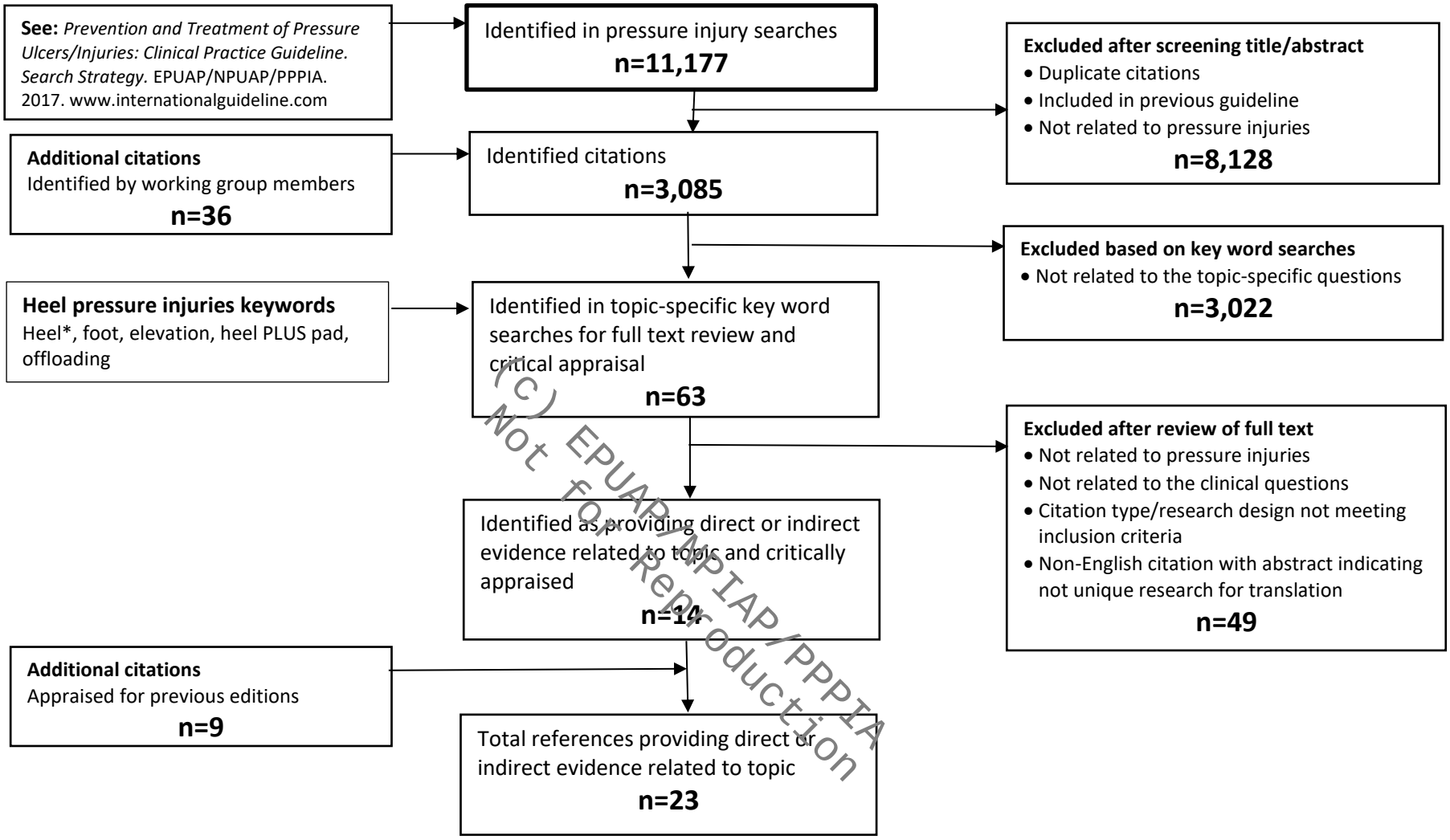
Search results for 2019 International Pressure Injury Guideline: Heel Pressure Injuries



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.

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 1: What factors put individuals at risk for heel pressure injury development?							
Luboz et al., 2015	Observational modelling study **to investigate the influence of patient-specific calcaneus shape on strains within the foot that may influence pressure on soft tissues**	Finite element models were developed based on 18 different calcanei in a database FEMs had 4 soft tissue layers representing skin, fat, Achilles tendon and muscle	• Leg with foot FEM is dropped from 1mm height onto a cushion • Five simulations performed with the cushion at different inflations at different positions (e.g. foot vs calf)		**Conclusions: The results indicate that the shape of individual calcanei influences the strain on muscles and tissue and the risk of PU**	• Lab based modelling	**Indirect evidence: PU not an outcome measure**
Bucki et al., 2016	Observational modelling study **to investigate the influence of patient-specific models that determine PU risk based on foot shape and tensions**	Patient-specific finite element models based on models from three healthy feet		Plantar pressures established through simulation	**Author conclusions: cluster analysis is an alternative to peak VM strain alone and could be used to predict the risk of pressure ulcer and its localization within the foot**	• Lab based modelling	**Indirect evidence: PU not an outcome measure**
Tong, Yip, Yick, & Yuen, 2016	Quasi experiment **exploring the significance of positioning and mattress types on heel interface pressure**	Convenience sample of older adults recruited in a nursing home in Hong Kong (n=51) Inclusion criteria: • Aged ≥ 70 years • No current PU or scarring from previous PU	Participants were assigned to a mattress based on Norton scale scores: • standard mattress described as having 25% indentation force deflection of 30lb (n=40), or	• Heel pressure interface measured using sensors with participant lying in a standard position with participant on back and head elevated 30° • Pressures measured with heels in natural resting	**Heel angles in resting state** Subjects on both mattress types were most likely to have a resting heel angle of 60-69° or 90-99° **Heel interface pressures**	• Small study • Participants in each group had different levels of PU risk that may influence skin condition • Did not use PU as an outcome measure	**Indirect evidence: PU not an outcome measure**

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		Exclusion criteria: • Contractures of the leg • Leg amputation • History of leg surgery • Hemiplegia, diabetes, dyspnea, excessive lymphedema or edema Participant characteristics: • Mean age 80 to 83 years • Mean BMI 22	• foam pressure redistribution mattress described as having 25% indentation force deflection of 18lb (n=11)	position, and supported in 60° and 90° angle • Skin condition measurements taken using skin probes to measure moisture, sebum content and elasticity	• Regardless of mattress type, heel interface pressure is greatest when supported at 90° • Heel interface pressure decreases by 36-37% when supported at 60° • There was an overall significant difference in heel interface pressure based on mattress type ($p<0.01$) • Significant difference in heel interface pressure based on heel angles for both mattress groups ($p<0.05$) • Age, weight and BMI had no significant influence on heel interface pressure ($p>0.05$) **Heel skin condition** Moisture, sebum content and elasticity were not significantly different between the two mattress groups ($p>0.05$) **Author conclusion: an upright heel position increases the risk of heel PU in older adults.**		
Twilley & Jones, 2016	Case control study **exploring prevalence of heel PUs in individuals with peripheral arterial disease (PAD)**	Cases were recruited in a 253 bed step-down care community hospital in the UK (n=36 cases identified, n=15 met inclusion PLUS n=15 controls) Case inclusion criteria: • Aged ≥ 18 years	• Ankle-brachial pulse index (ABPI) performed	• PAD was identified as ABPI <0.9 or >1.3	**PAD prevalence** • Heel PU cases: 12/15 (80%) positive for PAD • Control group: 4/15 (26.7%) positive for PAD • OR for PAD 11, 95% CI 1.99 to 60.57	• Pilot study with small sample size • 2/15 pairs were not precisely age matched due to difficulty finding controls • Wide confidence interval may reflect the small sample size	**Level of evidence: N/A prognostic study of ineligible design** **Quality: Moderate**

