AWARD NUMBER: W81XWH-10-1-0840

TITLE: SCI Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population

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REPORT DATE: March 2016

TYPE OF REPORT: Final Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
March 2016	Final	30Sep2011 - 31Dec2015

4. TITLE AND SUBTITLE
SCI Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population

5a. CONTRACT NUMBER
W81XWH-10-1-0840

5b. GRANT NUMBER
SC090613

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Tampa VA Research and Education Foundation
5620 E. Fowler Avenue - Suite B
Temple Terrace, FL 33617

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Phase 2 was a prospective study to measure skin tissue thickness in Veterans with SCI (n=30) with high-resolution ultrasound as a potential indicator of pressure ulcer (PrU) risk. Phase 1 subjects could not be contacted, which resulted in recruitment delays and required an alternative approach for subject enrollment. Due to these delays, a no cost extension was requested to extend the study to complete the data collection. Data collection was completed for 6 patients at the time of the request. Fifteen patients were completed when the key person who was obtaining the ultrasound measurements left the facility. Due to the loss of personnel and the lack of study funds, it was not possible to bring on another investigator to complete the rest of the data collection for the study. The subject stratification of data collection groups consisted of: 3 patients with a history of zero PrUs, 2 patients with a history of 1-2 PrUs, and 10 patients with a history of 3+ PrUs. Due to the lack of personnel and study funds, Phase 2 was unable to be completed in full.

15. SUBJECT TERMS
Pressure ulcers, spinal cord injury, risk factors

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	12	19b. TELEPHONE NUMBER *(include area code)*

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1. **INTRODUCTION:** Risk factors for the development and recurrence of pressure ulcers (PrUs) have primarily been identified by research conducted in elderly and nursing home populations, or in the Spinal Cord Injury (SCI) Model systems, which includes primarily acute injuries. Literature examining PrU risk and recurrence in Veterans with SCI typically focuses on individuals who have already developed PrUs. Individuals that have not developed PrUs are not included, thus excluding an important 'control' population. Although more than 200 risk factors have been identified to affect PrU development, it is not clear how to stratify them into useful guidelines for PrU prevention in SCI. A retrospective survey of SCI outpatients, who completed their annual SCI Comprehensive Preventive Health Evaluation, was conducted in the first phase of this research based on our preliminary hypothesis that there are factors, biological and psychosocial, that increase or reduce vulnerability to PrUs among persons with SCI. Anthropometric measures of skin tissue thickness will be measured in the second phase of this research. The data obtained will be used to identify and stratify the factors that are different between patients who have never had a PrU and those who suffer from multiple PrUs, with emphasis on modifiable risk factors. Subsequent studies will then refine this list prospectively, leading to the development of evidence-based risk assessment tools and customized interventions that will be tested in future randomized controlled trials.

2. **KEYWORDS:** Pressure ulcers, spinal cord injury, risk factors

3. **OVERALL PROJECT SUMMARY:** Phase 1 was a SCI patient chart review (n=120) to identify pressure ulcer risk factors conducted by Dr. Lisa Gould as PI. She left the facility and Dr. Matthew J. Peterson became PI for Phase 2, a prospective study to measure skin tissue thickness with high resolution ultrasound as an indicator of pressure ulcer risk. The original proposed study for Phase 2 was to measure skin thickness from a subset of those individuals (n=30) who had their charts reviewed in Phase 1. However, since Phase 1 included a waiver of informed consent and HIPAA as a secondary data analysis study, the individuals of those charts that were reviewed did not consent to participate. Dr. Peterson received IRB approval to contact those Veterans via standard mail to ask them to participate upon initiating Phase 2, but he only heard back from 1 individual confirming interest. After several discussions with the IRB, permission was not granted to call these prospective participants to recruit them for Phase 2. Dr. Peterson, after additional discussions with Dr. Patricia Henry (Science Officer) and with limited remaining study funds, decided to move forward with recruiting Veterans that met the inclusion/exclusion criteria despite not having participated in Phase 1. Due to the recruitment delays from the lack of success from the mailings, a no cost extension was requested in July 2015 to extend the study through the calendar year of 2015 to complete the data collection. Data collection was completed for 6 patients at the time of the request. Fifteen patients were completed into October when Dr. Gutmann (key personnel: the physician obtaining the ultrasound measurements) left the facility. Due to the loss of personnel and the lack of study funds, it was not possible to bring on another investigator to complete the rest of the data collection for the study. The subject stratification of data collection groups consisted of: 3 patients with a history of zero PrUs, 2 patients with a history of 1-2 PrUs, and 10 patients with a history of 3+ PrUs. Again, regrettably, due to the lack of personnel and study funds, Phase 2 was unable to be completed in full.

4. **KEY RESEARCH ACCOMPLISHMENTS:** Nothing to report.

