

## Clinical study

## Assessing the impact of a patient education programme on pressure ulcer prevention in patients with spinal cord injuries



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## ABSTRACT

**Objectives:** There is currently a low level of evidence for the impact of patient education on the management of patients with chronic neurological disease at risk of developing pressure ulcers. The objective of this study was to assess the impact of a patient education programme on pressure ulcer prevention in patients with chronic spinal cord injuries.

**Materials and methods:** This study included adult patients with any spinal cord injury, regardless of the cause. Participants attended 2 group workshops focusing on pressure ulcer prevention.

Various clinical data were gathered during an initial individual interview and at 3, 6 and 12 months, along with rating scale values from the Hospital Anxiety and Depression Scale, Rosenberg self-esteem scale, Schwarzer self-efficacy scale, a quality of life scale (SF-36) and the revised Skin Management Needs Assessment Checklist (Revised SMnac), which was used as the primary endpoint.

**Results:** Twenty patients were included in the study. The mean patient age was 52 years (SD: 9,8). Sixteen patients had traumatic spinal cord injuries, with a median injury duration of 234 months (IQR: 123–407). Seventy-five percent had had a pressure ulcer in the twelve months prior to the study. Patient education was shown to have a significant impact on skin management ability, with a highly significant increase in the overall revised SMnac score at 3 months. These results were stable over time, from 6 to 12 months. Six patients developed a pressure ulcer during the study (30%).

**Conclusion:** This study supports the hypothesis that a therapeutic educational program conducted at the chronic phase in spinal cord injured individuals has an impact.

## 1. Introduction

In France, the incidence of traumatic spinal cord injuries is estimated to be between 1000 and 1200 new cases per year, with a prevalence of around 50,000. Once a spinal cord injury is considered to be stable, subsequent prognosis is dependent on the prevention and treatment of comorbidities through regular ongoing monitoring. Life expectancy can sometimes therefore reach that of the general population [1].

Other diseases may result in spinal cord injuries; primarily neoplasms and degenerative diseases, but also vascular disorders and autoimmune diseases [2]. Finally, spinal cord injuries may also be congenital in origin.

Patients with spinal cord injuries are permanently exposed to the risk of developing a pressure ulcer. Pressure ulcers are a complication of

the decubitus position defined by the National Pressure Ulcer Advisory Panel as a “skin lesion of ischemic origin linked to a compression of the soft tissues between a hard surface and bone projections” [3]. They are the second most common complication after a spinal cord injury, in both the acute and chronic phases [4], and have multiple repercussions: functional, social, psychological and financial. Pressure ulcers may also develop into a true life-threatening emergency for patients, with sepsis representing the second leading cause of death in patients with spinal cord injuries [4].

A number of risk factors for the development of pressure ulcers have been identified, the majority of which can be modified, and require patients to be involved in their care.

Adherence to preventive behaviours is inadequate in spinal cord injury patients [5–8]: Twenty-nine percent of pressure ulcers are considered by patients themselves to be linked to inadequate prevention

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Therapeutic patient education for individuals with a chronic disease allows them to take back control of their disease, enabling them to better understand their treatment and disease, and adapt their behaviour accordingly [9].

The role of therapeutic patient education in the French healthcare system was enshrined in French law in 2009 by the law on hospital reform and patients, healthcare and territories, known as the HPST law [10]. In June 2007, the Haute Autorité de Santé [French National Authority for Health] published a methodological guide to “structuring a patient education programme for chronic diseases” in order to encourage their implementation [11].

There is only a weak level of evidence in the literature for the impact of patient education on the management of individuals with chronic neurological disease at risk of contracting pressure ulcers, due to the low number of studies conducted, with small participant numbers: Cogan et al. in his review of recent literature [12] includes 5 studies (3 randomised controlled trials, and 2 experiments) involving 513 patients. He concludes that, actually, there is no evidence of the effectiveness of behavioral or educational interventions in preventing the occurrence of pressure ulcers in adults with spinal cord injury.

