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Exploring Factors Associated With Complications Among Persons With Spinal Cord Injury Undergoing Surgical Closure of Stage 4 Pelvic Pressure Injuries

ABSTRACT

This study examined physiological and environmental variables associated with wound complications in persons with spinal cord injury (SCI) who underwent surgical repair of stage 4 pelvic pressure injuries (PI). A cohort of 88 patients undergoing 100 surgeries at one tertiary care hospital in Toronto, Canada, was identified. Patient-specific risk and operative variables were obtained from patient records and administrative data. Bivariate and Poisson regression analyses were used to model predictors of open versus closed wounds, 3 to 6 weeks following the surgical procedures. Eighty-eight patients having 100 surgical encounters were identified. Twenty-nine percent of the surgical encounters in females were open at 3 to 6 weeks postoperatively. Patients who had received more than 50 homecare nursing visits in the year before the index surgical date were less likely to have an open incision at the surgical follow-up clinic visit (incidence rate ratio [IRR] = 0.49; 95% confidence interval [CI] = 0.24, 0.99; p = 0.048). Patients who required surgical revision were more likely to have an open incision at the surgical follow-up clinic visit (IRR = 1.89; 95% CI = 1.15, 3.09; p = 0.01). Increased age, living in northern Ontario, and smoking were linked to a higher risk of open incision, though these findings were not statistically significant. Female gender and having peripheral vascular disease were identified as reducing the risk of having an open incision at the surgical follow-up clinic visit, but the findings were not statistically significant. Complication rates (incision open at routine surgical follow-up) were found to be 37% in this sample of SCI patients undergoing surgical closure of stage 4 PI. Future prospective studies to mitigate some of the risk factors are warranted.

Key Words: Pressure injury, surgical reconstruction, spinal cord injury, complications, risk factors

Exploration des facteurs associés aux complications chez les personnes atteintes d'une lésion de la moelle épinière ayant subi une fermeture chirurgicale de lésions de pression pelviennes de stade 4

RÉSUMÉ

Cette étude a examiné les variables physiologiques et environnementales associées aux complications des plaies chez des personnes atteintes d'une lésion de la moelle épinière (LME) ayant subi une réparation chirurgicale de lésions de pression (LP) pelviennes de stade 4. Une cohorte de 88 patients ayant subi 100 interventions chirurgicales dans un hôpital de soins tertiaires à Toronto, au Canada, a été identifiée. Les facteurs de risque propres aux patients ainsi que les variables opératoires ont été extraits des dossiers médicaux et des données administratives. Des analyses bivariées et des régressions de Poisson ont été

utilisées pour modéliser les prédicteurs de plaies ouvertes par rapport aux plaies fermées, de 3 à 6 semaines après les interventions chirurgicales. Quatre-vingt-huit patients ayant eu 100 interventions chirurgicales ont été recensés. Chez les femmes, vingt-neuf pour cent des plaies chirurgicales étaient encore ouvertes de 3 à 6 semaines après l'intervention. Les patients ayant reçu plus de 50 visites de soins infirmiers à domicile au cours de l'année précédant la date chirurgicale de référence étaient moins susceptibles de présenter une incision ouverte lors de la visite de suivi chirurgical (rapport de taux d'incidence [RTI] = 0,49; intervalle de confiance [IC] à 95 % = 0,24–0,99; p = 0,048). Les patients ayant nécessité une révision chirurgicale étaient plus susceptibles de présenter une incision ouverte lors de la visite de suivi chirurgical (RTI = 1,89; IC à 95 % = 1,15–3,09; p = 0,01). L'âge avancé, le fait de vivre dans le nord de l'Ontario et le tabagisme étaient associés à un risque accru d'incision ouverte, bien que ces résultats n'aient pas été statistiquement significatifs. Le sexe féminin et la présence d'une maladie vasculaire périphérique ont été associés à une réduction du risque d'incision ouverte lors de la visite de suivi chirurgical, sans toutefois atteindre la signification statistique. Le taux de complications (incision ouverte lors du suivi chirurgical de routine) était de 37 % dans cet échantillon de patients atteints de LME ayant subi une fermeture chirurgicale de LP de stade 4. Des études prospectives futures visant à atténuer certains facteurs de risque sont justifiées.

Mots clés : Lésion de pression, reconstruction chirurgicale, lésion de la moelle épinière, complications, facteurs de risque

Conflicts of Interest:
The authors gratefully acknowledge use of the data and services from St. Michael's Hospital, McMaster University, and the Institute of Clinical Evaluative Sciences and funding from the Ontario Neurotrauma Foundation Grant # 2017-RHI-SURGIC-1024.

This article is based on a chapter in the doctoral research of Laura Teague that was originally completed in July 2020. Dr. Teague had begun the process of preparing her research for submission to *NSWOC Advance* (now the *Canadian Journal of Wound, Ostomy and Continence*) when she passed away in November 2023. Dr. Karen Campbell, a long-time colleague and friend of Laura's, continued the process, acting as a corresponding author, to ensure Laura's work was shared as she had intended. While Karen was able to revise the writing to suit our format, the research and references are Laura's own and were up-to-date at the time of her initial research. Her family has agreed to the publication of this work posthumously in her memory.