5. **CONCLUSION:** Future work will analyze the skin tissue thickness data from these 15 patients and compare the results to the research literature. Specifically, this comparison will aim to see if those patients with a history of PrUs tend to have thinner skin tissue thickness, i.e., are at greater risk for PrU development, and whether ultrasound measurements could be used to predict PrU risk for Veterans with SCI.

6. **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:** Nothing to report.

7. **INVENTIONS, PATENTS AND LICENSES:** Nothing to report.

8. **REPORTABLE OUTCOMES:**

Peer-Reviewed Scientific Journals (included in appendix):

Lisa J. Gould, MD, PhD; Christine M Olney, PhD, RN; Jane S Nichols, MSN, CWON; Aaron R Block, MD, MPH; Ross M Simon, MD, MPH; Marylou Guihan, PhD. Spinal Cord Injury Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population. Medical Hypotheses. 2014;83(5):552-558. DOI: 10.1016/j.mehy.2014.08.027

9. **OTHER ACHIEVEMENTS:** Nothing to report.

10. **REFERENCES:** Not applicable.

11. **APPENDICES:**

- The manuscript submission that was accepted for publication to Medical Hypotheses, "Spinal Cord Injury Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population."

Medical Hypotheses 83 (2014) 552–558

Contents lists available at ScienceDirect

Medical Hypotheses

journal homepage: www.elsevier.com/locate/mehy

Spinal Cord Injury survey to determine pressure ulcer vulnerability in the outpatient population ☆

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ARTICLE INFO

Article history:
Received 21 July 2014
Accepted 24 August 2014

ABSTRACT

Pressure ulcers are one of the most common causes of morbidity, mortality and rehospitalization for those living with Spinal Cord Injury (SCI). Literature examining risk and recurrence of pressure ulcers (PrUs) has primarily focused on the nursing home elderly who do not have SCI. More than 200 factors that increase PrU risk have been identified. Yet unlike the elderly who incur pressure ulcers in nursing homes or when hospitalized, most persons with SCI develop their pressure ulcers as outpatients, while residing in the community. The Veterans Health Administration (VHA) provides medical care for a large number of persons with chronic SCI. Included in the VHA SCI model of chronic disease management is the provision of an annual Comprehensive Preventive Health Evaluation, a tool that has potential to identify individuals at high risk for PrUs. This research was motivated by the clinical observation that some individuals appear to be protected from developing PrUs despite apparently 'risky' behaviors while others develop PrUs despite vigilant use of the currently known preventative measures. There is limited literature regarding protective factors and specific risk factors that reduce PrU occurrence in the community dwelling person with chronic SCI have not been delineated. The purpose of this study is to examine the preliminary hypothesis that there are biological and/or psychosocial factors that increase or reduce vulnerability to PrUs among persons with SCI. A limited number of refined hypotheses will be generated for testing in a prospective fashion. A retrospective cross-sectional survey of 119 randomly selected Veterans with SCI undergoing the Comprehensive Health Prevention Evaluation during the year 2009 was performed. Factors that differed between patients with 0, 1 or $\geqslant$2 PrUs were identified and stratified, with an emphasis on modifiable risk factors. Three hypotheses generated from this study warrant further investigation: (1) cumulative smoking history increases the risk of PrUs independent of co-morbidities, (2) being moderately overweight, BMI > 25, with or without spasticity, is a modifiable factor that may be protective and (3) increased use of a caregiver does not reduce PrU risk. Prospective studies that focus on these hypotheses will lead to evidence-based risk assessment tools and customized interventions to prevent PrUs in persons with SCI in the outpatient setting.

Introduction

Development of pressure ulcers (PrUs) is one of the most common complications of Spinal Cord Injury (SCI). Although there has been a dramatic improvement in life-expectancy for persons with SCI since the 1970's, this is mostly attributed to reduced mortality during the initial 2 years post-injury. Sepsis associated with genitourinary conditions and PrUs remains the major source of morbidity and mortality for those with chronic SCI [1,2]. PrUs are one of the major causes of rehospitalization after the initial injury and account for 8% of deaths after SCI. The economic impact of PrUs is large, with the cost of treating a single full thickness PrU estimated at $70,000, leading to $11 billion of US expenditures in healthcare [3]. For Veteran patients with SCI the presence of a PrU adds approximately $73,000 to their total annual healthcare cost with annual hospitalization averaging 61 days compared to 9 days for those without PrUs [4]. This does not include the tremendous impact on the person with SCI, including time off work; the need for assistance with such things as child care, pet care, and household care; and the impact on the family and/or caretakers.

☆ *Source of Support:* The research reported in this publication was supported by the DoD Spinal Cord Injury Research Program of the Office of the Congressionally Directed Medical Research Programs, Hypothesis Development Award SC090613 awarded to Dr. Gould. The work was supported with resources and the use of facilities at the James A Haley Veterans Hospital, Tampa, FL.