In light of this literature and because there are in our rehabilitation centre hospital stays for spinal cord injured (SCI) patients described as “recidivists” in terms of serious pressure ulcers, we led a study to assess the impact of a patient education programme on pressure ulcer prevention in individuals with SCI at the chronic phase. Our goal was to increase evidence of impact regarding the risk of pressure ulcers after the acute phase. One of the question in our rehabilitation units is do we have evidence to develop therapeutic patient education programmes for our SCI patients, what kind and when? We chose to measure the evolution of knowledge and habits in pressure ulcers prevention with a tool validated in French [13–15]: the revised Skin Management Needs Assessment Checklist (Revised SMnac) which is a knowledge self-evaluation tool and also a tool for educational needs assessment. Moreover we were interested in the impact of a patient education programme on the cognitive and psychological aspects which are poorly studied in the literature.

## 2. Methods

### 2.1. Study design

This single-centre, prospective, interventional study without control group was conducted at the Saint-Hélier Physical Medicine and Rehabilitation Division in Rennes (France), between November 2015 and September 2017.

### 2.2. Inclusion and exclusion criteria

The patients included in the study were adults with a spinal cord injury for any reason, with or without a history of pressure ulcers, who understood French, and freely consented to participate in the study. A score below 27 on the Mini Mental Test (MMS) was a criterion for exclusion.

### 2.3. Conduct of the study (Table 1)

All the spinal cord injured patients admitted to our rehabilitation centre (consultations or hospitalizations) with inclusion criteria during the inclusion period were asked to participate in the study. The inclusion period was open until 20 patients were recruited. After receipt of signed consent forms, an initial individual interview was carried out with patients to define their objectives, provide information on how the workshops would be run and hand out the rating scales along with instructions on how to complete them.

Two group workshops, each lasting 1 h 30 min, were held 15 days

apart, led by a facilitator with expertise in patient education and an expert on pressure ulcers, with the objective of preventing the development of pressure ulcers. The goal of the training during the first workshop was to improve the knowledge concerning pressure ulcers and the behaviors (preventive measures) using Regnier's abacus (“agree or “do not agree”) to involve each participant. Each statement was discussed again in groups and debated to promote peer to peer education. The key messages were repeated by the facilitator and illustrated using films, slides and hand-outs. During the second workshop we incorporated contextually based strategies within patient education programmes to facilitate the transfer of knowledge within life situations in order to obtain the adapted behaviors to everyday situations. Assessments were carried out in subsequent interviews at 3 months, 6 months and 1 year. Clinical and demographic data were gathered at each interview, along with rating scale results for the revised Skin Management Needs Assessment Checklist (Revised SMnac), the Hospital Anxiety and Depression Scale (HAD), the Rosenberg self-esteem scale, the Schwarzer self-efficacy scale, the SF-36 quality of life scale and a knowledge assessment scale (Visual analogic scale knowledge) designed to allow patients to self-assess their knowledge in relation to pressure ulcer prevention. The revised SMnac is the French version of the SMnac. It is a 19-item self-administered questionnaire spread out over three categories (skin check, preventing pressure ulcer, preventing wounds) with 4, 11, and 4 items, respectively.

Hospital Anxiety and Depression Scale (HAD) is a 14 item self-administered questionnaire to evaluate anxiety and depression. It has two components with seven questions.

The Rosenberg self-esteem is a 10-item self-administered questionnaire to evaluate self-esteem. It has two components with five questions each for positive and negative self-esteem. Each item is scored from 1 to 4 (1 = do not agree at all and 4 = completely agree). The total score ranges from 10 to 40.

The SF 36 is a 36-item self-administrated questionnaire to evaluate de quality of life with two components: physical and mental health of an individual. It focuses on eight dimensions of health (physical activities, social activities, moral, physical and emotional resistance to daily tasks, physical pain, general mental health, vitality, perception of health status in general).

All these scales are validated in French.

The Schwarzer self-efficacy scale is a 10-item self-administrated questionnaire to evaluate the perception of self-efficacy. Each item is scored from 1 to 4.

The primary endpoint was the revised SMnac rating score for skin management. The secondary endpoints were the self-efficacy rating score, the self-esteem rating score and the number of pressure ulcers developed by patients.

**Ethical considerations:** This project was submitted to the Rennes University Hospital Centre ethics committee for evaluation on 16/06/2015, under submission number 15.47, and received a favourable opinion.