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		• In-patient • Category/Stage II to IV PU of the heel Control inclusion: • In patient without PU of the heel • Matched to case for age, gender and ethnicity • Ineligible if in palliative care, had active or suspected cellulitis, unable to lie flat for one hour, no consent.			**Severe PAD (ABPI<0.8) prevalence** • Heel PU cases: 5/15 (33%) positive for PAD • Control group: 3/15 (20%) positive for PAD • OR for severe PAD , 2 95% CI 0.38 to 10.51 **Author conclusions: There may be a strong correlation between peripheral arterial disease and heel PU suggesting reduced blood flow is a risk factor for PU.**	• No comparison of participant characteristics is presented (e.g. co-morbidities, age, BMI etc) • Case-control studies are ineligible for inclusion for supporting evidence-based recommendations (see Methodology)	
B. Delmore, S. Lebovits, B. Suggs, L. Rolnitzky, & E. A. Ayello, 2015	Case control identify major risk factors that precede the development of heel pressure injuries	• Main analysis - 337 participants (37 with HPU and 300 without HPU); Validation analysis - 80 participants (12 with HPU and 68 without HPU). • Study was conducted in a 705 bed tertiary urban a hospital and rehabilitation unit in New York City, USA • Inclusion criteria: All patients admitted with an HPU or developed an HPU from 2009 to 2011, and had at least a 3-day hospital stay. • Exclusion criteria: Actively dying patients, obstetric and psychiatric patients, and paediatric patients less than 8 years old. • Additional data extracted includes stage and location of	N/A	• Data were retrospectively extracted from a medical chart review. • Risk factors measured include diabetes mellitus, vascular disease, neuropathy, age 70 or more years, perfusion problems, morbid obesity, surgical procedure, admission Braden Scale score of 18 or less, immobility, ventilator days >3 days, activity status, ICU stay >3 days • Univariate logistic regression analysis was employed to predict major risk factors.	**Significant risk factors** • diabetes mellitus (Odds ratio = 2.9; P = 0.02) • vascular disease (3.8; 0.01), immobility (4.7; 0.003), • Braden Scale score of ≤18 (21.8; <0.001) **Hospital vs community-acquired** No significant differences between hospital-acquired HPUs and community-acquired HPUs with respect to diabetic mellitus (x^2 = 0.14; P = 0.71), vascular disease (0.07; 0.80), immobility (1.81; 0.18), Braden Scale score of ≤18 (1.98; 0.16).	• Retrospective study, relies on the accuracy and completeness of patient data collected to ensure the validation and significance of results. • Single study site. • Only univariate analysis performed. Unsure if risk factors have any effect on one another. • Case-control studies are ineligible for inclusion for supporting evidence-based recommendations (see Methodology)	**Level of evidence: N/A prognostic study of ineligible design** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		any other PU, age, hospital LOS, height, weight, BMI, type of surgery, and length of procedure in minutes.					
Gaubert-Dahan, Castro-Lionard, Blanchon, & Fromy, 2013	Cross sectional study investigating relationship between heel pressure injuries and severity of peripheral neuropathy	Participants were recruited in aged care centres in two hospitals in France (n=210) Inclusion criteria: Not stated Exclusion criteria: • MMSE < 10 • Central or medullar nervous system disease Participant characteristics: • Mean age 85 years • No difference in physical activity limitations, hip fracture, diabetes, nutritional status	• Sensory peripheral neuropathy assessed using 10g monofilament • Sensory deficits measured using pin prick	• Presence of a pressure injury at admission • Sensory peripheral neuropathy graded using Neuropathy Symptom Score and Neuropathy Disability Score •	**Heel pressure injury prevalence** • 12.3% (26/210) • Primarily Category/Stage I pressure injuries (13/26) • IN people with light neuropathy, prevalence was 4%, moderate neuropathy 11%, severe neuropathy 26% **Sensory peripheral neuropathy association with heel pressure injuries** • Higher NSS seen in people with heel pressure injuries vs those without (mean 3.6 ± 2.6 versus 2.3 ± 2.3, p=0.009) • Higher NSS seen in people with heel pressure injuries vs those without (mean 12.8 ± 5.6 versus 9.8 ± 5.9, p=0.011)	• Cross sectional design • Recruitment not well reported	**Level of evidence: 4** **Quality: Moderate**
Clinical question 2: What are accurate and effective methods for assessing heel skin and tissue?							
Crowell & Meyr, 2017	To Retrospective chart review determine whether ankle brachial pressure index (ABPI) is an accurate and reliable measure of arterial flow to the rearfoot in patients	• Participants were admitted to US hospital (n=83 with 92 heel pressure injuries) Inclusion criteria: • heel pressure injury • undergone consultation with foot/ ankle surgery service • Participant characteristics:	ABPI assessment 80.72% patients (81.52%) feet) had an ABPI	• Number with at least 1 non-compressible ankle artery • Number with non-compressible ankle arteries (unable to obtain ABPI reading) • Number with non-compressible PTA or ATA	Outcomes • 46.67% feet had at least one non-compressible artery • 34.67% feet non-compressible ankle arteries • 8% feet non-compressible PTA and 4% feet non-compressible ATA **Author conclusions:**	• Small sample size • Participants included may not represent a broader population (high percent had comorbidities that reduce arterial function) • Relied on medical record data	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	with heel pressure injuries	• Mean age 60.4 ±15.18 years (range 28-90) • 51.81% male • 95.18% had diabetes • 24.10% end-stage renal disease • Pressure injury was plantar in 31.52% of 92 feet, posterior in 21.74% feet, posterior-lateral in 18.48% feet, posterior-medial in 5.43% feet, and undocumented in 22.83% feet.		• Number with at least 1 compressible artery with an ABI calculated using PTA • Number with at least 1 compressible artery with an ABPI calculated using the ATA reading	**ABPI testing in patients with heel pressure injuries may be inaccurate and unreliable due to the number of patients with non-compressible ankle arteries.**	• No gold standard to compare ABPI or determine if it was or was not accurate • No testing of reliability of measures	
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Clinical question 3: What are effective local management strategies (e.g. skin care, prophylactic dressings) in preventing heel pressure injuries?							
Skin care							
Houwing, van der Zwet, van Asbeck, Halfens, & Arends, 2008	Double blind, randomized, multicenter, placebo-controlled study	Participants were recruited from 8 nursing homes in the Netherlands (n=79) Inclusion: • pressure reliving support surface available • At risk of PU using Braden score of 20 as cut-off point Exclusion: • being treated with another topical cream	Participants were randomly assigned to: • control group with no topical application receiving regular repositioning (n=18) • placebo Vaseline cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=32) • 5% DMSO cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=29)	• Incidence of PU evaluated by 2 external observers every 2 days and categorized using EPUAP staging	• No difference between the control group and the placebo treatment group therefore massage had no influence on PU incidence Massage with a 5% DMSO cream demonstrated a higher incidence of PU development compared to the control and to the placebo groups (OR of PU at heal or ankle 8.80 95% CI 2.61 to 29.6)	• Methods of randomization and allocation concealment not reported	**Level of evidence: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• surgery within the previous 2 weeks of about to undergo surgery • existing PU • dark skin Characteristics: • Mean age between 80 and 85 years for the three groups • >50% participants were always incontinent of urine •					
Lupianez-Perez et al., 2015	Non-inferiority RCT **determining if olive oil (non oxygenated fatty acid) is as effective as hyperoxygenated fatty acid (HOFA) for preventing Category/Stage 2 and greater PU**	Participants immobilized patients receiving home nursing services in Spain (n=831 recruited, n=574 completed trial) **Inclusion criteria:** • ≥18 years • Family member or paid caregiver able to apply treatment • Braden Scale ≤16 • ≤ 10 on Mini Nutritional Assessment (MNA) **Exclusion criteria:** • Existing PU • Refusal, lived outside zone, follow-up an another center • Hospitalization during the sampling period • Terminally ill **Characteristics:**	• All participants received regular preventive care including cushions, pressure relieving mattress, mobilization equipment (use not significantly different between groups) • High use of incontinence pads in both group • Application of spray twice daily to sacrum, hips and heels. Randomized to receive either: ○ Hyperoxygenated fatty acid (HOFA) product that included Equisetum Arvense, Hypericum Perforatum and perfume (n=437 ITT, n=314 per protocol) ○ Liquid spray of 97% virgin olive oil with 3% Hypericum Perforatum	• Category/Stage 2 PU or greater during 16 week follow up period confirmed via inspection • Assessment performed at baseline, weekly and at conclusion or until PU identified	**Per protocol analysis** *(best analysis to report for non-inferiority trial)* ○ Sacrum PU rate: 3.08% vs 2.55%, Absolute risk reduction (ARR) 0.53 (95% CI -2.2 to 3.6) ○ Right heel: 1.92% vs 1.27%, ARR 0.65 (95% CI -1.43 to 2.73) ○ Left heel: 1.15% vs 0.96%, ARR 0.2 (95% CI -1.49 to 1.88) ○ Right trochanter: 1.54% vs 0% ARR 1.54 (95% CI 0.04 to 3.03) ○ Left trochanter: 0.38% vs 0.32%, ARR 0.07 (95% CI -0.91 to 1.04) **Intention to treat analysis** ○ Sacrum PU rate: 2.28% vs 2.52%, ARR -0.23 (95% CI -2.31 to 1.85)	• Superiority of HOFA in Category/Stage 2 has not been established. Previous studies are in Category/Stage I PU, and the most accessible English-language publication Bou 2005 does not specify Category/Stage. In that trial, the ARR was approximately 10%, which is the margin of difference defined in this current trial. • Power calculation was conducted and conditions were met • Did not present overall between group analysis, only	**Level of evidence: 1** **Quality: Low**

