common in immobile patients with high/very high-risk Braden scale score, i.e., 30% considering 10% incidence of PUs among all orthopaedic patients.^[5-7] For the effect size of 30% between PP1 and PP2 at 80% power, 5% type I error and 10% attrition rate, the calculated sample size for each arm was 45. Intervention assignment was done using block randomization (size-four) by an independent biostatistician. Envelope method was used for allocation concealment of the consenting patient. No blinding was done.

Data variables and data collection instruments

A pre-tested, semi-structured questionnaire was used to collect the socio-demographic and clinical characteristics of the study participants. The details of PU development and its stage were noted on the proforma using pressure ulcer scale for healing (PUSH) tool 3.0 during each follow-up visit.^[27] Pre-and post-intervention knowledge assessment (at the last follow-up visit) of the patient and caregivers (where a patient cannot respond) was done using a semi-structured questionnaire. Score 2, 1, and 0 was assigned to fully correct, partially correct, and wrong answer or do not know responses. The knowledge and practice assessment tool (score range) included nine domains namely awareness of the patients' disease condition (0-6), problems in bedridden patients (0-14), general information on PUs (0-9), PUs preventive practices (0-15), PU management practices (0-10), information on contractures (0-6), bowel care (0-14), urinary care (0-5), and hygiene (0-5). The reliability of the knowledge assessment tool was tested using test-retest method (Pearson correlation coefficient = 0.721, p value <0.001).

Structured follow-up

Study participants of both groups were followed daily from the day of admission till discharge at the study hospital and at home

weekly once for two weeks and fortnightly until three months after discharge. In total, each patient had seven follow-up home visits apart from daily hospital follow up visits.

Statistical analysis

Descriptive statistics like mean and standard deviation were calculated for age, duration of hospital stay and PUSH score. Similarly, number and proportion were calculated for gender, education, presence of comorbidity, mode of injury, current orthopaedic problem, admission type, baseline Braden score category, and stage of PU using statistical package for social sciences (SPSS) ® version 16. Intention to treat analysis was done for hypothesis testing. The difference in pre-and post-intervention knowledge and practice between groups was tested using unpaired t-test. Cumulative incidence, incidence rate, rate ratio, preventive fraction and its confidence intervals were calculated and compared between the group using STATA ® 12.1 special version (Edx/Harvard/MIT edition). Kaplan-Meier survival analysis was carried out to compare the difference in the incidence of PU within hospital between the groups using SPSS and compared using the Breslow test. A p value of <0.05 was considered statistically significant.

Ethical clearance and trial registration

Ethical clearance was obtained from the Institute Ethics Committee. Written informed consent was sought from all patients and or caregivers. The treating consultant and nursing staffs were informed in case of PU development in any patient irrespective of the intervention group continuing the preventive package. This RCT was prospectively registered in the Clinical Trial Registry India (CTRI/2011/07/001862).

Results

Of the 278 patients from Chandigarh tri-city, a total of 97 patients were found eligible. Among them, two patients were not willing to participate, and three patients were excluded because neither the patient nor the primary caregiver was able to read Hindi/English. The loss to follow up in this study was 10% (9 patients), five from PP1 and four from PP2 [Figure 1]. The mean age of the patients in PP1 and PP2 were 49.1 and 46.7 years, respectively. Males were more than females in both groups. The distribution of basic demographic characteristics of patients and caregivers are given in Table 1, and there was no statistically significant difference observed between PP1 and PP2. Most (>90%) of the primary caregivers (CG1) were from patients' family (son/daughter-30%, spouse-23%) itself. None of the seven hired caregivers had any formal training.

Twenty-one percent of the patients were unconscious during admission. Hypertension (34.8%), diabetes mellitus (12%), coronary artery disease (9.8%), chronic arthritis (9.8%) and chronic obstructive pulmonary disease (1.1%) were the common comorbidities reported in the study participants. The distribution of clinical characteristics and baseline PU risk assessment are