### 2.4. Statistical analysis

Missing data for the revised SMnac were imputed using the mean of the items reported. Sub-scores and the total score were calculated from these values.

A descriptive univariate analysis was conducted for each visit. For the quantitative variables, the mean, standard deviation were calculated for normal distributed continuous data, median, quartile, minimum and maximum values were calculated for data was not normal distributed. For the qualitative variables, the number and frequency of each modality were calculated.

To analyse whether the different scores measured changed over time, linear mixed models were used, with the different time-points considered as fixed effects and patients modelled as random effects. This made it possible to account for the fact that the measures were

**Table 1**  
Conduct of the study.

Different steps	Selection Signature of consent	Initial individual interview	Workshop1	Workshop2	Individual interview	Individual interview	Individual interview
Interview content		Information about workshop Individual target Data recording Assessment scales			Data recording Assessment scales	Data recording Assessment scales	Data recording Assessment scales
Study period	T0	J15 ± 7	J30 ± 7	J120 ± 7	J210 ± 7	J390 ± 7	
SMnac score	+			+	+	+	
Knowledge VAS			+	+	+	+	
Satisfaction VAS			+				
Self efficacy scale	+			+	+	+	
Self esteem scale	+			+	+	+	
SF 36	+			+	+	+	
HAD scale	+			+	+	+	
Pressure ulcer number	+			+	+	+	

repeated, and to avoid excluding patients with incomplete data from the study. The normality and heteroscedasticity of residuals were checked graphically.

The mixed model made it possible to determine whether there was a change over time. The time effect was tested with a likelihood ratio test (LRT). Where the effect of the time-point was significant, contrast analysis between the different time-points were carried out, with a Tukey multiplicity adjustment, in order to analyse more precisely the evolution at the various visits. The mean differences between 2 visits was also estimated in the contrast analysis, altogether with the 95% confidence intervals, and plotted.

To determine the impact or link between different factors on the level of or change in knowledge, linear mixed models were also used. For this, models including the visit, the factor and the interaction between the two were used. The different effects were tested using maximum likelihood estimation tests. If the factor had a primary effect, this meant it had an impact on the overall level of knowledge, and if the interaction was significant, that it had an impact on change in knowledge following the patient education programme.

Statistical analyses were carried out using R (version 3.2.5), by the biostatistics team of the Department of Medical Research at the Lille Catholic Institute Hospital Group.

### 3. Results

#### 3.1. Study population characteristics (Table 2)

Twenty patients were included in the study: 6 women and 14 men. Three patients were lost to follow up before the final interview.

The mean age of participants was 52.2 years (SD:9,8).

Of the 20 patients included, 16 had a traumatic spinal cord injury. The 4 others had non-traumatic spinal cord injuries (myelomeningocele, a syringomyelic cavity, spinal cord ischaemia and an intramedullary tumour).

The duration of injury varied (median: 234 months, IQR [123–407], min: 14 max: 684).

Eleven patients were paraplegic and nine patients were tetraplegic. All participants had a moderate level of dependence according to the Functional Independence Measure (FIM) scale. (median score: 103,5 IQR [59–116,2])

Twelve of them lived alone. The patients had varying levels of education, and four of them were in active employment.

The initial psychiatric and cognitive assessment found comparable Mini Mental Test scores in all the patients (mean score 29, SD:1). Two patients presented with clear symptoms of anxiety, and none with depression based on the HAD scale. Self-esteem on the Rosenberg scale and Schwarzer self-efficacy varied between the patients. The SF-36

**Table 2**

Characteristics of sample at the beginning of the study: V0.