The corresponding author declares that there are no undisclosed conflicts of interest regarding the publication of this paper. David Breukelman agreed, as Laura's next of kin, for Karen Campbell to act on Laura's behalf in the preparation of this article and in providing NSWOCC with nonexclusive rights to publish and otherwise deal with or make use of this article, and any photographs/images contained in it, in Canada and all other countries of the world.

Dr. Dillon Browne agreed, as Gina Browne's next of kin, for Karen Campbell to act on Gina's behalf in the preparation of this article and in providing NSWOCC with no-exclusive rights to publish and otherwise deal with or make use of this article, and any photographs/images contained in it, in Canada and all other countries of the world.

All other authors consented directly to the corresponding author to provide NSWOCC with nonexclusive rights to publish and otherwise deal with or make use of this article, and any photographs/images contained in it, in Canada and all other countries of the world. All authors declare that there are no undisclosed conflicts of interest regarding the publication of this paper.

Availability of Data and Materials:
The data supporting the findings are available upon request from the corresponding author.

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INTRODUCTION

Spinal cord injury (SCI) is devastating to patients and their families, causing permanent disability, high morbidity, and mortality. In addition to immobility caused by the injury, denervation impairs wound healing in patients with SCI and increases their risk of developing pressure injuries (PIs).[1] Consequently, PIs are a common and serious secondary health issue for these individuals, resulting in both economic and medical burdens.[2-4]

The prevalence of PIs in the SCI population exceeds that of the general population and ranges from 8 to 59%.[2,3,5,6] Moreover, PIs in the SCI population impair quality of life, work or school attendance, and community integration.[1] In Canada, the economic burden of PIs in persons with SCI is significant but not fully understood. In a small Ontario sample of community-dwelling SCI persons, the estimated mean costs of a chronic PI were found to be C$4,725 per month, or C$56,700 annually.[7] In the US study by Brem et al,[8] the estimated direct healthcare cost of treating a single stage 4 PI in the community and the hospital was found to be US$124,327 and US$129,248, respectively. In a systematic review, the cost of PI treatment per patient across different healthcare settings ranged from €1.71 to €470.49 per day.[9] Countries included were Spain, US, Germany, France, Canada, and Italy.[9] A review of 52 cases of PI surgical closure in Denmark by Filius et al.[10] reported a mean direct cost of €20,957, with the majority of the cost being associated with hospitalization days.

PIs range in severity from non-blanchable erythema (stage 1) to full-thickness tissue loss (stage 4).[11] Best practice guidelines suggest that surgical reconstruction with a flap is an option for chronic stage 4 PIs that have failed more conservative approaches to treatment.[11-16] Patients become candidates for surgery after a comprehensive assessment. If they can be optimized nutritionally, are free of infection, are free of substance use (e.g., cigarettes, alcohol, and street drugs), and are willing and able to participate in postoperative recovery protocols, patients are offered surgical closure. Patients are assessed in a preadmission facility for anesthesia purposes. They undergo surgical reconstruction of the PI and recover on a therapeutic mattress while in the hospital for approximately 8 days. A 4–5 week institutionalization in rehabilitation or convalescent care with bed rest is always considered our standard of care. However, some patients choose to recover at home, as they have adequate resources and pressure redistribution mattresses to rest on. If the patient's incision remains closed 3–6 weeks after the surgical date, a progressive seating program in a rehabilitation centre is started.

Despite the efforts to select optimal surgical candidates, a systematic review of the literature and subsequent studies indicate that complication rates associated with PI surgical flap closure range from 8.9 to 58%.[13,17,18] Furthermore, PI recurrence rates among persons living with SCI whose PIs were treated through surgical flap closure ranged from 11 to 29% in cases with postoperative complications and 6 to 61% in cases without postoperative complications.[14,19-21] Reports describing various surgical flap treatments, complication rates, and risk factors for PI recurrence have identified the importance of structured rehabilitation care in the postoperative phase.[12,22] The high rate of surgical wound complications and the extensive costs associated with PI management suggest the importance of identifying predictors of wound complications.[12-14,17,23]

The purpose of this study was to explore factors associated with complications (open incision) of surgically reconstructed stage 4 PIs in SCI patients at 3 to 6 weeks' follow-up.

METHODS

Research Ethics Board approval was obtained from St. Michael's Hospital in Toronto, Ontario, as well as from the Institute of Clinical Evaluative Sciences (ICES) for the duration of the study. Data were obtained from an original cohort of adult SCI subjects studied to identify costs and healthcare utilization pre- and post-PI reconstruction, and were linked using a unique identifier to health administrative data (Figure 1). Of the 108 patients with 136 encounters, we excluded 11 (8.1%) patients who underwent surgery within 1 year. We further excluded 11 (10.2%) with 16 (11.8%) encounters as the outcomes were unknown. Finally, we excluded 7 (6.5%) patients with 7 (5.1%) missing covariates, which included income quintile and healthcare utilization in the 1-year lookback. In total, 88 patients with 100 procedures were included in this analysis.

Gender, age at time of SCI, age at time of surgery, level of SCI, completeness of SCI, rural address, Northern Ontario address, living status, employment status, neighbourhood income quintile, Charlson co-morbidity index, history of autonomic dysreflexia, smoking status, history of peripheral vascular disease, length of stay, revision surgery, discharge disposition, and 50+ community nursing visits in the year prior to surgery were recorded. Follow-up was 3 years from the index surgery admission date.

