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Original article

Risk factors of pelvic pressure ulcer recurrence after primary skin flap surgery in people with spinal cord injury

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ABSTRACT

Background: Flap surgery for deep pelvic pressure ulcers (PPUs) has been found effective, but the recurrence rate remains high and few risk factors have been identified.
Objective: We evaluated risk factors for PU recurrence after primary flap surgery in people with spinal cord injury (SCI).
Patients and methods: This observational retrospective study based on medical charts included all individuals with SCI who underwent primary flap surgery for a PPU in the Hérault department in France between 2006 and 2014. Overall, 100 biomedical, psychological, socioeconomic and care management factors were studied. The primary outcome was PPU recurrence (surgical site and/or other pelvic site). The secondary outcome was recurrence at the surgical site. Cox proportional hazards regression was used to determine associated factors, estimating hazard ratios (HRs) and 95% confidence intervals (CIs).
Results: We included 85 patients. Half had a PPU recurrence, and in one-third, the recurrence was at the surgical site. On multivariate analysis, global PPU recurrence was associated with colostomy (HR = 2.79) and living with a partner (HR = 2.29). Non-traumatic SCI and sacral wound were associated with PPU recurrence (HR = 3.39, HR = 0.48) and recurrence at the surgical site (HR = 3.3, HR = 0.3).
Conclusion: Risk factors of PPU recurrence are based on both biomedical and social models. After primary flap surgery, the risk of recurrence justifies regular follow-up and strict monitoring.

1. Introduction

The onset of a pressure ulcer (PU) is a common occurrence in people with spinal cord injury (SCI), with a prevalence evaluated at 30% in international studies [1,2]. Care management of this complication has become a public health challenge, with longer hospital stays than for other causes (urinary tract and pulmonary infections) [2–5]. PUs increase the risk of complications secondary to SCI (e.g. spasticity of lower limbs, overactive bladder), and skin-related sepsis was found as a cause of mortality in this population [5,6].

Surgical management is often essential for stage 3 and 4 pelvic PU (PPU; Appendix 1) [7–9]. The number of flaps is limited in light of the surgical area and there is a need for multidisciplinary preoperative assessment [10].

Postoperative recurrence rates are high, ranging from 8% to 41% in a SCI population [11–15]. Few studies focused on postoperative PU recurrence risk factors in this population. Grassetti et al. [12] found history of coronary disease and a pedicled flap as risk factors for recurrence, and the presence of kidney disease was protective. For Thiessen et al. [14], risk factors of recurrence were ischial localization and postoperative flap dehiscence.

The main limitation of these studies was the inclusion of individuals undergoing surgery for the first time and with a history of multiple surgery, which raises several biases: on the one hand,

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history of surgery is a risk factor of postoperative PU recurrence in people with chronic SCI in several studies [16–19] and on the other, the clinical and psychosocial profiles between individuals undergoing surgery for primary PU and for recurrent PUs [20]. Another limitation of these studies is the lack of theoretical anchoring within a bio-psychosocial model [i.e. lack of analysis of sociodemographic and psychological-behavioral factors previously identified as risk factors for PU recurrence in individuals with chronic SCI (24)]. The preparation and organization of the care management could also play a role in the success or failure of PU surgery, yet they were not studied.

The objective of this study was to evaluate the risk factors of PPU recurrence after primary flap surgery in people with SCI based on a bio-psychosocial model.

2. Materials and methods

2.1. Study design

This was a retrospective and analytic observational study based on a historical cohort for prognostic purposes. We included individuals with chronic SCI and paraplegia or quadriplegia regardless of the cause of injury who underwent primary flap surgery for pelvic ulcer between January 1, 2006 and September 1, 2014 in the Hérault department of France. At the time of data collection, January 1, 2015, all medical charts of patients undergoing surgery and followed in the Hérault department were analyzed. The onset of the first recurrence was verified in the medical chart and during a phone interview with the individual, a family member or primary care physician.

3. Variables studied

3.1. Evaluation criteria

Recurrence is defined as any type of pelvic wound that requires local nursing care or any stage 2, 3 or 4 PPU according to the NPUAP classification [9].