Variable	Intervention group		
	mean	SD	
Age (yr)	52,2	9,8	
Time since onset (months)	median 234 number	IQR 123–407 percent	range 14–684
Educational status			
Primary school	2	10	
Secondary school	8	40	
High school (Bachelor's degree)	3	15	
Bachelor's degree + 2 years	4	20	
Bachelor's degree + 5 years	3	15	
Marital Status			
Single	12	60	
Couple life	8	40	
Sex			
Male	14	70	
Female	6	30	
Employment status			
No employment	10	50	
Retired	6	30	
Employment	4	20	
Level of impairment			
Cervical	9	45	
Thoracic/lumbar	11	55	
Previous pressure ulcer			
Yes	15	75	
Number pressure ulcer in the last 12 months			
1	13	65	
2	1	5	
4	1	5	

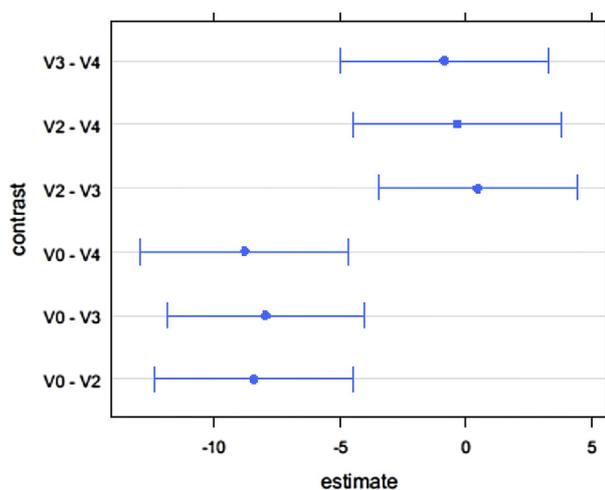
scores also varied (median score of 31.3 for the physical score (IQR [27.1–38.3]), median score of 51.3 for the psychological score (IQR [40.5–58.8]).

Of the 20 patients included, 15 of them had already had a pressure ulcer, and the same number had already had at least one pressure ulcer in the previous 12 months. 9 patients had a pressure ulcer during the inclusion period.

The initial revised SMnac score varied from one patient to another (median score 38.5, IQR [34.5–44.2]).

#### 3.2. Primary endpoint

This study demonstrated a significant impact from therapeutic patient education on skin management ability (overall effect:



V0 : initial  
 V2 : three months  
 V3 : six months  
 V4 : twelve months

Fig. 1. Representation of the average differences in the Revised SMNAC score between visits, and their 95% confidence interval.

V0: initial  
 V2: three months  
 V3: six months  
 V4: twelve months.

$p < 0.0001$ ). The SMnac results (overall score) following the patient education sessions were significantly higher in the interviews at 3 months (V2), 6 months (V3) and 12 months (V4) in comparison to the initial interview (V0) (Fig. 1): the respective differences were  $-8.4$ ,  $p < 0.0001$ ,  $-7.9$ ,  $p < 0.0001$ , and  $-8.7$ ,  $p < 0.0001$ . A difference was also observed for the three sub-scores of the SMnac (overall effect was significant for the 3 sub - scores: respectively  $p = 0.0001$ ,  $p < 0.0001$  and  $p = 0.00026$  - there is significant improvement between the initial interview and subsequent visits, excluding the third sub-score for which only the difference in the third month was significant) (Fig. 2).

Patient competencies were maintained over time, with scores stable from the second interview onwards.

### 3.3. Secondary endpoints

No significant difference was observed between the initial and following visits in the self-efficacy rating scale ( $p = 0.94$ ) or the self-esteem rating scale ( $p = 0.52$ ).

