Search results for 2019 International Pressure Injury Guideline: Spinal Cord Injury

**Identified in pressure injury searches**
- n=11,177

**Identified citations**
- n=3,085

**SCI keywords**
- Spinal cord injury, SCI, spine, spinal, cervical, immobile, immobilization, paraplegia, quadruplegia, quadriplegic, paraplegic, collar, backboard, ambulance

**Excluded after screening title/abstract**
- Duplicate citations
- Included in previous guideline
- Not related to pressure injuries
- n=8,128

**Excluded based on key word searches**
- Not related to the topic-specific questions
- n=2,974

**Excluded after review of full text**
- Not related to pressure injuries
- Not related to the clinical questions
- Citation type/research design not meeting inclusion criteria
- Non-English citation with abstract indicating not unique research for translation
- n=90

**Total references providing direct or indirect evidence related to topic**
- n= N/A*

* Recommendations related to all special populations are included in the topics to which the recommendation relates (e.g. support surfaces), and the references supporting these recommendations are included in the search reports for those topics.

**Individuals with Spinal Cord Injury: data extraction and appraisals**

**Articles Reviewed for International Pressure Injury Guideline**

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resource and are not for reproduction.


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<th>Ref</th>
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| Morita, Yamada, Watanabe, & Nagahori, 2015 | Case control study investigating lifestyle factors that influence risk of PU in individuals with SCI in community | Cases: people with SCI admitted to a Japanese rehabilitation hospital from 01/11 to 12/11 for treatment of PU (n=31) Controls: outpatients of the same facility who had lived in the community without PU for the preceding 12 months | Structured questionnaire interview | Daily living factors: • Wheelchair and cushion factors • Protective activities • Urination/defecation • Social participation Risk assessment: • Braden scale • SCI pressure ulcer scale (SCIPUS) Interface pressure (IP) measurement of wheelchair surface | PU risk Braden scale: 15.7±1.4 cases vs 16.3±1.4 controls, p=0.068 SCIPUS: 6.2±2.1 cases vs 3.9±1.5 controls, p=0.000 Life-style factors (interview data): case vs control Number wheelchairs in possession: 1.8±0.7 vs 2.2±0.8, p=0.64 Number seat cushions in possession: 1.8±0.7 vs 2.3±0.7, p=0.005 Average hrs/day in chair: 12.2±4.6 vs 15.2±2.4, p=0.002 Number baths per week: 3.5±2.3 vs 5.1±2.2, p=0.012 Independent driving: significantly more controls (p=0.004) At least weekly skin monitoring: no significant difference Knowledge of PU pressure relief methods: 1.3±0.6 vs 2.4±1.4, p=0.000 Number pressure relief maneuvers/hr: 2.2±3.3 vs 1.8±1.6, p=0.664 | • Low generalizability • Relied on self-reported preventive health data and relied on recall for case group • Case-control matching led to significant difference in age, time since injury and previous history of PU • Wide confidence interval for seat cushions in possession

**Risk factors (note relevant included studies and recommendations are in the risk section)**

- Low
- Generalizability
- Relied on self-reported preventive health data and relied on recall for case group
- Case-control matching led to significant difference in age, time since injury and previous history of PU
- Wide confidence interval for seat cushions in possession

**Level of evidence:** N/A

**Quality:** High

(not an eligible design for inclusion in risk factor analysis)
## Individuals with Spinal Cord Injury: data extraction and appraisals

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| Richard-Denis, Thompson, Bourassa-Moreau, Parent, & Mac-Thiong, 2016 | Cross sectional study investigating influence of acute care setting in development of PU | Participants were retrospectively recruited at one inpatient rehabilitation center in the US over five years (n=123) | Participants were categorized as being discharged from a specialized SCI center (n=90) or from a non-specialized SCI center (n=33) | • Demographic data  
• Severity of SCI on AIS grades ranked by a specialist physician  
• Skin assessment and diagnosis of PU using NPUAP staging system on admission to rehab facility | Pressure measurement  
Max IP, contact area and average IP were not significantly different between cases and controls  
Multivariate analysis  
Number of seat cushions in possession: odds ratio for PU 8.110 (95% CI 1.799 to 36.571)  
Average time spent in wheelchair: JR for PU 1.581 (95% CI 1.154 to 2.166)  
SCIPUS score: OR for PU 0.395 (95% CI 0.233 to 0.667) | Study conclusions: The authors found that recall of pressure relief maneuver reported in interview numbers ≠ diary for controls. Number of cushions in possession, time spent in chair and SCIPUS score were associated with risk of PU. |
|                      |               |        |                 |                                    |         |                          |

### Factors predicting occurrence of single PU (logistic regression)

- Type of acute care facility (specialized vs non-specialized) Odds ratio (OR) 0.28 95% CI 0.12 to 0.68  
- ASIA grade ASIA < D versus ASIA D OR 2.96 95% CI 1.22 to 7.21  

### Factors predicting occurrence of single PU (logistic regression)

- Type of acute care facility (specialized vs non-specialized) OR 0.059 95% CI 0.01 to 0.27  
- ASIA grade ASIA < D versus ASIA D OR 10.21 95% CI 1.14 to 91.18  

### Limitations and comments

- Method of assessment of PU undocumented (e.g. blinded?)  
- Relied on retrospective data  
- Participants in each cohort had significant differences in confounding factors  
- Small sample size  
- Difference in LOS may explain difference in PU rates  

### Level of evidence:
N/A

### Quality:
Moderate

(note: study design not included in risk factors)
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| Van Der Wielen, Post, Lay, Glasche, & Scheel-Sailer, 2016 | Cohort study investigating factors associated with development of hospital-acquired PU | Participants were observed in an acute and rehabilitation spinal center in Switzerland for 6 months (n=185) | All participants received best practice for PU prevention based on risk assessment | • HAPU  
  • Participants were examined every 12 hours during admission and HAPU graded according to EPUAP classification | Incidence rate  
  • 29.7% developed a HAPU  
  • Of PUs, 30.9% were grade 1, 58.2% grade 2, 10.9% grade 3  
  
Factors associated with having a PU  
  • Time since SCI injury, with HAPU being more common in individuals with injury within preceding 12 months or with injury > 26 years ago (p=0.002)  
  • Reason for admission, with first rehabilitation being most common reason for admission in individuals with HAPU (51.5%), followed by orthopedic surgery (41.4% p=0.006)  
  • Length of stay (p<0.001)  
  
Regression analysis for time until occurrence of first HAPU  
  • Time since first lesion odds ratio (OR) 1.04, 95% CI 1.01 to 1.06, p=0.005  
  • Readmission for PU as the reason for admission OR 2.03, 95% CI 0.91 to 4.54, p=0.085  
  • Readmission for other reasons OR 2.29, 95% CI 0.78 to 6.72, p=0.132  
  
Time to PU closure  
  • 67.3% PU healed during admission | • Does not describe who performed skin assessments  
• Does not report wound management strategies  
• Small patient group without reporting comorbidities  
• >30% PUs unhealed on discharge so no data on complete healing | Level of evidence: 1  
Quality: High  
(note: study included in risk factors chapter) |
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| Li, DiPiro, & Krause, 2017 | Cross sectional study to develop a latent structural model to demonstrate the relationship between factor structures of risk health behaviors and PI outcomes among participants with spinal cord injury (SCI) | Include the following information: • Number of participants: 1871 • Clinical setting: large specialty hospital • Country: Southeastern USA • Inclusion criteria: Traumatic SCI, at least 1 year since SCI onset, 18 years of age or older and some residual deficits from the SCI (not complete recovery, AIS A–D) • Exclusion criteria: none Participant characteristics not reported under risk factors | • Socio-demographic characteristics • years since SCI and injury • Smoking and alcohol consumption measured by self-reported questions adapted from the Behavioral Risk Factor Surveillance System. • Participants responded to various questions regarding general prescription compliance, measured on a 5-point scale (never, occasionally, sometimes, often and always). • The latent PI was treated as the outcome in the modeling in relation to the risk behavior dimension and also several exogenous variables including sex, age, race, marital status, years since SCI and injury severity. | • Median time to healing was 31 days (IQR 20 to 62 days) • Median heal time Grade 1 PU 25 days • Median heal time Grade 2 PU 34 days • Median heal time Grade 3 PU 39 days | • Risk behavior dimension mediated relationships between latent PI and: o smoking (indirect effect=0.323*0.436=0.141), o alcohol consumption (indirect effect=0.323*0.087=0.0281), o general prescription compliance (indirect effect=0.323*0.351=0.113) o specific prescription use (indirect effect=0.323*0.502=0.162). | Years since SCI showed a marginal significant positive association with PI. • Race was significantly associated with latent PI, with Blacks scoring higher on latent PI compared with Whites. • No significant relationships between the latent PI and sex, marital status or chronologic age. • More severe SCI was associated with worse PI outcomes (non-ambulatory: C1–C4 vs ambulatory: 0.450, non-ambulatory: C5–C8 vs ambulatory: 0.361, non-ambulatory: non-cervical vs ambulatory: 0.232). The generalizability of our findings was limited because all study participants were recruited from one specialty hospital. A self-report assessments to collect data was used, thus the findings are subject to recall bias and misreporting. The findings are restricted to risk behaviors. • All self-report assessments were obtained by mail, with up to three mailings conducted and a follow-up phone call. | Level of evidence: 4 Quality: high (note: study design not included in risk factors)

## Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury
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<td>Costa, Caliri, Costa, &amp; Gamba, 2013</td>
<td>Retrospective study based on review to identify factors associated with the occurrence of pressure ulcers in patients at General Hospital in Maceió, Brazil</td>
<td>Participants recruited in ICU in Brazil (n=232 SCI patients however, on 106 (45.7%) of patients records there were no documentation about PI, n=136 included in analysis)</td>
<td>PI were measured: During hospitalization (admission to discharge OR death) Risk factors measured: Age, Cause of SCI, SCI surgical or clinical management, LOS</td>
<td>Rate of PI: 82/126 = 65% (IC 95%: 56.1 a 73.4) Category of PI was not documented Average age 34.4 (SD14.83), Median 30</td>
<td>• Study included patients of all ages 47 (20.3%) were younger than 22. Research done in one public University Hospital in Northeast of Brazil. Results might be different of other parts of the country.</td>
<td></td>
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<tr>
<td>Chopra et al., 2016</td>
<td>Retrospective cohort study exploring risk factors for infected PU in gun shot victims with SCI</td>
<td>Sample of records in one hospital in US identified through screening for relevant ICD codes of admission in a 4 year period (n=201)</td>
<td>Review of electronic health record to identify disease severity and development of infection. Costs associated with infected PU Risk factors associated with infected PU</td>
<td>Prevalence of infection 38% of first admissions had confirmed PU infection Bivariate analysis for infection risk factors Charlson Comorbidity Index score ≥2: odds ratio (OR) 3.13, p&lt;0.0001 low albumin (&lt;2.4 mg/dL): OR 3.00, p=0.002 paraplegia: OR 2.00 p=0.046) stage III or IV PU: OR 5.55, p=0.046 Participants with non-infected PU were more likely to have limited ADL (57% vs 42%, p=0.043) Outcomes infected versus non-infected PUs Non-infected PUs had significantly more admissions (302 versus 93)</td>
<td>Unclear if risk factors were pre or post wound infection Relied on database records Costs were specific to one hospital and may not be generalizable Co-morbid conditions and severity of SCI was not considered Patterns of organism resistance were not analyzed and</td>
<td>Level of evidence: 3 Quality: high</td>
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## Individuals with Spinal Cord Injury: data extraction and appraisals

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<td>Street, Noonan, Cheung, Fisher, &amp; Dvorak, 2015</td>
<td>Retrospective cohort study with logistic regression analysis exploring factors associated with adverse events in emergency admissions</td>
<td>All adults with acute traumatic spinal cord injury (TSCI) treated in a 2 year period at an acute spinal unit in Canada. Retrospective review of data records for acute admissions (n=171)</td>
<td>Exploratory analysis conducted to determine unadjusted effects of patient characteristics on number and type of adverse events. Independent variables found to be collinear with the outcome variable were excluded from final models.</td>
<td>14 intraoperative and 22 pre- or postoperative adverse events common in patients undergoing spinal surgery that are included in the Spine Adverse Events Severity System (SAVES)</td>
<td>Most common adverse events for TSCI patients: UTI 19.4%, pneumonia 13.7%, neuropathic pain 5.8%, PU 5.8%, delirium 8.2%</td>
<td>Level of evidence: 3 Level of quality: low</td>
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| | | | | Non-significantly longer length of stay (8 days versus 7 days, p=0.33) | • Non-significantly longer length of stay (8 days versus 7 days, p=0.33) |
| | | | | • Significantly more likely to be readmitted within 1 year (OR 2.26, 95% CI 1.25 to 4.1, p=0.01) | • Significantly more likely to be readmitted within 1 year (OR 2.26, 95% CI 1.25 to 4.1, p=0.01) |
| | | | | • Significantly higher financial cost (USD$16,735±8,310 versus USD$12,356±7,007, p<0.001) | • Significantly higher financial cost (USD$16,735±8,310 versus USD$12,356±7,007, p<0.001) |
| | | | | | may be site-specific |

**Clinical question 2: What are the unique pressure injury prevention strategies for individuals with spinal cord injury?**
## Interventions and information associated with the acute injury phase (Support surfaces and MDRPI)

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| **Weber, Rauscher, & Winsett, 2015** | Observational study in to compare a padded transport board and a long spinal board for ability to immobilize | healthy volunteers (n=42) | • Long spinal board  
• Padded board | • Movement during tilt on each board was measured at head, sternum and pelvis | • There was no significant difference in head movement between the two devices  
• Padded board was not as effective in immobilization at the pelvis and sternum compared to long spinal board | • Health volunteers  
• Pressure injuries not an outcome measure  
• Indirect evidence: PU not an outcome measure |
| **Tescher et al, 2016** | Observational study exploring tissue interface pressure of different cervical collars | A convenience sample of healthy volunteers (n=48)  
Inclusion criteria: Aged 18 to 65 years  
Participant characteristics: 50% female | • Evaluated for  
- neck pain  
- history of spinal surgery, physical or chiropractic therapy  
- history of neck trauma requiring medical care  
- cervical spondylosis  
- osteoporosis  
- Participants were fitted for 4 different collars that were used in a random order: Miami J standard collar, Miami J Advanced, Aspen standard, Aspen Vista | • Restriction of movement of cervical collars  
• Tissue interface pressure of cervical collars in upright and supine positions  
• Interface pressure measure at occiput and anterior mandible using a customized sensor pad | • Restriction of movement for all collars was statistically significant compared with no collar (p<0.001)  
• Statistically significant differences between the four collars have minimal clinical significance, although they are statistically significant  
• Miami J standard collar was associated with significantly lower interface pressure at mandible and occiput in both upright and the supine positions compared with the other collars (p<0.01)  
• Miami J Advanced collar was associated with significantly higher peak interface pressure than each of the other 3 collars at the mandible in both upright and supine positions (p<0.001)  
• High BMI correlated with increased peak interface pressure across all collar types, but was significantly lower for the Miami J standard than the Aspen standard collar. | • Healthy volunteers  
• Small population  
• Did not measure PU as an outcome  
• Controlled environment may reflect better collar fitting than application in a n emergency situation  
• Indirect evidence: PU not an outcome measure |
### Individuals with Spinal Cord Injury: data extraction and appraisals

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| W. H. W. Ham, L. Schoonhoven, M. J. Schuurmans, & L. P. H. Leenen, 2016b | Observational study describing pressure ulcers, indentation marks and pain from the extrication collar combined with headblocks | Participants were consecutively recruited in a level one trauma centre in Netherlands (n=342)  
- Inclusion criteria:  
  - trauma patient  
  - aged 18 years or over  
  - admitted to the ED with standard spinal immobilization.  
- Exclusion criteria:  
  - existing skin breakdown  
  - severe burn wounds (>10% body region),  
  - transferred from the ED to another hospital or from another hospital to our ED  
- Participant characteristics not reported under risk factors | N/A | The International NPUAP–EPUAP Pressure Ulcer Classification System, 2009  
ED nurses were trained to identify and categorize Ps from photographs  
trained ED nurses used a handout with descriptions and illustrations of PI corresponding to the PUI  
ED nurses were trained to use the transparent disc method  
inter-rater reliability was assessed.  
Nurses assessed skin areas exposed to pressure from the extrication collar and headblocks: chin, occiput, clavicles, back, chest and ears. | Rate of pressure injuries  
- 78.4% (95% CI: 73.6–82.6%) of the patients had Ps after removal or replacement of the extrication collar and headblocks in ED.  
- 258 (75.4%) trauma patients had at least one PI stage 1, and 10 (2.9%) had at least one stage 2 lesion, with a mean of 2.5 lesions per patients (682/268). PI stage 1 were mainly located at the chest (19.6%), back (16.1%) and the shoulders (12.6–16.9%). PI stage 2 were located at the back and shoulders. |  
Author conclusions: Achieving a good collar fit can be difficult. Following manufacturer instructions and correctly sizing is important to prevent skin breakdown  
- Any limitations  
- Any comments on results, design, funding, conflict of interest, power, potential flaw in conclusions  
- large proportion of eligible trauma patients (n = 144) were not included  
- Although the baseline characteristics of this excluded participants were comparable to the included patients, 52 of the missed patients were critically ill.  
- Skin inspection was not possible for occiput (96 times), back (71 times) and chin (2 times) |
| H. W. Ham, Schoonhoven, Galer, & To retrospectively compare | Include the following information:  
- Number of participants: 88  
- Clinical setting:  
- Cohort 1: Standard preventive care in the STICU consisting  
- Staging system used  
- Data were abstracted from paper charts as | Outcomes  
- In the total sample, only 1 patient developed CRPU within the first 14 days  
- impossible to confirm that preventive | Level of evidence: 4  
Quality: High |

Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury  
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| Shortridge-Baggett, 2014 | collar-related pressure ulcers (CRPUs) occurring in trauma patients admitted to the ICU wearing a C-collar before and after implementation of preventive interventions | Surgical trauma intensive care unit (STICU).  
- Country: US  
- Inclusion criteria: Patients were included in the convenience sample if they were directly admitted to the STICU from the ED in a C-collar.  
- Exclusion criteria: Patients had an existing PI at admission, had severe burn wounds (>10% of body surface or neck), or were discharged within 24 hours  
- The patient groups (2006 and 2008) did not differ on baseline characteristics | of the application of pressure-relieving mattresses in patients with increased risk according to Braden Scale scores, regular turning (every 2 hours), adequate hydration, and nutritional assessment (n=22).  
- Cohort 2: early C-collar removal (<24 hours) by optimized diagnostic procedures and use of an occipital (1-size) foam ring for patients in a C-collar was introduced (n=44) | well as electronic records on a standardized data collection tool  
- data were collected during the first 14 days of admission (days 1, 2, 3, 4, 7, and 14) or until C-collar removal or discharge from the STICU.  
- days of admission (incidence of 1/88, 1.1%).  
- No significant differences in risk factors at admission between cohorts  
- Logistic regression analysis to identify risk factors for CRPU development not possible due to low incidence | Prevention intervention: more C-spines were cleared within 24 hours in Cohort 2 (43.2%) compared with Cohort 1 (25%).  
The CRPU incidence was low. | interventiosns were done systematically and uniformly. |
| W. H. W. Ham, L. Schoonhoven, M. J. Schuurman s, & L. P. Leenen, 2016a | Study evaluating incidence and characteristics of pressure injuries in adult trauma patients | Participants were recruited consecutively (n=254)  
- Inclusion:  
  - trauma patient  
  - aged ≥ 18 years  
  - standard pre-hospital spinal immobilisation (i.e. backboard, headblocks and extraction collar)  
  - admitted through the emergency department | backboard should be used as an extrication and transportation device only and removed on arrival in ED  
- Individuals remained in extraction collar and headblocks, in the supine position until injury of the cervical spine was excluded/diagnosed | Pressure injury incidence 28.3% (CI 22.8% to 34.3%)  
- Pressure injury severity, anatomical site, time to development and relation to device  
- Pressure injury location 42.1% buttocks, 33.4% heels  
- Type 9.3% (95% CI, 31.3 to 47.8%) were not related to devices 28.1% category 1, 29.8% category 2, 21.1% category 3, 21.1% category 4 | Limited to single site  
Skin observation not conducted in ED so relationship between immobilization and pressure injuries is not clear, but many pressure injuries did occur by day 1 | Level of evidence: 4  
Quality: high |
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<td>Nemunaitis et al., 2015</td>
<td>Study evaluating sacral interface pressure and sensing area in spinal immobilized healthy volunteers</td>
<td>37 healthy volunteers</td>
<td>spine board vs pressure dispersion liner, low-viscosity gel PDL was an Oasis operating room overlay</td>
<td>Primary outcome is Interface pressure Interface pressures and sensing area recorded every minute for 40 minutes</td>
<td>55.7% of device-related PUs were related to immobilising devices (95% CI 44.7 to 66.3%) (primarily cervical collar)</td>
<td>• Data collection every second day</td>
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<td>Pernik et al., 2016</td>
<td>Observational cross-over study exploring vacuum mattress splint (VMS) to spine board for</td>
<td>Convenience sample of healthy participants were recruited in US (n=21) Inclusion: Aged &gt; 18 years No evidence of acute or chronic injury to any anatomical area being tested</td>
<td>Participants trialed: vacuum mattress splint folded and held around body as per manual while the pump was used to apply negative pressure under the center of the VMS</td>
<td>Tissue interface measured with pressure map taken frame every 25s for 200 frames • Mean pressure for activated cells • Number of cells exceeding 9.3kPa (69.8mmHg) Maximum pressure</td>
<td>Occiput • Mean pressure of all activated cells was significantly higher on spine board versus vacuum mattress splint (p&lt;0.001) • Maximum pressure was significantly higher in spine board versus vacuum mattress splint (74±15.1 kPa versus 20.4±4.8 kPa, p&lt;0.001)</td>
<td>• Primarily young, healthy individuals, although the range of BMIs varied • Small sample size • PU not an outcome</td>
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Participant characteristics:
• Median age 52 years
• 63.4% males
• Primarily falls patients (41.7%) cycle crashes (20.5%) and car crashes (15.7%)
• Median time in ED 213 minutes • Median hospitalization 54 days

• existing skin breakdown
• severe burns (10% body)
• transferred from other hospital

Author conclusions on modeling: Gel liner could reduce risk of pressure injuries

Level of evidence: Indirect (PU not an outcome)
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|     |               |        | Ultra Vue 1b spine board | Sacrum  
- Mean pressure of all activated cells was significantly higher on spine board versus vacuum mattress splint (p<0.001)  
- Maximum pressure was significantly higher in spine board versus vacuum mattress splint (104.3±21.0 kPa versus 41.8±9.4 kPa, p<0.001)  
Scapulae  
- Mean pressure of all activated cells was significantly higher on spine board versus vacuum mattress splint (p<0.001)  
- Maximum pressure was significantly higher in spine board versus vacuum mattress splint (54.5±16.3 kPa versus 30±7.6 kPa, p=0.0006)  
Heels  
- Mean pressure of all activated cells was significantly higher on spine board versus vacuum mattress splint (p<0.0001)  
- Maximum pressure was significantly higher in spine board versus vacuum mattress splint (92.3±22.4 kPa versus 53.4±15.8 kPa, p=0.01) | Author conclusion: Cells on the vacuum mattress were shown to still exceed the threshold of 9.3kPa and average maximum pressure was not reduced below this threshold, despite being lower than the spine board | |

Vacuum board has a higher cost ($150-300 versus $200-$800 USD)
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<tr>
<td>Mok, Jackson, Fang, &amp; Freedman, 2013</td>
<td>Determine whether a rate of pressure injuries changed since the introduction of vacuum spine board immobilisation</td>
<td>The sample consisted of consecutive groups of service members from Iraq and Afghanistan over 2 time periods who had sustained spinal injury. The clinical setting was prehospital retrieval from those countries to Germany.</td>
<td>Vacuum spine board (VSB) was introduced in July 2009. The first 60 patients evacuated following introduction of VSB were included in this cohort until August 2010. The controls were servicemembers who have sustained spinal injury prior to introduction of VSB. The researchers chose the time between February 2008 to June 2009 as the retrospective cohort. Patients with unstable cervical spine isolated transverse process, spinal process, compression fractures</td>
<td>The nurse completed a mandatory question “is a pressure ulcer present (yes/no)” on admission to LRMC. They used the NPUAP staging guideline to determine the grade of pressure injury. Medical records were also reviewed the documentation of pre-existing pressure injuries or other skin injuries before their evacuation. Due to variability in documentation two definitions of pressure injury was used for analysing the records a broad definition of pressure injury was any documentation of an injury to a pressure surface of the body. A strict definition was documentation of pressure injury on at least two notes with the initial intensive care unit assessment not being one of the two it must have if it must record a stage and it must be clearly stated that it was not sustained as part of the initial trauma. Secondary outcome measures effect of pressure injuries on subsequent surgical planning</td>
<td>VSB group broad definition: pressure injury incidence was 13 of 60 patients (22%). Strict definition: pressure injury incidence was eight of 60 (13%). Five pressure injuries were stage I Three pressure injuries were stage II</td>
<td>• the authors presented a great deal of information regarding flight times and transit times however they did not indicate this outcome measure and so I did not include it in the assessment all results they didn’t draw and an association between intubation and our pressure injuries however further exposure outcome research on this would need to be undertaken before you could comfortably say that there is a clear association this paper is useful as a very defined group but generalizability would be a problem.</td>
<td>3</td>
<td>high</td>
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# Individuals with Spinal Cord Injury: data extraction and appraisals