The following differentiations were made:

- local recurrence at the surgical site, which occurred after postoperative wound healing
- recurrence at another pelvic site, occurring somewhere else in the pelvic region but not at the surgical site, regardless of the wound healing stage of the operated PU.

As described in previous publications [21,22], all site recurrences were labeled "any PPU recurrence".

3.2. Potential risk factors studied

First, we pre-selected the potential risk factors. Biomedical variables and those related to the organization of the preoperative and postoperative care management were selected on the basis of analytic studies that focused on the risk of PU recurrence during the life course of an individual with SCI [23–31] and PU recurrence after surgery [13,14,17,32].

To explore the social dimension, we used the theoretical model "Social Determinants of Health" designed by the WHO [33], more specifically the figure by Whitehead et Dahlgren [34] previously used in a cohort of people with SCI [35].

Then a multidisciplinary expert committee (AG, JM, HR, CM, CV) met to select the relevant factors. Overall, 100 variables were collected and classified into 7 categories (Appendix 2):

- social determinants of health (20 variables);
- medical data (25 variables);
- cutaneous data (11 variables);
- preoperative care management (12 variables);
- surgical care management (8 variables);
- postoperative care management (15 variables);
- postoperative complications (9 variables).

4. Sample size

We used Cox proportional-hazards regression analysis to identify variables predicting PPU recurrence. With the event being the recurrence, we wanted to highlight 5 to 7 predictive variables. We needed 50 to 70 recurrences for 10 to 20 events to reveal a predictive variable. According to the recurrence rate of 50% found in a preliminary study, we estimated that we needed to include 100 individuals with SCI.

5. Statistical analysis

Estimating survival for each subgroup of variables involved using the Kaplan–Meier method. The start date was the date of the primary surgery and the endpoint date was January 2015 or time of death. Univariate analysis with the log-rank test was used to test differences in survival distributions for each subgroup. Variables with $P > 0.15$ on univariate analysis were included in a multivariate Cox regression model to identify risk factors. Clinical or scientific relevant data (according to data found in the literature) were added, regardless of their P value on univariate analysis. Variables were entered in the model by backward selection and were significant at $P < 0.05$ according to the Wald test. The Cox model hypothesis was validated for each variable. When needed, the variable was taken out of the model. Upon completion of the multivariate analyses, variables with a statistical relationship with the criterion studied were considered risk factors. For individuals who were not able to be contacted or who died, their data were censored in the final analysis as allowed by the Cox model. Statistical analyses involved using SAS v9.4 (SAS Institute, Cary, NC, USA) and R v3.0 (R Foundation for Statistical Computing). The study was approved by the regional Ethics Committee (ref: Q-2014-11-01).

6. Results

Overall, 85 people with SCI who benefited from primary flap surgery were included in the study (Fig. 1). The main characteristics of the population are in Table 1.

6.1. Postoperative recurrence

In all, 44 (51.8%) of participants experienced PPU recurrence after primary flap surgery, and 60% of the events occurred at the surgical site. The median delay to the first recurrence was 12.1 (range 1–99) months post-surgery for any pelvic site recurrence and 9.9 (1–48) months for the first recurrence at the flap site. The ischial location was the most common recurrence site; 15% of the participants who had a recurrence had more than one PPU and 56% of these were stage III or IV according to the NPUAP classification [9].

Overall, 23 (52.3%) of the participants with a PPU recurrence had secondary surgery. In 63% of the cases, a new flap was used and in 18.5%, the surgical indication was septicemia (Fig. 2).