Data were retrieved from a variety of sources, including:

- Patient records.
- Discharge Abstract Database (CIHI-DAD).
- National Ambulatory Care Reporting System (NACRS).
- National Rehabilitation Reporting System (NRS).
- Registered Persons Database (RPDB).
- Homecare Database (HCD).

Statistical analysis was performed using SAS V9. 3, R. Descriptive data (categorical) are expressed in frequencies and percentages. Continuous variables are expressed in mean +/- standard deviation (SD) and median with interquartile range (IQR). A chi-squared (x^2) test was employed for categorical variables. One-way analysis of variance (ANOVA) was used to compare continuous variables. Kruskal–Wallis one-way analysis of variance was employed for continuous nonparametric values, expressed as median. Generalized estimating equations (GEEs) with exchangeable correlation structures were used to account for repeated measurements within subjects. The Wilcoxon Rank-Sum Test was employed to compare visit counts presurgery to 1 year postsurgery. Bivariate Poisson regression analyses were used to model predictors of open versus closed incisions at 3–6 weeks following the surgical procedure. A risk reduction (RR) >1 indicates that individuals with certain characteristic ulcers had increased risk with open incisions compared with those with closed incisions (Table 1).

RESULTS

Seventy-one percent of all surgeries performed were on male patients. The mean age at the time of SCI was 23.31 years (*SD*=13.47). The mean age at the time of surgery was 43.15 years (*SD*= 12.58). Twenty-three (23%) of the SCIs were cervical, 59 (59%) were thoraco–lumbar, and 18 (18%) were unknown. Completeness of the SCI was recorded for 11% of the subjects; 37%, had incomplete SCI, and 52% were unknown. Ninety-three percent lived at an urban address, and 10% lived at a northern Ontario address. Forty-seven percent lived in homes, 20% lived in apartments, and <5 (8.1%) were in assisted living. The living situation was unknown in 28% of the cohort. Eight percent were employed full time; 24%

were receiving a disability pension; and 55% had an unknown source of income.

Sixty-two percent of patients had closed incisions, and 29% had open incisions at the 3–6 week follow-up after index surgery. Significantly more patients in the open incision group were smokers (p=0.039) and had revision surgery. More patients in the group with closed incisions had over 50 nursing visits in the year prior to the index surgery, approaching statistical significance (p=0.061). Table 2 displays the univariate (unadjusted) robust Poisson model. This analysis accounts for repeated subjects using a GEE with an exchangeable correlation structure. Statistically significant variables in the univariate model were employed to build the Poisson regression model.

Table 3 summarises the multivariate analysis using the Poisson regression model. Persons receiving greater than 50 homecare nursing visits in the year prior to the index surgical date had a decreased risk of having an open incision at the surgical follow-up clinic visit (RR=0.49; 95% CI=0.24-0.99; p=0.048). Persons who required surgical revision had an increased risk of an open incision at the surgical follow-up clinic visit (RR=1.89; 95% CI=1.15-3.09; p=0.01). Increased age, income quintile, living in northern Ontario, and smoking were linked to greater open incision risk, but these results lacked statistical significance. Being female and having peripheral vascular disease were identified as reducing the risk of open incisions at the surgical follow-up clinic visit However, these risk factors were not statistically significant.

DISCUSSION

In the present study, 37 (37%) of patients experienced complications. Having consistent homecare visits was associated with a decreased risk of an open incision, whereas a person who required surgical revision had an increased risk of an open incision at the surgical follow-up clinic visit. Increased age, northern Ontario residence, and smoking were found to increase the risk of open incision but were not statistically significant. Being female and having peripheral vascular disease were identified as reducing the risk of an open incision at the surgical follow-up clinic visit, but these findings were statistically insignificant. To our knowledge, this is the first study to examine biophysical and environmental variables at 1 year prior to the surgical procedure.

Interestingly, there were no significant differences in complication rates across recovery locations (home with home care, rehabilitation, or other institution). This finding may be due to the small sample size or the intentional decision to send persons at higher risk to rehabilitation facilities. Further research is required to explore this phenomenon.

A retrospective study by Kierney et al.[24] was conducted in the U.S. to determine PI recurrence rates in 158 patients who underwent surgical flap closure of 268 PIs. This sample included traumatic and nontraumatic SCI persons. The follow-up time was 3.7 years. They reported a recurrence rate of 19% (49/268) over the same site. Analysis of risk factors associated with recurrence was not explored beyond identifying the location and type of surgery and the type of SCI. While the outcomes of that study cannot be compared with those of the present study, it is noteworthy that 81% of the patients did not re-ulcerate at the same operative site for an extended period of time.

Schryvers et al.[14] published one of the first reviews of PI reconstruction outcomes in Canada. In their sample size of 168 patients with 598 encounters of stage 4 PIs undergoing reconstruction, the outcomes included suture line dehiscence and revision surgery. They reported that 31% (185/598) had suture line dehiscence, with 11% (66/598) requiring revision surgery. They collected socio-demographic data and found that 95% (159/168) had SCI. While no robust statistical analyses were conducted, descriptive statistics were used to suggest that social factors, such as unemployment, living situation, race (indigenous), and drug use, in addition to surgical technique, may influence outcomes. Srivastava et al.[25] conducted a small prospective study of 25 SCI patients with 39 PIs to determine outcomes of PI reconstruction. Four participants (16.6%) had initial complications: wound dehiscence 8.3% (2) and delayed graft healing 8.3% (2). The duration of follow-up was 12 to 21 months (mean=15.4, +7.45 months). Four participants (17.3%) had ulcer recurrence. Given the small sample size, a regression analysis to explore risk factors for complications would not have been adequately powered and therefore would not have been useful.

