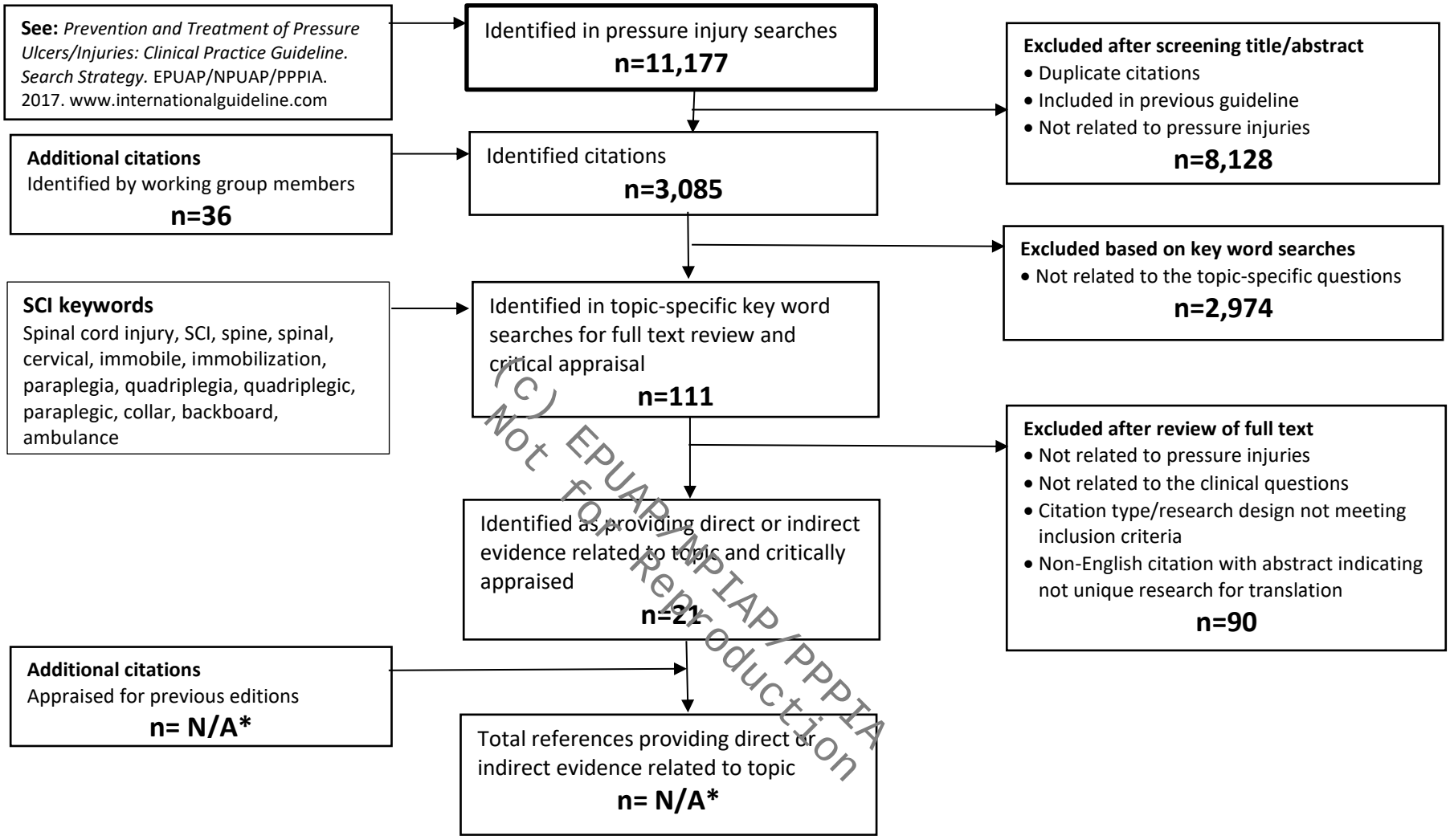
Search results for 2019 International Pressure Injury Guideline: Spinal Cord Injury



* 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.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

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 resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 1: What are the unique pressure injury risk factors to consider for individuals with spinal cord injury?							
Risk factors (note relevant included studies and recommendations are in the risk section)							
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 No exclusion criteria Cases and controls were matched for gender, level of injury, severity of paralysis Characteristics: Mean age: 55.4yrs for cases versus 45.3yrs for controls (p=0.005) Mean years since injury : 24 for cases versus 14.6 for controls, p=0.007 PU history significantly more previous history for cases, p=0.031	Structured questionnaire interview Diary of habits maintained by controls for 1 week (only for controls)	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 week 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	**Level of evidence: N/A** **Quality: high** **(not an eligible design for inclusion in risk factor analysis)**

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					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:)R 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.**		
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) Inclusion criteria: • Admitted to rehab facility in the five-year period following hospitalization for surgical management of acute SCI Exclusion criteria: • Nonsurgical management of SCI • Aged < 18 years Participant characteristics:	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	**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 0.0595% CI 0.01 to 0.2 7 • ASIA grade ASIA < D versus ASIA D OR 10.21 95% CI 1.14 to 91.18	• 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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		• Participants in a specialized center were significantly older (mean age 51.9 years versus 44.7 years, p=0.045) • Approx 81% male Participants in non-specialized center had significantly longer mean length of stay (64.4 days versus 45.4 days)				•	
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) Inclusion criteria: • Admitted in the 6 months observation period • Aged ≤ 18 years • AIS grade A-D Exclusion criteria: • None Participant characteristics: • 73% male • 25% aged < 35 years and 11% aged > 66 years	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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					• 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		