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<thead>
<tr>
<th>Ref</th>
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<tbody>
<tr>
<td>Berg et al., 2010</td>
<td>Observational study exploring impact on tissue oxygen saturation of immobilization on a long spine board</td>
<td>Healthy volunteers (n=74) Aged over 18 years Exclusion: Smoking Diabetes Skin rash over spine</td>
<td>supine positioning on a long rigid spine board buckled straps across chest and legs 30 minutes trial</td>
<td>Oxygen saturation(StO$_2$) reading at 30 minutes at sacrum and at a control site Two raters with high interrater reliability (r=0.814, p&lt;0.001)</td>
<td>• StO$_2$ measurement was significantly higher after exposure to pressure (p&lt;0.001) • No change in StO$_2$ at control site</td>
<td>• No comparison to a pressure point immobilized with no spine board • Healthy volunteers</td>
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<tr>
<td>Powers, Daniels, McGuire, &amp; Hilbish, 2006</td>
<td>Observational study reporting rate of pressure injuries associated with cervical collars</td>
<td>Participants were recruited In 3 critical care units in US (n=484) Inclusion cervical collar in place on admission Collar in situ at least 24 hours Exclusion:</td>
<td>• Procedure was removal of extrication collar within 8 hours of admission and replaced with acute-care collar • 12 hourly skin checks • Change collar pad 24 hourly</td>
<td>Skin breakdown, Time spent in cervical collar was significant predictor of skin breakdown (p&lt;0.0001)</td>
<td>• 6.8% developed a pressure injury</td>
<td>• no data collection methods reported</td>
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## Electrical stimulation to prevent pressure injuries (Biophysical agents)

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<tr>
<td>Bersch, Tesini, Bersch, &amp; Frötzler, 2015</td>
<td>A retrospective record review to identify the focus of</td>
<td>Retrospective record review conducted on patient records over a 2 year period at one in Switzerland paraplegic center (n=241)</td>
<td>FES: Different stimulation protocols allow the stimulation direct via nerve or muscle depending on the pulse width</td>
<td>• number of patients treated with FES • focus of the FES intervention</td>
<td>Use of FES for PU interventions increased from 2011 to 2012: 2011: preventing (n=5, 4.6%); treating (n=1, 0.9%) PUs</td>
<td>Participant characteristics not reported</td>
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</tbody>
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Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury © EPUAP/NPIAP/PPPIA
### Individuals with Spinal Cord Injury: data extraction and appraisals

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<th>Limitations and comments</th>
<th>Quality</th>
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<tbody>
<tr>
<td>Kane et al., 2017</td>
<td>Investigate the feasibility of using intermittent electrical stimulation as a potential method for preventing pressure injuries</td>
<td>20 mobiles linked to human intensive care unit in Alberta Canada</td>
<td>Two channel electrical stimulator impulse EMS D7 connected to hypo-allogenic electorates were applied directly to the skin over the bottom designated places. The stimulators sent 85 Hz electrical poles to 10 seconds every 10 minutes to cause contraction. Duration of stimulus was increased over several days on day 1p of the device for four hours skin was assessed at the 2 hour mark. The NPUAP grading system was used to assess skin Day two involved increasing stimulation to 8 hours. If no reactions were observed days 3 to 5 consisted of 12 hours stimulation. Day 6 increased to 16 hours, day 7 to 20 hours finally 24 hours was achieved by daily eight and remained until discharged or four weeks or became mobile or deceased.</td>
<td>• number of FES treatments relating to different stimulation fields&lt;br&gt;• number of patients that had an upper or lower motor neuron lesion</td>
<td>• 2012: preventing (n=15, 5%); treating (n=12, 8.9%) PUs&lt;br&gt;• Treatments poorly documented</td>
<td>Effectiveness of intervention unknown Intervention regimens unknown</td>
<td>Quality: low</td>
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<td>registered nurses, clerks, occupational therapists, physiotherapist, and nursing students were trained in the use of IES&lt;br&gt;• Skin checks were carried out every 2 hours&lt;br&gt;• The NPUAP was slightly modified to include “level 1 no evidence of skin issue” – “level 5 – Stage IV Pi”&lt;br&gt;• Nurses also assessed contraction strength on a 4 point likert scale&lt;br&gt;• Time of day IES was used and duration recorded as well as when assistance was required (eg. Changing electrodes) time to complete these activities&lt;br&gt;• Nurses were asked to rate the ease of positioning the patient to apply the device&lt;br&gt;• Rate the ease of finding an adequate muscle contraction&lt;br&gt;• Participants were asked if the system was distracting,</td>
<td>Pressure injury rate&lt;br&gt;None occurred over the 4 week study&lt;br&gt;Adverse events&lt;br&gt;No untoward reactions or adverse events occurring as a result of IES.&lt;br&gt;Contraction rate&lt;br&gt;Contractions were rated 3-4 (can see weak contraction/flicker-can see strong contraction) difference between beginning and end of stimulation p&gt;0.05&lt;br&gt;Outcome 3&lt;br&gt;Total caregiver time to apply the device averaged 5.9 mins ± 0.3 standard error of the mean. Removal of the device averaged 2 mins ± 0.1 standard error of the mean&lt;br&gt;None of the 15 respondents reported that the stimulation was painful or cumbersome.&lt;br&gt;The results suggest that intermittent electrical stimulation is safe and feasible to implement</td>
<td>It was confined to the ICU so none of the patients completed the 4 weeks that was stated in the protocol. There were deviations from the protocol whereby nurses increased the therapy outside of the recommended duration. Informed consent was often delayed The study was very poorly designed and more of a quality project than feasibility study. and it would be a long bow to draw any association between use of IES and prevention of PIs</td>
<td>Level of evidence: 3&lt;br&gt;Quality: low</td>
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<td>C. A. J. Smit et al., 2013</td>
<td>3 aims of the study: determine the effect of 3hrs of ES-induced gluteal and hamstring activation on interface sitting pressure distribution in people with SCI determine the effects of 1:1s vs 1:4s cycles on interface pressures and muscle fatigue over time determine the usability of the ES shorts</td>
<td>10 people with sci in a rehab unit in Amsterdam, The Netherlands. They were counterbalanced which increases the data to be collected Inclusion criteria: • Upper motor neuron lesion-SCI • AIS - A-C • 18-70 years old • Intact reflexes in the gluteal and hamstring muscles. • Previous surgery under the buttocks is not a contraindication Exclusion criteria: • Flaccid paralysis/areflexia • Hx severe autonomic dysreflexia • Current Pls under the ITs/sacrum • Severe cognitive or communicative disorders • Intolerance for ES • Other contraindications for ES Participant characteristics: • M/F 7/3 • Average age 40.6yrs • Tetra/Para 7/3 • AIS A/B/C 6/3/1 • Average Time since injury 162 days • Weight 83.2kg</td>
<td>Intervention for 8 days to 4 weeks</td>
<td>irritating or uncomfortable each day</td>
<td>in the ICU. It was also acceptable to staff and patients</td>
<td>Interface pressures under the ischial tuberosities were measured 3 times every hour (last minute of both rest and stimulation periods) On the final day of the ES protocol, participants completed a questionnaire on the usability of the shorts. • Interface pressures • IT pressures decreased from 106 mmHg to 37.2 mmHg for the 1:1 sec protocol (39%); 103 mmHg to 31.2 mmHg for the 1:4 sec protocol (32%). • Over time, the 1:4 sec protocol had greater effect for IT pressure change p=0.04 pressure reduction over time Significant difference between protocols for pressure reduction over time p&lt;0.001 with 1:4 sec being more effective. ES delivered through a custom made electrode garment to gluteal and hamstring muscles provides significant pressure relief to the Its. In this study, a ratio of 1:4s gave better results The FSA map only records surface pressures. There is no literature that describes the relationship between surface pressures and deep tissue deformation. The need to use ultrasound gel may be undesirable to some people due to leaving wet spots on clothing. ES is not suitable for people with a flaccid paralysis</td>
<td>Indirect evidence: PU not an outcome measure</td>
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### Table: Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury

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<tr>
<td>C. A. Smit et al., 2013</td>
<td>Compare the acute affects of ES induced muscle activation on IT pressures, blood flow and oxygenation to 3 standard pressure relief techniques</td>
<td>12 males from the rehabilitation research centre in Amsterdam, The Netherlands.</td>
<td>Participants had a 1x1.5cm² probe, 0.1cm thick attached under the left ischial tuberosity with surgical tape. It was then connected to the oxygenation device. The participants performed 3 different pressure relief movements (PRMs): push ups, bending forwards and leaning sideward whilst interfaced pressures were measured. Prior to each measurement, the participants were asked to rest for 5 mins.</td>
<td>• Ischial tuberosity pressures rest, PRM, ES</td>
<td>Ischial tuberosity Rest (156±26 mmHg) Push ups (19±44 mmHg, p&lt;0.001) Bend forward: (56±33 mmHg, p&lt;0.001) Lean sideward (44±38 mmHg, p&lt;0.001) ES (67±45 mmHg, p=0.03)</td>
<td>• No Blinding  • No randomisation  • Technical issues with the oxygenation device  • Not all outcome s were reported the same way  • Did not state that they were going to report correlations  • Small numbers</td>
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<td>Oxygenation Rest not reported Push ups p=0.01 Bend forward: p=0.01 Lean sideward p=0.01 ES p=0.57</td>
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<td>Blood flow Rest Push ups p=0.02 Bend forward: p=0.02 Lean sideward p=0.03 ES p=0.75</td>
<td>PRMs acutely reduced IT pressure and improved oxygenation and BF in SCI. The currently used ES method cannot replace PRMs,</td>
</tr>
<tr>
<td>Liu &amp; Ferguson-Pell, 2017</td>
<td>Observational study comparing surface electrical</td>
<td>Adults with SCI (n=14)</td>
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**Participant characteristics**
- Average age: 38 ± 12 yrs
- Tetra/para: 7/5
- AIS A/B: 9/3
- Average Time since injury: 14 ± 7.75 yrs
- Weight: 82.2 ± 15kg
- Participant characteristics and any baseline differences