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http://dx.doi.org/10.1016/j.mehy.2014.08.027
0306-9877/

Unlike the elderly who incur PrUs when hospitalized or in nursing homes, most persons with SCI develop their PrUs as outpatients, while residing in the community [5]. For this reason, the actual prevalence of PrUs in the SCI population is currently unknown, with reported figures varying from 8% to 40% and a recurrence rate of up to 79% [6]. The Veterans Health Administration is responsible for approximately 27,000 Veterans with SCI/D, accounting for 26% of all persons with SCI/D (Spinal Cord Impairment/Disability) in the United States (http://www.queri.research.va.gov/about/factsheets/sci_factsheet.pdf). As our wounded warriors return from Iraq and Afghanistan, VA is faced with managing a very challenging cohort of patients with SCI. Along with SCI, the constellation of injuries for many of these Veterans may include severe pelvic trauma, burn wounds and multiple amputations and/or severe fractures. One can anticipate that the lifetime risk of PrUs in this population will be even higher than past cohorts. Therefore it is imperative that factors which increase PrU risk be identified and mitigated.

Most published research that identifies risk factors for development and recurrence of PrUs has been conducted in the nursing home elderly or in the SCI Model Systems (sponsored by National Institute on Disability and Rehabilitation Research), which includes primarily younger patients with acute SCI injuries [3,8,9]. The literature examining risk and recurrence of PrUs in the Veteran SCI population, i.e., with long-term chronic SCI, focuses on the patients who have already developed PrUs [6,10]. Those who do not develop PrUs are excluded from the study samples, thereby excluding a critical "control" population. More than 200 risk factors have been identified as being involved in PrU development [11]. For example, immobility and incontinence are common factors for all persons at risk: elderly, newly injured or chronic SCI. However, there is such a wide variety of factors implicated in the literature that are specific to the SCI population that it is not clear how to stratify them to develop useful guidelines for PrU prevention [7,11–13]. Because they are recurrent, severe ulcers are reported for a minority of the general patient population, occurring primarily in the SCI patient population [14,15]. It is our premise that the list of potential risk factors affecting PrU vulnerability must be refined so that the people at highest risk can be identified and protected.

The retrospective survey of SCI outpatients completing their annual SCI Comprehensive Preventive Health Evaluation described here is based on our preliminary hypothesis that there are biological and/or psychosocial factors that increase or reduce vulnerability to PrUs among persons with SCI. Our study objective included identifying and stratifying the factors that are different between patients with 0, 1 or $\geqslant$2 PrUs, with emphasis on modifiable risk factors. The goal of the study is to generate a limited number of refined hypotheses that can be tested in a prospective fashion and will ultimately lead to the development of evidence-based risk assessment tools and customized interventions to prevent PrUs in SCI persons in the outpatient setting.

Methods

Study design

Cross-sectional retrospective.

Sample size justification

Assuming that the prevalence of PrUs in the SCI population is at least 25%, a sample of 120 charts is required to guarantee that 30 of those will be patients who have had PrUs (with 95% confidence).

Participants

A computer-generated random number table was used to select 120 patient charts from nearly 1400 outpatients with SCI who completed their Comprehensive Preventive Health Evaluation (aka "annual exam") at a VA SCI Center between January 1 and December 31, 2009. These evaluations are typically conducted in the outpatient setting, unless the patient lives too far away from the center to complete the entire evaluation as an outpatient. Patients with and without PrUs were included. Patients with SCI due to terminal disease, multiple sclerosis or amyotrophic lateral sclerosis were excluded from the random selection based on ICD-9 coding.

Procedures

The study team developed an electronic data extraction tool, which included demographics as well as physical, medical, and psycho-social variables documented in the literature to be associated with the increased risk of developing PrUs [11,12] and likely to have been assessed and documented in the annual health evaluation.

Data extraction was conducted by three study team members (a nurse practitioner, a medical student and a nurse scientist). The data extraction team members were trained on how and where to find the data in the electronic medical records. Reliability was established among the extraction team members, who practiced together prior to building the data base. A rule book was developed with the first 15 cases, to ensure the data were interpreted and recorded accurately. Verification of extracted data elements was conducted by the senior author on approximately 10% of the patient charts.

Primary outcome

The primary outcome of interest was whether the Veteran with SCI ever developed a PrU.

Independent variables

Table 1 lists the variables identified by the study team, the variable definitions and examples of code used by our statisticians, which may assist other studies with analysis. For the purposes of our analysis, we re-coded a number of variables. For example, we created a new variable: "Good Nutrition", reflecting nutritional status using the recorded albumin and pre-albumin levels at the time of the annual exam (2009). Also, we identified a number of variables with missing data. The sample mean was used for the missing values.