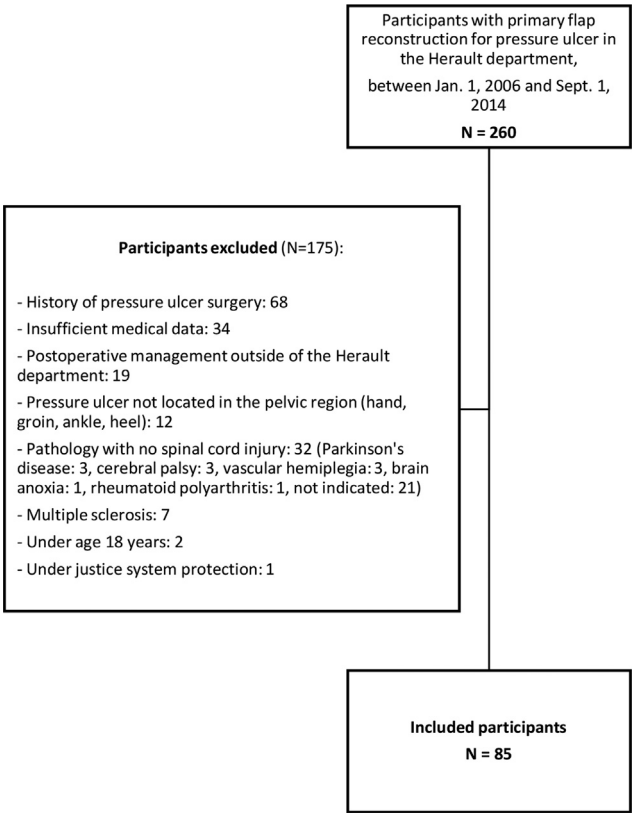

Fig. 1. Flow of participants in the study.

6.2. Survival curves and survival median

The median survival without a PU was 27.2 months for all PPUs. It was not reached for PU recurrence at the surgical site because less than half of these individuals had a recurrence solely on this criterion. The probability of PPU recurrence was constant until month 48 and became very low beyond that timeline. For recurrence at the surgical site, 3 stages were observed: the probability was high up to month 30, decreased between months 30 and 40 and became stable beyond month 50. Thus, the frequency was estimated at 60% for PPU recurrence and 50% for PU at the surgical site (Figs. 3 and 4).

6.3. Risk factors of postoperative recurrence

For global PPU recurrence, in the multivariate model, 3 variables were identified as risk factors: presence of a colostomy (HR = 2.79), non-traumatic SCI (HR = 3.39), and living with a partner (HR = 2.29) (Table 2). Sacral versus ischial localization of the surgical site was a protective factor (HR = 0.48).

For recurrence at the surgical site, 2 variables were identified as risk factors: non-traumatic SCI (HR = 3.32) and duration of the postoperative hospital stay in intensive care or a surgical care unit (HR = 2.7) (Table 3). Sacral versus ischial localization was a protective factor (HR = 0.33).

7. Discussion

This study illustrates the natural progression of PU surgery in people with SCI and difficulties in achieving sustainable wound healing: postoperative recurrences are common and do not occur only at the surgical site. The at-risk period can last up to 4 years, and 52% of recurrences require a secondary surgery.

Table 1
Description of the included population (n = 85).

		Missing data
Sociodemographic data		
Age at surgery (years)	49 (21–83)	–
Sex		–
Men	68 (80)	
Women	17 (20)	
Marital status		–
Living with a partner	33 (39)	
Single	52 (61)	
Occupation		3
Employed	13 (16)	
Unemployed	60 (70)	
Retired	12 (14)	
Home human assistance		
Familial	7 (8)	
Professional	39 (46)	
Both	7 (8)	
Medical data		
Time since injury (months)	156 (2–693)	–
Level of injury		–
Cervical	22 (26)	
Thoracic	60 (71)	
Lumbar	3 (3)	
AIS		–
A	67 (79)	
B	9 (11)	
C	8 (9)	
D	1 (1)	
Etiology of the injury		–
Traumatic	68 (80)	
Non-traumatic	17 (20)	
BMI (kg/m^2)	23.8 (14.5–40)	8
Active smoker	32 (38)	–
Regular physical activity	7 (8)	1
Surgical data		
Localization of the operated PU		–
Ischial region	50 (58.8)	
Sacrum	20 (23.5)	
Trochanter	8 (9.4)	
Sacrococcygeal	5 (5.9)	
Ischioperineal	2 (2.4)	
Evolution of the PU (months)	9 (2–98)	–
Type of surgery		–
One-step	59 (70)	
Two-step	26 (30)	
Type of flap		1
Musculocutaneous	45 (54)	
Skin	39 (46)	

Data are n (%) or median (minimum–maximum). AIS: ASIA Impairment Scale; BMI: body mass index; PU: pressure ulcer.