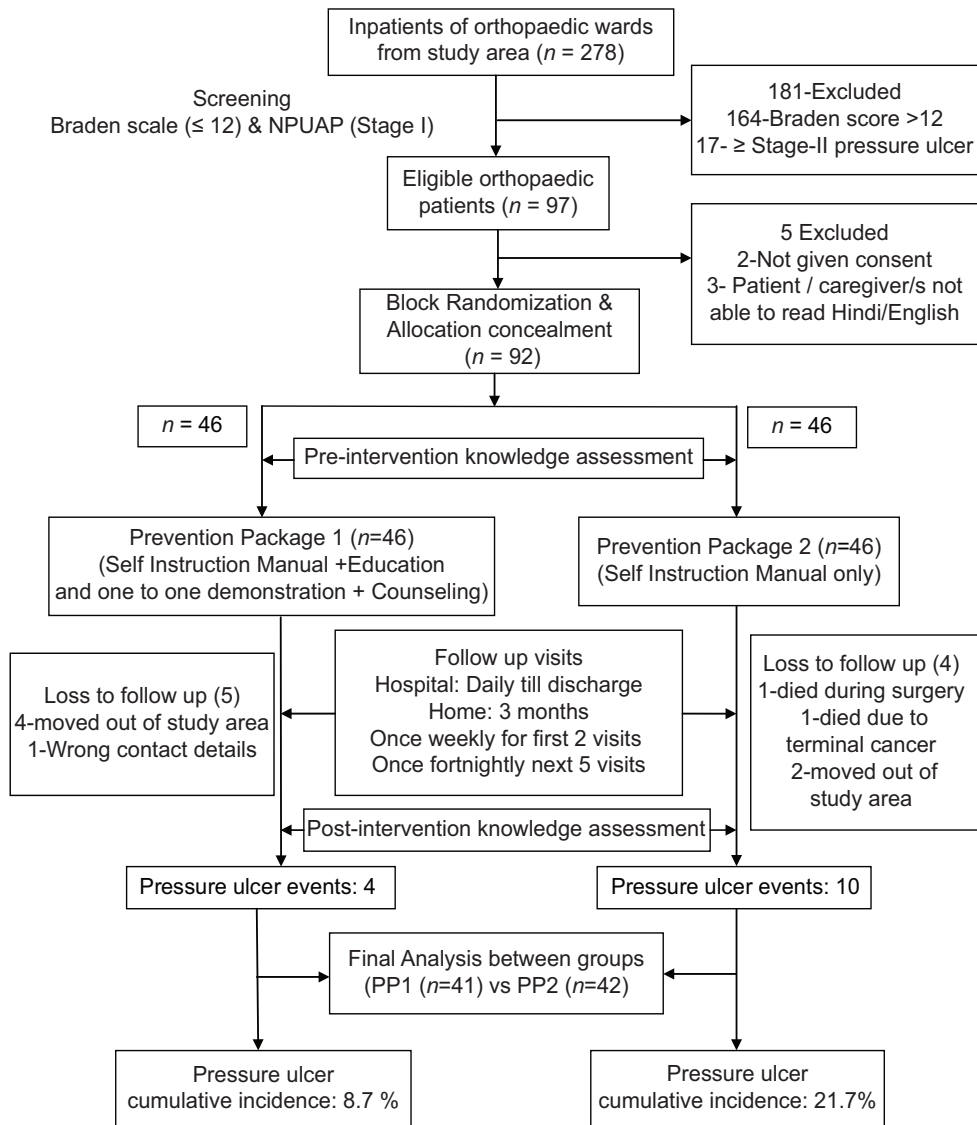


Figure 1: Pressure ulcer prevention trial algorithm conducted among immobile orthopaedic patients in India

given in Table 2 and was not significantly different between PP1 and PP2.

At baseline, 11% (7) of patients had stage one PU, and the rest were in high/very high-risk category. A total of 14 patients developed 15 PU events in the study period [Table 3]. Among them, 14 events occurred at the hospital, and the remaining one happened at home as a recurrent event in a patient after two weeks of first PU. Sacrum^[8] was the most common place of PU, followed by the heel.^[4]

Cumulative incidence of PU in PP1 and PP2 was 8.7% and 21.7%, respectively. PU incidence rate for the full study period ($p=0.043$) in PP1 and PP2 was 0.9 and 2.41 per thousand person-days (TPDs), and the same while in hospital ($p=0.041$) was 6.1 and 16.8 per TPDs, respectively. Preventive fraction in PP1 was 0.63 (95% confidence interval (CI): -0.12, 0.88) and

in population was 0.31. The mean (\pm standard deviation) total PUSH score at first follow-up was 10.3 (± 4.9) and 10.8 (± 2.7) and the last follow-up was 2.3 (± 2.6) and 1.2 (± 1.9) in PP1 and PP2, respectively. Since none of the groups attained the median survival, only mean survival time was calculated [Figure 2]. Mean survival of PP1 and PP2 were 26.4 (CI-23.7, 29.0) and 35.3 (CI-29.0, 41.7) days, respectively and the survival curves were significantly different ($p=0.045$).

