Journal of Tissue Viability xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of Tissue Viability

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

Risk factors associated with heel pressure ulcer development in adult population: A systematic literature review

Alisen Dube [a,b,c,*], Viola Sidambe [c], Amy Verdon [c], Eloise Phillips [d], Sarahjane Jones [b], Maxine Lintern [e], Mark Radford [a,f,g]

[a] Faculty of Health, Education and Life Sciences, Birmingham City University, Birmingham, UK
[b] School of Health, Science, and Wellbeing, Staffordshire University, Staffordshire, UK
[c] University Hospital Coventry and Warwickshire NHS Trust, Coventry, UK
[d] School of Pharmacy, Aston University, Birmingham, UK
[e] Faculty of Business, Law and Social Sciences, Birmingham City University, Birmingham, UK
[f] Health Education England, Birmingham, UK
[g] NHS England and NHS Improvement, Birmingham, UK

ARTICLE INFO

Keywords:
Literature review
Systematic review
Heel
Pressure ulcer
Risk factors
Predictors
Contributory factors
Adults
Nursing

ABSTRACT

Aims: The main aim of this systematic literature review was to identify risk factors for development of heel pressure ulcers and quantify their effect.
Background: Pressure ulcers remain one of the key patient safety challenges across all health care settings and heels are the second most common site for developing pressure ulcers after the sacrum.
Design: Quantitative systematic review.
Methods: Data sources: Electronic databases were searched for studies published between 1809 to March 2020 using keywords, Medical Subject Headings, and other index terms, as well as combinations of these terms and appropriate synonyms. Study eligibility criteria: Previous systematic literature reviews, cohort, case control and cross-sectional studies investigating risk factors for developing heel pressure ulcers. Only articles published in English were reviewed with no restrictions on date of publication. Participants: patients aged 18 years and above in any care setting. Study selection, data extraction, risk of bias and quality assessment were completed by two independent reviewers. Disagreements were resolved by discussion.
Results: Thirteen studies met the eligibility criteria and several potential risk factors were identified. However, eligible studies were mainly moderate to low quality except for three high quality studies.
Conclusions: There is a paucity of high quality evidence to identify risk factors associated with heel pressure ulcer development. Immobility, diabetes, vascular disease, impaired nutrition, perfusion issues, mechanical ventilation, surgery, and Braden subscales were identified as potential risk factors for developing heel pressure ulcers however, further well-designed studies are required to elucidate these factors. Other risk factors may also exist and require further investigation.
Prospero id: PROSPERO International prospective register of systematic reviews: CRD42017071459.

1. Introduction

Pressure ulcers (PUs) remain one of the key patient safety challenges across all health care settings alongside falls, urinary tract infections (UTIs) in patients with a catheter and new venous thromboembolisms (VTEs) [1].They affect mainly those with mobility problems, the acutely ill and the elderly. At least 200,000 people in the United Kingdom (UK) are estimated to develop a new PU each year. On average, PU treatment costs £1.45 million per day [2] and these costs are expected to rise with the aging population.

PUs, also commonly known as bedsores, pressure sores, decubitus or pressure injuries, are localised damage to the skin and/or underlying soft tissues caused by sustained pressure or shear at the weight bearing, bony prominence areas such as buttocks, hips, heels, sacrum, spine and elbows, of immobilised individuals (or related to medical devices) [3,4]. The skin damage can range from non-blanching redness to the skin

* Corresponding author. Staffordshire University, Centre of Excellence in Healthcare Education, Room BL132 Black Heath Lane, Stafford ST18 OYB, UK.
E-mail address: alisen.dube@staffs.ac.uk (A. Dube).

https://doi.org/10.1016/j.jtv.2021.10.007
Received 14 May 2021; Received in revised form 29 September 2021; Accepted 22 October 2021
Available online 28 October 2021

(category 1) to complete loss of skin exposing inner structures such as bone and tendons (category 4), as per the revised NHS Improvement PU classification criteria [4]. As a result, PUs can be very painful, debilitating and cause emotional distress to the affected individuals and their relations. In older adults, they have been reported to increase average hospital length of stay by four days [5,6].

Historically, Pus have been attributed to poor quality care and being a common complication of some long term conditions [7]. Despite growing efforts to reduce PUs, prevalence rates remain as high as 10% in the acute setting and remains largely unknown in long term care settings [8]. PUs have been reported to disproportionately affect different anatomical body sites; heel pressure ulcers (HPUs) remain the second most common type of PU after sacral PUs, accounting for at least 20% [9]. Numerous studies have investigated risk factors associated with all PUs without differentiating anatomical sites [10–12]. Furthermore, some of these studies explore risk factors for development of PUs in specific patient populations, However their study results continue to lack a specific focus on HPUs, as they remain the second most common type of PU [13–17]. The existence of evidence suggesting that risk factors associated with HPU development may be different due to the anatomy and anatomical position of the heel in the body [18–20] indicates that current prevention strategies may be insufficient for HPU eradication. Overall PU incidence and prevalence rates have barely reduced recent years [1,3], possibly because preventative strategies including risk assessment tools do not target those areas that remain problematic i.e., heels.