Ahluwalia, Martin, and Mahoney[12] conducted a retrospective review of stage 3 and 4 PI reconstruction in 78 patients from a consecutive cohort who had 104 flap procedures following surgical reconstruction of a stage 3 or 4 PI between 1997 and 2007 in Toronto, Canada. Complications and recurrence rates were examined by PI location and reconstruction method, enabling direct comparison of surgical outcomes. Complications were defined as any incision that failed to heal immediately postoperatively, including minor dehiscence, infection, and flap necrosis. They reported an overall flap complication rate of 16% (17/104), with a wound recurrence rate of 7% (7/104), and concluded that a combination posterior medial thigh fasciocutaneous flap with a biceps femoris muscle flap could be recommended as a first-choice option for ischial pressure wound reconstruction. No univariate or multivariate analyses were performed. While this review was intended to evaluate outcomes of flap selection, other variables, such as those collected in the administrative database, were not considered to potentially influence flap outcomes.

Keys et al.[23] conducted a retrospective review of 135 American veteran patients with SCI who underwent 227 PI flap closure procedures with a primary outcome of recurrence of

Figure 1: *Flow Chart of Study*

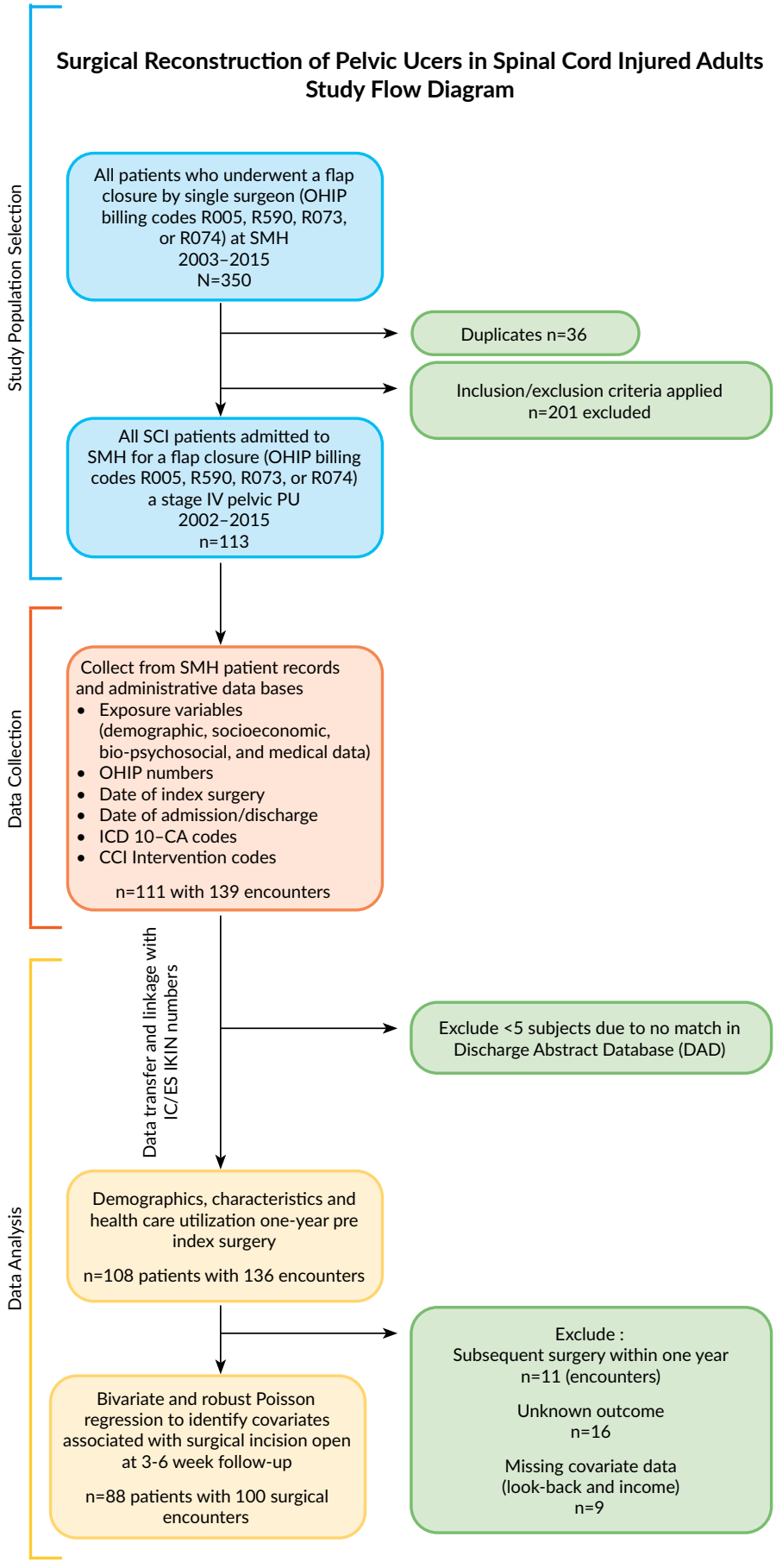

Table 1: *Demographics and Bivariate Analysis of Incision Closed vs. Open*

VARIABLE	INCISION CLOSED (N=62)	INCISION OPEN (N=38)	TOTAL (N=100)	P
Gender				
Female	20 (32.3%)	9 (23.7%)	29 (29.0%)	0.359
Male	42 (67.7%)	29 (76.3%)	71 (71.0%)	
Age at time of SCI (years)				
Mean ± SD	20.54 ± 10.90	25.14 ± 16.56	23.31 + 13.47	0.104
Median (IQR)	23 (17–28)	25 (17–36)	23 (17–30)	0.206
Age at time of surgery (years)				
Mean ± SD	41.44 ± 11.72	45.95 ± 13.56	43.15 ±12.58	0.082
Median (IQR)	41 (32–51)	47 (38–57)	43 (34–53)	0.10
Level of SCI				
Cervical	15 (24.2%)	8 (21.1%)	23 (23.0%)	0.81
Thoracic/Lumbar	37 (59.7%)	22 (57.9%)	59 (59.0%)	
Unknown	10 (16.1%)	8 (21.1%)	18 (18.0%)	
Completeness of SCI				
Unknown	22 (35.5%)	15 (39.5%)	37 (37.0%)	0.74