The overall recurrence rates are comparable to those in the literature (12–20, 29, 30), but the kinetics of these events has rarely been described. Keys et al. described a critical period between months 15 and 22 [19]; however, the study did not focus solely on primary surgeries, and recurrences could occur even earlier for secondary surgeries. When focusing solely on the follow-up of primary surgeries, as in our study, the at-risk period stretched to 48 months. This result can be explained in part by the remodeling phase of wound healing. Tew et al. [36] described 3 phases for wound repair of PUs: inflammation, proliferation and tissue remodeling. Initially the PU is at risk of reopening until the formation of a stable epithelium at 3 months postoperatively, on average. The remodeling phase starts when wound healing is complete and can last up to 2 years. At the end of this phase, a new lesion is considered a new PU. Authors did not apply this description to the surgical site. In our opinion, a parallel scenario could occur in the postoperative period but with a longer remodeling phase according to the degree of scar tissue generated by the surgical gesture. After a certain postoperative delay, the solidity of the wound repair remodeling seems to offer resistance

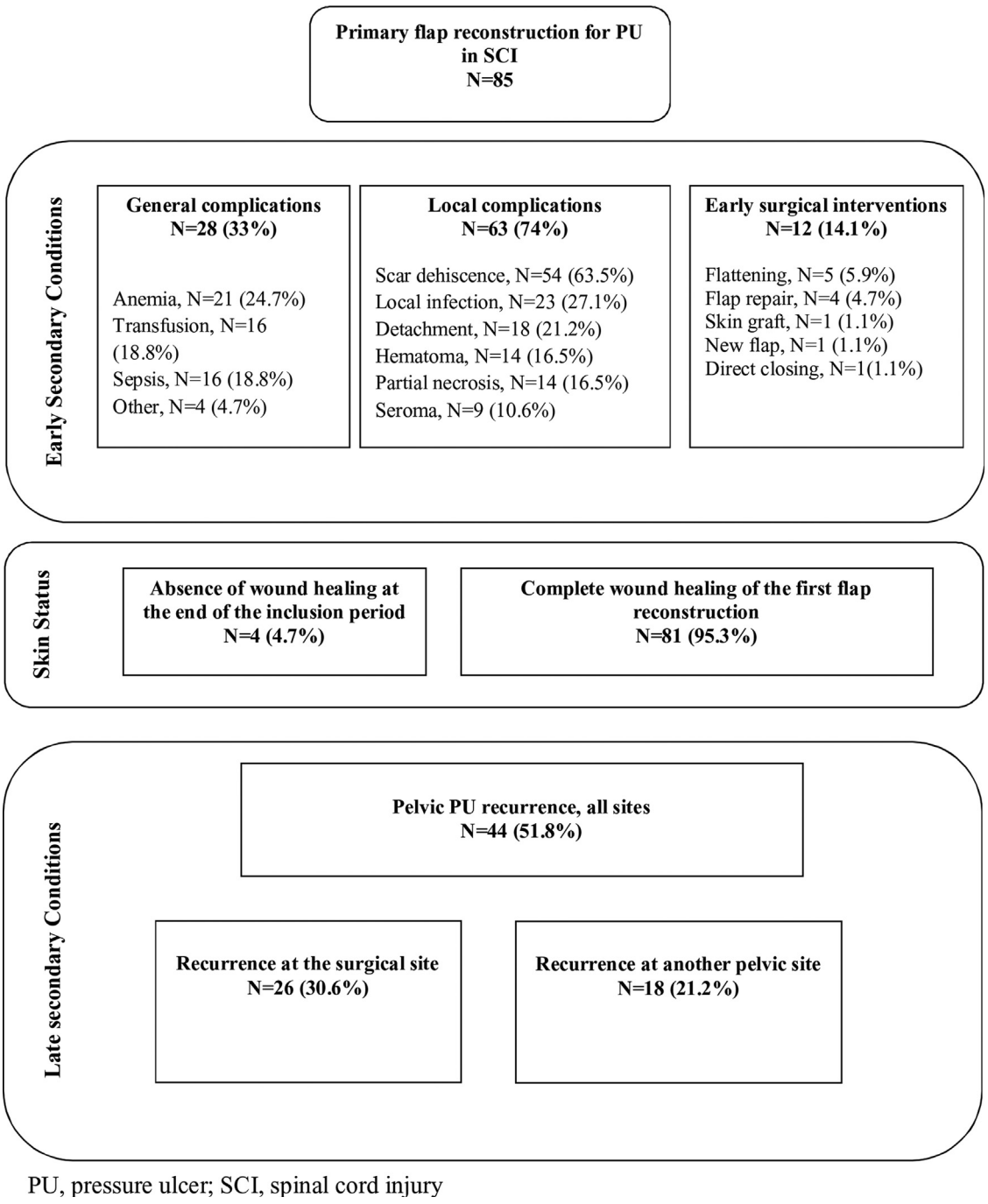

Fig. 2. Description of complications and recurrences of surgery. PU: pressure ulcer; SCI: spinal cord injury.