The most recent EPUAP/NPIAP/PPPIA guideline, alongside its PU definition, states that besides pressure, friction and shear, there are other contributory factors associated with PUs, however their significance is yet to be established [8]. Furthermore, in 2013, Coleman and colleagues concluded that there was no single risk factor associated with PU development in their systematic review; instead a complex mixture of factors jointly contribute [21]. For this review, a risk or contributory factor is defined as any characteristic that is associated with a negative outcome [22] in this case the development of a HPU. As risk factors play a fundamental role in the prediction and prevention of HPUs, it is therefore vital to understand and identify HPU contributory factors in order to maximise patient safety.

2. The review

2.1. Aims

The main aim of this systematic review was to identify risk factors for developing HPUs in the adult population and quantify the relationship between identified risk factors and HPU development.

2.1.1. Review questions

What are the risk factors for developing heel pressure ulcers as identified from a systematic review of the current literature?

What is the overall strength of association between each risk factor and the development of heel pressure ulcer based on this systematic review?

What are the heel pressure ulcer incidence and prevalence rates from eligible studies (cohort and crossectional studies respectively)?

3. Methods

The review followed the PRISMA reporting guidelines for reporting systematic reviews and meta-analyses [23].

3.1. Inclusion criteria

Type of studies: the review included all cohort, case control and cross-sectional studies investigating risk factors for developing HPUs (grade/category/stage 1–4, Suspected/Deep Tissue Injury (S/DTI) and unstageable as defined by the NPUAP et al. (2014) (8) guidelines or similar). For the purpose of this review, and to be in line with the new [4] PU recommendations, HPU severities are described as categories (replacing all previous terminologies i.e., grade or stage). Only studies published in English were reviewed with no restrictions on date of publication.

Outcome measures: included the presence or development of HPUs (categories as defined by the NPUAP et al. (2014) guidelines or similar) and/or identification of a risk factor under investigation.

Participants: Study populations were defined as adult patients aged 18 years or above in any care setting (i.e., primary or secondary).

3.2. Exclusion criteria

All studies not meeting the eligibility criteria were excluded accordingly at different stages as depicted in Fig. 1.

3.3. Electronic searches

A systematic literature search was conducted in PUBMED (1809–March 2020), EBSCO- MEDLINE (from 1879–March 2020), CINHAL (1937–March 2020), Ovid-EMBASE (1947–March 2020), Cochrane Library (from 1946–March 2020), NICE/NHS evidence (from 1880–March 2020), PROQUEST, TRIP databases, Scopus (from 2004–March 2020) and Web of Science (from 1900–March 2020) using keywords, Medical Subject Headings (MeSH), and other index terms, as well as combinations of these terms and appropriate synonyms. The syntax was designed specifically for each database, guided by the Cochrane handbook and also adopted from previously published PU systematic literature reviews [21,24,25]. Search terms focused on the terms heel, pressure ulcer(s), pressure sore(s), decubitus, pressure injury, risk factors, contributory factors, predictors, adult, hospital, community, and their synonyms (see Table 4 for examples of database search strategies). Reference lists of all included studies were inspected for further relevant studies.

3.4. Selection of studies

The main reviewer (AD) screened titles and abstracts for relevant articles prior to appraising the full texts. Identified articles were managed using EndNote X8; reasons for all full text paper screen exclusions were documented. The second reviewer (SJ) independently re-inspected all identified titles and abstracts to ensure reliability of selection. Where disputes arose, the full report was reviewed for a detailed scrutiny. SJ also reviewed full articles of studies that met the review criteria to ensure reliability of selection. Any disagreements were to be resolved by discussion, or by attempting to contact the study authors for clarification. Both reviewers were in agreement with the screening outcome. Clarification was sought from authors of one potential eligible study, but as no response was received, the study was therefore excluded.

3.5. Data extraction

AD and SJ extracted data independently from all included studies using a predefined form. Study authors were contacted for missing data or clarification were appropriate; Twilley and Jones (2016) study data were available for further analysis as part of the review. A third reviewer (EP) was available to help resolve any disagreements, however, for this review the authors were in agreement and no further clarification was required. Data were extracted onto standard, predesigned forms. Study-specific aims and objectives - study location, design, population, sample size, eligibility criteria, methodology and outcome measures (relative risk estimates, mean difference, odds ratio (OR), risk ratio (RR), hazard ratio (HR), p-values and confidence intervals (CI)) - as presented by study authors were also extracted or calculated by the reviewers.