Complete	6 (9.7%)	<=5 (13.2%)	11 (11.0%)	
Incomplete	34 (54.8%)	18 (47.4%)	52 (52.0%)	
Lives at Rural Address				
No	59 (95.2%)	34 (89.5%)	93 (93.0%)	0.28
Yes	<=5 (4.8%)	<=5 (10.5%)	7 (7.0%)	
Northern Ontario Address				
Yes	<=5 (4.8%)	7 (18.4%)	10 (10.0%)	0.03
Living Status				
Home	24 (38.7%)	23 (60.5%)	47 (47.0%)	0.06
Apartment	12 (19.4%)	8 (21.1%)	20 (20.0%)	
Assisted living	<=5 (8.1%)	0 (0.0%)	<=5 (5.0%)	
Unknown	21 (33.9%)	7 (18.4%)	28 (28.0%)	
Employment Status	<=5 (6.5%)	<=5 (10.5%)	8 (8.0%)	0.36
Full time	16 (25.8%)	8 (21.1%)	24 (24.0%)	
ODSP	<=5 (1.6%)	0 (0.0%)	<=5 (1.0%)	
WSIB	10 (16.1%)	<=5 (5.3%)	12 (12.0%)	
Unemployed	31 (50.0%)	24 (63.2%)	55 (55.0%)	
Unknown	<=5 (6.5%)	<=5 (10.5%)	8 (8.0%)	0.36

VARIABLE	INCISION CLOSED (N=62)	INCISION OPEN (N=38)	TOTAL (N=100)	P
Nearest Census-Based Neighbourhood Income Quintile (within CMA/CA)				
1	13 (21.0%)	9 (23.7%)	22 (22.0%)	0.57
2	14 (22.6%)	7 (18.4%)	21 (21.0%)	
3	8 (12.9%)	<=5 (7.9%)	11 (11.0%)	
4	14 (22.6%)	6 (15.8%)	20 (20.0%)	
5	13 (21.0%)	13 (34.2%)	26 (26.0%)	
Charlson Community Index				
0	34 (54.8%)	21 (55.3%)	55 (55.0%)	0.22
1	<=5 (1.6%)	0 (0.0%)	<=5 (1.0%)	
2	27 (43.5%)	14 (36.8%)	41 (41.0%)	
3	0 (0.0%)	<=5 (5.3%)	<=5 (2.0%)	
4	0 (0.0%)	<=5 (2.6%)	<=5 (1.0%)	
History of autonomic dysreflexia				
Unknown	<=5 (8.1%)	<=5 (7.9%)	8 (8.0%)	0.99
No	48 (77.4%)	29 (76.3%)	77 (77.0%)	
Yes	9 (14.5%)	6 (15.8%)	15 (15.0%)	
Current smoker				
Yes	14 (22.6%)	16 (42.1%)	30 (30.0%)	0.04
History of peripheral vascular disease				
No	60 (96.8%)	34 (89.5%)	94 (94.0%)	0.136
Yes	<=5 (3.2%)	<=5 (10.5%)	6 (6.0%)	
Length of stay (days)				
Mean ± SD	7.89 ± 3.08	8.58 ± 6.48	8.15 ± 4.65	0.473
Median (IQR)	8 (6-8)	7 (5-8)	7 (6-8)	0.21
Revision surgery required				
Yes	<=5 (3.2%)	10 (26.3%)	12 (12.0%)	<. 0.01
Discharge Disposition				
Community	13 (21.0%)	15 (39.5%)	28 (28.0%)	0.20
Rehab	44 (71.0%)	20 (52.6%)	64 (64.0%)	
Other institution	<=5 (3.2%)	<=5 (5.3%)	<=5 (4.0%)	
Unknown	<=5 (4.8%)	<=5 (2.6%)	<=5 (4.0%)	
50+ HC nursing visits (year prior)				
Yes	57 (91.9%)	30 (78.9%)	87 (87.0%)	0.06

Note. *N*=97.