to good-quality mechanical constraints in operated patients. A second explanation could be behavioral: prevention behaviors adopted by patients who are recurrence-free after this 4-year delay might be the most effective protective factor.

In our opinion, these observations underline the need for cautious postoperative monitoring during the 4-year period, with the need to look at follow-up modalities adapted to each patient. In light of the recurrence rate, which also affected the surgical site in our cohort as in other studies [12,17,21,22,37,38], the entire pelvic region must be monitored postoperatively. One of the solutions could be therapeutic education programs. The care management team should be able to evaluate patients' capacities to manage the cutaneous risk: What are their skin surveillance strategies? What are signs alerting them that a lesion is starting? What strategies do they implement to manage the beginning of a PU? Some patients will be unable to implement an effective strategy, and the medical team will have to perform regular check-ups. Other patients will quickly be autonomous in their self-management and will need only motivational support. For example, Rintala et al. [30] showed lower recurrence rate after PU surgery with individualized therapeutic education and structured motivational support versus more sporadic follow-up or no therapeutic education programs. In the study, the mean recurrence time was 19.6 months with "monthly follow-up and therapeutic education program",

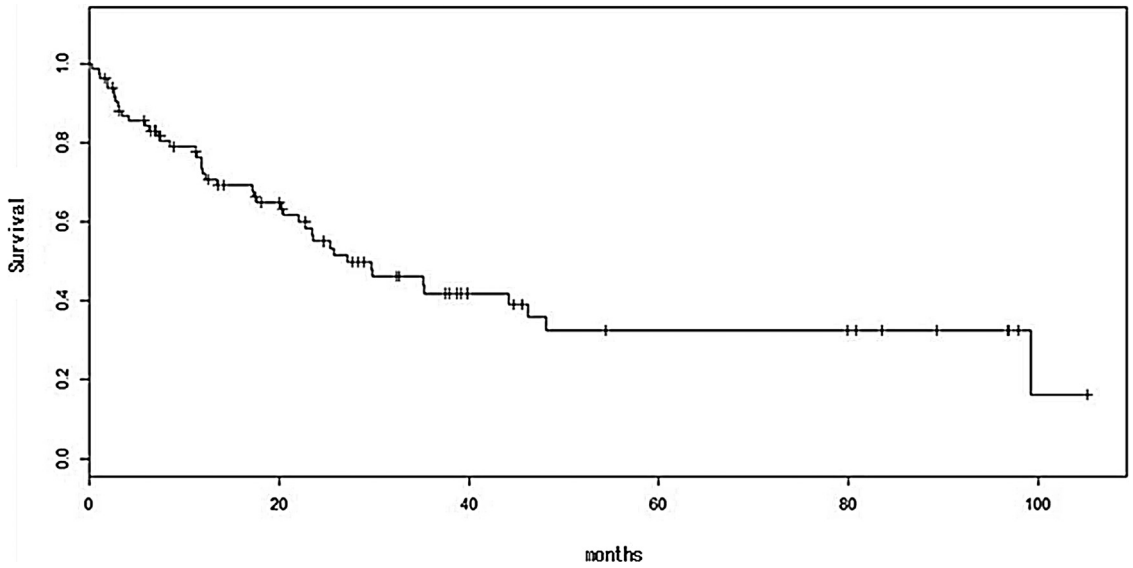

Fig. 3. Survival rate for pelvic PU recurrence.