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		• No significant differences at baseline in comorbidities, Braden scale score, MNA score or mobility levels • Approximately 45% were chair bound, approximately 40% bed bound and approx. 15% walk occasionally • High levels of Category/Stage I PU at baseline (e.g. approx. 94%) of patients at sacrum and heels) but not significantly different between groups	and perfume (n=394 ITT, n=260 per protocol)		○ Right heel: 34.77% vs 28.6%, ARR 6.17 (95% CI -0.16 to 12.5) ○ Left heel: 34.26% vs 28.38%, ARR 5.89 (95% CI -0.42 to 12.2) ○ Right trochanter: 24.52% vs 27.69%, ARR 6.83 (95% CI 0.53 to 13.12) ○ Left trochanter: 13.96% vs 10.76%, ARR 3.2 (95% CI -1.28 to 7.69) **Author conclusion: Olive oil is as effective as HOFA in preventing Category/Stage 2 PU in patients at high risk.**	analysis by anatomical site • 30% drop out including those getting a PU, those inadequately administering product, hospital admissions, lost to follow up, withdrawal and refusals • Unclear how stage 2 PU was defined as some participants had "partial skin loss" at baseline (but PU at baseline was an exclusion criteria) • Potentially insufficient follow up period •	
Prophylactic dressings							
Levy, Frank, & Gefen, 2015	Observational study exploring mechanisms of efficacy for prophylactic dressings	Finite modelling	Used multilayer and single layer dressings on different support surfaces	Mechanical properties including shear, elasticity at different tissue layers and in different dressing layers.	Multilayer dressing was beneficial over single-layer dressing for dissipating tissue strains because it promoted internal shear in the dressing. This was effective on different support surfaces because it diverted load away from the heels.	• Computational modeling • Accuracy of modeling is hard to evaluate; however authors have high standing in the field and the paper is peer reviewed	**Indirect evidence (laboratory study)**
Levy & Gefen, 2016	Computer simulations to explore shear stress	Finite models (n=20) of heels	• Support surface was modeled on flat elastic foam		• Peak effective strains were found at the bone-fat interface in all the model variants and	• Computational modeling	**Indirect evidence**

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	with and without a multilayered foam dressing	20 finite element models representing diabetic tissue and healthy tissue in different foot postures (neutral, 10° and 30°) were developed	• Dressing was modelled as 3 layers (airlaid, nonwoven and polyurethane foam) • Models were exposed to loads designed to replicate the calcaneus bone against a flat support surface during supine position.		these were shifted distally with an increase in plantar flexion • Peak effective strains in the soft tissues of the heel decreased in presence of the dressing in healthy models (by 14.8%) and for diabetic models (by 13.5%) • Effect of prophylactic dressing is a cushioning effect that persists over time **Author conclusions: Prophylactic dressings provide a cushioning effect to heel soft tissues heel, and also temper deformations from the tissues by deforming internally themselves in shear mode thereby lowering exposure to strains and stresses**	• Accuracy of modeling is hard to evaluate; however authors have high standing in the field and the paper is peer reviewed	**(computer modelling)**
Santamaria et al., 2015	Historically controlled cohort study evaluating effectiveness of the multi-layer soft silicone foam dressing for heels	Participants were recruited in trauma and critical care setting in Australia (n=412 probable admissions, n=357 transferred to ICU and eligible, n=302 analyzed) Inclusion criteria • all major critically ill and trauma patients admitted to ED and transferred to the ICU Exclusion criteria • under 18 years of age	• standard preventative care included risk assessment, routine re-positioning, nutrition support, incontinence management) • Regimen for intervention group (n=150): Mepilex® Border Heel dressing (Molnlycke) applied to both heels & retained with Tubifast tubular bandage on admission to the ED, dressings partially peeled	• Skin inspection performed by research team every 24 hours • Research team members underwent inter-rater reliability testing prior to study commencement • Pressure Ulcer staging identified using the AWMA (Australian Wound Management Association) system	**Pressure injury incidence** Control 9.2% versus intervention 0%, p<0.001 Most were Category/Stage I pressure injuries **Challenges** Adhesive border tabs and margins rolled easily and were difficult to unravel during skin inspections (especially when wearing gloves) Heel dressing was difficult to maintain in position in agitated	• More participants were discharged before first assessment in control group • Control group had been a control group for another study	**Level of evidence: 3** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• pre-existing heel pressure ulcer • spinal injuries preventing repositioning Participant characteristics: • Similar patient demographics in cohorts • Longer average length of stay in ICU for patients in study group (107 hours vs 86 hours, p=0.007)	back every 24 hours for skin inspection, • Regimen for control/comparison group: preventative care only		people (needed to use tubular bandage) **Author conclusions: use of prophylactic multi-layer silicone foam dressings can prevent hospital acquired pressure injuries on the heels of critically ill patients**		
Souza, Reichembach Danski, Johann, Marques De Lazzari, & Mingorance, 2013	Non-randomized study **investigating efficacy of polyurethane film for preventing heel PU in ICU patients**	Participants were recruited in a teaching hospital ICU in Brazil (n=100) Inclusion criteria: • Aged ≥ 18 years • No PU present at entry to study Exclusion criteria: • Pre-existing PU • Refusal • Discharge or death Participant characteristics • Mean age 53.3 years • 50% sample female • 85% sample Caucasian • 15% sample diabetic • 50% received vasoactive drugs • 72% received sedatives	• Assessed with Braden Scale within 48 hours of admission and classified as high, moderate or low risk • Participants acted as own control: • Left heels treated with transparent polyurethane film dressing replaced as needed plus standard care (defined as clinical guideline care) n=100) • Right heel receiving standard care only (n=100)	• Daily skin assessment • Maximum time in study (until death or discharge) was 24 days except two patients who were inpatients for > 40 days	**PU incidence** • Overall incidence 32% of heels • 8% participants had bilateral PU • Significantly fewer heels receiving a prophylactic dressing experienced a PU compared to control heels (6% versus 18%, p<0.001) **Mean time without a PU** Prophylactic dressing group 19.2 days (95% CI 17.3 to 21) **Author conclusion: Transparent polyurethane film was effective in the prevention of heel PU.**	• No blinding • Selection criteria not well defined • Participants acted as own controls • Control management was not defined (unclear if it included heel suspension) • Individuals who were discharged or died were excluded – unclear how many commenced trial	**Level of evidence: 2** **Quality: Low**
Knowles, Young, Collins, &	Controlled trial exploring **efficacy**	Participants were recruited in five long term care homes in the UK (n=recruited 17 in two	• Prior to trial, all participants received standard heel care for 6	• 4-week trial • Photography and high definition ultrasound for	**Dermal water content (LEP:TP ratio) (n=14)**	• Control treatment was ambiguous	**Level of evidence: 2**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Hampton, 2013	**of silicone pads to prevent heel PU**	cohorts – unclear how many in each cohort) Inclusion criteria: • Moderate to high risk of PU using Waterlow scale Exclusion criteria: • Not stated Participant characteristics • Mean age 90 years • All participants had previous PU • 6/17 had Category/Stage 1 PU at recruitment	weeks. This care included a range of polymer-based heel relieving product • Participants were treated with: ○ Silicone pad designed as a prophylactic dressing to protect the heel from shear forces that is shaped to fit over the heel and held in position with a tubular bandage (KerraPro Heel®) on one foot ○ alternative polymer-based heel pad (or no pad or wool pad) on the other foot • Participants received concurrent education in repositioning	skin assessment (day 1 and 28) • Scans also taken of normal skin adjacent to heel skin • Daily skin checks • Primary outcome measure was the ratio of Low Echogenic Pixels (LEP) to Total Pixel count (TP), which evaluates dermal water content and therefore indicate level of edema	• Experimental heel pad at baseline 0.693±0.068 and at 28 days 0.362±0.048 • Control heel pad at baseline 0.659±0.055 and at 28 days 0.652±0.103 • Uninjured skin approx. 0.34 • At baseline, LEP:TP indicated that heels in both groups were oedematous	• Presence of PI at baseline was unclear • Unclear how measurements were taken • No blinding • Increase in staff awareness of heel pressure injuries and preventive care potentially influenced the results	**Quality: Low**
Miller, Sharma, Aberegg, Blasiole, & Fulton, 2015	Observational study **effect of silicone border foam dressing on interface pressure compared to no dressing**	Healthy volunteers recruited via verbal and email invitations (n=50) Inclusion criteria: • Aged ≥ 18 years Characteristics: • Mean age 39.6±15.2 years • Mean BMI 26.6±5.9	• All participants applied the silicone border foam dressing (Mepilex®) to one heel (side randomized by coin) • Participants lay on a viscoelastic hospital bed mattress • Participants repeated the trial with no dressing	Interface pressure at the heel recorded 4 minutes after lying down	**Average interface pressure** • Silicone foam dressing significantly reduced interface pressure compared to no heel dressing (p<0.001) **Factors that influenced interface pressure** • Dressing vs no dressing (p<0.001) • Weight (p=0.02)	• Healthy volunteers • Positioning may not have been identical • Relationship between high interface pressure and PU not demonstrated in this study	**Indirect evidence (health volunteers)**
(Santamaria, Gerdtz et al., 2013)	RCT investigating the influence of a **silicone foam dressing in reducing incidence of heel and sacral PU**	Participants were recruited in an acute hospital and admitted to ICU in Australia (n=440) Inclusion:	Participants were randomized to receive: • Control group: normal PU care • Intervention group: a five layer foam dressing dressing	• Skin assessed every 2 to 4 hours by researcher • All researchers underwent inter-rater reliability in staging PU (AWMA staging	• There was significantly less PUs in the intervention group (4.3% versus 17.8%, p=0.002) • There was significantly less heel PUs in the intervention group (3.1%	• Patients who did not have first skin assessment after dressing applied were excluded • Non-blinded assessment and	**Level of evidence: 1 Quality: moderate**