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)
	
	(measures associations)
		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.
					• Risk behavior dimension mediated relationships between latent PI and:
					○ smoking (indirect effect= 0.323*0.436= 0.141),
					○ alcohol consumption (indirect effect=0.323*0.087=0.0281),
					○ general prescription compliance (indirect effect=0.323*0.351=0.113)
					○ 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 (rnon-ambulatory:C1–C4 vs ambulatory=0.450, rnon-ambulatory:C5–C8 vs ambulatory=0.361, rnon-ambulatory: non-cervical vs ambulatory=0.232).
					
					Author conclusions: risk behaviors had a significant adverse effect on the number of PI in the past year, number of weeks in the past year that a PI resulted in reduced sitting time, the number of
						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)

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					times hospitalized for a PI and current PI.		
Costa, Caliri, Costa, & Gamba, 2013	Retrospective study based on review to identify **factors associated with the occurrence of pressure ulcers in patients at General Hospital in Maceió, Brazil**	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) Inclusion criteria: SCI patient of any (5-89 y old), Exclusion criteria: patient records that had no documentation about PI		• PI were measured: During hospitalization (admission to discharge OR death) • Risk factors measured: Age, Cause of SCI, SCI surgical or clinical management, LOS	• 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 **Significant factors in the model:** • Age ≤30 (61%) • Cause of SCI: by Gunshot or Firearm (OR = 3.64, CI 95% =1.44 – 9.15, p 0.005) • SCI Surgical management: OR=12.81, 95% CI: 2.56 to 64.19, p 0.002) • LOS>10 days (adjusted OR=5.09; 95% CI: 1.21 to 21.34, p 0.026)	• 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.	**No appraisal done (translated from Spanish)** **(Note: Does not meet inclusion for risk)**
Chopra et al., 2016	Retrospective cohort study **exploring risk factors for infected PU in gun shot victims with SCI**	Sample of records in one hospital in US identified through screening for relevant ICD codes of admission in a 4 year period (n=201) Inclusion criteria: • Aged > 14 years • Presence of PU • History of gun shot wound • First admission and readmissions Participant characteristics: • Mean age 37.4± 9 years • 89% male • 84% admitted from home • 77% first admissions were related to issues other than PU management primarily sepsis	Review of electronic health record to identify disease severity and development of infection.	• Costs associated with infected PU • Risk factors associated with infected PU	**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<0.0001 • low albumin (<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)	• 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	**Level of evidence: 3** **Quality: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		(21%), UTI (9%) and osteomyelitis (4%)			• 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 higher financial cost (USD$16,735±8,310 versus USD$12,356±7,007, p<0.001)	may be site-specific •	
Street, Noonan, Cheung, Fisher, & Dvorak, 2015	Retrospective cohort study with logistic regression analysis exploring **factors associated with adverse events in emergency admissions**	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) Inclusion criteria: • TSCI • Admission to an acute spinal unit across Canada that participated in the national-level database Participant characteristics: • 81.3% male • 22.8% of participants had no adverse events • Mean length stay in acute care 40.8±40.9 days • Mean physical component summary 31 • Mean mental component summary 52.2 • 73% adverse events were pre/post operative	• 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	• 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) • Health related quality of life (HRQOL) determined by SF-36 and Functional Index Measure (FIM)	**Most common adverse events for TSCI patients** UTI 19.4%, pneumonia 13.7%, neuropathic pain 5.8%, PU 5.8%, delirium 8.2% **Binary logistic regression model to determine the patient factors that affect PU occurrence** • Independent variables used in model age at injury, initial motor score, and gender. • Motor score was the only factor strongly predictive of occurrence of PU (p<0.05). One point decrease in motor score increased PU risk by factor of 0.04	• Level of preventive interventions used in facilities involved in database is unknown • Confounding factors (e.g. staffing models, weekend admissions etc) not considered, but length of stay generally long • Method of diagnosing PU not stated, regularity of inspection unknown • Unclear if PU was present on admission	**Level of evidence: 3** **Quality: low**
Clinical question 2: What are the unique pressure injury prevention strategies for individuals with spinal cord injury?							