Statistical analysis

Statistical comparisons between PrU groups (0, 1, 2+ PrUs) were performed using either Student's *t*-test, one-way ANOVA or Chi-square, as appropriate. All analyses were performed using SAS (ver. 9.2 Cary, NC) with statistical significance assumed to be $p \leqslant 0.05$, two-tailed. Bivariate analyses comparing patients with and without PrUs identified a set of independent variables that were significantly different between the two groups. Correlational analyses were conducted to examine potential multicollinearity between the independent variables. The final set of variables was entered into a stepwise regression. Unconditional logistic regression was used to model the probability of at least 1 PrU after adjustment for potential confounders. Odds ratio and 95% confidence intervals are presented.

Table 1
Independent variable definitions and analysis code examples.

Variable	Variable definition	Examples of code used for analysis
Age	2011 minus year of birth	
BMI	*Body mass index:* height weight formula: BMI formula: divide weight in pounds by height in inches squared, then multiply the results by a conversion factor of 703	If BMI<25 then overweight = 0; else overweight = 1
Gender	Male or female	
Years since initial injury	2009-Year of initial injury	
Marital status	Married, living with partner, single, divorced, widowed	
Education level	Unknown, HS GED or grad, some college, college grad, post graduate	
Caregiver	Another person in the home environment that provides bowel and bladder care	If CG = no or CGhours = . or 0, then CGsupport = 0; else CGsupport = 1
Caregiver status	Live-in, visiting, unknown	
Race/ethnicity	African American, Asian, Caucasian, Hispanic, Native Hawaiian/Pacific Islander	
Mechanism of injury	Motor vehicle, motor cycle, violence, fall, sports, medical, other, unknown	
LOI	*Level of injury*: the level in the spinal cord at which the injury is recorded – ASIA score	If ASIA_A = no or ASIA_B–D = yes, then newASIA_A = 0; else newASIA_A = 1
LOS	*Length of stay*: number of days in hospital (1) acute care; (2) rehab; (3) past year	If LOS_hosp in prior year = . or 0 or ≤3; then prior_hosp = 0; else prior_hosp = 1
FIM	*Functional independence measure*: chart recorded functional ability in 2009	
Mobility	Gait, gait-assist, manual wheel chair, power wheelchair	
Cushion	Yes, no, unknown	
Bed mobility	Yes, no, unknown	
Support surface	Type of bed surface at home	
Transport surface	Type of sitting surface during transportation	
Employment	Pre and post injury employment	
Good Nutrition	Albumin and pre-albumin	If albumin ⩽ 3.5 or pre-albumin < 18, then good_nutrition = 0; else good_nutrition=1
Athletic participation	Minutes per day/days per week	
Spasticity	Yes/no; medicated	
Contractures	Yes/no; mild, moderate, severe	
Cognitive/psychiatric Conditions	*Mental status:* anxiety, bipolar, depression, personality Disorder, dementia, schizophrenia/delusional, brain damage	
Pressure ulcer	Length of time to first PrU from date of injury? Number of PrUs? (Since injury) Location of each? How long to heal? Surgery for PrUs? Type of surgery? Flap?	Example of PrU location: If location = ischial then ischial = 1; else ischial = 0
Co-morbidities	DM: Type 1/Type 2, Hgb A1c, Hgb level, anemia, CAD, CHF, pain, hyper/hypothyroid, heterotrophic ossification, autonomic dysreflexia, osteomyelitis	Example of co-morbidities: If hemoglobin < 13, then anemia = 1; else anemia = 0

Human subjects

The local Institutional Review Board for Human Subjects Research and the Veterans Hospital Research and Development Committee approved a waiver of informed consent and HIPAA for this chart review.

Results

Sample demographics

The study sample characteristics are presented in Tables 2 and 3. One patient was excluded from the analysis due to a large amount of missing data, thus the final sample size was 119. The mean age across all groups was 62 ± 12.5 years. Seventy-four percent of the sample studied sustained their SCI more than 10 years prior to the study and 35.5% had SCI greater than 30 years in duration. Similar to other VA studies, 98% were male, with the majority (56.8%) Caucasian. Nearly half (43%) had tetraplegia. More than half had greater than 50% service-connected status (although not necessarily related to their SCI).

Of the 119 study subjects 39.5% had no previous PrUs, 29.5% had 1–2 PrUs and 31% had ⩾3 PrUs since the time of injury. Of those with at least 1 PrU, the time to healing varied, with 26% PrUs healing rapidly (0–3 months) while 10% of the PrUs were documented as having never been successfully healed, leaving the Veteran to manage chronic open wound(s) for a prolonged period of time. There was no difference in age, level of education or marital status and presence of PrUs. Violence as the etiology of SCI was more common among those with ⩾1 PrU.