Table 2: *Univariate (unadjusted) Robust Poisson Model*

VARIABLE	IRR	95% CI		P
Male gender				
Yes	1.33	0.71	2.41	0.36
Living in a northern residence				
Yes	1.80	1.24	3.15	0.02
Greater than 50 homecare nursing visits in year prior				
Yes	0.56	0.34	0.97	0.03
Revision surgery				
Yes	2.66	1.74	3.87	0.00
Disposition to rehabilitation facility				
Rehab	0.59	0.37	0.94	0.03
Peripheral arterial disease				
Yes	1.82	1.05	3.16	0.03
Smoking				
Yes	1.74	1.08	2.79	0.02
Skin flap on anatomical ischium				
Yes	0.6			0.19
Bladder incontinence				
Yes	0.80	0.31	1.98	0.63
Bowel incontinence				
Yes	0.71	0.37	1.55	0.36
Rural residence				
Yes	1.34	0.76	3.04	0.44
Income quintile				
5	1.20	0.78	2.31	0.55
4	0.62	0.62	0.41	0.23
3	0.62	0.12	0.64	0.38
2	0.89	0.28	1.64	0.74
Regional Postal Code				
P-Northern	1.47	0.65	41.6	0.42
M-Toronto	0.67	0.26	1.83	0.43
L-GTHA	0.93	0.37	2.39	0.88
Discharge disposition				
Unknown	0.32	0.10	2.32	0.19
Other institution	0.94	0.36	2.45	0.90
Current consumption of >2 alcoholic drinks/day				
Yes	1.31	0.32	5.35	0.71
Type of anesthesia				
Unknown	1.03	0.51	2.65	0.95
Regional	0.53	0.09	3.09	0.48
Monitored	1.35	0.44	3.98	0.59
Spinal	1.77	0.74	4.07	0.18

VARIABLE CONT'D	IRR CONT'D	95% CI CONT'D		P CONT'D
Cause of SCI				
Unknown	0.62	0.25	2.12	0.41
Traumatic	0.97	0.57	1.81	0.91
Nontraumatic	0.28	0.04	1.80	0.18
Completeness of SCI				
Complete	0.89	0.54	1.59	0.66
Incomplete	1.19	0.56	2.55	0.66
Positive intraoperative wound culture				
No	1.35	0.43	6.22	0.67
Yes	1.38	0.42	4.60	0.60
Diabetes				
Yes	1.44	0.94	2.58	0.17
Family Support				
Yes	1.35	0.43	4.48	0.62
Hypertension				
	1.43	0.90	2.54	0.18
SCI Injury Level				
Unknown	1.19	0.61	2.91	0.67
Thoracic/ Lumbar	1.06	0.54	2.08	0.86
Cervical	1.32	?	?	0.40
Marital Status				
Unknown	1.73	0.72	4.01	0.21
Divorced	0.86	0.26	2.75	0.81
Married	0.88	0.48	1.70	0.69
Myocutaneous flap performed in location 1				
	0.96	0.54	1.59	0.88
Obesity				
Yes	0.63	0.25	2.09	0.41
Osteomyelitis				
Yes	1.32	0.47	3.56	0.59
Osteoporosis				
Yes	0.64	0.11	3.49	0.61
Use of chronic pain meds				
Yes	1.13	0.63	1.96	0.66
History of pneumonia				
Yes	0.87	0.17	4.28	0.86
Renal disease				
Yes	0.71	0.18	2.89	0.64
Help at home				
Yes	0.88	0.46	1.78	0.71
History of spasticity				
Yes	1.44	0.83	2.40	0.17

Note. N=100.

Table 3: *Incidence Rate Ratio of Open Incision at Follow-up in a Surgical Clinic Using a Poisson Regression*

VARIABLE	IRR	95% CI		P
Age (per year older)	1.01	0.99	1.03	0.13
Female vs. male	0.86	0.45	1.61	0.63
Income quintile 5 vs. other	1.42	0.83	2.45	0.20
Northern Ontario residence	1.30	0.73	2.30	0.38
Skin flap on anatomical location 1	0.76	0.36	1.63	0.48
50+ homecare nursing visits (year prior)	0.49	0.24	0.99	0.05
Surgical revision needed	1.89	1.16	3.09	0.01
Peripheral vascular disease	0.85	0.39	1.87	0.69
Smoking	1.72	0.91	3.23	0.09

Note: N=100

PI at the operative site. Secondary outcomes included incisional dehiscence and operative revision. Their follow-up time was 6 weeks; the final endpoint was unclear. They reported 88 recurrences of PIs after flap surgery (39%) of 227 operations performed. Thirty-six (16%) had dehiscence necessitating a return to the operating room. A glycosylated hemoglobin (A1C) level less than 6% and previous same-site flap failure were associated with both dehiscence and recurrence (OR=2.15 and 3.84; and OR=6.51 and 3.27). Younger age and albumin less than 3.5 g/dL were associated with early flap failure (OR=5.95 and 2.45). Ischial wound location correlated with late recurrence (OR=4.01). They also reported that patients with multiple risk factors had operative success rates that approached zero. The younger age as a risk factor was in contrast to our study findings. The PI (ischial) site as a risk factor would be congruent, as this bony prominence would be exposed to the highest risk for people sitting in wheelchairs for prolonged periods.

Sameem et al.[13] conducted a meta-analysis of 55 studies, which showed an overall surgical complication rate of 19% and a 9% ulcer recurrence rate. Follow-up times ranged from 1 to 93 months. Site complications included wound infection, hematoma, abscess, surgical wound dehiscence, and ulcer recurrence. This study compared outcomes based solely on operative techniques. There were no analyses of risk factors for surgical complications or recurrence rates. While there was heterogeneity in patient populations and follow-up times, the study author concluded that PI flap closure is an effective intervention in the context of careful patient selection and optimization during the pre- and post-operative periods.