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Interventions and information associated with the acute injury phase (Support surfaces and MDRPI)							
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 Measurements taken I supine position and then in upright seated position	• 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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Author conclusions: Achieving a good collar fit can be difficult. Following manufacturer instructions and correctly sizing is important to prevent skin breakdown		
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 PIs 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 injures • 78.4% (95% CI: 73.6–82.6%) of the patients had PIs 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. **MV analysis** No variables significantly increased the probability of developing PIs. **Author conclusions: The severe indentation marks may be an inflammatory reaction and first sign of tissue damage. There was a high incidence of PI stage 1 and severe indentation marks from the application of the extrication collar and headblocks. Time, injury severity and patient characteristics were not associated with PIs, and indentation marks**	• 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)	**Level of evidence: 4** **Quality: High**
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	• impossible to confirm that preventive	**Level of evidence: 3**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
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 oxygenation, 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 (25.0%). **The CRPU incidence was low.**	interventions were done systematically and uniformly.	**Quality: Moderate**
W. H. W. Ham, L. Schoonhoven, M. J. Schuurmans, & L. P. Leenen, 2016a	Study evaluating incidence and characteristics pf 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 extrication collar) • admitted through the emergency department Exclusion criteria:	• backboard should be used as an extrication and transportation device only and removed on arrival in ED • Individuals remained in extrication collar and headblocks, in the supine position until injury of the cervical spine was excluded/diagnosed	• Pressure injury incidence • Pressure injury severity, anatomical site, time to development and relation to device	Pressure injury incidence 28.3% (CI 22.8% to 34.3%) 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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		• existing skin breakdown • severe burns (10% body) • transferred from other hospital 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 •			55.7% of device-related PUs were related to immobilising devices (95% CI 44.7 to 66.3%) (primarily cervical collar) **Author conclusions: Pressure injuries in immobilised trauma patients is high**	• Data collection every second day	
Nemunaitis et al., 2015	Study evaluating sacral interface pressure and sensing area in spinal immobilized healthy volunteers	37 healthy volunteers	spine board vs pressure dispersion liner, low-viscosity gel PDL was an Oasis operating room overlay	Primary outcome is Interface pressure Interface pressures and sensing area recorded every minute for 40 minutes	**Interface pressure** highest pressure was generated at the sacral prominence of each subject. Mean interface-pressures were higher on the spine board alone than with the gel liner ($p < .0001$) Peak pressure increased by a mean of 3% over 40 minutes With gel liner **Author conclusions on modeling: Gel liner could reduce risk of pressure injuries**		**Level of evidence: Indirect (PU not an outcome)**
Pernik et al., 2016	Observational cross-over study **exploring vacuum mattress splint (VMS) to spine board for**	Convenience sample of healthy participants were recruited in US (n=21) Inclusion: Aged > 18 years No evidence of acute or chronic injury to any anatomical area being tested	• 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	• 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	Occiput • 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 (74±15.1 kPa versus 20.4±4.8 kPa, $p<0.001$)	• Primarily young, healthy individuals, although the range of BMIs varied • Small sample size • PU not an outcome	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	interface pressure	Participant characteristics: 57% males Average age 25 years Average BMI 24 (19.2 to 36.4) Average weight 67.7 (51.7 to 69.8)	Ultra Vue 16 spine board For each trial, participant lay in supine position with shoes off but clothing on		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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Mok, Jackson, Fang, & Freedman, 2013	Determine whether a rate of pressure injuries changed since the introduction of vacuum spine board immobilisation	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. **Inclusion criteria** unstable thoracic and lumbar spine injuries **Exclusion criteria** unstable cervical spine isolated transverse process, spinal process, compression fractures **Baseline characteristics** both groups were similar at baseline with the exception of intubation during transport where more people in the VSB group were intubated.	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 injury were included in the non – VSB group. And looking to compare the difference between pressure injury rates	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 presure 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 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	**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 **VSB group PI locations** buttocks = 4 sacrum = 2 occiput = 2 **Non- VSB group** incidence of pressure injury 3/30 (10%) in both broad definition and strict definition. Three pressure injuries were stage II **non-VSB group PI locations** buttocks = 1 sacrum = 2 Occiput = 2 The difference in incidence of PIs between cohorts using a strict definition was 13% versus 10%, p =0 .7 the difference in incidence of PIS between cohorts using a broad definition was 22% versus 10%, p = 0.2 therefore there was no statistically significant difference of PI development in flight between groups. There was no impact of surgical planning due to the presence of pressure injuries compliance of VSB indicated used in accordance with the clinical practice guidelines was found in 15 of the 60	• 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's 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.	**Level of evidence: 3** **Quality: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