3.6. Assessment of risk of bias and quality assessment of included studies

Currently there is no standardised method of assessing risk bias for systematic reviews of risk factors. Therefore, each eligible study was assessed for risk of bias using the assessment framework for ascertaining quality in prognostic studies (QUIPS) [26] in conjunction with STrengthening the Reporting of Observational studies in Epidemiology (STROBE) guidance. STROBE offers guidance on methodological considerations in the analysis and publication of observational studies [27,28]. The risk of bias assessment rated the relevant methodological parameters of studies across six areas: study participation (clear eligibility criteria to assess risk of selection bias), attrition (withdrawals and dropout rates as appropriate), risk factor measurement (validity and reliability of data collection tools used and providing clear definitions or descriptions of risk factors), outcome measurement (validity and reliability of outcome measurement with clear definitions), study confounders (clearly identified and adjusted for using appropriate methods), statistical analysis and reporting (use of correct statistical methods, and appropriate model building approaches as appropriate).

Predesigned risk of bias assessment forms designed following the QUIPS tool were utilised and within each of the six domains a range of questions were rated based on the adequacy of reporting as either 'yes', 'partial', 'no' or 'unsure'. Based on these ratings, each domain was consequently assessed for its potential overall risk of bias as being either high, medium or low after considering all parameters within each domain. Results of the risk of bias assessment were used to provide classification of overall study quality. Overall study quality was achieved by aggregation, and where numbers were equal, the higher bias classification was recorded. Studies were therefore classified as 'high quality' if the overall risk of bias was deemed low, 'moderate quality' if the risk of bias was deemed moderate and 'low quality' if the overall risk of bias was deemed high. Risk of bias and quality were assessed by two independent reviewers (AD, SJ). To maximise quality, the third reviewer (EP) extracted data from five randomly selected articles and also reviewed these articles for risk of bias and methodological quality.

3.7. Data synthesis

Although a meta-analysis was initially planned, it was not conducted due to the clinical and statistical heterogeneity of the eligible studies. As a result, the findings are presented in a narrative form including a summary of main findings and quality assessment results in the form of tables. Risk factors for HPU development were grouped into categories as guided by other similar systematic reviews [16,21]. Coding was conducted by two independent reviewers (AD, SJ); disagreements were resolved by discussion and consensus was achieved.

4. Results

4.1. Search outcome

Of the 3,012 titles and abstracts retrieved, 1,258 were duplicates. Based on the review selection criteria, 1,754 abstracts were screened, and 35 full texts were retrieved and reviewed. Fig. 1 shows the flowchart of this selection. Of the 35 potentially suitable articles, 22 were excluded. Reasons for exclusion at full article review were: non-English articles (n = 4, two were duplicates), case series (n = 7), theoretical study (n = 1), HCPs as study participants (n = 1), conference papers of eligible studies/letter to editor (n = 7), HPU classification not following the EPUAP criteria (n = 1) and no response from study author clarifying study eligibility (n = 1).

4.2. General study characteristics

Thirteen studies met the eligibility criteria, which recruited a total of 9,228 participants with a median age of 73 years (range 41.0–101). Three studies reported two separate analyses using different study populations within the same paper [29–31]. The main analyses in all three studies were aimed at identifying potential HPU risk factors using multivariate logistic regression analysis. The second analyses used different study populations to clarify and validate the statistical significance of findings from the main analyses. For the purpose of this review, these studies were analysed and reported once. Therefore, a total of thirteen studies are reported in this review. Delmore et al. (2015) (30) and Delmore et al. (2019) (31) were conducted by the same authors, the latter being a replicate study using separate multicentre data and a larger sample size. For this review, they are reported as separate studies distinguished by the year of publication. Muntlin-Athlin et al. (2016) (32) and Manderlier et al. (2019) (33) were secondary analyses of HPU risk factors based on data collected from a randomised controlled trial (RCT) and a cross-sectional point-prevalence survey, retrospectively [33,34]. Table 1 provides further study characteristics of all eligible studies.

Five eligible studies were published in the United States of America (USA), two in France and three in the UK, and Canada, the Netherlands and Sweden produced one study each. Duncan et al. (2003) (n = 53) [35] and Delmore et al. (2015) (n = 417) [30] did not report gender distribution amongst their study participants (see Table 1). Edwards et al. (2006) (36) reported gender for only 68% of HPU participants and none for the control group. For the eleven eligible studies that reported gender distribution of study participants, 57.1% (5270/9228)were female. Tourtual et al. (1997) (29), Demers (2005) (37) and Delmore et al. (2019) (31) were the only studies to report ethnicity for their study participants: the majority of the were reported as either white-20.5% (571/2780), or as other ethnic background 66.4% (1846/2780).

Median HPU incidence rate was 17.4% (range: 2.9%- to 29.5%) based on the incidence rate from the four prospective and two retrospective cohort studies [29,32,35–38]. Median prevalence was 11.7% (range: 1.5%–20.8%) based on the two cross-sectional studies and two retrospective case control cohort studies [30,31,31,33]. Across all studies, the participant population was diverse and included: patients from hospital wards with high HPU prevalence, a geriatric rehabilitation centre, major abdominal surgery, elective or trauma orthopaedic surgery, nursing homes and patients receiving community care.