**Intervention(s)**
- Surface functional electrical stimulation and stimulating sacral nerve roots by functional magnetic stimulation (FMS) or a

**Outcome Measures & Length of Follow-up**
- Schial skin index of hemoglobin (IHB) and oxygenation (IOX)

**Results**
- Blood perfusion was significantly higher during FMS than the baseline (IHB 1.05 ± 0.21 before vs. 1.08 ± 0.02 during stimulation, p = 0.03; IOX 0.18 ± 0.02 before vs. 0.19 ± 0.02 during stimulation, p = 0.05)

**Limitations and comments**
- Only 4 participants experienced FMS and FES

**Level of evidence:** 4  
**Quality:** low
### Individuals with Spinal Cord Injury: data extraction and appraisals

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<td></td>
<td>stimulation to sacral nerve root stimulation</td>
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<td>sacral anterior root stimulator implant (SARS)</td>
<td>0.21 before vs. 0.46 ± 0.30, p = 0.01 during stimulation</td>
<td>blood perfusion significantly increased with SARS (IHB 1.01 ± 0.02 before vs. 1.07 ± 0.02 during stimulation, p = 0.003; IOX 0.79 ± 0.81 before vs. 2.2 ± 1.21 during stimulation, p = 0.036).</td>
<td>• Small trial, participant selection not reported Short study duration, unclear if results would be sustained over longer than 3 hour periods Unclear if a clinically significant effect, PU development was not an outcome measure</td>
</tr>
<tr>
<td></td>
<td>Cross over RCT investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure distributions</td>
<td>Five participants</td>
<td>All participants completed two protocols of ES (50 Hz, 70 to 80 mA, 2 ch neuro-stimulator administered for a 3 hour session via custom clothing to the gluteal and hamstring muscles) in a randomised order 3 minutes stimulation in a 1sec on:1 sec off protocol followed by 17 min rest 3 minutes stimulation in a 1 sec on:4 sec off protocol followed by 17 min rest</td>
<td>Seated pressure value before protocol commenced then at 1 hour, 22 hour and 3 hour Measured during the 3 minute stimulation and the last minute before stimulation</td>
<td>Peak pressure significantly decreased (&gt;0.05) from baseline Protocol A: 183 ±13mmHg at rest to 168 ±17mmHg during stimulation Protocol B: 179 ±14mmHg at rest to 147 ±24mmHg during stimulation Within the stimulation period muscle fatigue was apparent in protocol A but not protocol B Study conclusions: for patients with SCI, an ES regimen of 3 minutes stimulation in a 1sec on:1 sec off followed by 17 minutes rest achieves reduction in interface pressure without muscle fatigue</td>
<td>• Small trial, participant selection not reported Short study duration, unclear if results would be sustained over longer than 3 hour periods Unclear if a clinically significant effect, PU development was not an outcome measure</td>
</tr>
<tr>
<td></td>
<td>Comparitive study investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure</td>
<td>Ten participants</td>
<td>All participants completed two 1-hour protocols of ES using electrical stimulation garments applied over normal garments. All participants all used their own Interface (IT) pressures recorded during the 3 min of stimulation and during the last minute of the preceding rest period using a pressure mapping device</td>
<td>In all participants, both protocols caused a decrease in IT pressure Protocol B provided significantly greater pressure release than Protocol A (mean pressure relief (37.8mmHg±23.2mmHg versus 11.8±11.7mmHg) o Unclear if the washout period of 30 minutes is suitable</td>
<td>o Unclear if the washout period of 30 minutes is suitable</td>
<td>Indirect evidence Quality: moderate</td>
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### Individuals with Spinal Cord Injury: data extraction and appraisals

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<td><strong>distributions</strong></td>
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<td>wheelchair with a regular cushion</td>
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<td>Protocol B achieved a significant reduction over time in IT pressure from 44mmHg at commencement to 28.5mmHg at cycle end (p=0.01)</td>
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<tr>
<td><strong>Protocols</strong></td>
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<td>Study conclusions: ES of muscles in participants with SCI reduces interface pressure in seated position. Stimulation of gluteal and hamstring muscles appears to be more effective than stimulating only the gluteal muscles.</td>
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<td><strong>Pressure relief maneuver to prevent pressure injuries (Repositioning)</strong></td>
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**Sonenblum & Sprigle, 2016**

To describe differences in in-seat behavior observed between individuals with a spinal cord injury (SCI) with and without a history of recurrent pressure injuries.

29 adults more than 2 years post SCI

Inclusion:
- used a wheelchair as primary mobility device
- had the ability to independently perform weight shift maneuvers

Participants were grouped according to whether they had a history of recurrent pressure injuries i.e., having had two or more pressure injuries in the pelvic area (n=12) or no pressure injuries (n=17)

- Participants were instrumented with a custom weight shift monitor (WSM) composed of 8 piezoresistive force sensors beneath their wheelchair cushion, and a data logger to store the measured forces.
- Participants instructed to go about their daily life as if the data monitor was not present.
- Daily time in wheelchair, number of transfers, and frequency of pressure reliefs (full unloading), weight shifts (30% load reduction), and in-seat movements (transient center of pressure movements or unloading).

- Participants in both groups performed few pressure reliefs and there was no difference between groups
- The median participant spent 10.3 hours in his wheelchair and performed 16 transfers to or from the wheelchair daily. Pressure reliefs were performed less than once every 3 hours in both groups.
- Weight shifts were performed significantly more often by the No Pri Group (median (interquartile range) 2.5 (1.0–3.6) per hour) than the Pri Group (1.0 (0.4–1.9), with P = 0.037 and effect size r = 0.39).
- In-seat movements were performed 46.5 (28.7–76.7) times per hour by

- Future work to better understand the relationship between in-seat movement, individual characteristics, and Pri outcomes required

**Level of evidence:** 4

**Quality:** low
### Individuals with Spinal Cord Injury: data extraction and appraisals

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<tr>
<td>Sonenblum, Vonk, Janssen, &amp; Sprigle, 2014</td>
<td>Observational study measuring effect of pressure relief maneuvers on interface pressure</td>
<td>Individuals with SCI (n=17)</td>
<td>Participants performed forward lean (small, intermediate and full) and side lean (intermediate and full) while on 3 different cushions</td>
<td>Interface pressure</td>
<td>the No Pri group and 39.6 (24.3–49.7) times per hour for the Pri group (P = 0.352, effect size r = 0.17). • The study indicated no significant correlation between weight shift frequency and age, nor differences in weight shift frequency according to sex</td>
<td>Conclusions: Weight shifts that can be produced by functional activities and that partially unload the buttocks should be considered as an important addition to individuals’ Pri prevention regimen.</td>
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<tr>
<td>Morita et al, 2015</td>
<td>Case control study investigating lifestyle factors that influence risk of PU in individuals with SCI in community</td>
<td>Cases: people with SCI admitted to a Japanese rehabilitation hospital for treatment of PU (n=31) Controls: outpatients of the same facility who had lived in the community without PU for the preceding 12 months (n=30) No exclusion criteria</td>
<td>Structured questionnaire interview Diary of habits maintained by controls for 1 week (only for controls)</td>
<td>Risk assessment: Braden scale</td>
<td>Pressure relief maneuvers: case vs control Average hrs/day in chair: PU group versus no PU group, 12.2±4.6 vs 15.2±2.4, p=0.002 Number pressure relief maneuvers/hr: 2.2±3.3 vs 1.8±1.6, p=0.664 Knowledge of PU pressure relief methods (number of methods known): pressure</td>
<td>Low generalizability • Replied on self-reported preventive health data and relied on recall for case group • Case-control matching led to significant</td>
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| Makhsous et al., 2007 | Observational study measuring effect of pressure relief maneuvers on blood oxygenation | Individuals with paraplegia SCI (n=20) and tetraplegia (n=20) Control subjects (n = 20) | Two 1-hour sitting protocols:  
- dynamic protocol, sitting configuration alternated every 10 minutes between normal sitting and an off-loading configuration and  
- wheelchair pushup protocol, normal sitting configuration with standard wheelchair pushup once every 20 minutes | Transcutaneous partial pressures of oxygen and carbon dioxide measured from buttock overlying the ischial tuberosity and interface pressure (using oximeter) Interface pressure (average and peak pressure) |  
- During normal sitting configuration, average tcPO$_2$ at IT was less than 10 mmHg for all groups.  
- In the off-loading configuration, tcPO$_2$ at IT was maintained above 50 mmHg for all groups  
- During pushups, tcPO$_2$ at IT increased  
- However, significantly shorter perfusion recovery time for tcPCO$_2$ was found in the control group than the 2 SCI groups (control: 202.8 ± 10.4 s, paraplegic: 251.8 ± 9.2 s, and tetraplegic: 254.6 ± 8.9 s; P < 0.001).  