				compliance with VSB use in accordance with the clinical practice guidelines	patients (83%). Five patients had unstable cervical injuries and five had stable thoracolumbar injuries. The authors concluded that VSB spinal immobilisation is safe for patients evacuated from theatre accompanied by a CCATT. They report that skin checks and techniques to limit pressure injury are especially important in the intubated patient.		
Berg et al., 2010	Observational study exploring impact on tissue oxygen saturation of immobilization on a long spine board	Healthy volunteers (n=74) Aged over 18 years Exclusion: Smoking Diabetes Skin rash over spine	supine positioning on a long rigid spine board buckled straps across chest and legs 30 minutes trial	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<0.001)	• StO_2 measurement was significantly higher after exposure to pressure (p<0.001) • No change in StO_2 at control site	• No comparison to a pressure point immobilized with no spine board • Healthy volunteers	**Indirect evidence: PU not an outcome measure** **Quality: Low**
Powers, Daniels, McGuire, & Hilbish, 2006	Observational study reporting rate of pressure injuries associated with cervical collars	Participants were recruited In 3 critical care units in US (n=484) Inclusion cervical collar in place on admission Collar in situe at least 24 hours Exclusion:	• 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	Skin breakdown,	• 6.8% developed a pressure injury Time spent in cervical collar was significant predictor of skin breakdown (p<0.0001)	• no data collection methods reported	**Level of evidence: 4** **Quality: moderate**
Electrical stimulation to prevent pressure injuries (Biophysical agents)							
Bersch, Tesini, Bersch, & Frotzler, 2015	A retrospective record review **to identify the focus of**	Retrospective record review conducted on patient records over a 2 year period at one in Switzerland paraplegic center (n=241)	FES: Different stimulation protocols allow the stimulation direct via nerve or muscle depending on the pulse width	• number of patients treated with FES • focus of the FES intervention	Use of FES for PU interventions increased from 2011 to 2012: 2011: preventing (n=5, 4.6%); treating (n=1, 0.9%) PUs	Participant characteristics not reported	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	functional electrical stimulation (FES) used on patients with SCI	Inclusion criteria: • Aged ≥ 16 years • Received FES treatment as a • part of rehabilitation		• number of FES treatments relating to different stimulation fields • number of patients that had an upper or lower motor neuron lesion	2012: preventing (n=15, 5%); treating (n=12, 8.9%) PUs Treatments poorly documented	Effectiveness of intervention unknown Intervention regimens unknown	**Quality: low**
Kane et al., 2017	Investigate the feasibility of using intermittent electrical stimulation as a potential method for preventing pressure injuries	20 mobiles linked to human intensive care unit in Alberta Canada **Inclusion criteria** • aged between 18 and 90 predicted minimum length of stay or four days no pressure injury present **Exclusion criteria** • BMI greater than 30 • patients on neuromuscular blocking drugs • patients with myasthenia gravis • patients with burns • patients with open wounds to the buttocks • patients with rhabdomyolysis • patients with unstable spline/ pelvic/hip fractures • patients with pacemakers Median age was 52 years patients were moderate to very high risk category for developing pressure injury as per Braden score duration median four days	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 1 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.	• registered nurses, clerks, occupational therapists, physiotherapist, and nursing students were trained in the use of IES • Skin checks were carried out every 2 hours • The NPUAP was slightly modified to include "level 1 no evidence of skin issue" – "level 5 – Stage IV PI" • Nurses also assessed contraction strength on a 4 point likert scale • Time of day IES was used and duration recorded as well as when assistance was required (eg. changing electrodes) time to complete these activities • Nurses were asked to rate the ease of positioning the patient to apply the device • Rate the ease of finding an adequate muscle contraction • Participants were asked if the system was distracting,	**Pressure injury rate** None occurred over the 4 week study **Adverse events** No untoward reactions or adverse events occurring as a result of IES. **Contraction rate** Contractions were rated 3-4 (can see weak contraction/flicker- can see strong contraction) difference between beginning and end of stimulation p> 0.05 **Outcome 3** Total caregiver time to apply the device averaged 5.9 mins ± 0.3standard error of the mean. Removal of the device averaged 2 mins ± 0.1 standard error of the mean None of the 15 respondents reported that the stimulation was painful or cumbersome. **The results suggest that intermittent electrical stimulation is safe and feasible to implement**	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	**Level of evidence: 3** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			Intervention for 8 days to 4 weeks	irritating or uncomfortable each day	**in the ICU. It was also acceptable to staff and patients**		
C. A. J. Smit et al., 2013	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	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 PIs 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	2 protocols of 3 hour duration using different duty cycles. Stimulation ranged from 70mA – 115mA **Protocol One:** 1 sec ES: 1 sec rest 3 min cycle – 17 min rest repeated for 3 hours. **Protocol Two:** 1 sec ES: 4 sec rest 3 min cycle – 17 min rest, repeated for 3 hrs. The intervention commenced 5 mins after the participant was seated in a 'normal position' in the wheelchair. (feet on footrests, arms on armrests or lap and lower back against the backrest. Participants completed both protocols on separate days	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<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	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