Table 2
Demographics.

Parameter	0 PrU *N* = 47 *N* (%)	>=1 PrU *N* = 72 *N* (%)	*p*
Male	45 (95.7)	72 (100.0)	0.308
Age, year (mean, SD)	63.1 ± 12.7	60.4 ± 12.0	0.243
Caucasian	26 (55.3)	42 (58.3)	0.933
Education			–
⩽HS	20 (40.0)	31 (43.1)	–
College/college grad	21 (44.7)	24 (33.3)	–
Post college	2 (4.0)	6 (8.3)	–
Unknown	4 (8.5)	11 (15.2)	0.439
Current employment (FT/PT)	4 (8.0)	7 (9.7)	0.999
Married	22 (46.8)	34 (47.2)	0.773
Service connected ⩾ 50%	28 (59.6)	32 (44.4)	0.107
Caregiver	20 (42.6)	36 (50.0)	0.426
Caregiver hours/days	2.9 ± 3.3	5.5 ± 6.8	0.016

Note. Values expressed are either mean ± SD or *N* (%).

Variable consolidation/multivariable model development

As shown in Table 3, the bivariate analysis found a high number of independent variables that were significantly associated with number of previous PrUs, including: service-connected status, functional independence measure (FIM) score, American Spinal Injury Association (ASIA) score, body mass index (BMI), albumin, pre-albumin, smoking, hospital days for rehabilitation, hospital days in past year, bed mobility, contractures, caregiver hours per

Table 3
Bivariate analysis of clinical characteristics.

	0 PrU *N* = 47	>=1 PrU *N* = 72	*p*
Mechanism of injury			
MVA	13 (27.7)	25 (34.7)	–
Motorcycle	5 (10.6)	7 (9.7)	–
Violence	2 (4.3)	12 (16.7)	–
Fall	5 (10.6)	7 (9.7)	–
Sports	4 (8.5)	6 (8.3)	–
Med/surg complication	8 (17.0)	10 (13.9)	–
Other	10 (21.2)	5 (6.9)	0.172
Level of injury			
C1–C7	20 (42.6)	33 (45.8)	–
T/L	27 (57.4)	38 (52.8)	–
Unknown	0 (8.0)	1 (1.4)	0.904
Duration of injury ⩾ 10 years	34 (72.3)	53 (73.6)	0.879
FIM	101.8 ± 20.0	84.4 ± 26.5	0.001
ASIA			
A	10 (21.3)	37 (51.4)	–
B–D	37 (78.7)	35 (48.6)	0.015
BMI	28.4 ± 5.7	25.9 ± 4.3	0.007
BMI			
⩽20	3 (6.4)	7 (9.7)	
20–25	6 (12.8)	23 (31.9)	
26–30	24 (51.1)	29 (40.3)	
>30	14 (29.8)	13 (18.1)	
Albumin (g/dl)	4.4 ± 0.4	4.1 ± 0.4	0.001
Pre-albumin (mg/dl)	25.3 ± 5.5	21.5 ± 5.6	0.001
Hemoglobin (gm/dl)	14.3 ± 1.8	13.5 ± 3.5	0.151
Tobacco current	10 (21.3)	25 (34.7)	0.179
Tobacco past	34 (72.3)	45 (62.5)	0.268
Smoking/pack years	18.5 ± 18.3	31.2 ± 25.0	0.003
Packs per day	1.0 ± 0.6	1.0 ± 0.6	0.999
COPD	3 (6.4)	10 (13.9)	0.200
Diabetes mellitus	9 (19.1)	11 (15.3)	0.581
LOS, rehab	79.0 ± 55.6	201.3 ± 145.4	0.001
LOS, hosp in prior year	5.3 ± 17.0	25.9 ± 57.1	0.018
Years since injury	25.7 ± 17.1	22.6 ± 13.8	0.279
Osteomyelitis	0 (0.0)	10 (13.9)	0.066
Spasticity	31 (66.0)	47 (65.3)	0.939
Bed mobility	41 (87.2)	50 (69.4)	0.025
Contractures	1 (2.1)	13 (18.1)	0.008
Pain (chart)	3.2 ± 3.0	3.0 ± 2.9	0.717
Location			
Ischial	–	38 (52.8)	–
Sacrum	–	5 (6.9)	–
Heel	–	15 (20.8)	–
Trochanter	–	14 (19.4)	–
Other	–	17 (23.6)	–
Hx of depression	11 (23.4)	24 (33.3)	0.246
Hx of alcohol	31 (66.0)	49 (68.1)	0.812

Note. Values expressed are either mean ± SD or *N* (%).

day, osteomyelitis, diabetes, and ulcer location (ischium, heel, trochanter, other).