**Dynamic sitting protocol had significant improvement tissue perfusion in the buttock area through periodically repositioning the concentrated pressure from buttocks to the thighs. Interface pressure relief achieved by wheelchair pushups was not sufficient to allow an optimal recovery of the buttock tissue perfusion in individuals with SCI** | difference in age, time since injury and previous history of PU  
- Wide confidence interval for seat cushions in possession | Level of evidence: 2 Quality: moderate |
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<tr>
<td>Ghaisas, Pyatak, Blanche, Blanchard, &amp; Clark, 2015</td>
<td>Retrospective analysis of outcomes of one cohort in trial to identify associations between PU status and lifestyle change</td>
<td>Retrospective secondary analysis of outcomes for the treatment group in a previously conducted trial. All participants who completed 12 months of the intervention were eligible for inclusion (n=47 eligible, n=17 included)</td>
<td>Participants were classified as having achieved lifestyle changes vs no changes</td>
<td>Treatment note review to categorize participants based on making lifestyle changes</td>
<td>1,922 notes were reviewed (mean 40.9/participant)</td>
<td>• Analysis was limited to treatment arm of a trial (i.e. bias sample) with no control</td>
<td>3</td>
<td>Low</td>
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<td></td>
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<td>• Experienced PU during intervention period</td>
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<td>• Participants who did not adhere to lifestyle changes were excluded but reasons were not clear (others were included and described as making minor or no lifestyle change)</td>
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<td>Inclusion criteria:</td>
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<td>• Unclear how PU status was assessed and whether recurrence was considered</td>
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<td>• Completed 12 months of the intervention with sufficient participation</td>
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<td>• Subjective outcome measures</td>
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<td></td>
<td>• Experienced PU during intervention period</td>
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<td>• Does not state how PU status assessed</td>
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<td>Exclusion criteria:</td>
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<td>• Factors that could influence success of smoking cessation program (e.g. baseline number, social factors such as other</td>
<td>3</td>
<td>Low</td>
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<tr>
<td>Lane, Selleck, Chen, &amp; Tang, 2016</td>
<td>Retrospective cohort study investigating efficacy of smoking cessation in individuals with SCI</td>
<td>Groups recruited through electronic record review at an outpatient wound clinic in the US</td>
<td>Smoking cessation program initiated at the wound clinic and based on US national guidelines using the 5As program</td>
<td>Chart review</td>
<td>Impact of smoking cessation on smoking status</td>
<td>• Factors that could influence success of smoking cessation program (e.g. baseline number, social factors such as other</td>
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<td></td>
<td></td>
<td></td>
<td>Quadruplegic or paraplegic due to SCI</td>
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<td>Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury © EPUAP/NPIAP/PPPIA Page 22</td>
<td>3</td>
<td>Low</td>
</tr>
<tr>
<td>Ref</td>
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<td>Limitations and comments</td>
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</table>
| Carlson et al., 2017| To test the efficacy of a lifestyle-based intervention designed to reduce incidence of Medically serious pressure injuries (MSPrIs) in adults with SCI. | Participants were recruited in rehabilitation facility in US N=170 plus additional 62 non-randomized controlled (results not included here)  
Inclusion criteria:  
- Adults (≥ 18 years of age)  
- SCI (paraplegia or tetraplegia)  
- history of at least one stage 3 or stage 4 PI in the past five years  
- currently utilizing RLANRC services  
- existing medical chart at facility.  
- English- or Spanish-speaking  
- contactable by telephone  
Randomized to either  
- The Pressure Ulcer Prevention Program (PUPP) consisted of six modules.  
Lifestyle-based intervention, knowledge on prevention, and application to a person's circumstances, information, activities, and exercises. Ongoing and intensive  
- The smoking cessation program (n=83)  
  • Cases– seen in the 6-months after the smoking cessation program was introduced (n=75)  
  • the smoking cessation program  
<table>
<thead>
<tr>
<th>Sample</th>
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<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
|                      | Exclusion criteria:  
- Pregnant  
- Mental impairment  
- Wards of the state/prisoners  
Participant characteristics:  
- No significant difference between groups for demographics  
- Mena age 44 years  
- Approx 47% participants black  
- Approx 80% male  
- Approx 50% smokers at baseline | the smoking cessation program (n=83)  
  • Cases– seen in the 6-months after the smoking cessation program was introduced (n=75)  
  • the smoking cessation program | Impact of smoking cessation on choice to have PU surgery  
There was no statistically significant difference in percent of participants who desired and underwent surgery (45% control versus 35% case, p=0.35)  
Impact of smoking cessation on PU healing  
• More smokers than non-smokers had a PU (smokers 24.1% versus non-smokers 10.8%, p=0.03)  
• Smokers had higher decrease in number of wounds (65.2% versus 33.3%, p=0.03)  
Smokers experienced significant increase in total wound size compared to non-smokers and smokers who stopped smoking (17.8cm³ versus -14.2cm³ versus -170.3cm³, F=5.6, p=0.004) | smokers in family) were not collected  
Relied on report of patient re smoking status  
Small sample size  
Relied on data base entries  
Full extent of intervention was not reported (e.g. how many sessions per patient)  
Sustainability not demonstrated  
Unclear who assessed wounds and what strategies used for same |
|                      |                                                                                  |                                                                                        | Annualized MSPrI rates  
No significant difference between groups.  
At 12 months, 0.56 intervention versus 0.48 controls  
At 24 months, 0.44 intervention versus 0.39 control  
Rate ratio for serious MSPrIs at 12 months in intervention group was 1.15 (95% CI 0.76 to 1.76, p = not significant).  
Rate ratio for serious MSPrIs at 24 months in intervention group was 1.14 (95% CI 0.72 to 1.82, p = not significant).  
Secondary analyses:  
Risk level II (≥ 2 MSPrIs in the past 2 years) | Limited generalizability  
Participants had higher MSPrI rate, require a more intensive intervention, and sustain greater PI risk even with intervention services.  
Results of this study may not be directly | Level of evidence: 1  
Quality: high |
### Individuals with Spinal Cord Injury: data extraction and appraisals

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</tr>
</thead>
<tbody>
<tr>
<td>Previnaire, Fontet, Opsomer, Simon, &amp; Ducrocq, 2016</td>
<td>Retrospective case series reporting the effectiveness of lipofilling surgery for preventing PU recurrence</td>
<td>Retrospective review of consecutive patients undergoing lipofilling at one center in France (n=10)</td>
<td>Lipofilling (fat grafting) was performed using three stages: water-jet assisted liposuction, decantation, and reinjection of the autologous fat in three-dimensional plan.</td>
<td>• Follow up at day 14, and 1, 3, and 6 month mean follow up 16 mths (range 4-24) • Evaluations included: weight and BMI, seating pressure map, photographic assessment: skinfold thickness using caliper pinch test, Fat waste as a global assessment, Self-perceived QOL using patient global</td>
<td>PU recurrence: 30% of patients had a PU following surgery (3 Stage I, one Stage 2) QOL: improved in 6 patients, unchanged in 4 patients and worsened for none Ischial tuberosity adipose tissue thickness: Significant improvement (3.5 to 5.5 cm) in 7/9 patients</td>
<td>• Follow up time frame may be insufficient to truly evaluate the effectiveness of the intervention • Surgeon performing procedure was also responsible for measuring at least some of the outcome measures • Small sample size</td>
</tr>
</tbody>
</table>

#### Lipofilling surgery to prevent recurrence of PU

- Previnaire, Fontet, Opsomer, Simon, & Ducrocq, 2016
- Retrospective case series reporting the effectiveness of lipofilling surgery for preventing PU recurrence
  - Inclusion criteria:
    - Adult patients with SCI
    - History of ischial tuberosity and pelvic PU surgery
    - At risk of PU recurrence due to unsatisfactory adipose tissue thickness
  - Participant characteristics:
    - Lipofilling (fat grafting) was performed using three stages: water-jet assisted liposuction, decantation, and reinjection of the autologous fat in three-dimensional plan.
  - Results:
    - PU recurrence: 30% of patients had a PU following surgery (3 Stage I, one Stage 2)
    - QOL: improved in 6 patients, unchanged in 4 patients and worsened for none
    - Ischial tuberosity adipose tissue thickness: Significant improvement (3.5 to 5.5 cm) in 7/9 patients
  - Limitations and comments:
    - Follow up time frame may be insufficient to truly evaluate the effectiveness of the intervention
    - Surgeon performing procedure was also responsible for measuring at least some of the outcome measures
    - Small sample size
  - Level of evidence: 4
  - Quality: moderate