C. A. Smit et al., 2013	Compare the acute affects of ES induced muscle activation on IT pressures, blood flow and oxygenation to 3 standard pressure relief techniques Determine if there is a relationship between sitting pressures and oxygenation or blood flow	12 males from the rehabilitation research centre in Amsterdam, The Netherlands. Inclusion criteria: • Upper motor neuron lesion • AIS A or B • Aged 18-60 years • Intact spinal reflexes • Intact gluteal and hamstring muscles • Intact skin under ITs Exclusion Criteria: • Participants with flaccid paralysis and areflexia • Hx severe autonomic dysreflexia • Current IT PIs • Severe cognitive or communicative disorders • Intolerance for ES or any other contraindication for ES 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	Participants had a 1x1.5cm^2 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 sidewards whilst interfaced pressures were measured. Prior to each measurement, the participants were asked to rest for 5 mins. Interface pressure and oxygenation measurement started 30 seconds prior to relief procedures to obtain baseline, then each of the PRMs were performed for as long as possible for a maximum of 2 mins. After 30 mins of rest, two self adhesive surface electrodes were applied to the gluteal and hamstring muscles were activated by electrical stimulation.	• Ischial tuberosity pressures rest, PRM, ES • IT oxygenation, rest, PRM, ES • IT blood flow rest, PRM, ES • The testing lasted 4 hours and there was no follow up	**Ischial tuberosity** Rest (156±26 mmHg) Push ups (19±44 mmHg, p<0.001 Bend forward: (56±33 mmHg, p<0.001) Lean sideward (44±38 mmHg, p<0.001) ES (67±45 mmHg, p=0.03) **Oxygenation** Rest not reported Push ups p=0.01 Bend forward: p=0.01 Lean sideward p=0.01 ES p=0.57 **Blood flow** Rest Push ups p=0.02 Bend forward: p=0.02 Lean sideward p=0.03 ES p=0.75 PRMs acutely reduced IT pressure and improved oxygenation and BF in SCI. The currently used ES method cannot replace PRMs,	• 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	**Level of evidence: 4** **Quality: low**
Liu & Ferguson-Pell, 2017	Observational study comparing surface electrical	Adults with SCI (n=14)	surface functional electrical stimulation and stimulating sacral nerve roots by functional magnetic stimulation (FMS) or a	• schial skin index of hemoglobin (IHB) and oxygenation (IOX)	• 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 ±	Only 4 participants experienced FMS and FES	**Level of evidence: 4** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	stimulation to sacral nerve root stimulation		sacral anterior root stimulator implant (SARS)		0.21 before vs. 0.46 ± 0.30, p = 0.01 during stimulation • 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). • FMS was significantly better than FES		
(Janssen, de Koning et al., 2010)	Cross over RCT **investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure distributions**	Five participants Selection, setting and inclusion/exclusion criteria are not reported. Characteristics: • Incomplete SCI • All male • Mean age 41 ±13yrs Mean weight 83 ±15kgs	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 1sec on:4 sec off protocol followed by 17 min rest	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	Peak pressure significantly decreased (p<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 reset achieves reduction in interface pressure without muscle fatigue**	• Small trial, participant • selection not reported Short study duration, • unclear if results • would be sustained • over longer than 3 • hour periods • Unclear of a clinically • significant effect, PU • development was not • an outcome measure	**Indirect evidence Quality: low**
(Smit, Haverkamp et al., 2012)	Comparative study **investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure**	Ten participants Inclusion • Complete or incomplete upper motor neuron lesion • Intact gluteal and hamstring muscles Exclusion:	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	• 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 o	**Indirect evidence Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	distributions	• PU of buttocks • Flaccid paralysis, intolerance to electrical stimulation • History of severe autonomic dysreflexia • Severe cognitive or communication problems Characteristics: • Mean age 33.7±8.9 years • Mean body mass 76.0±13.5kg Primarily C3 to C8 injuries	wheelchair with a regular cushion **Protocols** • Both protocols: four blocks of 3-min stimulation (1 sec on, 4 sec off) and 17 min of rest in between blocks • Protocol A: gluteal (g) muscles were stimulated • Protocol B: gluteal + hamstring (g + h) muscles were stimulated There was a 30 min rest period in between protocols		• Protocol B achieved a significant reduction over time in IT pressure from 44mmHg at commencement to 28.5mmHg at cycle end (p=0.01) **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.**		
Pressure relief maneuver to prevent pressure injuries (Repositioning)							
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 piezo-resistive 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). ▪ Pressure map/mat	• 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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					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 **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.**		
Sonenblum, Vonk, Janssen, & Sprigle, 2014	Observational study measuring effect of pressure relief maneuvers on interface pressure	Individuals with SCI (n=17)	▪ Participants performed forward lean (small, intermediate and full) , side lean Intermediate and full) while on 3 different cushions	▪ Interface pressure ▪ Blood flow flux	• All position except small front leaning produced significant reduction in ischial IP compared to upright ($p<0.001$) Effect size ranged from 0.939 (intermediate front lean) to 3.11 (full front lean) • All position except small front leaning produced significant increase in blood flow compared to upright ($p<0.001$) Effect size ranged from 0.581 (intermediate front lean) to 1.1 (full side lean)	•	**Level of evidence: 4** **Quality: moderate**
Morita et al., 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 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	Structured questionnaire interview Diary of habits maintained by controls for 1 week (only for controls)	Daily living factors: • Wheelchair and cushion factors • Protective activities • Urination/defecation • Social participation Risk assessment : • Braden scale	**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	• Low generalizability • Relied on self-reported preventive health data and relied on recall for case group • Case-control matching led to significant	**Level of evidence: 3** **Quality: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Cases and controls were matched for gender, level of injury, severity of paralysis Characteristics: • Mean age: 55.4yrs for cases versus 45.3yrs for controls (p=0.005) • Mean years since injury : 24 for cases versus 14.6 for controls, p=0.007 • Pressure injury history significantly more previous history for cases, p=0.031		• SCI pressure ulcer scale (SCIPUS) Interface pressure (IP) measurement of wheelchair surface	injuries versus no pressure injuries 1.3±0.6 vs 2.4±1.4, p<0.0001 **Pressure measurement** Max IP, contact area and average IP were not significantly different between cases and controls **Study conclusions: The authors found that recall of pressure relief maneuver reported in interview numbers ≠ diary for controls.**	difference in age, time since injury and previous history of PU • Wide confidence interval for seat cushions in possession	