Larson et al.[26] studied 101 SCI patients with 179 encounters of PI reconstruction. The complication rate was 17.3% (35/179). Suture-line dehiscence, infection, and distal flap necrosis were the complications recorded. The mean follow-up period was 436 days. They examined nutrition (low albumin levels) and positive bone cultures as risk factors for complications and ulcer recurrence, but did not find any significant differences between those with and without complications. These findings were aligned with the present study.

Chiu et al.[27] conducted a similar study with 181 surgical flap encounters between January 2002 and December 2013. Their study compared outcomes between different types of reconstruction procedures. Outcome measures included suture line dehiscence, infection, hematoma, flap necrosis, and PI recurrence. Complication and recurrence rates for all flaps were 46.5% (84/181) and 16% (29/181), respectively, and there were no statistical differences between the types of flap reconstruction. In multivariate regression analysis, serum albumin of less than 3.0 g/dl, ischial site of surgery, and paraplegia were found to be significant risk factors for wound complications. This study had 48% (87/181) of the encounters with SCI.

Diamond et al.[28] conducted a retrospective review of 320 patients who underwent PI flap closure in the U.S. from 2011 to 2012. This study included all persons with PI and was not specific to SCI. The 30-day flap failure rate was 1.9% (n=6), the reoperation rate was 4.7% (n=15), the SSI rate was 8% (n=25), and dehiscence was 4.7% (n=15). The overall 30-day complication rate was 19% (n=61). In their regression analysis, previous steroid use was found to increase the odds of flap failure (OR 15.42, p=0.02). In our study, steroid use was not found to be a significant risk factor.

Bamba et al.[18] conducted a retrospective chart review of 276 patients who underwent flap reconstruction for a PI between 1997 and 2015. The characteristics of patients were analyzed to identify those with complications, including PI recurrence, wound dehiscence, and wound infection. The demographics indicated that 82.6% (231/276) of the sample had SCI. They reported an overall complication rate of 58% (162/276). In this sample, multivariate regression analysis of ischial PI was found to be the only independent risk factor for both major and minor complications (RR=2.63; 95% CI=1.52-4.54; p < .01). In our study, the location of the reconstruction did not increase the risk of open incision.

Gargano and colleagues[29] conducted a prospective study reviewing sequential patients treated with two types of flap coverage over 36 months from 2011 to 2014. Fourteen (70%) were SCI patients. A total of 8 (40%) complications occurred in the conventional surgical flap operations. While they found no statistical differences between the two groups, the sample size was small, and no multivariate analysis was performed.

In a larger, retrospective review of 1,248 patients from 2005 to 2015 in Utah, U.S., Kwok et al.[30] reported an overall complication rate of 35.0% (437/1,248 following PI reconstruction). Complications included mortality, postoperative blood transfusion, surgical site infection, UTI, sepsis, wound dehiscence, pneumonia, septic shock, ICU stay with ventilation, renal impairment, myocardial infarction, pulmonary embolism, and DVT. The reported rates of surgical site infection and wound dehiscence were 8.09% and 4.57%, respectively. There were no reoperation encounters reported. These findings are difficult to compare with our study, as it was unclear how many of the subjects had SCI. The surgical site complication rate was significantly lower than in other studies. Surgical wound complications accounted for 12.7% (158/1,248) of the 35% complication rate that was reported. On multivariate regression, obesity was independently associated with complications (OR=11.325; 95% CI=1.00, 1.74; p < 0.044), and flap closure was again associated with fewer complications (OR=0.71; 95% CI 0.55, 0.91; p < 0.008).

Tran et al.[31] reviewed administrative data on PI reconstruction outcomes from the National Surgical Quality Improvement Project (NSQIP) database in Boston, U.S. The study reviewed 755 surgical encounters and reported an overall complication rate of 25% at day 30, post-operatively. While surgical incisional dehiscence, superficial and deep organ space infection, reoperation, and readmission infection accounted for 6.9% (52/755) of the complication rate, they also included bleeding, septic shock, deep vein thrombosis, and pulmonary embolism as complications. Moreover, only 28% (210/755) of the sample had SCI as a diagnosis. Consequently, comparing these results with the present study is not feasible.

Finally, Wong et al.[32] conducted a systematic review of the literature to compare outcomes of reconstructive surgery for closing PIs (stage 2 or above) with no surgery or alternative forms of surgery across care settings. They found no randomized controlled trials supporting or refuting the role of reconstructive surgery for PIs. They concluded there is a need for more rigorous and robust research in this area.

Our study has several strengths and limitations. This is the first known study that combines patient records with administrative data to explore factors that may influence outcomes of surgical flap closure of PIs in SCI persons. Second, using retrospective data from patient records and administrative databases rather than survey data may reduce recall bias and response bias. The nature and size of the sampling (a convenience sample from a single centre study, a single surgeon, and a convenience sample in Canada) can therefore limit the generalizability of the findings. Environmental and psychosocial variables, such as timely access to surgical consultation, surgical wait times, delays in access to coordinated SCI-specific health care, mental health, lifestyle choices, and high-risk behaviours, were not available in either the patient records or administrative databases and could introduce confounding factors.