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		• Emergency dept. and ICU admission • Aged ≥ 18 years Exclusion: • Suspected/actual spinal injury precluding repositioning • Pre-existing sacral or heel PU • Trauma to sacrum or heels Participant characteristics: • Mean age 54 to 56 years • Primarily admitted due to critical illness • Mean stay in ED was 6 hours, mean time in OR was 4 hours, mean time in ICU 86 to 91 hours • Mean Braden score 12	applied to heels (retained with net stocking) and sacrum. Dressings were applied in ED and changed every 3 days unless soiled/dislodged	system) prior to the study commencement	vs 12.5%, p=0.002) • There was significantly less sacral PUs in the intervention group (1.2% versus 5.2%, p=0.05) • Number need to treat = 10	analysis • Inconsistency in reporting (Table 2 reports 2 different % of PU incidence) • No confidence intervals reported • Category/Stage not reported	

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(Torra I Bou, Rueda López et al., 2009)	multi-center RCT **comparing a protective bandage to a non-adhesive hydrocellular dressing for preventing PU**	Participants recruited from 3 long term care facilities and 3 home care programs in Spain (n=130 recruited, 111 completed trial) Inclusion: • At risk of PU according to Braden score • Able to consent Exclusion: • Existing heel PU • Diabetes • Using a preventative support surface • Using local device for offloading heel pressure Characteristics: • Groups were comparable at baseline • Mean age approx. 85 years • Primarily female participants • Mean Braden score 13.4±3 • Mean time spent in bed each day was approx. 14.5 hours, with repositioning approx. every 3 to 4 hours	All participants treated according to the standard PU prevention care in the facilities including skin inspections and regular repositioning. Participants were randomly allocated to either: • Bandage group: protective bandage of the heel (gauze pad and wrap covering ankle articulation) • Dressing group: polyurethane foam hydrocellular dressing (Allevyn® Heel, Smith and Nephew) applied to heel and fixed with a net tubular bandage Study duration was 8 weeks	• PU development at 8 weeks determined according to skin assessments • Relative risk of developing a PU	• The dressing group had a significantly lower incidence of heel PU at 8 weeks (3.3% versus 44%, p<0.001) • Bandage group required replacement of bandages significantly more often than dressings required replacement (2.04±1.1 times/week versus 0.58±0.48 times/ week, p<0.001) • Relative risk of developing a PU was 13.42 (95% CI: 3.31 to 54.3) for the bandage group compared to the dressing group Financial costs • Estimated cost per dressing was $3.55USD for standard protective dressing versus $12.92 for the non-adhesive hydrocellular dressing • Overall cost including labor and supplies was $160.04 CAD for the standard bandage and $88.29 CAD for non-adhesive hydrocellular foam dressing • **Study conclusions: A preventative hydrocellular dressing is associated with a lower incidence of PU in older adults at high risk compared with a non-standard protective bandaging intervention.**	• Minimal reporting of methods • Co-morbidities and risk factors not reported (e.g. nutritional status) • Protective bandaging is not considered a standard preventative strategy for heel PU therefore was not a reasonable comparison • Does not indicate the reasons for changing dressings	**Level of evidence: 1** **Quality: low**
(Forni, Loro et al., 2011)	Retrospective cohort study i**nvestigating effectiveness of sterile**	Participants recruited from an orthopaedic ward in Italy (n=158, 156 completed study). Study used an historical control group.	• Study group: received sterile polyurethane foam pad measuring 10 x 10 cm (Allevyn® Heel, Smith and Nephew) in	• Presence/absence of PU in the treated limb using NPUAP staging	**Participants with stage I PU (sore skin) as a risk** (n=56 in study group, n=49 in control group) • Significantly less	• Historical control • Length of plaster cast insitu is not reported and may be	**Level of evidence: 3** **Quality:**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	polyurethane foam pad applied inside a foot plaster cast for reducing device-related heel PU	Inclusion: • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel • Sore skin (stage I PU) on presentation OR undergoing chemotherapy Exclusion: • Cast not including foot • PU > stage I • Not having a risk factor of sore skin or chemotherapy	contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. • Control group: retrospective participants with the same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.		participants in the experimental dressing group who presented with stage I PU experienced PU of the heel on cast removal (3.6% versus 42.9%, p < 0.0005 • The relative risk of heel PU on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk of a heel PU associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4).	significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups	**moderate**
Marshall, Branthwaithe, & Chockalingam, 2016	Quasi-experiment comparing the **ability of three heel devices in reducing heel pressure**	Participants were volunteers recruited via public notice in UK (n=32) Inclusion criteria: • Consenting Exclusion criteria: • Orthopedic abnormalities • Previous PU • Unable to mobilize from supine to seated position Participant characteristics: • Primarily females • Mean age 39.9 years (range 30-50) • Mean BMI 27.06±5.04	• Participants all wore the following devices, with 30 minute washout periods: ○ Focused rigid heel casts made from Benecast FLEX® ○ Focused rigid heel casts made from 3M semi rigid material ○ ADERMA ® (Smith and Nephew) dermal heel cups polymer gel ○ Barefoot • Devices were worn with pressure sensors in 8 positions on the heel and foot	• Mean peak pressure at each pressure sensor	**Peak pressure** • Mean peak pressure was significantly lower with both focused rigid heel casts compared to barefoot at all sensor points • Mean peak pressure was significantly lower with both focused rigid heel casts compared to heel cups • Mean peak pressure was significantly lower with heel cups compared with barefoot at only one sensor point • No significant difference in peak pressure between the two focused rigid heel cast designs in seated positions	• Non-randomised and non-blinded trial • Healthy participants with low-no PU risk • Explored in laboratory conditions with leg maintained in static position – does not explore the performance of devices with mobility in or out of bed • Does nor explore relationship to PU development	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			• Measurements were taken continuously for 15 seconds in supine and the seated with lateral border of foot at 90° to the couch with foot dorsiflexed to 90°		**Author conclusion: focused rigid heel devices made from gel reduce pressure when compared with no device or a generic dermal heel cup**		
Clinical question 4: What heel repositioning interventions are effective in preventing heel pressure injuries?							
Donnelly, Winder, Kernohan, & Stevenson , 2011	RCT **comparing complete offloading to standard care for prevention of heel PUs**	Participants were recruited from a fracture trauma unit in Ireland (n=239, n=227 completed study) Inclusion: • Aged 65+ years • Fractured hip in previous 48 hours Exclusion: • Existing heel pressure damage • History of previous PU • Considered unsuitable by research team or no consent Characteristics: • Mean age 81 yrs • Mean Braden score 15 • low prevalence of peripheral vascular disease and diabetes • Approximately 1/3 sample were at moderate to high risk of malnutrition	• Participants were randomized to receive either: ○ heel elevation achieved using a commercial device (Heelift® Suspension Boot) plus pressure-redistributing support surface (n=120, 9 withdrew) ○ standard care that included a pressure-redistributing support surface (n=119, 3 withdrew) • Pressure redistribution support surfaces included cut foam mattresses, alternating mattresses and mattress overlays selected according to individual needs.	Primary outcome: • Number of new category 1 or greater PUs on heels or other sites assessed daily for signs of tissue discoloration or ulceration (skin temperature, induration, oedema, pain, itching) with all skin damage photographed and confirmed by a blinded skin viability nurse who categorized damage on NPUAP scale Secondary outcomes: • Participant opinion assessed via questionnaire • Concordance with an offloading device	**Effectiveness in preventing PU** • Significantly fewer PUs in any body location in heel elevation group (7% versus 26%, p<0.001) • Significantly fewer patients in the heel elevation group developed a PU on ankles, feet or heels (0 (0%) versus 29 (24.4%) , p<0.001) • Control group more likely (p=0.001) to suffer pressure damage at all time points. **Acceptability and concordance** • The heel elevation device was rated: ○ comfortable by 59% participants ○ interfering with sleep by 32% participants ○ adversely affecting movement in bed by 41% participants • Reasons for poor concordance included weight and bulk (36%), heat (31%) and discomfort (24%).	• Potential observer bias due to non-blinding; however, all pressure damage was confirmed by a blinded assessor • Half of the subjects had support surface upgraded by nursing staff (protocol violations) • Duration of time spent in bed/days treatment was not reported • Study failed to recruit *a pirori* sample size	**Level: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• No differences between groups in types of injury or time taken to get to hospital • Significantly more of the control group waited >72 hours between injury and surgery (p=0.0009) • Significantly more of the heel elevation group had surgery of > 2 hrs duration (p=0.034)			**Adverse events** 45 adverse events (no significant association between the groups and adverse events, p=0.691)		
Clinical question 5: What support surfaces and devices are effective in preventing heel pressure injuries?							
Air cell heel protection boots							
Jones, Ivins, Ebdon, & Clark, 2017	Cross sectional study evaluating heel bootees primarily for prevention, but included 4 individuals with existing pressure injury	Participants were recruited in six rehabilitation wards in the UK over 3 months (n=163 screened, n=17 included) Inclusion criteria: Able to consent Exclusion: • High risk of falls • Not at risk of pressure injuries • Not able to consent • Declining general health Participant characteristics: • Age range 57-92 years • Waterlow score range 17 to 28	• Participants received a correctly sized pressure reliving bootee (Maxxcare™ Pro Evolution Heel boot, Invacare) • Bootee sizing based on circumference measurement of posterior heel to anterior ankle joint • Boot has four air-filled cells protecting posterior ankle	• Evaluation on day 0, 3, 7 and once between day 10-14 (on discharge) • Waterlow risk score • Wound photography as each assessment • Clinician rating on 5-point Likert scale of ease of application and removal of boot and effectiveness of offloading	**Pressure injury incidence** 0% **Wound healing** • One Category/Stage II pressure injury (of 2) achieved almost 50% reduction in wound surface area after 14 days • One category/Stage I pressure injury (of 2) fully healed in 3 days **Comfort** • 76% of participants reported the boot was comfortable • 2/17 participants reported the boot was too hot in warm weather **Clinician feedback**	• Across six facilities, only 17 individuals consented to participate • Individuals did not have comparable pressure management plans, some had static and some had dynamic surfaces • Very high rate of ineligibility and attrition	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Primarily assessed as having high or very high pressure injury risk • At baseline, 2/17 had a heel Category I pressure injury, 2/17 had a heel Category II pressure injury and the remainder had intact heel skin			• 100% of clinicians (n=not reported) reported the boot to be easy to apply and remove and had effectiveness in offloading		
Low friction fabric boots							
Gleeson, 2016	Reduce hospital acquired heel pressure ulcer	• Participants recruited in hospital in UK Inclusion criteria: • risk assessment tool • one or more of: history of heel ulcer, diabetes, stroke, paralysis, hip fracture, dementia, peripheral vascular disease, leg spasms, agitation, leg oedema	• Baseline in 2011 • Low friction bootees (Parafricta) introduced for all at-risk patients in 2012 • Education and training on the prevention and management of pressure ulcers in 2013 • New assessment tool in 2014 • Full pathway in 2015	• Incidence of avoidable pressure ulcer monitored monthly and compared to previous year • Incidence of avoidable heel pressure ulcer monitored monthly and compared to previous year • Estimation of the cost savings compared to 2011 • Follow-up period: from 2011 to 2015	**Incidence of pressure injuries** • 6.4% in 2012 • 52.1% in 2013 • 30.4% in 2014 • Increase avoidable pressure ulcer incidence in 2015: 5.1% **Avoidable heel pressure ulcer incidence compared to previous year** • 32% in 2012 • 67.6% in 2013 • 0% in 2014 • 27.3% in 2015 **Cost saving (compared to 2011)** • £53,371.52 in 2012 • £196,116.12 in 2013 • £158,748.44 in 2014 • £149,912.00 in 2015 **Author conclusion: The low friction bootees, when used in routine practice, have played a part in the reduction of heel pressure ulcer**	• Does not describe inclusion criteria or selection methods • No confidence intervals • Unclear methods to assess outcome measures • Monocentric study • No description of incidence measurement • The risk assessment tool is not presented • No definition of avoidable • No participant characteristics	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Foam/cushion boots							