All eligible studies defined HPUs based on NPUAP et al. (2014) (8) or similar guidelines that were available at the time the studies took place. Only three studies did not report the number of HPUs by severity [30,32,37]. In total, 10.1% (935/9228) of participants were either recruited with or developed a HPU during study follow-up. Of the studies that reported HPUs by severity: 38.8% (306/788) were category 1; category 2–27.4% (216/788) category 3–7.5% (59/788); category 4–5.5% (43/788); Unstageable- 18.4% (145/788) and DTI- 2.4% (19/788). Only three out of nine studies that reported HPU by severity observed unstageable and DTI HPUs; the patient population in these studies were heterogeneous [31,33,39]. Tourtual et al. (1997) [29] and Campbell et al. (2006) [38] study participants developed superficial HPU (either a category 1 or 2), except for one participant from the Tourtual et al. (1997) (29) study who developed a category 3 HPU.

4.3. Quality of studies

Table 2 provides a summary of the risk of bias and quality assessments. The review only included studies of observational design that investigated risk factors for HPUs only; four were prospective cohort studies [29,32,35,38], two were retrospective cohort studies [36,37], three were cross-sectional studies [33,39,40], two were retrospective matched case control cohort studies [30,31], and two were prospective matched case control studies [41,42] (see Table 1 for full study characteristics).

Three studies [36,37,39] performed and reported descriptive analysis results based on participants who had HPUs. Four out of eleven (36.4%) studies performed multivariable logistic regression analysis in

Table 1
Summary characteristics of eligible studies (n = 11).

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
Tourtual et al (1997) USA	Main analysis: n = 209 patients Validation analysis: n = 291 patients **Setting:** Wilson Memorial Regional Medical Centre, part of United Health Services Hospitals in the Broome County Metropolitan area of Johnson City, New York. **Population:** Acute inpatients admitted to units that experienced high HPU prevalence based on their previous survey.	**Inclusion criteria**: All patients who gave informed consent and were admitted to four nursing units participating in the study. Exclusion criteria not specified.	Two Prospective cohort studies Chi-square, *t*-test, logistic regression	The purpose of this research was to determine the predictors of hospital acquired HPU.	**Main analysis** Mean age: 67.6 yrs (18.2) Female: 56.5% (118/209) Ethnicity (white): 96.2% (201/209)	HPU incidence rate 26.8% (56/209) Category 1: 94.6% (53/56) 2: 5.4% (3/56) 3:- 4:-	Age	0.0001	MD: 13.7	9.7; 17.8
							LOS	0.0001	MD: 12.9	6.8; 18.9
							Height	0.002	MD: 2.1	−3.4; −0.8
							Weight Initial	0.0001	MD -26.4	−40.3; −12.4
							Weight Final	0.04	MD: 18.9	−36.7; −1.1
							Albumin Initial	0.0001	MD: 0.4	−0.6; −0.2
							Albumin Final	0.002	MD: 0.4	−0.7; 0.2
							Protein-Initial	0.04	MD: 0.4	−0.7; −0.02
							Haemoglobin-(g/L) Initial	0.009	MD: 0.9	−1.6; −0.2
							Highest pulse	0.05	MD: 5.9	−0.005; 11.9
							No. of diagnosis	0.0001	MD: 3.5	2.5; 4.6
							Admitted with PU	0.005	RR: 2.3	1.4; 3.7
							Incontinence	0.00001	RR: 2.7	1.7; 4.3
							Limb weakness			
							Left	0.02	RR: 1.7	1.1; 2.7
							Right	0.07	RR: 1.5	1.0; 2.4
							Both	0.4	RR: 1.6	1.0; 2.6
							Preventative ointment on heels on admission	0.04	RR: 2.0	1.2; 3.4
							Had a diagnosis of neoplasm	0.004	RR: 2.0	1.3; 3.0
							Circulatory problems of lower limb	0.004	RR: 1.0	1.0; 3.2
							CHF	0.01	RR:1.8	1.2, 2.8
							Respiratory disease	0.002	RR: 2.2	1.4; 3.4
							Any 3-consecutive worsening of appetite	0.0004	RR: 2.4	1.4; 3.7
							Nutrition services documented	0.000001	RR: 5.8	2.8; 12.3
							Sheets tightly tucked in before development of HPU	0.009	RR: 1.9	1.1; 3.3
							Braden Scale			
							Sensory perception	0.0001	MD: 0.4	−0.6; −0.2
							Moisture	0.03	MD: 0.2	−0.4; 0.02
							Activity	0.02	MD: 0.3	−0.06; −0.05
							Mobility	0.0001	MD: 0.5	−0.7; −0.3
							Nutrition	0.03	MD: 0.3	−0.5; −0.02
							Friction and shear	0.0001	MD: 0.5	−0.7, −0.4
							Total Braden Score	0.0001	MD: 2.3	−3.2, −1.4
					Validation Analysis					
					Mean age: 67.8 yrs (17.0) Female:58.1%	HPU incidence 21.7% (63/291) Category†	Age	0.0001	MD: 7.6	3.8; 11.4
							LOS	0.0001	MD: 8.4	4.5; 12.2
							Admitted with PU	0.02	RR: 2.5	1.4; 4.7