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**		**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Lifestyle changes (HRQoL)							
Ghaisas, Pyatak, Blanche, Blanchard, & Clark, 2015	Retrospective analysis of outcomes of one cohort in trial **to identify associations between PU status and lifestyle change**	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) Inclusion criteria: • Completed 12 months of the intervention with sufficient participation • Experienced PU during intervention period Exclusion criteria: • Experience no PU • Poor adherence to lifestyle changes	• Participants were classified as having achieved lifestyle changes vs no changes • Participants were classified as having improved or worsening PU status	Treatment note review to categorize participants based on making lifestyle changes	1,922 notes were reviewed (mean 40.9/participant) Four patterns identified: • Positive lifestyle change and positive PU status change (n=19) • Positive lifestyle change and no change or worsening in PU status (n=3) • Minor or no lifestyle change and positive PU change (n=1) • Minor or no lifestyle change and no change or worsening in PU status (n=2) Four case studies are presented to represent each pattern. Discussion of factors: • People with positive lifestyle change were motivated, had identifiable goals and had support • People with no lifestyle change lacked a sense of urgency, had knowledge gaps regarding skin health, prioritized other issues	• Analysis was limited to treatment arm of a trial (i.e. bias sample) with no control • 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) • Unclear how PU status was assessed and whether recurrence was considered • Subjective outcome measures • Does not state how PU status assessed	**Level of evidence: 3** **Quality: low**
Lane, Selleck, Chen, & Tang, 2016	Retrospective cohort study investigating efficacy of **smoking cessation in individuals with SCI**	Groups recruited through electronic record review at an outpatient wound clinic in the US Inclusion criteria: Quadriplegic or paraplegic due to SCI Aged ≥ 18 years	• Smoking cessation program initiated at the wound clinic and based on US national guidelines using the 5As program • Controls- seen in the 6-months prior to	Chart review	**Impact of smoking cessation on smoking status** There was a statistically significant increase in the number of participants who stopped smoking during the period of observation (44% vs 21%) ($\chi 2$= 4.45, p=0.03)	• Factors that could influence success of smoking cessation program (e.g. baseline number, social factors such as other	**Level of evidence: 3** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		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) •		**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 (17.8cm^3 versus -14.2cm^3 versus -170.3cm^3, 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 •	
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	• Blinded assessments of annualized MSPrI incidence rates at 12 and 24 months, based on: skin checks, quarterly phone interviews with participants, and review of medical charts and billing records. Secondary outcomes included number of surgeries and various quality-of-life measures	**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	• 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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• cognitively intact (based on unadjusted score ≥ 7 on the Short Portable Mental Status Questionnaire [SPMSQ] • willing to undertake recommended lifestyle changes for MSPrI prevention • Exclusion criteria: • Ambulatory • less than 6 months post-injury; • unstable or worsening stage 3, or any stage 4, PI present • Participant characteristics and any baseline differences • All baseline characteristics indicating treatment groups were balanced	exposure to PUPP content (n=83) • Control group: no intervention (n=87) Standard care included clinic visits to undergo skin checks and receive necessary medical treatment and advice when a PI was present.		years and/or a current stable or healing stage 3 MSPrI) had the strongest association with MSPrI incidence at 12 months OR 6.1, 95% CI 3.4 to 11.0 Both groups improved significantly from baseline on physical functioning (effect size (ES =0.40 for intervention, 0.50 for control), physical role limitations (ES=0.72 for intervention and 0.32 for control), emotional role limitations (ES=0.31 for intervention and 0.38 for control), social functioning (ES=0.28 for intervention and 0.38 for control), pain (ES=0.41 for intervention and 0.33 for control), and depression (ES=-0.36 for intervention and -0.33 for control). **Author conclusions: Evidence for intervention efficacy was inconclusive**.	applicable to more typical SCI populations •	
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**	Retrospective review of consecutive patients undergoing lipofilling at one center in France (n=10) 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.	• 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	**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	• 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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 8 patients paraplegic and 2 patients tetraplegic • Mean age 44.1± yrs (range 36 to 58) • Mean time since SCI 21.1± 9.4 yrs • Mean time since last PU repair surgery 5.2±5.6yrs • Mean previous surgical repair of PU 3.2 • Eight patients at mild risk of PU and 2 at no risk; however 50% had recurrent stag II PUs following previous surgery • All patients used air filled or contour foam seating cushions		impression of improvement (PGI-I) questionnaire ○ PUs graded using NPUAP staging system		• Unclear why these specific patients were chosen	
Background information - Prevalence rates							