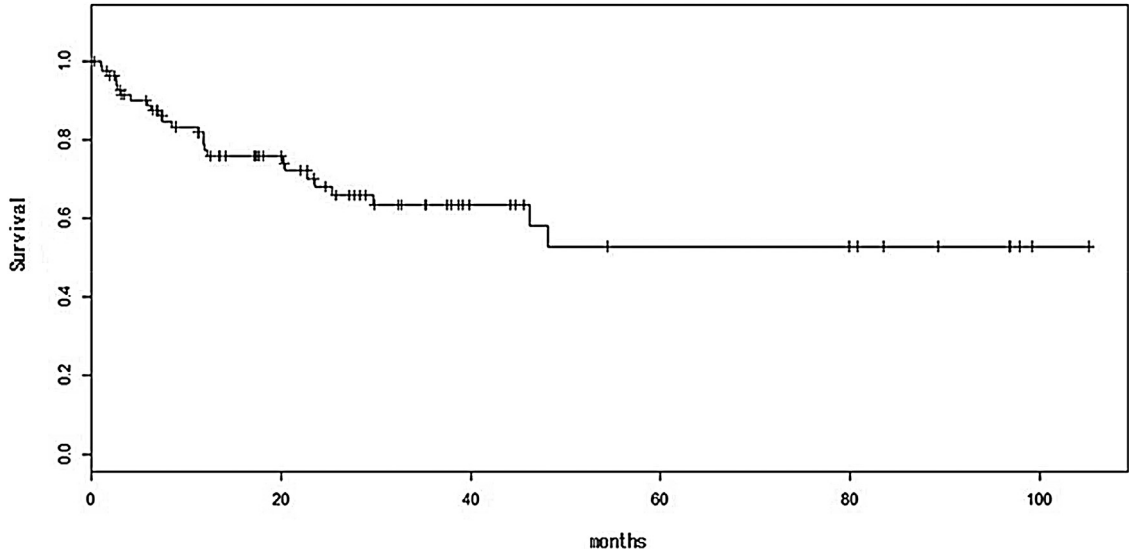

Fig. 4. Survival rate for recurrence at the surgical site.

10.1 months with "monthly follow-up only" and 10.3 months with "follow-up every 3 months only" ($P = 0.007$). The recurrence rate in these groups was 33%, 60% and 90%, respectively ($P = 0.07$).

In our study, risk factors of recurrence after primary surgery were evaluated at the surgical site or more largely on the pelvic region. The profile of identified factors fits with a bio-psychosocial logic, as we hypothesized. Some factors, such as ischial localization of the PU, are major recurrence risk factors, also found in several studies on postoperative recurrences (17, 22, 38) or more largely as a PU risk factor in this population (24). This finding can be explained at a pathophysiological level by the repartition of pressure points in the sitting position: pressure peaks are found at ischial and sacrococcygeal levels, and the sacrum is usually less affected by pressure.

Living with a partner, found as a risk factor of PPU recurrence, contradicts a study of PU risk factors finding that living with a partner was a protective factor with a moderate level of evidence [1]. Being single is often branded as the typical profile of people at risk of PU recurrence. Our study focused on primary surgery, which often occurs early in the clinical history of SCI. This factor may reflect a poor organization of the skin surveillance at home, with family caregivers not being properly trained in identifying the beginning of a skin lesion. Mattresses may be less adapted at home because they are often the object of compromise for the couple.

Table 2
Factors predicting pelvic pressure ulcers (PUs) at all sites after multivariate analysis.