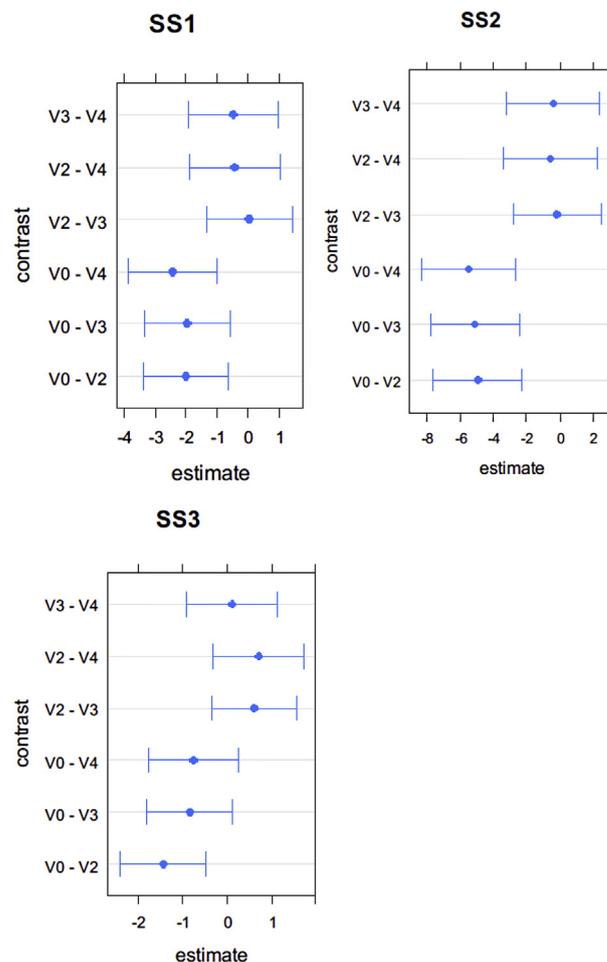
Fifteen patients had had a pressure ulcer in the previous year (75%). Nine patients (45%) had an existing pressure ulcer at the start of the study. Of these patients, skin condition only worsened in one patient; skin condition improved in 2 patients, remained stable in 2 patients, and in 4 patients the pressure ulcers healed.

Six patients developed a new pressure ulcer during the study (30%); in 83% of cases these were stage 1 or 2 ulcers, and two of them healed during the study.

There was no link between the level of or change in knowledge and the development of pressure ulcers.

A significant impact from patient education on quality of life as measured on the SF-36 scale was noted between the first and third visits for the physical score ( $p = 0.0023$ ), with no impact on the psychological score.

A significant impact from patient education on the knowledge visual analogue scale ( $p = 0.002$ ) was found, reflected in perception of improved skin management ability among patients. As with the SMnac,



SS1 : sub score 1 of Revised SMnac = skin check  
 SS2 : sub score 2 of Revised SMnac = preventing pressure ulcer  
 SS3 : sub score 3 of Revised SMnac = preventing wounds

Fig. 2. Representation of the average differences of the three SMNAC sub-scores between visits and their 95% confidence interval.

SS1: sub score 1 of Revised SMnac = skin check  
 SS2: sub score 2 of Revised SMnac = preventing pressure ulcer  
 SS3: sub score 3 of Revised SMnac = preventing wounds.

this improvement was maintained from the second interview onwards.

No significant impact on the level of or change in knowledge was observed from level of spinal cord injury, marital status, level of education or professional status (SMnac). However, a slightly significant effect from level of dependence (FIM score) on sub-score 1 of the SMnac was identified. Level of education had a significant impact on change in knowledge as measured by the visual analogue scale.

## 4. Discussion

Pressure ulcers are the most common type of complication among patients with chronic spinal cord injuries, with their prevalence increasing from 15% in the first year to nearly 30% at 20 years of injury duration [16]. It has also been shown that the risk of developing pressure ulcers is stable in this population during the first ten years, then tends to increase from the fifteenth year of injury [17], supporting the need for long-term monitoring and the implementation of prevention strategies.

The literature reports numerous intervention methods aiming to modify behaviour in relation to pressure ulcer prevention among patients with spinal cord injuries, including telemedicine using telephone interviews, telephone answering systems, computer animations,

educational workshops ... and even techniques using financial motivation [18].

There is currently weak level of evidence concerning the role of patient education in the management of pressure ulcer risk in spinal cord injury patients, and numerous questions remain, for example in relation to the opportune moment to provide these educational programmes, appropriate assessment tools and the type and duration of intervention [12,16,19,20].

For our study we decided to use group workshops, in line with the 2007 Haute Autorité de Santé guidelines on running patient education programmes, enabling knowledge transmission and sharing experience [16], with assessment of the impact of this programme at 3, 6 and 12 months using the revised SMnac scale.

The revised SMnac scale is a validated tool for assessing the knowledge and behaviours of spinal cord injury patients in relation to pressure ulcer prevention. It is also a tool of educational needs assessment. The overall score and sub-scores of the revised SMnac scale have also been validated in French. That is why we felt that the revised SMnac scale was a reliable and reproducible measure for assessing preventive behaviour, which is why we chose it as the primary endpoint, despite the fact that its sensitivity to change has only been demonstrated in the acute injury phase [13–15].