---

**Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury**

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### Background information - Prevalence rates

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Wannapakh, Arrayawichanon, Saengsuwan, &amp; Amatachaya, 2015</td>
<td>Prospective cohort study investigation rate of complications in individuals with SCI for 6 months following rehabilitation</td>
<td>Individuals with SCI consecutively recruited on discharge from rehabilitation center in Thailand (n=108 screened, n=104 eligible, n=100 completed study)</td>
<td>Participants classified as:</td>
<td>Incidence of pressure ulcers (and other signs/symptoms) was measured monthly through telephone interview</td>
<td>WB participants:</td>
<td>Unclear why these specific patients were chosen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inclusion criteria:</td>
<td></td>
<td>Other complications were collected from physician</td>
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<tr>
<td></td>
<td></td>
<td>≥18 years of age</td>
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<tr>
<td></td>
<td></td>
<td>SCI due to trauma, non-progressive disease</td>
<td></td>
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<td></td>
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<td>Sub-acute or chronic stage of injury</td>
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<td></td>
<td></td>
<td>America Spinal Injury Assoc. (ASIA) Impairment Scale (AIS) A and B</td>
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<tr>
<td></td>
<td></td>
<td>Exclusion criteria:</td>
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<tr>
<td></td>
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<td>AM (ambulatory, able to walk ≥100m with or without walking device), n=50</td>
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<td></td>
<td></td>
<td>WB (wheelchair bound), n=50</td>
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</tbody>
</table>

#### Data Tables: 2019 Guideline Update: Individuals with Spinal Cord Injury

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</thead>
<tbody>
<tr>
<td>Kovindha, Kammuang -Lue, Prakongsai, &amp; Wongphan, 2015</td>
<td>Cross sectional study investigating prevalence of PU in a cohort of people with SCI</td>
<td>Participants were people in Thailand with SCI enrolled in a study investigating support surfaces (n=129)</td>
<td>Self-reported questionnaire appears to be confirmed by clinical record review</td>
<td>• Self-reported PU that was not confirmed clinically</td>
<td>PU prevalence rate • 26.4% had a current PU • 27.9% had a healed PU • 45.7% had never had a PU • No significant difference between having/not having a PU based on age, gender, impairment, education, work status or geographic location</td>
<td>• Sampling of participants is unclear, unclear how representative they are of wheelchair user in Thailand with SCI • Primarily self-reported data (confirmation through record review is inferred but not reported clearly) • Participants were enrolled in a trial for support surface – unclear how this may influence the results • Similarity with respect to</td>
</tr>
</tbody>
</table>

Inclusion criteria:  
• Enrolled in a study investigating PU preventive strategies  
• age ≥18 years  
• 1+ years post-SCI ability to communicate and provide information use a wheelchair

Exclusion criteria:  
• ASIA impairment scale D

Characteristics:  
• 89% participants aged 31 to 60 years  
• Primarily AIS-A category

Characteristics:  
• Signs/symptoms that could influence incidence of complications (e.g. deformities, brain disorders)

Characteristics:  
• AM group significantly older than WB group (48 vs 42 yrs, p=0.027)  
• Significantly longer time since injury for WB group (38 vs 69 mths, p=0.015)  
• No significant difference in stage of injury or level of injury

Anatomical location of PUs  
Sacrum 32.4%  
Tochanter 20.6%  
Ischium 38.2%  
Knee and malleolus 5.9%

Prevalence and HRQOL  
• No significant difference between having/not having a PU based on limitation in mobility, limitation in self-care, pain discomfort or difficult major life area  
• People with PU were significantly more likely to have severe-mild depression (p=0.015)
### Individuals with Spinal Cord Injury: data extraction and appraisals

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Hoh, Rahman, Fargen, Neal, &amp; Hoh, 2016</td>
<td>Database review of prevalence of hospital acquired Category/Stage III and IV PUs in individuals with SCI</td>
<td>United States Nationwide In-patient Sample database (NIS) hospitalizations from 2002–2010 for admissions for diagnosis of cervical fracture with SCI (n=10,669 admission with SCI)</td>
<td>Retrospective database analysis of Patient Safety Indicators and hospital-acquired conditions including Pressure ulcer stages III and IV</td>
<td>PUs were only included in the data base for years 2008-2010 (covering n=3,785 admissions with SCI)</td>
<td>Prevalence of HAPU Category/Stage III or IV in admissions for cervical fracture and concurrent SCI 1.48% (95% CI 1.14% to1.92%)</td>
<td>Preventive care is not reported</td>
</tr>
<tr>
<td>Ploumis et al., 2011</td>
<td>Retrospective study reporting PU prevalence rates</td>
<td>Patients admitted to rehabilitation from level 1 SCI trauma center (n = 78) and admitted from non-SCI level 1 trauma centers (n = 131) from 2005 to 200 Total n= 209</td>
<td>Database review</td>
<td>Pressure ulcers were graded as per NPUAP classification.</td>
<td>Point prevalence on admission More patients from non-SCI centres (n = 44, 34%) than SCI centres (n = 24, 12%) had PUs (p=0.001) Percentage of patients with grade III and IV pressure ulcers (6% SCI, 11% non-SCI)</td>
<td>Relied on database entries to be correct No interrater reliability Incomplete discharge notes from the acute care hospital were excluded.</td>
</tr>
<tr>
<td>Wilson, Arnold, Singh, Kalsi-Ryan, &amp; Fehlings, 2012</td>
<td>Prospective cohort study reporting all complications in SCI patients</td>
<td>411 patients in 6 US trauma centers over a 7-year period (n=411)</td>
<td>No intervention</td>
<td>Mean length of stay (LOS) was 34.3±54.6 days Any complication was related to significant increase in LOS, p&lt;0.001 39% experienced at least one complication</td>
<td>Unclear how PU was defined and identified</td>
<td>Relied on database information Unclear how PU was identified Limited to Category/Stage III or IV PU Level of evidence: N/A Quality: moderate</td>
</tr>
</tbody>
</table>
### Mathew, Samuelkamaleshkumar, Radhika, & Elango, 2013

**Type of Study:** Cross-sectional study investigating relationship between practices and PU development in people with SCI  

**Sample:** Participants were a sample from an Indian rehabilitation center (n = 108)  

- Inclusion:  
  - T2 or below lesion  
- Characteristics:  
  - Age range 16 to 65 years  
  - 9% had no education, 20% had college level education  
  - 55% had SCI lesion < 10 years  
  - 68% complete injury (ASIA-A)  
  - 76% were working  

- Participants completed a survey with primarily closed questions regarding their work and leisure history, preventative practice and history of PU  

- **Outcome Measures & Length of Follow-up:** Demographics and PU history  

- **Results:**  
  - PU account for 4.6% of complications (which is equivalent to approx. 2.6% of people, assuming only 1 PU per person)  
  - 82% of respondents had experienced a PU  
  - 65% of PUs that formed were primarily related to poor pressure relief practice, 15% were related to accidents, 12% were related to lack of education  
  - There was no significant relationship between work history, leisure activity and self-care and PU history  
  - Participants with complete injury were more likely to experience a PU (p=0.001)  
  - Participants working in manual work were more likely to have a PU than those in home based or office occupations (p=0.04)  

- **Limitations and comments:**  
  - Unclear how cause of PU was determined  
  - Self-reported data, unclear how the diagnosis of PU was made (classified as mild-severe)  
  - Unclear how participants were selected for inclusion  
  - Single site in developing nation  

**Level of evidence:** N/A  
**Quality:** Low

---

### Wu, Ning, Li, Feng, & Feng, 2013

**Type of Study:** Retrospective cross-sectional study investigating factors related to increase hospital length of stay  

**Sample:** Participants were recruited from 17 hospitals in one city in China over a four year period (n=631)  

- Inclusion:  
  - SCI  
  - aged > 14 years  
  - not deceased during length of stay  
  - complete records  
- Characteristics:  
  - 85% participants male  

- **Outcome Measures & Length of Follow-up:** Demographics and medical history  

- **Results:**  
  - Any medical complication was related to an increased acute care length of stay  
  - Pressure ulcer was related to an increased length of stay in acute care (incidence 2.7%, p=0.000)  