T. Meyers, 2017	RCT to investigate the use of a foam heel protector (bootee-type) compared to the standard of care in the prevention of hospital-acquired heel pressure injuries	Participants were recruited in three ICUs in USA (n=54) Inclusion criteria: • ≥5 days of sedation in ICU • Immobile for a minimum of 6-8 hours daily • Braden Scale score ≤18 • Braden Scale mobility subscale score of ≤2 Exclusion criteria: • Participants who became mobile and discontinued use of heel protector before 5 days Participant characteristics: • Mean age 40.7 to 44.6 years (depending on group) • Average Braden score ranged from 12.6 to 1.7	• Participants were randomized to receive either: ○ Heel offloading with heel protector (Prevalon® Heel Protector, Sage Products) and feet held in neutral position. Heel protector removed every shift for skin assessment. Daily passive ROM exercise with physical therapist assistance. (n=37), or ○ Heels offloaded with 1-2 pillows with hourly evaluation and repositioning. Passive ROM exercises were also performed daily with physical therapist (n=17).	• Braden Scale scores • Heel skin assessment every shift by trained nursing staff Heel pressure injury incidence measured using a non-validated heel skin assessment tool. • Range of motion measured using goniometric measurements • Adverse events were recorded every other day • Follow up until discharge from the ICU	**Pressure injury incidence** Intervention group (0%) significantly less likely to develop a pressure injury compared to control group (41%), p<0.001. **Prevention of plantar fracture contractures** • Patients in the intervention had goniometer measurements indicating significantly better performance (p=0.004). • Improvement in angle of plantar flexion contractures were observed in more individuals in the intervention group. **Author conclusions: Use of heel protectors is more effective for preventing hospital-acquired heel pressure injuries**.	• No investigator/observer blinding • Unclear if ITT analysis performed • Unclear if there was differences based on site • Adequate power to detect significant difference is unknown	**Level of evidence: 1** **Quality: High**
Baath, Engstrom, Gunningberg, & Muntlin Athlin, 2016	RCT exploring the **efficacy of early intervention with foam heel suspension boot to prevent PU in older adults**	Participants were recruited via 5 ambulance stations servicing 16 wards at 2 hospitals in Sweden (n=405 allocated, n=183 analyzed) Inclusion criteria: • Aged ≥ 70 years • Experiencing neurological symptoms	• Site managers and researchers received education on risk and skin assessment using PUCLAS 2 • Ambulance care consisted of heel skin inspection, which was not standard care at time of study • In ambulance participants were randomized to receive either:	• Risk assessment using Modified Norton Scale (score ≤ 20 = risk) • NPUAP/EPUAP Classification System • Pain using an 11 point Numeric rating Scale • risk and skin assessments were performed on days 1,3,7 and discharge (and weekly for longer admissions)	**Heel pressure ulcer incidence** Significantly reduced heel PU incidence in intervention group versus control group (14.6% versus 30%, p=0.017) All PUs in intervention group were Category/Stage I and almost all in control group were Category/Stage I (only one Category/Stage II to IV PU) **Pain**	• Sufficient participants to meet power calculation • No interrater reliability established between assessors, but all received standard education • Approx. 50% of allocated participants did not receive the intervention and	**Level of evidence: 1** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Transferred to hospital by ambulance and admitted to a participating ward • Described by ambulance services as having 'reduced general condition • Not requiring life support • No pre-existing heel PU at ambulance pickup Exclusion criteria: • None stated Participant characteristics: (not significantly different between groups) • Mean age 86 years • Approx 2/3rds female • Modified Norton Scale in emergency department (ED) showed approx. 2/3rds of participants were at risk of PU • Mean transport time approx. 30 mins • Mean hospital stay 7.9 to 10.4 days	○ Polyurethane foam heel suspension boot (Heelift® Standard, DM Systems Inc) applied in ambulance and used throughout full hospital stay (n=103) or ○ Normal care (n=80) • In ED all participants received a skin and PU risk assessment • On the ward, the heel management protocol continued until discharge with suspension boot used when in bed	• Participant evaluation of boot comfort, usefulness and acceptability	Intervention group Pain ratings ranged from 0 to 4 and control group pain ratings ranged from 0 to 7. **Evaluations of suspension boot** • One experience of blisters with straps • 39% respondent stated it caused friction • 71% described it as 'nice and warm' or 'sweaty' • 48% rated it as comfortable in supine position • 25% rated it as comfortable for side lying • 76% rated it as 'ugly' • 30% rated it as 'itchy' **Author conclusions: Heel PU prevention using suspension boots and started during the ambulance care is effective in reducing heel PUs in older adults.**	were excluded from analysis. • No blinding in study • No monitoring of time spent wearing boots	
Rajpaul & Acton, 2016	Retrospective analysis exploring relationship between acquisition of foam heel protectors and pressure ulcer incidence	Record analysis conducted in two hospitals un UK over 12 months Inclusion for use of boots: • Heavy sedation or unconscious • Immobile	• Patients in both facilities received heel suspension boot (Prevalon™ Pressure-Relieving Heel Protector) at discretion of clinicians according to inclusion criteria and to use heel suspension when skin damage was first noted	• Pressure ulcer incidence • Number of heel suspension boots purchased by facility • Cost savings calculated using published costs of UK£1,214 for Category/Stage 1 PU and	**Pressure ulcer incidence** • Hospital 1: 43.8% reduction in heel PU over 12 months • Hospital 2: Incidence of Category/Stage III and IV heel PU decreased by 67% over 12 months **Cost savings**	• Relies on documentation • Conducted during a quality improvement program that included other PU preventive strategies • Sampling, population sizes, selection of	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Diabetic, vascular or renal disease • Large, edematous, contracted or cachexic limbs, necrotic feet, Risk of tissue damage to foot/heels • Stroke		UK£12,108 for Category/Stage IV PU	Hospital 1: UK£68,716 savings in the final 8 months of quality improvement program compared with first 4 months Hospital 2: cost savings projected to be UK£294,964 over 5 years. **Author conclusions: Heel protector boots are associated with a reduction in PU incidence and costs.**	records not reported, unclear whether the results were generalizable • Characteristics and comparability of populations over time not reported • Method to assess and classify PUs not reported	
Bales, 2012	quasi-experimental clinical trial **comparing IV bags to foam pressure relieving boots for preventing PU**	Participants were recruited in a USA orthopaedic unit (n=30) Inclusion: • hip or knee surgery • aged 55 to 70 years • Normal ambulatory level prior to admission • Normal albumin level • No diagnosis of diabetes or peripheral vascular disease • No pre-existing PU of heel or Achilles area Characteristics: • Average age 60.97 years • 70% knee surgery, 30% hip surgery • Demographics not reported or compared between groups	• Participants received either: o intravenous (IV) bags used to offload heel pressure (n=15) o commercial heel suspension foam boot designed to offload the foot (Heelift®, DM Systems Inc) (n=15) • Devices were used for the duration of hospital stay (duration unreported)	• Daily skin assessment of heels and Achilles tendon area for redness, warmth, coolness and pain • Daily assessment via visualization and palpation to assess pain, skin condition and non-blanchable erythema and PU staging using NPUAP classification • Nurse opinion on design, texture, ease of use and preventative characteristics of interventions	• Significantly less participants using the pressure relieving boot showed signs or symptoms of pressure (blanchable erythema and warmth) compared with the IV bag group (0 versus 6, p=0.006) • Significant correlation between nurses' opinions on design and ease (r=0.569, p=0.043); design and texture (r=0.786, p=0.001) and design and prevention (r=0.788, p=0.001).	• Small convenience sample size without *a priori* power calculation • Duration of care not reported • Unclear how similar participants were with respect to co-morbidity and PU risk factors at commencement of trial • Other pressure relieving interventions including level of mobility not reported	**Level: 2** **Quality: low**
T. R. Meyers, 2010	Case series investigating **the effectiveness of a foam heel**	Participants were recruited from an ICU in the USA (n=53)	• All participants had the foam cushion heel protector device (Prevalon™ Pressure-	Primary: • Development of a new heel PU or worsening of a preexisting heel PU as	• There was a 55% reduction in the number of abnormal heels between admission and discharge (from 21% on	• Absence of a control group • Lack of standardized skin assessment	**Level: 4** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	protection device in prevention and treatment of PUs	inclusion: • aged ≥ 18 years • sedated • ICU for ≥5 days • Braden Scale score of ≤16 on admission to ICU Exclusion: • aged < 18 years • Medical condition contraindicating use of heel protection device • Not deemed at high risk of heel PU Characteristics on admission: • 21% of participants (16 heels) had at least one abnormal heel (PU stage I to IV)	Relieving Heel Protector) applied to both heels. • The device maintained foot in neutral position and floated heel off the bed. • Heel protector device was removed every shift for skin assessment and range of movement exercise • Participants with existing PU had a hydrocolloid dressing applied to heels changed as ordered by treating physician.	assessed using the Braden Scale and defined using NPUAP classification scale. Secondary: • Development of a new plantar flexion contracture or worsening or a preexisting plantar flexion contracture measured using goniometer measurements second daily Measurements continued until patient transferred; heel protector was discontinued or Braden Score >16	admission to 9% on discharge) • No new heel PUs developed during admissions • Patients with normal heels had significantly (p=0.0136) higher Braden Scale scores compared to those with abnormal heels (stage 1 to 4 PUs) • No patients developed plantar flexion contractures	• Unclear what other interventions were used e.g. support surface, PUs dressings • Unclear over what timeframe the intervention was delivered to each participant • No reporting of comorbidity or other risk factors for PU • Severity and duration of PU on admission not reported	
Chenewo rth, Hagglund, Valmasso i, & Brannon, 1994	Quasi study comparing treatment with a laminated foam boot to gauze padding foot wrap	Participants were recruited in an ICU (n=50) Inclusion: • Heel redness observed • Moderate -severe clinical severity Characteristics: Acuity of condition was not different between groups	• In cohort one, reddened heels were treated with gauze padding, ABD pad and tape to create a foot wrap (n=11) • In cohort two a laminated foam boot (Lunax®, BIO-SONICS) was applied to reddened heels (n=14)	• Monitoring of heel condition every three days until heel blistering, discharge or death • Non validated assessment tool included area measurement, Staging using basic system, draining, wound color and improved vs deteriorated vs no change	Heel condition In foot wrap group, 5/11 remained the same, 5/11 worsened and 1/11 died In the boot group, 13/14 decreased in size, with 5 going on to heal 1/14 remained the same **Patient assessment/practicality** Boot could be removed for washing Warmer but could be cut at top if too hot Boot has an optional brace to prevent foot drop	• Non validated assessment tool, unclear who performed the assessments • Limited information about aprticipants • No statistical analysis • Small sample size • Nurses may have become more alert to pressure injuries in second half of the study when the boot was used, improving other aspects of care	**Level: 2** **Quality: low**
Viscous elastic or gel							