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
					(169/291) Ethnicity (white): 98.3% (286/291) Mean age: 67.6 yrs (18.2)	1: 92% (58/63) 2: 6.3% (4/63) 3: 1.6% (1/63) 4:- **Overall incidence rate: 23.8% (119/500)**	Incontinence (any) Limb weakness-Left, Right, Both Pulses (not palpable on one or the other extremity): Popliteal Posterior Tibial Current diagnosis of circulatory problems of lower limb Told has a diagnosis of: CHF Circulatory problems of lower limb Braden Scale Sensory perception Moisture Activity Mobility Nutrition Friction and shear Total Braden score **Logistic regression results** Braden moisture Braden Friction and Shear	0.0003 0.03 0.005 0.01 0.08 0.005 0.06 0.03 0.002 0.0001 0.0001 not significant 0.0001 0.0001 0.00001 0.01	RR: 1.3 RR: 1.6 RR: 1.9 RR: 1.8 RR: 1.5 RR: 1.9 RR: 1.5 MD: 0.2 MD: 0.3 MD: 0.5 MD: 0.4 MD: 0.1 MD: 0.4 MD: 2.2 Not reported Not reported	1.1; 1.5 1.0; 2.5 1.2; 3.1 1.1; 2.9 1.0; 2.3 1.2; 3.0 1.0; 2.4 −0.4; −0.03 −0.5; −0.1 −0.8; −0.3 −0.7; −0.2 −0.3; 0.1 −0.6; −0.2 −3.1; −1.3 Not reported
Duncan et al (2003) **UK**	n = 53 patients **Setting:** large district general hospital **Population:** Major abdominal surgery patients	**Inclusion criteria:** Age of 20 years who had major abdominal surgery. use of epidural as pain relief during the peri-operative period No specified exclusion criteria	Prospective study Correlation analysis	The objective of this study was to investigate the relationship between post-operative epidural analgesia and incidence of heel pressure sores	Mean age†: 69 years Gender and Ethnicity not reported	HPU incidence: 20.8% (11/53) Category 1: 72.7% (8/11) 2: 27.3% (3/11) 3:- 4:-	Level of epidural Pre-operative risk assessment Post-operative risk assessment Concentration of local anaesthesia Hypotension	Not reported Not reported 0.002 0.003 Not reported	Not reported Not reported Reports statistically significant correlation with no values. Reports negative correlation (no actual values) Not reported	Not reported
Edward et al. (2006) **UK**	n = 637 setting: The Nuffield Orthopaedic Centre NHS Trust (tertiary	**Inclusion criteria:** All patients who had undergone a hip and knee replacement and subsequently developed a	Retrospective record review Descriptive analysis	Highlight the risk of developing HPU in patients receiving peripheral nerve blocks.	Mean age: 74.3 (no sd reported) Range (52–89) Gender: Female 76.5% (26/34)	Cases: 7.8% (50/637) Category (*only reported for 32/50 HPU)	Type of surgery *Knee replacement* *Hip replacement* Pain control *PNB*	– – – – –	16.6% (46/280) 1.1% (4/357) 70% (35/	Descriptive only frequencies reported