- **Limitations and comments:**  
  - Unclear how PU was defined and identified  

**Level of evidence:** N/A  
**Quality:** Moderate
### Background information - economics

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Chan et al., 2013</td>
<td>To determine the cost in terms of resources of an individual with SCI living in the community in Canada</td>
<td>Sample (n=12) derived from a pilot RCT (sample size n=14, however 2 excluded due to incomplete data) comparing an interdisciplinary pressure ulcer prevention approach to bed rest Clinical setting: community dwelling individuals in Toronto and Ontario, Canada Included in the RCT if: • Adults 18+ with SCI resulting in quadriplegia or paraplegia • Stage II-IV PU present 3+ months, likely to heal in 6 months • Wheelchair user • Is limiting their mobility (bed rest) secondary to concerns about skin condition • Assessment • Ability to comply Excluded: • Unable to provide consent • Osteomyelitis requiring surgical intervention • Medically unstable or unable to tolerate interventions provided by research team • Limited life expectancy Participant characteristics: • No differences between groups at baseline • Average age was 52.4 years, 42% quadriplegics, 50%</td>
<td>Individuals were randomized to: • interdisciplinary pressure management or bed rest for 3 months followed by a 4-month period where they had the option to continue with current treatment or switch to another treatment option. • Of the 12 individuals • On average duration of current pressure ulcer was 25 months • The staging system used was NPUAP staging system was 2007 • Follow up was 4 months</td>
<td>number of hours spent in bed • No significant differences activity • No significant differences wound healing outcomes • No significant differences Costs • Total average cost per patient in the community with an SCI is $4748 per month • The majority of cost 59% were attributed to nursing and allied health professional’s costs, and hospital admissions • Stage 3 was greater average monthly cost • 65 and older had costs that were double the monthly cost of under 65s • Pressure ulcers &lt;10 cm² incurred double the cost</td>
<td>• Pressure injury was experienced for several months prior to recruitment therefore treatment costs were not fully captured. • No participants healed by study end. • Participants may have been recall bias • Costs are likely to be under estimated due to lack of relevant information about unpaid education time and nursing time.</td>
<td>Economic Analysis High Quality</td>
</tr>
</tbody>
</table>
Individuals with Spinal Cord Injury: data extraction and appraisals

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<td>paraplegics, 8% unknown, 67% had previous pressure ulcer • 8% stage 2, 67% stage 3 and 25% stage 4 • Average wound size 22 cm², average depth was 3 cm • Majority of pressure ulcers were located on the sacrum</td>
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Additional evidence from systematic reviews to support discussion

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</thead>
<tbody>
<tr>
<td>Naing &amp; Whittaker, 2017</td>
<td>To assess the effects of anabolic steroids for treating pressure ulcers</td>
<td>Systematic review identified only 1 RCT conducted in Veterans Affairs medical centers in USA (n=212 people with spinal cord injuries and Category/Stage III and IV pressure injuries) 22 studies were excluded that include: duplicates, non RCTs, reviews, not related to pressure injuries, editorials, guidelines.</td>
<td>In the single included study, the intervention group was administered orally 20mg/day of oxandrolone while the comparison group received a placebo.</td>
<td>• Outcomes were measured at 24 weeks that included re-epithelialisation with a dry cicatrix for 96 hours. • Staging system EPUAP/NPUAP 2009</td>
<td>Pressure injury healing at 24 weeks There was no significant difference in complete healing rates at 24 weeks between oxandrolone group and placebo (1 study, n=212, risk ratio 0.81, 95%CI 0.52 to 1.26, p=0.35) Conclusion: Evidence is lacking for the use of anabolic steroids in treating pressure injuries</td>
<td>• Trial reported the systematic review was terminated before completion • Sample is homogenous may limit generalizability to other pressure injury populations</td>
</tr>
</tbody>
</table>

Additional evidence from systematic reviews to support discussion

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</tbody>
</table>
### Table 1: Level of Evidence for Intervention Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Experimental Designs</th>
<th>Quasi-experimental design</th>
<th>Observational-analytical designs</th>
<th>Observational-descriptive studies (no control)</th>
<th>Indirect evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Randomized trial</td>
<td>Prospectively controlled study design</td>
<td>Cohort study with or without control group</td>
<td>Observational study with no control group</td>
<td>studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models</td>
</tr>
<tr>
<td>Level 2</td>
<td></td>
<td>Pre-test post-test or historic/retrospective control group study</td>
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<td>Cross-sectional study</td>
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<tr>
<td>Level 3</td>
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<td>Case series (n=10+)</td>
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<td>Level 4</td>
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<tr>
<td>Level 5</td>
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</table>

### Table 2: Levels of Evidence for Diagnostic Studies in the EPUAP-NPUAP-PPPIA Guideline Update

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Individual high quality (cross-sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Non-consecutive studies or studies without consistently applied reference standards.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies or poor or non-independent reference standard.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mechanism-based reasoning, study of diagnostic yield (no reference standard).</td>
</tr>
</tbody>
</table>

### Table 3: Levels of Evidence for Prognostic Studies in the EPUAP-NPUAP-PPPIA Guideline Update

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>A prospective cohort study.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.</td>
</tr>
</tbody>
</table>

### Appraisal for Studies Providing Direct Evidence (i.e. Eligible for Supporting an Evidence-Based Recommendations)

Each criterion on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria
# Individuals with Spinal Cord Injury: data extraction and appraisals

## CROSSSECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representative sample</th>
<th>States number invited</th>
<th>Participants</th>
<th>Clear outcome measures</th>
<th>Valid reliable outcome measurement</th>
<th>Comparable results for multiple sites</th>
<th>Confounders identified and accounted for</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
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## RCTS

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<th>Author/year</th>
<th>Focussed question</th>
<th>Assignment randomised</th>
<th>Adequate concealment method</th>
<th>Subjects and investigators blinded</th>
<th>Groups comparable at commencement</th>
<th>Only difference betw groups was treatment</th>
<th>Valid, reliable outcome measure</th>
<th>Drop out in study arms is reported and accepted</th>
<th>Intention to treat analysis</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
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COHORT STUDIES

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<th>Author/year</th>
<th>Focussed question</th>
<th>Comparable source populations</th>
<th>States number invited</th>
<th>Likelihood of outcome at enrolment considered</th>
<th>Per cent drop out in study arms is reported</th>
<th>Comparison btw drop outs and participants</th>
<th>Clear outcome measures</th>
<th>Assessment blinded, or discuss potential bias</th>
<th>Valid, reliable assessment with supporting reference</th>
<th>More than one measure of exposure</th>
<th>Confounders identified and accounted for</th>
<th>Provides confidence intervals</th>
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CASE CONTROL STUDIES

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<tr>
<th>Author/year</th>
<th>Focussed question</th>
<th>Comparable source populations</th>
<th>Same exclusion cases and controls</th>
<th>Per cent drop out in study arms is reported</th>
<th>Comparison btw participants and non participants</th>
<th>Cases clearly defined</th>
<th>Established that controls are non-cases</th>
<th>Knowledge of primary exposure not influence case ascertainment</th>
<th>Confounders identified and accounted for</th>
<th>Provides confidence intervals</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
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PROGNOSTIC STUDIES
### Individuals with Spinal Cord Injury: data extraction and appraisals

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Adequate description of baseline characteristics</th>
<th>Satisfactory study attrition</th>
<th>Clear outcome measures/prognostic factors</th>
<th>Range of prognostic factors/confounders measured and identified</th>
<th>Method of measuring prognostic factor is reported, valid and reliable</th>
<th>Same method of measure of prognostic factor for all participants</th>
<th>Continuous variables or appropriate cut offs</th>
<th>Percent participants with complete data acceptable</th>
<th>Appropriate imputation method</th>
<th>Confounders/prognostic factors accounted for in analysis</th>
<th>Selective reporting avoided</th>
<th>Adequate sample size (10 PIs per factor)</th>
<th>Level of evidence</th>
<th>Quality</th>
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<td>Chen et al., 2016</td>
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### ECONOMIC EVALUATIONS

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Focussed question</th>
<th>Economic importance of question is clear</th>
<th>Choice of study design is justified</th>
<th>All costs are included and valued appropriately</th>
<th>Outcome measures to answer study question are relevant and measured appropriately</th>
<th>Discounting of future costs and outcome measures is performed correctly when appropriate</th>
<th>Assumptions explicit and a sensitivity analysis conducted</th>
<th>Results provide information relevant for policy providers</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
<th>Other relevant topics</th>
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### SYSTEMATIC REVIEWS FOR DISCUSSION

**RATING CRITERIA:**
### Individuals with Spinal Cord Injury: data extraction and appraisals

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>PICO research question and inclusion criteria</th>
<th>Rationale for selection of study designs</th>
<th>Comprehensive search?</th>
<th>Duplicate study selection?</th>
<th>Duplicate data extraction?</th>
<th>Adequate description of included studies?</th>
<th>Risk of bias assessed?</th>
<th>Source of funding reported?</th>
<th>Appropriate meta-analysis including weighting and adjustment for heterogeneity</th>
<th>Meta-analysis considers risk of bias of studies</th>
<th>Discussion considers risk of bias of studies</th>
<th>Assessment of publication bias if quantitative analysis is done</th>
<th>Potential conflicts of interest of authors reported and managed</th>
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References


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