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Malkoun, Huber, & Huber, 2012	Cross-over quasi-experiment **investigating interface pressure at the heel and Achilles tendon of different offload devices <u>in the OR setting</u>**	Consecutive subjects were recruited from an outpatient vascular laboratory (n=116) Characteristics: • mean age 56yrs ±18.3 • mean weight 78.1kg±14.5 • mean BMI 27.3±4.7	• Comparison of interface pressures for: ○ Action® Heel Support ○ Oasis Elite viscous elastic gel (VEG) heel block ○ Action® Overlay VEG mat ○ Prototype leg elevation device, Viater® Medical ○ Regular theatre table	• Interface pressure reading at four anatomical sites using XSensor® X3 pressure mapping system • Measurements were taken 2 minutes after the device was put into place • Measurements were taken at the heel, Achilles tendon, lateral malleolus, and calf	• Offloading devices (Oasis block and prototype) generated significantly ($p<0.0001$) less pressure at heel compared to the other devices/surfaces. • Prototype device and Oasis block median pressure 0 mmHg at heels • Theatre table and the Action® VEG mat median pressure 0 mmHg at Achilles tendon but 193.2 mmHg and 174.8 mmHg respectively at heel • Prototype device applied significantly ($p<0.0001$) less pressure to the Achilles tendon than the Action® heel support or Oasis block • Prototype device significantly ($p<0.0001$) less pressure at lateral malleolus than Oasis block or Action	• No blinding	**Indirect evidence (interface pressure)** **Quality: low**
Pillows							
Cadue et al., 2008	RCT comparing foam cushion to no elevation for preventing pressure injuries	Participants were recruited in an ICU (n=70)	• Participants were randomized to received: • Foam cushion under the legs to 'float' the heels free from the bed surface or • No intervention at the heels		• Pressure injuries were lower with the pillow (8.5% versus 54.2%). • There was also a longer heel-pressure-ulcer-free time for foam cushions (time to development of heel pressure injury 5.6 days versus 2.8 days in the control group(	• No power calculation • Unclear how participants selected • Statistical significant not reported	Level: 1 Quality: low
Multifaceted quality improvement intervention							