Pre-intervention domain wise and overall knowledge and practice score were not significantly different between PP1 and PP2 except for the awareness of the patient's disease condition ($P=0.047$). The post-intervention overall score between PP1 and PP2 was significantly different ($p < 0.001$) [Table 4]. Even within the PP2 group, there was a significant ($p < 0.001$) increase in overall knowledge post-intervention compared to the pre-intervention period (data not tabulated).

Table 1: Socio-demographic characteristics of immobile orthopaedic patients and their caregivers in two pressure ulcer prevention group in India

Characteristics	Prevention Package 1 (n=46)		Prevention Package 2 (n=46)		Total (n=92)	
	n	(%)	n	(%)	n	(%)
Patient						
Mean age (in years) [SD]	49.1	[19.7]	46.7	[19.0]	47.9	[19.3]
Gender	Male	27 (58.7)	26	(56.5)	53	(57.6)
	Female	19 (41.3)	20	(43.5)	39	(42.4)
Education	Illiterate	1 (2.2)	3	(6.6)	4	(4.3)
	< High School	19 (41.3)	14	(30.4)	33	(35.9)
	≥ High School	26 (56.5)	29	(63.0)	55	(59.8)
Primary Caregivers						
Mean age (in years) [SD]	39.7	[16.0]	35.7	[10.8]	37.7	[13.7]
Gender	Male	21 (45.7)	30	(65.2)	51	(55.4)
	Female	25 (54.3)	16	(34.8)	41	(44.6)
Education	Illiterate	1 (2.2)	2	(4.3)	3	(3.3)
	< High School	9 (19.6)	12	(26.1)	21	(22.8)
	≥ High School	36 (78.3)	32	(69.6)	68	(73.9)
Number of CGs per patient	One	6 (13.0)	10	(21.7)	16	(17.4)
	Two	35 (76.1)	34	(73.9)	69	(75.0)
	Three or more	5 (10.9)	3	(4.3)	7	(7.6)

All are column percentages; SD-Standard Deviation

Table 2: Baseline clinical characteristics of immobile orthopaedic patients in two pressure ulcer prevention package group in India

Patient Characteristics		Prevention Package 1 (n=46)		Prevention Package 2 (n=46)		Total (n=92)	
		n	(%)	n	(%)	n	(%)
Co-morbidity (n=91)	None	21	(45.7)	27	(60.0)	48	(52.7)
	One	15	(32.6)	11	(24.4)	26	(28.6)
	≥2	10	(21.7)	7	(15.6)	17	(18.7)
Mode of injury (n=87)	Road accident	23	(54.8)	22	(48.9)	45	(51.7)
	Fall	19	(45.2)	23	(51.1)	42	(48.3)
Current Orthopedic problem involves fracture of	Multiple bones	35	(76.1)	26	(56.5)	61	(66.3)
	Femur only	10	(21.7)	18	(39.1)	28	(30.4)
	Pelvis only	1	(2.2)	2	(4.4)	3	(3.3)
Type of admission	Direct	20	(43.5)	16	(34.8)	36	(39.1)
	Referral	26	(56.5)	30	(65.2)	56	(60.9)
Referral after (n=52)	≤1 day	19	(73.1)	13	(50.0)	32	(61.5)
	2-3 days	6	(23.1)	9	(34.6)	15	(28.9)
	≥4 days	1	(3.8)	4	(15.4)	5	(9.6)
Braden scale score or Stage I pressure ulcer (PU)	≤10	5	(10.9)	6	(13.0)	11	(12.0)
	11	21	(45.6)	23	(50.0)	44	(47.8)
	12	17	(37.0)	13	(28.3)	30	(32.6)
	Stage 1 PU	3	(6.5)	4	(8.7)	7	(7.6)
Mean days of hospital stay [SD]	16.4	[10.9]	16.3	[8.9]	16.3	[9.9]	

All are row percentages; SD-standard deviation

Discussion

Our study compared the impact of two structured educational intervention packages among patients and caregivers on PU prevention. The educational package used in PP1 successfully improved the knowledge and practice of the patients and caregivers and prevented PU incidence. The intervention considered patient and caregivers as a single unit to deliver the intervention. We have also observed a significant improvement in knowledge and practice in PP2 post-intervention compared to baseline.