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
	centre) population; orthopaedic patients	HPU between August 2002 and Dec 2004			Ethnicity not reported *results were only from 34 patients that developed HPU	1: 14 2:17 3:- 4:1	*PNB (3 in 1)* *Spinal* *Epidural* *Epidural + Sciatic* *Epidural + PNB* *CSE* *CSE + femoral + sciatic* *NB*	– – – 	50) 2% (1/50) – 22% (11/50) 2% (1/50) – 2% (1/50) 2% (1/50)	
Demers (2005) Florida, USA	N = 103 **Setting**: Three 150–250 beds hospitals from within a multihospital system **Population:** hospital patients	**Inclusion criteria:** Patients aged 18 years or older admitted during the year 2003 with a primary or secondary diagnosis of vascular disease indicated with ICD-9-CM:443.9 **Exclusion criteria** Pre-existing heel ulcer, a diagnosis of diabetes mellitus, incomplete medical records, and patients admitted for less than 24 h.	Retrospective cohort study		Range age: 41–100 years (mode 71–80 years) Gender Female: 55.3% (57/103) Ethnicity white; 81.6% (84/103) black: 10.7% (11/103) Hispanic:7.8% (8/103)	HPU incidence: 2.9% (3/103) Categories not reported	Braden scale ≤18	0.2	OR: 2.7	0.2; 31.5
Meaume and Faucher (2008) France	**n = 82 patients** **Setting:** 3 hospitals in a Paris region **Population:** all hospital inpatients	Cases-Patients with established heel pressure ulcers Controls-patients without heel pressure ulcer matched on age and gender No exclusion criteria specified	Cross sectional non interventional matched case control Parametric and non-parametric tests	Explore for lower limb atherosclerosis with the goal of attempting to associate the presence of blood	Mean age†: 86.2 years Female: 69.5% (57/82) Ethnicity-not specified	Cases 48.8% (40/82) **Category** 1: 10% (4/40) 2: 50% (20/40) 3: 30% (12/40) 4: 10% (4/40)	Evidence of atherosclerosis (PAD) Evidence of severe vs moderate atherosclerosis	States difference statistically significant at p-value no actual p value reported	†OR: 2.1 †OR: 15	0.8; 5.7 1.7; 132.9
Clegg et al (2009) USA	n = 84 patients **Setting**: 8 health care system in North Carolina and Virginia **Population:** Patients under Wound Ostomy Continence nurses and experienced HPU	The sample included patients 18 years or older, who were under the care of a participating WOC nurse and who experienced a HPU **Exclusion** No under 18 years old	Retrospective cross-sectional study Descriptive statistics (no control group)	The purpose of the multisite research project was to describe the physical characteristics and medical history of patients experiencing HPU	Mean age 73.1 (16.2) (Range: 18–98) Female: 58% (49/84) Ethnicity not specified	Cases 100% (84) Category 1: 12% (10/84) 2: 25% (21/84) 3: 4% (3/84) 4: 10% (8/84) Unstageable: 31% (26/84) SDTI: 19% (16/84)	Height (in) Mean (SD) Weight (lb) Mean (SD) BMI Mean (SD) Braden scale score Mean (SD) Serum albumin (g/L), Mean (SD) Pre-albumin(g/dL) Mean (SD) Pulse oximetry (%) Mean (SD) Blood urea nitrogen(mg/dL) Mean (SD) Creatinine(mg/dL) Mean (SD) Time in surgery (minutes), mean (SD)	N/A	65.7 (5.9) 164.04 (47.2) 27.4 (11.3) 13.4 (3.3) 2.4 (0.8) 13.8 (5.7) 96.2 (2.9) 28.9 (21.9) 1.7 (1.3) 125.5 (36.8) 53 (63)	N/A

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
							Palpable pedal pulse, (Y) n (%)			
							Pedal oedema, (Y) n (%)		22 [26]	
							Diabetes, (Y) n (%)		47 (56)	
							Smoker, (Y) n (%)		7 [8]	
							Vasopressor use, (Y) n (%)		7 [8]	
							Corticosteroid use, (Y) n (%)		7(8)	
							Systemic infection, (Y) n (%)		24(29)	
							End-stage renal Disease, (Y) n (%)		22(26)	
							Surgery this admission, (Y) n (%)		7(8)	
							History of peripheral arterial disease, (Y) n (%)		33 [40]	
							History of venous stasis disease, (Y) n (%)		5(6)	
Campbell et al (2010) Canada	n = 150 patients **Setting:** 850 academic bed, tertiary care facility London Health Centre, University Hospital, located in a small urban canter in south-western Ontario Canada. **Population:** Patients admitted for elective orthopaedic surgery or treatment of a fracture	**Inclusion criteria:** if they or their substitute decision-maker provided written informed consent to participate in the research study; were older than 18 years; had an orthopaedic condition of the pelvis, hip, or lower extremity; and were ulcer-free on both heels on admission. **Exclusion criteria:** Participants were excluded if they were actively dying or if it was impossible to view both heels for any reason (e.g. excessive pain or cast in place)	Prospective study Descriptive Chi-squared tests and student t-test	1.The incidence of HPU in an orthopaedic population of an acute care hospital in Canada. 2.Demographic, procedural, and prevention practices and medical risk factors associated with increased risk of developing a HPU. 3. The natural history/ sequelae of Category 1 heel PU	Mean age: 70.6yrs (12.9) Female: 69.3% (104/150) Ethnicity not specified	**Hip patients** Incident rate: 16% (8/50)	Haemoglobin (g/L) mean (SD)	0.9	†MD: 1.7 (13.4)	−28.5; 25.2
							Age (years)	0.6	†MD: 3 (5.8)	−8.6; 14.6
							Pulse (per minutes) mean (sd)	1	†MD: 0 (5.8)	−11.6; 11.6
							HP relief measures used (n)	0.016	†OR: 7.5	0.87; 64.4
							Respiratory disease (n)	0.96	†OR: 1.24	0.13; 11.2
							Altered mental status (n)	0.41	†OR: 0.69	0.15; 3.2
							LOS mean (SD)	0.51	†MD: 3 (4.2)	−5.5; 11.5
						Elective patients Incidence rate: 13% (13/100)	Haemoglobin (g/L) (SD)	0.01	†MD: 16.2 (6.0)	4.3; 28.1
							Age (years)	0.79	†MD: 3 (3.4)	−9.7; 3.7
							Pulse (per minutes)	0.05	†MD:10 (6.6)	−3.0; 23.0
							HP relief measures used (n)	0.55	†OR:0.95	0.1; 9.4
							Respiratory disease (n)	0.011	†OR: 5.8	1.4; 23.9
							Altered mental status (n)	0.029	†OR: 3.9	1.1; 14.0
							LOS mean (SD)	0.217	†MD: 2 (3.6)	−5.1; 9.10
						Combined patients **Overall incidence rate: 14% (21/150)** Category: 1: 81%(17/21) 2: 19% (4/21) 3: 4:	Haemoglobin (g/L) mean (SD)	0.056	†MD: 10 (6.1)	−2.1; 22.1
							Age (years) mean (SD)	0.602	†MD: 1.7 (3.1)	−7.8; 4.5
							Pulse (per minutes) mean (SD)	0.279	†MD: 5 (3.6)	−2.1; 12.1
							HP relief measures used (n)	0.133	†OR: 3.5	1.1; 11.5