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Hanna-Bull, 2016	Retrospective record review of **a quality improvement initiative to implement heel protectors to reduce heel PU**	Quality improvement initiative set in an acute care facility in Canada	A QI bundle to reduce prevalence of heel PU Key components: • Interdisciplinary skin and wound care team drove the initiative • Standardization of heel offloading methods and devices promoted compliance by staff • Heel protectors were made easily accessible and structures were in place for reordering regularly • Ongoing staff education • Ongoing prevalence monitoring • Heel protectors used for patients with Braden Scale score ≤ 18, limited mobility and 2 or more comorbid conditions	Prevalence data extracted using a retrospective analysis at baseline, 1 year and 4 years	**Reduction in heel PU was established** • Prevalence baseline: 5.8% • Prevalence 1 year: 4.2% • Prevalence 4 years: 1.6% 45% of patients were assessed as being at risk and 36% of those patients received heel protectors	• No details provided regarding the specific heel protectors used by the facility • Similarity between populations between time frame was not reported • Relied on reporting, which may have reduced as nurses were accountable if a patient was reported with a PU	**Level of evidence: 4** **Quality: Low**
Clinical question 6: What are effective local management strategies for treating heel pressure injuries?							
Heel dressings							
Campbell, Campbell, & Turner, 2015	Retrospective record analysis exploring the **effectiveness of a padded heel dressing (PHD) in managing heel ulcers, including for pain relief**	Convenience sample of patients with heel ulcers in a 5 year period (n=20 consecutive patients treated with PHD and 20 consecutive patients with other dressings) Inclusion/exclusion criteria not reported	Padded heel dressing: wound dressing attended and non-adherent dressing used. Cast padding applied (diagram provided in article).	Ulcer outcome (closed, amputations, lost to review) Total weeks of care Nursing visit cost	**Ulcer outcome** 100% of PHD dressing group ulcers healed versus 65% in non-use group (p<0.01) In non-use group 15% had amputation, 20% lost to followup. **Weeks care**	• Etiology of ulcers is not confirmed but presumed to be pressure ulcers • Selection of patients is unclear as no inclusion/exclusion criteria • Comparison of participant	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: • PHD non-use group were significantly older (79.5 versus 74.6 years, p<0.04) • No significant difference in comorbidities or ulcer depth.			Total weeks care was significant lower in PHD group (368 weeks fro 20 patients, versus 527 weeks for 13 patients, p<0.001) **Nursing cost** lower for PHD group ($114,080 versus (245,055, p<0.001) nb: Canadian dollars) In another preliminary trial (n=10), nurses rated the PHD easy to apply, stayed intact and was less expensive than advanced dressings	characteristics is minimal • Evaluation of ulcers is unclear • Relied on documentation • Small study without adequate power • Concurrent management strategies not reported or considered	
Bateman, 2014	Observational study **evaluating foam cushion for treating heel pressure injuries**	• Participants were recruited in elderly care, respiratory and orthopedic wards in a UK hospital via referral to acute wound care service, consecutive referrals included (n=50) Inclusion criteria: • able to sit out of bed • One or more of following indications: ○ Blanching erythema of foot ○ Category/Stage I to IV pressure injury of foot ○ Diabetes or vascular insufficiency (with or without skin damage) or	• Ward staff received education on the device • Participants were supplied with a foam pad to use for pressure redistribution for feet and heels • Participants advised to have bare feet or fabric coverings to their feet while using the device (e.g. dressings, bandages, socks or tights). But not hard footwear • Patients' existing care packages (e.g. dressing regimen, physiotherapy, etc) unchanged. Including: ○ 84% receiving physio ○ 68% using foot stool • Spare foam pad supplied for use during laundering	• Patients' foot status was recorded by the lead wound care nurse • Daily monitoring of Braden risk score, pressure injury category and tissue status. • Patient experience in regard to comfort and ease of use was measured • Patient mobility status. • Ability to undertake usual physiotherapy with the foam pad in position. • Assessment from participants and physiotherapists • Assessment for 2 months, or until discharge	**Improvement in foot/heel pressure injuries** • 100% of Category/Stage I pressure injuries classified as improved • 80% of Category/Stage II pressure injuries improved • 100% of Category/Stage III pressure injuries improved • 66% of Category/Stage IV pressure injuries improved **Subjective evaluation** 100% of participants and physios would use foam pad in future **Cost** Each unit cost £3	• No statistical analysis • Poorly defined outcome measure • Minimal information on use of product (e.g. hours used/day) • No confounders identified or considered	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		presence of other foot/ankle tissue damage of any etiology ○ Braden score of ≤18 Exclusion criteria: • Not meeting clinical indications above Participant characteristics: • Mean age 72 years (range 34 to 93) • Mean Braden score 14 (range 7 to 21) • 20% had intact foot skin • 20% had blanching erythema • Category/Stage I 24%, Category/Stage II 10%, Category/Stage III 8%, Category/Stage IV 6%					
Clinical question 7: What factors affect healing of heel pressure injuries?							
McGinnis, Greenwood, Nelson, & Nixon, 2014	Prospective cohort study to investigate prognostic factors associated with the healing of heel pressure injuries	Participants were recruited in elderly care, medical and surgical wards in the UK (n=336 patients screened, n=140 included with 183 pressure injuries) Inclusion criteria: • aged ≥18 years • at least one heel Category/stage II or greater pressure injury	At inclusion, patient related variables: age, gender, ethnicity, speciality, hemoglobin, smoking, medication, Braden scale risk factor, co-morbidity and ulcer related variables: duration prior to recruitment, neuropathy, ABPI, severity, area, tissue type, surrounding skin, pain Univariate analysis	• At inclusion, ulcer related variables: ○ duration prior to recruitment, ○ neuropathy, ○ ABPI, ○ severity, ○ area, ○ tissue type, ○ surrounding skin, ○ pain • Weekly follow-up while in hospital and monthly	**Outcomes** • Median time to healing was 121 days (range 8 to 440) • 77 healed pressure injuries • 2 ulcers lost of follow-up • 11 ulcers that did not heal after 18 months or end of study • 5 ulcers on a limb that was amputated prior to healing • 88 ulcers on patients who died prior to healing	• Variables were excluded from the cox regression due to small numbers of observations (erythema, skin maceration) • No variable on nutritional status • Analysis at pressure injury level (not patient level)	**Level of evidence: 3 (prognostic)** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion criteria unethical to approach them. Participant characteristics not reported under risk factors: ethnicity	Cox proportional hazards regression with variables that were significant ($p \leq 0.2$) following the univariate analysis	post discharge until 18 months, ulcers healed, death or amputation	**Factors significant in univariate analysis** • specialty as care of the elderly and vascular, • comorbidity as fracture, • medication as nutrition medication, analgesics and respiratory medication, • some arterial disease (0.6≤ABPI<0.8) or severe arterial disease (ABPI<0.6), • ulcer severity, • ulcer area, • surrounding skin as erythema and macerated Two factors predictive of healing in multi-variable analysis • the presence of a severe (versus superficial) ulcer (hazard ratio = 0.48, 95% CI 0.3-0.75 ,p=0.001) • presence of peripheral arterial disease (hazard ratio = 0.40, 95% CI 0.20-0.81,p=0.010)	• Monocentric study • sample size was not met (n=200)	
Other topics							
Al_Majid, S, Vuncanan B, Carlson N, Rakovski C	To examine the effect on sacral pressure of offloading the heels with or without a multilayered silicone foam dressing to the sacrum	Participants were a convenience sample of healthy volunteers in US (n=50) Participant characteristics • Primarily female • Mean age 46.4 years (range 24 to 71)	• Participants were positioned supine position on standard operating room bed • Pressure mapping under the following conditions: ○ with and without heels not offloaded by placing two standard pillow	Interface pressure measured using pressure mapping	**Interface pressure when heels were offloaded** • After adjusting for age, heel offloading was the only variable that significantly increased sacral pressure regardless of presence of sacral dressing (p<0.001)	• Healthy volunteers • Indirect outcome measure, unclear if this would influence incidence of pressure injuries	**Indirect evidence (healthy volunteers)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• BMI: normal (n=24), Overweight (n=14), Obese (n=10), Extremely obese (n=2)	under the calves and knees, with the knees slightly flexed. ○ with and without a multilayered silicon foam dressing applied to the sacrum • Entire procedure took 7 minutes		• Heels offloaded and sacral dressing applied: mean 72.7±15.2 mmHg • Heels offloaded and no sacral dressing • Mean 73.8±17.8 mmHg **Interface pressure without heel offloading** • Heels not offloaded and sacral dressing applied: mean 62.8±14.5 mmHg • Heels not offloaded and no sacral dressing: mean 62.2±13.2mmHg **Author conclusions: Offloading the heels can increase sacral pressure**		
Muntlin Athlin, Engström, Gunningberg, & Bååth, 2016	Describe heel pressure ulcer prevalence and nursing actions in relation to pressure prevention during the care delivery chain for older patients with neurological symptoms or reduced general condition. Investigate early predictors for the heel pressure ulcer development	183 patients in ambulance stations (n=5) and wards (n=16) in Sweden Inclusion criteria: • Older patient (70+) with neurological symptoms or reduced general condition • • Exclusion criteria; • Need of life threatening medical support • discharged from the ED • unable to sign informed consent Study data was a secondary analysis from previous RCT	Usually N/A	Skin inspections at different points in the care delivery were examined and pressure ulcer stage reported Nursing Actions reported: PI risk assessment • Nursing care prevention actions Predictor Variables: Modified Norton scale subcategories: • Mental condition • Physical activity • Mobility • Incontinence	Skin inspections: 92% performed in the ED 92% performed on Day 1 of ward admission 87% on Ward Day 3 100% Ward Day 7 Pressure injury development: 9%(15) ED 11%(18) Day 1 10% 912) Day 3 18%(9) Day 7 Pressure injury stages 39 patients(21%) developed heel PI Reported as category 1-3 for ED and 1-4 for Ward	Limitations reported by researchers: Lack of data regarding preventive measures in the ambulance unable to be obtained ED waiting times not able to be retrieved which can influence PI development NO multivariate analysis included:	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		investigating heel pressure ulcer prevention interventions across the continuum. Heel lift boots application in the ambulance was the intervention for that study.		• Total risk score.	No difference in vital sign measurement in PI + /PI- groups. No p values reported Day 1 measurements of the modified Norton scale differed between the groups (PI+/PI-) for the following variables: Mental condition: Mean rank: 55.8 vs76.5(p =0.01) Physical Activity: Mean rank 49.7 vs 78(P = 0.01) Mobility: Mean Rank 48.6vs78.2(p=0.000) Incontinence: Mean Rank 51 vs 77.7(p =0.002) Total Risk Score: Mean Rank 50 vs 76.7 (p=0.002) Fewer patients with PI received an oral nutritional supplement as compared to the PI- group (17 vs 30; p = 0.000) NO statistically significant differences between the groups was noted for nursing preventive actions including pressure reducing mattresses and turning schedules. **No MV analysis conducted only univariate**	Study only included univariate analysis. Stages of PI were were group based on location. The number of PI for each stage was not reported Study was also part of a secondary analysis from an RCT which utilized a heel lift boot, which could confound the study results.	
Health economics							
Santamaria et al., 2014; Santamaria &	Evaluate the cost-benefit of using soft silicone foam dressings in PU prevention	Sub-study of a RCT where participants were recruited in an ICU in Australia (n=440) 440 participants	Participants were randomized to receive: • Standard pressure injury prevention care plus Mepilex® Border Sacrum	• Incidence of PU in ICU • Daily skin inspection • 4-point staging system by the Australian Wound	**Incidence** • intervention: 3.1% (n=5 of 161), control group 13.1% (n=20 of 152)	• Cost-benefit study • No societal cost of PUs	**Level of evidence: N/A economic analysis**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Santamaria, 2014		Inclusion: older than 18 years admitted to the ED and transferred to ICU Exclusion: pre-existing sacral or heel PUs trauma to sacral or heel areas	or Mepilex® Heel was applied. Daily skin inspection by partially peeling off the dressing to visualize the skin, reapplying the bandage. Change of bandage every third day or if soiled or dislodged (n=219), or • Control: standard pressure injury prevention care, daily skin inspection	Management Association • Cost analysis included dressing (prophylactic dressing plus tubular bandage (for heels) • Compares to costs for dressings and preventive support surfaces and nutrition management •	**Cost of PU treatment within the trial** • Marginal cost of PU prevention was $8017.2, average cost of $36.61 per person • Total treatment cost in control group ($25173.2), intervention ($6920.2) • Average cost lower in the intervention group than in control group ($70.82 vs $144.56) **Cost savings of preventing pressure injury** • Annual national saving of 34 million AUD associated with using heel and sacral pressure injuries in ICU	• Only data from ICU stay, not from the whole trajectory • Assumes preventive care cohort has no specialized mattress or nutrition for prevention of pressure injuries	**Quality: 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). Low and moderate quality cross sectional studies.