This is the first study to demonstrate the feasibility and effect of educational intervention on reducing the PU incidence in India. The strengths of the study were objective assessment of risk followed by interventions to high-risk study participants and pragmatic nature of the intervention. Apart from patients with high and very high-risk Braden score, the study also recruited stage one pressure ulcer patients since this is a warning sign of a greater problem, and interventions at this point can prevent further progression to deep ulcers. This study followed the recommendations given for acute care setup on PU prevention by the Institute of Healthcare Improvement (IHI) viz. PU risk

assessment on admission day, daily (risk) reassessment, daily skin checkup, minimizing pressure, management of moisture, and optimization of nutrition and hydration.^[28,29]

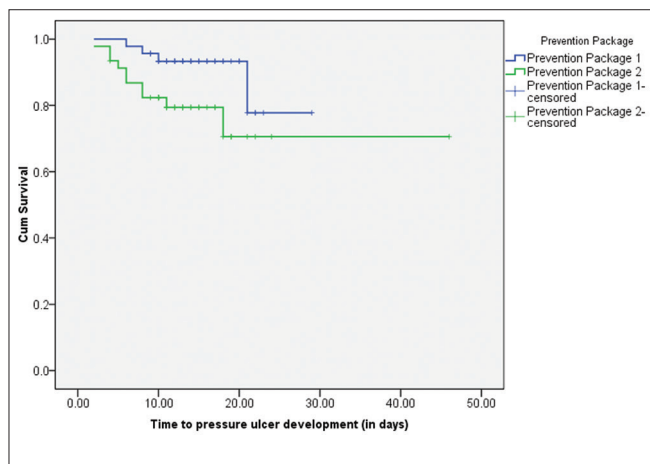


Figure 2: Kaplan-Meier survival curve of pressure ulcer incidence in prevention package (PP) 1 and 2 for hospitalized period

Table 3: Characteristics of incident pressure ulcers among immobile orthopaedic patients in two prevention package group in India

Patient Characteristics	Prevention Package (PP)		Total
	PP1	PP2	
Number of patients developed PU	4	10	14
Gender			
Male	2	5	7
Female	2	5	7
Baseline risk			
Braden-high risk	1	6	7
Braden-very high risk	2	2	4
Stage I PU	1	2	3
Number of PU events			
Single	3	8	11
Concurrent two PU	1	2	3
Recurrent	0	1	1
Site of PU			
Sacrum	3	5	8
Heel	1	3	4
Gluteus	0	1	1
Elbow	0	1	1

PU-Pressure ulcer

Education of the patients and caregivers was provided from the first day of admission, which could have allayed the fear and helped them gradually to learn the necessary technical skills by the time of discharge. The staggered approach of the delivery of intervention over three days probably alleviated the problem of information overload. The investigator also counselled and motivated the patients and caregivers, which could have made them to actively do the caregiving.^[30] In addition to equal follow-up for both the groups, our study reported less loss to follow up and also had adequate power (>80%) to test the hypothesis.

Ideally, PU should not develop among any patient irrespective of the type of healthcare facility.^[29] But the reality is quite different. The debate is still on whether the pressure ulcer is completely avoidable or not.^[31] At the same time, the development of PU will affect the quality of care provided by the healthcare facility. In most of the hospitals in India, the focus is still on treating (curative) the basic medical disorder for which the patient seeks medical care. Systematic protocol, i.e., disease-specific risk assessment and education of the patients about specific actions which are two indicators under the patient assessment and patient information and intervention standards of Health Promoting Hospital (HPH) initiative, is still lacking.^[32,33]

Orthopaedic patients are often advised by the health personnel to go for therapeutic immobilization using splints, cervical collars, or spinal boards before, during, and after surgery, depending on the diagnosis.^[5,7,34] Poor clarity of instructions and poor communication between health personnel, and between the health personnel and patient/caregivers can be cited as the reason for prolonged strict (unnecessary) immobilization of the patient.