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
							Respiratory disease (n)	0.016	†OR: 1.7	0.6; 4.7
							Altered mental status (n)	0.216	†OR: 0.6	0.2; 1.6
							LOS mean (SD)	0.161	†MD: 3.0 (2.1)	−1.2; 7.2
Gaubert-Dahan (2013) France	n = 210 patients **Setting:** two French university hospitals. **Population:** Individuals admitted to a geriatric rehabilitation centre from March 2009 to June 2010	**Inclusion criteria:** Individuals admitted to a geriatric rehabilitation centre in two French university hospitals from March 2009 to June 2010. **Exclusion criteria:** Individuals with a MMSE score of less than 10 were not included. Individuals with central or medullar nervous system disease (hemiplegic and paraplegic patients) were also not included.	Cross-sectional study Chi-squared and t-tests	To identify associated factors in older hospitalised adults	Mean age: 85 (72–101) Female: 74.8% (157/53) Ethnicity not specified.	HPU prevalence rate: 12.4% (26/210) Category 1: 50% (13/26) 2: 26.9% (7/26) 3: 15.4% (4/26) 4: 7.7% (2/26)	Sensory Peripheral Neuropathy (Light vs Moderate& Severe)	0.07	†OR: 3.8	†0.9; 16.6
							NSS	0.009	†MD: 1.3 (0.5)	0.3; 2.3
							NDS	0.011	†MD: 3.0 (1.2)	0.6; 5.4
							HPU Category and NSS	0.02	r = 0.45	Not reported
							HPU Category and activity limitation	0.02	r = 0.44	
							HPU Category and Hip fracture, cancer, diabetes mellitus and nutritional status	not significant correlation observed	no measure of association reported	
							HPU severity vs Neuropathy severity	0.04	no measure of association reported	
Delmore et al (2015) USA	**Main analysis** n = 337 patients Validation analysis n = 80 patients **Setting:** NYC based urban tertiary medical centre (discharged patients) **Population:** all discharged patients	**Inclusion criteria:** Admitted with HPU or developed a HPU between 2009 and 2011. Aged 8 or over At least a 3 day stay. Control-without heel pressure ulcers patients matched on age.	Retrospective case control cohort study (reviewing of medical records) Stepwise Logistic regression	To develop and validate a method of predicting whether patients will develop a heel pressure ulcer during their hospital stay.	**Main analysis** Mean: age 73yrs [20] Gender and ethnicity not reported **Validation analysis** Age, gender and ethnicity not reported.	**Main analysis** Prevalence rate: 11% (37/337) **Validation analysis** Prevalence rate: 15% (12/80) HPU severity not reported for both analyses. **Overall prevalence rate:** 11.8% (49/417)	**Univariate analysis** Age (mean, SD)	0.02	no measure of association reported for all variables.	Not reported for all variables
							Braden scale score (mean, SD)	<0.001		
							Diabetes (%)	0.03		
							Vascular disease	<0.001		
							Neuropathy	0.03		
							Immobility	<0.001		
							Perfusion issues	0.007		
							Morbid obesity	0.3		
							Cachexia	0.7		
							Surgery > 3h (%)	0.7		
							ICU >3 days (%)	<0.001		
							LOS in days (median, range)	<0.001		
							Multivariable modelling			
							Diabetes	0.02	OR: 2.9	1.2; 1.7
							Vascular disease	0.01	OR: 3.8	1.3; 11.1
							Immobility	0.003	OR: 4.7	1.7; 12.9
							Braden scale score </= 18	<0.001	OR: 21.8	6.3; 76.1
Muntlin-Athlin et al (2016) Sweden	n = 183 patients **Setting:** Five ambulance stations, two EDs and 16 wards at 2 hospitals across two county	**Inclusion criteria:** older adults 70+Neurological symptoms or reduced general condition according to medical directives at the medical	Prospective cohort study Descriptive Chi-squared test, Mann-Whitney *U* test and *t*-test	1.Describe heel pressure ulcer prevalence and nursing actions in relation to pressure ulcer prevention during the care delivery chain (i.e.	Mean age: 86.3 yrs (7.2) Female: 62.3% (114/183) †6 with unspecified gender	ED incidence rate: 8% (15/183) Category 1–3 not specified distribution. **Overall**	**Ambulance and ED vitals:** Respiratory rate Heart rate Reaction Level Scale Pulse oximetry (%) Blood pressure (systolic)	Reported as not significant with no actual p-values	No mean differences presented however unable to calculate	