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
10748	Hanna-Bull, 2016	Y	N	N	N	Y	N	NA	N	N	Y	4	low
11106	Rajpaul & Acton, 2016	Y	U	U	N	N	N	Y	N	N	N	4	Low
16215	Gleeson, 2016	Y	N	N	N	Y	U	NA	N	N	Y	4	Low
3136	Bateman, 2014	Y	Y	Y	Y	N	Y	NA	N	N	Y	4	Low
16100	Jones et al., 2017	N	N	U	N	N	U	U	N	N	N	4	Low
16189	Muntlin Athlin et al., 2016	N	Y	Y	N	Y	U	U	Y	Y	Y	4	Low
16842	Crowell & Meyr, 2017	Y	U	N	N	Y	U	NA	N	N	U	4	Low
5707	Gaubert-Dahan et al., 2013	Y	U	U	Y	Y	Y	NA	Y	Y	Y	4	Moderate

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
11032	Baath et al., 2016	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	1	moderate
14739	T. Meyers, 2017	Y	Y	Y	N	Y	Y	Y	Y	U	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	Primary SWG	Secondary SWGs
9591	Campbell et al., 2015	Y	Y	N	Y	Y	NA	Y	N	N	N	N	N	Y	U	3	Low		
8189	Santamaria et al., 2015	Y	Y	Y	Y	Y	Y	Y	U	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
946	B. Delmore, S. Lebovits, B. Suggs, L. Rolnitzky, & E.A. Ayello, 2015	Y	Y	Y	NA	N	Y	N	Y	U	Y	Y	Y	U	Risk Factor study not eligible for inclusion due to case-control design	moderate
10914	Twilley & Jones, 2016	Y	U	U	N/A	Y	Y	Y	Y	Y	N	Y	Y	Y	3 (prognosis)	moderate

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
2829	McGinnis et al., 2014	Y	Y	Y	Y	U	U	U	U	NA	Y	U	Y	1	Low

QUASI EXPERIMENTAL STUDIES

	Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent 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
1391	Knowles et al., 2013	N	N	U	N	Y	U	N	U	N	N	2	low
7029	Souza et al., 2013	Y	N	Y	Y	Y	N/A	Y	N/A	N	U	2	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
3165	Santamaria et al., 2014; Santamaria & Santamaria, 2014	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	N/A	High

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