We observed that our patient education programme had an impact on the knowledge and behaviours of patients with spinal cord injuries, measured by this validated scale and that this effect was maintained over time, at 3, 6 and 12 months. Most of the studies on the impact of patient education in the field of pressure ulcers, are focused on the recurrence of pressure ulcers. Few assess patients' knowledge and ability to adapt their behaviour to their own risk of pressure ulcers. To our knowledge none of them measured their behaviour facing a stage one of pressure ulcer (the stage of the reversibility if the good behaviour is adopted).

A recent multi-centre randomised study, Kim et al. [21], demonstrated the benefit of a patient education programme on self-care behaviors, self-care knowledge, and self-efficacy regarding pressure ulcer prevention in patients with a spinal cord injury using knowledge assessment at baseline and at 8 weeks (end of the intervention programme). May and all [22] in his one group study showed a significant improvement in knowledge after an inpatient education programme from admission to 6 months post discharge.

Garber et al [23] showed in his study with control group a better improvement of knowledge in the intervention group (inpatients education programme). But in the two cases they used a non validated scale.

A review of the literature from 2012, Gelis et al. [24], demonstrated the benefit of a patient education programme in preventing pressure ulcers in chronic disease. However, authors reported that these studies had low levels of evidence, and looked at very different areas: not only clinical but also psychological, functional, cognitive and in relation to care-related costs. The endpoints were also highly disparate.

We also demonstrated the impact of patient education on knowledge of pressure ulcer prevention using a visual analogue scale. This effect was less marked than on the SMnac score, probably reflecting the more objective nature of this endpoint. Despite its subjectivity, the efficacy visual analogue scale reflects the patient's perception of having control over his/her disease. This was consistent with the results obtained for the quality of life scale, where patient education had a significant impact on the physical component in our study. There are very few studies in the literature looking at the impact of patient education on quality of life in patients with spinal cord injuries. In 2001, Philipps et al [25]. in a randomised study evaluated the quality of life in patients who benefited from an education program during the initial care management phase. They found an improvement of quality of life in the intervention group but no impact on the self-esteem scale or the self-efficacy scale.

Few factors appeared to influence the level of or change in

knowledge in our study. Only the level of independence had a slightly significant impact on the first sub-score of the SMnac, and level of education on the knowledge visual analogue scale, but this is difficult to interpret due to the size of the population. There are data in the literature (Chen et al. [17], Gelis et al. [26]) that show significant risk factors for the development of pressure ulcers, including a low level of education, unemployment and a low level of independence. The protective factors identified were being married, ongoing studies and professional activity.

We did not identify a statistical link between the level of or change in knowledge assessed using the SMnac score and the development of pressure ulcers. A non-significant decrease was however observed in the incidence of pressure ulcers between the year prior to the study (75% developed a pressure ulcer) and the incidence of pressure ulcers during the study (30% developed a new ulcer, they made a self-diagnosis at the early stages). Similarly, in their literature reviews Cogan et al. [12] and Regan et al. [27] found no impact from patient education on the occurrence of pressure ulcers, despite good retention of instructions. It could be interesting to specify the stages of the pressure ulcers when we will observe a pressure ulcer recurrence in the future studies to assess if improving knowledge could improve self diagnosis at the early stages. For spinal cord injured individuals, this empowerment could be another way of managing their risk, without guilt, by simply adapting their behaviour to their situation when a stage one pressure ulcer appears.

#### 4.1. Study limitations

These results should be interpreted with caution, given the limited study size and the inherent lack of power. The other limitations were the quarterly interviews, which could have influenced the level of knowledge retention, even if they focused on the assessments. Finally, our study was a non-controlled, non-randomised study.

## 5. Conclusion

Based on a validated scale, this study supports the hypothesis that a patient education programme conducted at the chronic phase in spinal cord injured individuals has an impact on patient knowledge in relation to skin management, and that the competencies acquired persist over time. The results of this study could serve as a basis for implementing a randomised controlled trial with sufficiently large numbers to provide definitive answers regarding the role of patient education.

#### Declaration of interest

None.

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#### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jtv.2019.06.001>.

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