A number of randomized and non-randomized experimental studies have been conducted in the past on educating patients/caregivers on prevention of PUs.^[18,19,35-39] The educational approach used in these studies was named as ‘Therapeutic Patient Education’ (TPE) in a systematic review which included six studies (four RCTs and two non-RCTs). All

Table 4: Pre-and post-intervention change in pressure ulcer knowledge score among immobile orthopaedic patients/caregivers in two prevention package group in India

Domain No	Knowledge domain (n=83)	Mean Difference	95% CI		P
			Lower	Upper	
1.	Awareness of the patient’s disease condition*	0.29	0.03	0.56	0.028*
2.	Awareness of problems in bedridden patients	1.6	0.65	2.6	0.001*
3.	General information on pressure ulcer	1.2	0.56	1.8	<0.001*
4.	Prevention of pressure ulcer	2.9	1.95	3.8	<0.001*
5.	Treatment of pressure ulcer	1.5	0.68	2.5	0.001*
6.	Information on contractures	0.5	0.003	0.99	0.049*
7.	Information on bowel care	0.08	0.53	0.68	0.805
8.	Information on urinary care	0.41	0.12	0.72	0.009*
9.	Information on hygiene	0.46	0.08	0.84	0.018*
Overall knowledge on pressure ulcer (Domain 3-5)		5.6	3.5	7.6	<0.001*
Total score (Domain 1-9)		8.95	5.7	12.2	<0.001*

*p<0.05 and statistically significant

studies were done primarily among long-term immobile patients with neurological conditions and prevention of recurrent PU was the primary focus of these studies. All these interventions were patient-centred and administered either in person or through telemedicine/telephone. Provision of information booklet, workshops, and lectures were the modes of delivery of intervention used in these studies.^[17,21,22]

All except one study (started from ambulance even before admission) reported that the intervention was provided at the time of hospital discharge. Four*one-hour individualized education along with distribution of information booklets was used in most studies. One study tried incentivizing the patients financially for maintaining and following good skincare practices.^[38] Follow up frequencies varied between twice weekly to quarterly, and the duration of follow up ranged between 5 weeks and 24 months. Different follow up frequencies and duration were observed in the intervention and control groups. Though the reduction in the PU incidence was the main outcome, only one study showed a significant reduction in PU incidence rates.^[36] The main limitations of these studies were small sample size/low statistical power, and differential follow-up between intervention and control group. A small number of available studies was another issue.^[17,23] In a study conducted at USA, the focus was on skin care, moisture management, and pressure-relieving devices (PRDs) for which costly devices were used.^[20] Compared to the above studies, the intervention used in our study was simple, less expensive, and easy to implement. Madhanraj *et al.* reported a reduction in PU incidence among neurosurgical patients by caregivers' education in which PU care was one of the domains in the full spectrum of nursing care.^[40,41]

As this study proved the effectiveness of the intervention, this can be further taken up by the hospital/health systems along with other interventions like recruiting specialist nurses, establishing dedicated multidisciplinary wound management team, continued medical education and other quality improvement exercises. In our study, physical follow-up of each patient at the community level was done at a scheduled time point. It was feasible since all the patients were from Chandigarh tri-city. However, considering the patient flow from different states, telemedicine/telephone or back referral to primary health centres could be considered as a potential community follow up strategy. As there was a significant improvement in knowledge and practice, and a reduction in PU incidence even in PP2 i.e., just distribution of SIM can be an effective strategy for resource constraint settings to prevent PU.

Limitations

Blinding of the study population was not done since it was an educational intervention and a postgraduate thesis. Objective measurement of biological parameters like height, weight, blood pressure, haemoglobin, blood glucose, type and duration of anaesthesia and medications used by the patients was not collected which could have affected the PU development.

Sustainability of the intervention effect in the study wards is a problem since this trial intervened only the patients and caregivers, not the health personnel or the health system. The difference in survival curves of PP1 and PP2 has to be interpreted cautiously as none of the group attained median survival (0.5) by the end of the study period, and we have reported only mean survival time. Due to differential risk from admission to discharge, we used Breslow (Generalized Wilcoxon) test to compare the survival curves.

Conclusion

Individualized, structured education of patients/caregivers is effective in improving the knowledge and prevents the PU among orthopedically immobile patients. A comprehensive approach involving hospital administrators, healthcare professionals, patients, and caregivers may be further researched for a sustainable reduction in PU. Further, the use of information technology for sharing the information or education and follow up can be tested in future.

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Conflicts of interest

There are no conflicts of interest.

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