Wannapakhe, Arrayawichanon, Saengsuwan, & Amatachaya, 2015	Prospective cohort study **investigation rate of complications in individuals with SCI for 6 months following rehabilitation**	Individuals with SCI consecutively recruited on discharge from rehabilitation center in Thailand (n=108 screened, n=104 eligible, n=100 completed study) Inclusion criteria: • ≥18 years of age • SCI due to trauma, non-progressive disease • Sub-acute or chronic stage of injury • America Spinal Injury Assoc.(ASIA) Impairment Scale (AIS) A and B Exclusion criteria:	Participants classified as: • AM (ambulatory, able to walk ≥10m with or without walking device), n=50 • WB (wheelchair bound), n=50	• Incidence of pressure ulcers (and other signs/symptoms) was measured monthly through telephone interview • Other complications were collected from physician	WB participants: • 21 individuals experienced a pressure ulcer over 6 months (range of 1-4 per participant) • 4 individuals rehospitalization for pressure ulcer (range of 14 to 60 days) AM participants: • 3 individuals experienced a pressure ulcer over 6 months (range of 1 per participant) • 0 individuals rehospitalization for pressure ulcer **Conclusions: Being wheelchair bound was significantly related to experiencing a PU (p<0.05)**	• Unclear if patient report of pressure ulcer was confirmed • No control for hospital admission during trial period • Uncertain whether withdrawals were wheelchair bound or ambulatory • Does not report Category/Stage • Unclear if patient was given training to	**Level of evidence: 3** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 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				identify Category/Stage 1	
Kovindha, Kammuang-Lue, Prakongsai, & Wongphan, 2015	Cross sectional study **investigating prevalence of PU in a cohort of people with SCI**	Participants were people in Thailand with SCI enrolled in a study investigating support surfaces (n=129) 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	Self-reported questionnaire appears to be confirmed by clinical record review	• Self-reported PU that was not confirmed clinically • Health-related quality of life (HRQOL) questionnaires (EQ-5D)	**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 **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)	• 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	**Level of evidence: 4** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Prevalence and type of seating cushion No significant difference between having/not having a PU based on air filled versus foam cushions	preventive care is not reported	
Hoh, Rahman, Fargen, Neal, & Hoh, 2016	Database review of **prevalence of hospital acquired Category/Stage III and IV PUs in individuals with SCI**	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) Inclusion criteria: • Record indicates admission for cervical fracture Characteristics (with SCI group): • Mean age 47.7 ± 22.3 • 72.8% male • 76.1% located in teaching hospitals	• Retrospective database analysis of Patient Safety Indicators and hospital-acquired conditions including Pressure ulcer stages III and IV	• PUs were only included in the data base for years 2008-2010 (covering n=3,785 admissions with SCI) • Linear regression modelling • Data analyzed for population with SCI and population without SCI •	**Prevalence of HAPU Category/Stage III or IV in admissions for cervical fracture and concurrent SCI** 1.48% (95% CI 1.14% to1.92%) **Factors associated with PU** • Older age (p<0.001) • Higher comorbidity score (p<0.0001) Higher injury severity score (p<0.001)	• Relied on database information • Unclear how PU was identified • Limited to Category/Stage III or IV PU	**Level of evidence: 4** **Quality: High** **Primary SWG: Prevalence**
Ploumis et al., 2011	Retrospective study reporting PU prevalence rates	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	• Database review	• Pressure ulcers were graded as per NPUAP classification. •	**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)	• Relied on database entries to be correct • No interrater reliability • Incomplete discharge notes from the acute care hospital were excluded.	**Level of evidence: N/A** **Quality: moderate**
Wilson, Arnold, Singh, Kalsi-Ryan, & Fehlings, 2012	Prospective cohort study **reporting all complications in SCI patients**	411 patients in 6 US trauma centers over a 7- year period (n=411) Inclusion: • aged > 16 years • AIS Grade A_D • cervical level injury	• No intervention	•	• Mean length of stay (LOS) was 34.3±54.6 days • Any complication was related to significant increase in LOS, p<0.001 • 39% experienced at least one complication	• Unclear how PU was defined and identified	**Level of evidence: N/A** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• documented neurological exam within 24 hours of injury followup until acute discharge			PU account for 4.6% of complications (which is equivalent to approx. 2.6% of people, assuming only 1 PU per person)		
Mathew, Samuelkamaleshkumar, Radhika, & Elango, 2013	Cross sectional study investigating **relationship between practices and PU development in people with SCI**	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	• Demographics and PU history	• 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 • There was no significant correlation between level of injury and PU development • 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)	• 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	Retrospective cross sectional study **investigating factors related to increase hospital length of stay**	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	• No intervention	• Demographics and medical history	• 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)	• Unclear how PU was defined and identified	**Level of evidence: N/A** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Background information - economics							
Chan et al., 2013	To determine the cost in terms of resources of an individual with SCI living in the community in Canada	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 %	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 •	**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 <10 cm^2 incurred double the cost Although this is a relatively small pilot of study it does provide some useful information for planning economic resource management and also the impact of pressure ulcers on individuals living with SCI	• 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.	**Economic Analysis** **High Quality**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		paraplegics,8% unknown,67% had previous pressure ulcer • 8% stage2, 67% stage 3 and 25% stage 4 • Average wound size 22 cm^2, average depth was 3 cm • Majority of pressure ulcers were located on the sacrum					