CONCLUSION

This Canadian cohort of patients demonstrated a high rate of postoperative wounds being open at the postsurgery clinic follow-up visit. Our study and literature review show that complications of surgical flap closure present a

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3 Source: Allen D, Robinson T, Schmidt M, Kieswetter K. Preclinical assessment of novel longer-duration wear negative pressure wound therapy dressing in a porcine model. Wound Rep Reg. 2023;31:349-359. Information contained within conducted animal studies has not been evaluated by the U.S. Food & Drug Administration.

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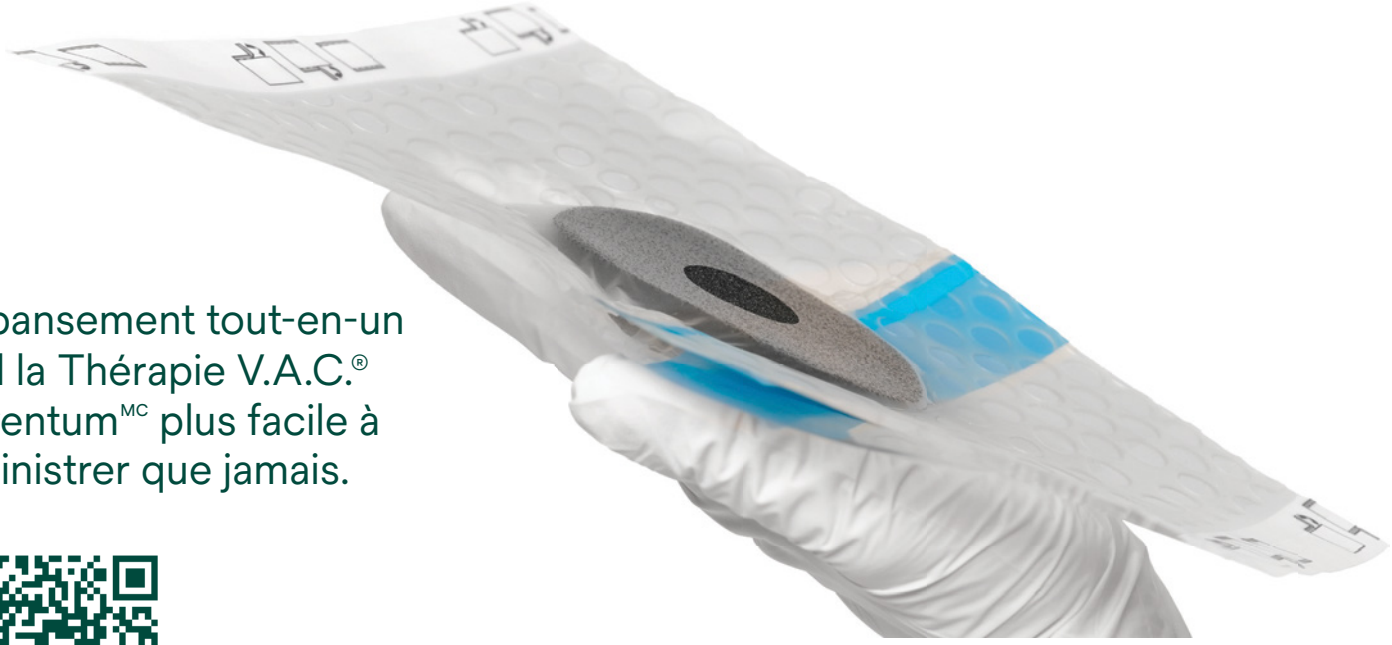

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2 Lors d'un essai d'utilisation simulé comportant 12 utilisateurs infirmiers et chirurgiens. Temps moyen de 1 min 48 s. SAT-MTF-05-995965, évaluation de marketing portant sur le Solventum V.A.C. Pansement Peel and Place.

* Par rapport à un Pansement en mousse pour thérapie par pression négative 3M[MC] traditionnel.

3 Source : ALLEN, D., T. ROBINSON, M. SCHMIDT et K. KIESWETTER. « Preclinical assessment of novel longer-duration wear negative pressure wound therapy dressing in a porcine model », *Wound Rep. Reg.*, vol. 31 (2023), p. 349-359. L'information contenue dans les études menées chez les animaux n'a pas été évaluée par la Food and Drug Administration des États-Unis.

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formidable challenge. These complications can contribute to delayed wound closure, delayed rehabilitation, reduced quality of life, and continued financial burden on the health-care system. Sameem et al.[13] provide data suggesting that there are no differences in outcomes based on the type of flap used for PI reconstruction. Significantly more of the patients who received more than 50 nursing care visits in the previous year had closed incisions at the surgical follow-up visit. Those who were incrementally older, from a northern Ontario residence, and requiring surgical revision were more likely to have an open incision. Although this is a small sample size, delivering regular nursing care and increasing access to specialized SCI care in rural areas may improve outcomes.

Our data, similar to other studies conducted in developed countries, suggest that not only surgeons but the entire interdisciplinary team need to revisit and collaborate on their risk-reduction efforts. This study identifies numerous risk factors to consider when offering flap reconstruction. Prospective studies or studies with data collected through registries specifically designed for SCI patients may identify more complete, relevant, and modifiable characteristics or risk factors that can inform prospective interventional studies within this rare population. Building screening tools and comparing models of care delivery in persons with SCI undergoing PI reconstruction are suggested to determine whether surgical outcomes can be improved in this complex patient population. •

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