Variables that were significant in the bivariate analyses were examined in a correlational analysis and some were found to be highly correlated with one another (e.g., LOS/LOS rehab).

Stepwise logistic regression was used to model the probability of at least one PrU after adjustment for potential confounders. Odds ratio and 95% confidence intervals are presented in Table 4. An initial model was run containing independent variables representing: Good Nutrition (albumin > 3.5 or prealbumin > 17, Consortium for Spinal Cord Medicine clinical practice guideline [18], caregiver support (yes/no), ASIA A (yes/no), overweight (BMI > 25, based on WHO criteria), prior hospitalization within previous year, anemia (hemoglobin < 13, WHO criteria for men), current smoker (yes/no), percent service-connected status, and FIM score. Non-statistically significant variables were excluded from the final model. The final model retained ASIA A (yes/no), overweight (BMI > 25), prior hospitalization within previous year, anemia, service-connected percent, and FIM score (Table 4 and Fig. 1).

Table 4
Odds ratios and 95% confidence intervals for the prediction of PrU.

Parameter	Odds ratio	95% CI	*p*
Good Nutrition	0.64	0.18–2.20	0.475
Caregiver support	1.99	0.92–4.33	0.082
Current smoker	1.71	0.76–3.79	0.184
FIM	0.97	0.96–0.99	0.001
ASIA A	4.02	1.74–9.27	0.001
Overweight (BMI > 25)	0.32	0.14–0.77	0.010
Prior hospitalization	1.79	0.71–4.51	0.215
Anemia	3.08	1.06–8.94	0.075
% Service connected	0.99	0.99–1.00	0.069

Note. FIM, functional independence measure; BMI, body mass index (kg/m^2).

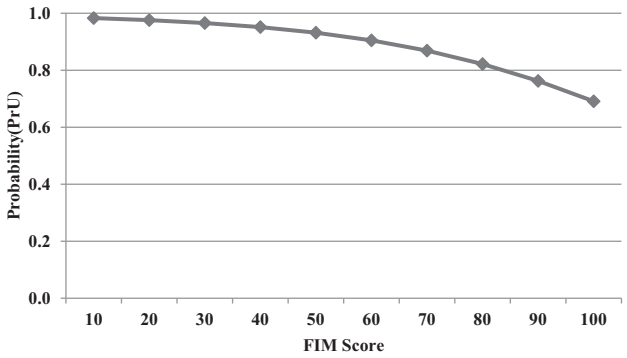

Fig. 1. Estimated probability of PrU based on median or most frequently occurring response per FIM deciles. *Note*. Estimated Prob(PrU) based on unconditional logistic regression model containing mean or most frequently occurring parameters: % service connected = 40, FIM (per deciles) ASIA A = no, overweight = yes, prior hospitalization = no, anemia = no.

Discussion

PrUs are a source of significant morbidity and personal distress for persons with SCI. This study demonstrates and confirms that PrUs affect a substantial portion of community-dwelling Veterans with SCI. More than one third of the patients coming for their annual exam had multiple PrUs at the time of their exam and two thirds had had at least one PrU since they were injured. In addition to identifying factors that increase PrU risk, we were interested in protective factors, i.e., can we learn something about those persons who don't develop PrUs that may be protective? Contrary to our initial expectations, there were a number of variables that did not distinguish between those with and without PrUs, including factors that have been identified in other studies, e.g., age, race, smoking history, nutrition and diabetes.

Although advanced age has been identified as a PrU risk factor, this was not the case in our study. This is congruent with a meta-analysis by Gelis et al. [16] which showed age did not predict PrUs in the SCI population. Because our sample did not include a wide range of ages, it may have precluded our ability to stratify PrU risk by age or to distinguish age from duration of SCI. It is most likely that duration of SCI is the more important risk factor for PrU risk [17].

Smoking is considered to be a potentially modifiable PrU risk factor [17,18]. However, in two separate studies, Weaver et al. [19] and Rabadi and Vincent [20] saw no correlation between smoking and PrU prevalence while Guihan et al. found an inverse although statistically non-significant relationship between smoking and PrU recurrence: 20.8% smokers with recurrence vs 27.5% smokers with no recurrence [13]. In this study, current smoking

and number of packs per day did not bear out as predictors of PrU risk. However, the total number of pack-years of smoking was significantly higher in those with $\geqslant 1$ PrU compared to those who never had a pressure ulcer ($p = 0.003$). It may be that cumulative smoking history is a proxy for multiple co-morbidities, particularly respiratory-related illness, depression, pain and alcohol use [19] or that PrUs that develop during times of smoking increase the lifetime risk for future PrUs. These conflicting findings require more investigation, as it is well accepted in the surgical literature that smoking impairs healing. There are many reasons to recommend smoking cessation, as the effect of smoking is transient and rapidly improves with smoking cessation [21]. Further clarification of the impact of smoking on PrU development, recurrence, and healing would be beneficial, as this is a truly modifiable factor.