Additional evidence from systematic reviews to support discussion

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Anabolic steroids for healing pressure injuries							
Naing & Whittaker, 2017	To assess the effects of anabolic steroids for treating pressure ulcers	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.	In the single included study, the intervention group was administered orally 20mg/day of oxandrolone while the comparison group received a placebo.	• Outcomes were measured at 24 weeks that included re-epithelialisation with a dry cicatrix for 96 hours. • Staging system EPUAP/NPUAP 2009	**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**	• Trial reported I the systematic review was terminated before completion • Sample is homogenous may limit generalizability to other pressure injury populations	**High**

Table 1: Level of Evidence for Intervention Studies

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

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

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

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS

Each criteria 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

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

Endnote ID	Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Level of evidence	Quality
9581	Kovindha et al., 2015	Y	N	N	Y	Y	U	NA	NA	N	N	4	low
9947	Bersch et al., 2015	Y	Y	U	NA	N	N	NA	N	N	N	Indirect evidence	low
13764	W. H. W. Ham et al., 2016b	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	High
13886	W. H. W. Ham et al., 2016a Int wound J	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	High
14551	Li et al., 2017	Y	Y	Y	Y	Y	U	NA	Y	Y	Y	4	HIGH
	Sonenblum & Sprigle, 2016	Y	N	U	N	Y	U	NA	Y	Y	U	4	Low

RCTS

Endnote ID	Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measure	Drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
14189	Carlson et al., 2017	Y	Y	Y	N	Y	Y	Y	Y	Y	NA	Y	Y	1	High

COHORT STUDIES

	Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
6709	Ghaisas et al., 2015	U	Y	Y	U	Y	Y	N	N	N	U	N	NA	N	U	3	low
8123	Wannapakhe et al., 2015	U	U	Y	Y	N	N	U	U	N	Y	N	N	U	U	3	moderate
9533	Street et al., 2015	Y	Y	Y	N	Y	NA	Y	N	N	N	U	Y	Y	U	3	low
11058	Chopra et al., 2016	Y	Y	Y	U	NA	NA	Y	N	Y	NA	N	Y	Y	Y	3	High
13701	Lane et al., 2016	Y	Y	Y	N	NA	NA	N	N	N	U	N	N	N	U	3	Low
6496	H. W. Ham et al., 2014	Y	Y	Y	N	NA	NA	Y	N	Y	U	Y	N	Y	Y	3	Moderate
14205	Kane et al., 2017	N	NA	N	Y	Y	N	N	N	Y	Y	N	N	N	N	3	lOW
60	Mok et al., 2013	Y	Y	NA	Y	NA	NA	Y	Y	Y	Y	Y	N	Y	Y	3	High

CASE CONTROL STUDIES

	Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
6683	Morita et al., 2015	Y	Y	NA	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	3	High

PROGNOSTIC STUDIES

	Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear outcome measures/prognostic factors	Range of prognostic factors/confounders measured identified and	Method of measuring prognostic factor is reported, valid and reliable	Same method of measure of prognostic factor for all	Continuous variables or appropriate cut offs	Percent participants with complete data acceptable	Appropriate imputation method	Confounders/prognostic factors accounted for in analysis	Selective reporting avoided	Adequate sample size (10 PIs per factor)	Level of evidence	Quality
12882	Chen et al., 2016	Y	U	Y	N	Y	Y	Y	U	U	N	U	Y	3 (prognosis)	Low

ECONOMIC EVALUATIONS

	Author/year	Focussed question	Economic importance of question is clear	Choice of study design is justified	All costs are included and measured and valued appropriately	Outcome measures to answer study question are relevant and measured and valued appropriately	Discounting of future costs and outcome measures is performed correctly when appropriate	Assumptions explicit and a sensitivity analysis conducted	Results provide information relevant for policy providers	Minimal bias	Reliable conclusions	Level of evidence	Quality	Other relevant topics
27	Chan et al., 2013	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	High	

SYSTEMATIC REVIEWS FOR DISCUSSION

RATING CRITERIA:

1 Partial yes: states review question, search strategy, in/exclusion criteria and risk of bias were a-priori; full yes: meta-analysis/synthesis plan, investigation of heterogeneity and justification for protocol deviation
2 Partial yes: At least 2 databases, provides keywords and search, justifies publication restrictions; full yes: searched reference lists of included studies, searched trial registries, consulted experts in field, searched grey literature, search within 24 months of review completion
3 At least two reviewers independently agreed on selection of studies to include or reviewers achieved 80% agreement on a sample of studies
4 Either two reviewers did data extraction and had >80% agreement, or two reviewers reached consensus on data to extract
5 Partial yes: list of all relevant studies that were read and excluded; full yes: every study that was excluded is independently justified
6 Partial yes: described populations, interventions, comparators, outcomes and research design; full yes: detailed descriptions of same plus study setting and timeframe for follow-up
7 FOR RCTS Partial yes: appraised risk of bias from unconcealed allocation and lack of blinding; full yes: appraised risk of bias on true randomisation, selection of reported result from multiple measurements/analyses
FOR non randomised studies: Partial yes: appraised confounding and selection bias; full yes: appraised methods to ascertain exposures and outcomes, selection of reported result from multiple measurements/analyses
8 Must include reporting of the source of funding of individual studies, or reports that the reviewers considered this even if individual funding sources aren't listed in review

Endnote ID	Author/year	PICO research question and inclusion criteria	Explicitly states a-priori protocol[1]	Rationale for selection of study designs	Comprehensive search[2]	Duplicate study selection[3]	Duplicate data extraction[4]	Excluded studies listed[5]	Adequate description of included studies[6]	Risk of bias assessed[7]	Source of funding reported[8]	Appropriate meta-analysis including weighting and adjustment for heterogeneity	Meta-analysis considers risk of bias of studies	Discussion consider risk of bias of studies	Assessment of publication bias if quantitative analysis is done	Potential conflicts of interest of authors reported and managed	Review Quality
15409	Naing & Whittaker, 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	NA	Y	NA	Y	Include

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