Variables	HR	95% CI	*P*-value
Living with a partner at the time of surgery	2.29	1.25–4.21	0.0074
Non-traumatic etiology of SCI	3.39	1.47–7.79	0.0041
Ischial localization of the operated PU (reference)	–		
Sacral localization (vs. ischial)	0.48	0.23–0.99	0.046
Trochanter localization	NS		
Presence of a colostomy	2.79	1.43–5.43	0.0026

HR: hazard ratio; 95% CI: 95% confidence interval; NS: not significant; PU: pressure ulcer. Non-statistically significant variables studied in the multivariate analysis: sex, time since injury, ASIA score, smoking, diabetes, age at surgery, living alone at the time of surgery, having children at the time of surgery, working at the time of surgery, antibiotics course in preoperative, duration of the hospitalization in the surgical unit or another intensive care unit, postoperative anemia.

Table 3
Factors predicting PU recurrence at the surgical site after multivariate analysis.

Variables	HR	95% CI	*P*-value
Non-traumatic etiology of SCI	3.32	1.24–8.87	0.017
Ischial localization (reference)	–		
Sacral localization (vs. ischial)	0.33	0.12–0.89	0.029
Trochanter localization	NS		
Duration of hospitalization in the surgical unit or another intensive care unit	2.68	1.10–6.52	0.030

HR: hazard ratio; 95% CI: 95% confidence interval; NS: not significant. Non-statistically significant variables studied in the multivariate analysis: sex, time since injury, level of injury, ASIA score, diabetes, onset of postoperative complications, age at surgery, having children at the time of surgery, living with a partner at the time of surgery, history of skin graft at the surgical site, number of flaps used in the surgical gesture, type of high-prevention mattress used, postoperative anemia.

Non-traumatic SCI was a risk factor for PU recurrence in the pelvic region but also at the surgical site. We did not find this notion in the literature, because studies of PU surgery often investigate people with traumatic SCI. Of note, individuals with non-traumatic SCI have a lower incidence of PU [39,40] but a different sociodemographic profile [41,42], more comorbid conditions and different PU risk factors than those with traumatic SCI: only the ASIA score [43] and the presence of anemia were retained as risk factors after a multivariate analysis [40].

Keys et al. also found the presence of a colostomy associated on univariate analysis but not multivariate analysis with recurrence [19]. Patients with a colostomy could have difficulties with self-care, such as stool evacuation (previous to their colostomy) or skin lesion prevention. Similar to other authors [11,12], we did not find an association between local and general complications and PU recurrence. Only one study contradicted this evidence by reporting wound dehiscence as a risk factor on multivariate analysis [17]. This element is important for patients with a difficult postoperative period: having complications after surgery — regardless of the complication — does not compromise long-term outcomes.

Long postoperative hospitalization in the ICU or surgery department (more than 4 days) was a risk factor of recurrence at the surgical site. This element has never been studied before in the context of PU surgery in people with SCI but should be matched with studies of people with SCI in the acute phase, with hospitalization duration in the intensive care also identified as a PU risk factor [44], and is a strong argument for transferring the patient to a specialized SCI rehabilitation unit.

Our results favor a structured organization between surgical departments and rehabilitation units to allow the identification of people with SCI at risk of recurrence, allowing for early transfer to a SCI rehabilitation center for personalized therapeutic education and long-term specialized follow-up.

8. Limitations

The data collection modalities seem reliable in our study, but results regarding risk factors should be interpreted with caution. The retrospective nature of the data collection did not allow us to enter certain variables in the multivariate model, such as nutritional variables (albumin level, body mass index), identified as a risk factor by Keys et al. [19], or psychological and behavioral data that are rarely studied in routine practice. These results could be strengthened by a prospective study, which would allow us to investigate systematically, and in addition to nutritional variables, psychological and behavioral factors, such as the evaluation of protective skin behaviors with the Skin Management Needs Assessment Checklist [45].

9. Conclusion

The PU recurrence rate after primary flap surgery is high in people with SCI and is related to bio-psychosocial risk factors and the organization of care. Vigilance is essential during the first 4 years after surgery; this cautious monitoring requires educating the patient and family caregivers to manage the risk of recurrence at home. New prospective studies are needed to consolidate these results.

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Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://.dx.doi.org.10.1016/j.rehab.2018.08.003.

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