One of the most interesting findings of our study is the suggestion of a protective effect of being moderately overweight. BMI is a notoriously poor surrogate marker of obesity and is particularly inaccurate in the chronic SCI population [22,23]. It is well documented that BMI underestimates adiposity in both men and women with SCI [22–24]. BMI in SCI does not distinguish between fat mass and fat-free mass and does not provide information about body fat distribution, therefore Spungen et al. used dual energy X-ray absorptiometry (DEXA) to measure body composition. In their study, compared to able-bodied controls of the same BMI, persons with SCI had 13% more total body fat, significantly decreased total lean tissue mass and a decreased percentage of lean body mass in the legs, trunk and total body [25]. This is particularly important when trying to understand the effect of BMI on PrU vulnerability, as increased abdominal girth concurrent with wasting of the buttock musculature has the potential to alter the pressure distribution in the seated individual. Although the impact of body composition on PrU risk has not been delineated, it is well documented that the loss of skeletal muscle oxidative capacity predisposes individuals to weight gain, Type II diabetes mellitus, and insulin resistance, similar to that seen in obese and elderly populations [26]. Thus, the apparent protection afforded by BMI > 25 suggests that this cohort of patients may have incomplete SCI or increased spasticity that preserves the muscle mass. Alternatively, we can hypothesize that a small increase in BMI may provide better pressure distribution in some patients. This combination of factors warrants future examination and analysis.

In developing the data extraction tool, we presumed that spasticity would increase PrU vulnerability [27]. Although our data did not reveal any difference in pressure ulcer prevalence between those with or without spasticity, documentation of spasticity in this study was based primarily on evidence of pharmacologic treatment. It has previously been shown that spasticity defends against skeletal muscle atrophy, improves peripheral circulation and improves glucose homeostasis [28–30]. Those with spasticity are likely to have a higher BMI due to preservation of the muscle mass. Thus, in light of the apparent protective effect on body composition and soft tissue metabolism important for wound healing, spasticity may be a positive, i.e., protective factor for PrU vulnerability. This warrants further investigation in the form of a prospective study that includes analysis of spasticity using the modified Ashworth scale, body composition as determined by Spungen et al. [25], and presence of PrUs.

Bowel and bladder management is often a focus of the annual health evaluation for the person with SCI. A causal relationship between bowel or bladder incontinence and PrUs in persons with SCI has been established in some studies [30,31] although the level of evidence is low [16]. Sumiya's study documents presence or absence of urinary incontinence but does not provide an operational definition [31]. In persons with SCI, catheter use would be deemed as appropriate bladder management and therefore mitigation of the risk factor unless incontinence persisted despite the presence of an indwelling catheter. In this retrospective review we were able to determine use of indwelling catheter, but presence or absence of incontinence was rarely noted. It appears other studies have experienced the same difficulty. For example, in a recent article citing urinary incontinence as a risk factor for pressure ulcers it was stated that 83% of the patients were incontinent, however, 99% had urinary catheters [32]. Because these data elements were so difficult to define, they were excluded from our final analysis.

To determine "caregiver" we looked for evidence in the CPRS for the Veteran receiving bowel and/or bladder care. The inference is that a caregiver would conduct skin assessments with bowel/bladder care, promote protective behaviors, and be a source of early detection for PrU development (Stage 1). We asked if there is a relationship between having a caregiver and the number of pressure ulcers. We found that there was no significant difference ($p = 0.426$) between the two groups (0 vs $\geqslant 1$ PrUs). This finding could suggest that caregivers do not provide PrU prevention. We further asked if there is a relationship between the amount of time caregivers spent in the home and the number of pressure ulcers the Veteran had sustained. The two groups were significantly different ($p = 0.016$) in that those with $\geqslant 1$ PrUs had significantly more hours per day of care giving. The supposition is that those with more PrUs need more care. But the significant relationship also begs the question of what caregivers could be doing to improve PrU prevention. This relationship between caregivers in the home environment, hours spent caregiving (PrU prevention), and PrU occurrence is intriguing and deserves further exploration. We found only tangential literature outside of the hospital setting to offer an evidence-based discussion regarding this relationship.

Limitations

The retrospective cross-sectional design resulted in some missing data and cannot exclude charting inaccuracies. The VA system has one of the most robust electronic medical records (EMRs) in the United States, greatly improving the ability to capture data. The chart abstraction tool was developed in collaboration with SCI/D providers who routinely perform the annual comprehensive health exam outlined in VHA Handbook 1176.01. The team consensus was that the variables chosen for chart abstraction were likely to be included in the EMR and would provide critical information about patient characteristics and behaviors associated with PrU risk. Nonetheless, our data retrieval experience was similar to that of other investigators and is limited by what is available in the clinical record.

All demographic data, clinical characteristics and numerical data including lab values were derived from a single point in time and may not reflect the study subject's health at the time of initial PrU development. Other limitations include use of albumin and pre-albumin as indicators of nutritional status, self-reported height for BMI calculations and use of the WHO categories of BMI in spinal cord injured persons.

Women are underrepresented in this study, as it reflects the current cohort of US military Veterans with SCI. This may limit generalizability to civilian spinal cord injured persons and to the future Veteran population.

Clear documentation regarding patient lifestyle factors was particularly challenging to locate. This limited our ability to include a number of variables that may be truly modifiable risk factors, e.g., caregiver availability, caregiver hours spent and care provided; primary transportation method used and use and type of protective sitting, sleeping and driving surfaces and pressure releases used while travelling. Because caregiver involvement appears to be an important element of pressure ulcer vulnerability, a prospective

study that includes a carefully worded survey will better delineate the crucial elements of caregiver support and the impact on patient lifestyle.

Conclusions

PrUs are among the most significant complications in Veterans with SCI in terms of quality of life and cost of care. Similar to patients who develop neuropathic diabetic foot ulcers, patients with SCI may be unaware of tissue damage until it is too late. Without constant vigilance and attention to the skin, reversible soft tissue damage can quickly become an irreversible defect with long-term sequelae. Despite decades of research, evidence for factors that increase PrU risk in persons with chronic SCI is quite limited [16]. This study was driven by the quest to develop a risk assessment tool that will better identify patients at risk for pressure ulcer development, but even more importantly to identify factors that may be protective. Thus far very few protective factors have been identified in the literature: college degree, being married, being employed, exercise and healthy diet [33]. This retrospective study is a first step in describing patient characteristics and PrU incidence of community-dwelling Veterans with SCI. The average age (62 years + 12.5 years) and duration of SCI (74% of the sample studied sustained their SCI more than 10 years prior to the study, 35.5% had SCI greater than 30 years in duration) confirms that community dwelling SCI Veterans are living longer and will therefore benefit from identification of modifiable PrU risk factors. From this research we have identified three hypotheses for additional study. (1) Cumulative smoking history increases the risk of pressure ulcers. Most physicians will identify smoking as a modifiable risk factor for poor wound healing, yet the data do not support current smoking as a risk factor for pressure ulcer development. A study that specifically measures the impact of smoking on PrU development, recurrence, and healing will allow the SCI team to better focus their efforts on smoking cessation when it matters most and will provide very specific and useful information for the SCI patient population. (2) This study suggests that being moderately overweight may be a protective factor. This is particularly interesting because multiple modalities, i.e., diet, exercise, physical therapy and medication could be utilized to preserve muscle mass and bone density, thereby transforming body composition into a protective factor. Whether spasticity factors into this equation is unclear. We propose that a prospective study that combines anthropometric measurements of fat and muscle distribution with validated measures of body composition such as DEXA, and objective measurements of spasticity and pressure distribution will better delineate parameters that will protect the spinal cord injured person from pressure ulcer development. (3) Increased use of a caregiver did not reduce PrU risk in this retrospective study. The obvious conclusion is that the patients already had pressure ulcers during the time that the study was conducted and the caregiver hours are increased due to time required for wound care and repositioning. However, there was no difference in caregiver hours between those with 1 or $\geqslant$2 PrUs. A prospective study focused on the relationship between pressure ulcer incidence and availability of a caregiver, caregiver tasks and whether the caregivers are providing PrU prevention measures and early detection could lead to improved use of these valuable resources for pressure ulcer prevention.

The ultimate goal is to develop an SCI-specific tool that can be incorporated into the electronic health record for use by the provider and patient to identify and modify risk factors that lead to PrU vulnerability, thereby reducing the lifetime risk and burden of chronic non-healing wounds. Such a tool will help identify those patients at highest risk for PrUs so that scarce resources can be focused on those most vulnerable.

Conflict of interest

The authors declare that there are no conflicts of interest.

Acknowledgments

The research reported in this publication was supported by the DoD Spinal Cord Injury Research Program of the Office of the Congressionally Directed Medical Research Programs, Hypothesis Development Award SC090613 awarded to Dr. Gould. The work was supported with resources and the use of facilities at the James A Haley Veterans Hospital, Tampa, FL. The content is solely the responsibility of the authors and does not represent the views of the Department of Veterans Affairs or the United States Government. The authors would like to acknowledge Scott Barnett, PhD, MSPH for statistical support and Barbara Bates-Jensen, PhD, RN for critical manuscript review.

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