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
	councils in Sweden. **Population**: older patients (70+) with "neurological symptoms" or "reduced general conditions, according to medical directives without HPU	call centre No heel pressure ulcer Admitted to one of the participating wards Able to sign consent form. **Exclusion criteria:** patients requiring life-threatening support and discharged from ED Unable to provide signed informed consent or did not have family member to sign.		pre-hospital and emergency care level, and further at the hospital ward), for older patients with neurological symptoms or reduced general condition. 2.Investigate early predictors for the development of heel pressure ulcer during the care delivery chain	Ethnicity-not specified.	**Incidence rate: 21% (39/183)** Category 1–4 not specified distribution	mmHg Blood pressure (diastolic) mmHg **Day 1** MNS Mental condition Physical activity Mobility Incontinence Total risk score	 0.01 0.001 <0.0001 0.002 0.002	due to lack of data (n) MR: 55.8 vs 76.5 MR: 49.7 vs 78.0 MR:48.6 vs 78.2 MR:51.0 vs 77.7 MR:50.3 vs 76.	 Not reported Not reported
Twilley and Jones (2016) UK	n = 30 patients **Setting:** community hospital providing stepdown care for acute hospitals **Population**: all inpatients	**Inclusion criteria:** Inpatients aged 18 and over with a Category 2, 3 or 4 pressure ulcers of the heel. **Exclusion criteria:** All inpatients without a pressure ulcer of the heel and matching the case group based on age, gender and ethnicity were eligible	Matched case-control (age, gender, and ethnicity) Odds Ratio	1. Explore the relationship between pressure ulcers of the heel and PAD. 2. Investigate the feasibility of conducting a statistically powered matched case control study that could further investigate aim [1]	Mean age: 86.5 (77–94) Female: 26.7% (8/30) Ethnicity not specified	HPU: 50% (15/30) Category: 2: 33.3% (5/15) 3: 47.7% (7/15) 4: 20% (3/15)	PAD	0.01†	OR: 11	2.0: 60.6
Delmore et al 2019 USA	Main analysis: n = 1.697 patients Validation analysis: n = 240 Setting: New York state-wide hospitals Population: Hospitalised adult patients aged 18 years or above	**Inclusion criteria:** All hospitalised adults aged 18 years or above. **Exclusion criteria:** Patients with heel vascular wounds as designated by the associated International Classification of Disease (ICD-9). Obstetric and psychiatric patients. Children younger than 18 years old.	Retrospective Case control cohort study Univariate and multiple regression analysis	1.To replicate previous research that found that found four independent and significant predictors of HPUs in hospitalised patients using a larger and more diverse patient population. 2.To create a clinical enabler for assessing patients at risk of HPUs.	Main analysis Mean age: 59.3 (21.7) Female: 59.7% (1,013/1,697) Ethnicity Spanish/ Hispanic origin: 0.2 (3/1697) Other: 94.3% (1600/1697) Unknown: 5.5% (94/1697) Validation analysis Mean age: 60.1yrs (20.6) Female: 57.5% (138/240) Ethnicity Spanish/ Hispanic origin: 0.4% (1/240)	Prevalence rate:19.-1% (323/1697) Categories: 1: 21.4% (69/323) 2:30.7% (99/323) 3: 5.0% (16/323) 4: 4.0% (13/323) Unstageable: 28.5% (92/323) Unspecified: 10.5% (34/323) Validation analysis Prevalence rate:33.3% (80/240) Categories 1: 27.5% (22/80) 2:26.3% (21/80)	Age> 65years Diabetes Vascular disease Perfusion issues Impaired nutrition Mechanical ventilation Surgery	<0.001 0.03 0.001 <0.001 <0.001 <0.001 <0.001	OR: 3.3 OR: 1.4 OR: 3.1 OR: 2.8 OR: 6.9 OR: 7.7 OR: 1.8	2.4; 4.6 1.0; 1.9 1.8; 5.2 2.1; 3.8 4.1; 11.5 4.2; 14.3 1.3; 2.5

(*continued on next page*)

Table 1 (*continued*)

Study Authors (year) and country	Study population (No. recruited, setting and speciality)	Eligibility criteria	Design and analysis method	Study aims and objectives	Population characteristics (Age, %Female, Ethnicity)	Prevalence and incidence rate % developing HPU and by Category	Risk factors investigated (no, list of risk factors)	p-value	Measure of association (OR, RR, MD (SD), correlation, frequencies)	95% Confidence intervals
					Other: 97.1% (233/240) Unknown: 2.5% (6/240)	3: 5.0% (4/80) 4: 5.0% (4/80) Unstageable: 31.3% (25/80) Unspecified: 5.0% (4/80) **Overall prevalence rate:** 20.8% (403/1937)				
Manderlier et al (2019) Netherlands		n = 4,842 patients **Setting:** nursing homes and community care facilities across Netherlands **Population**: all patients	**Inclusion criteria:** Participants had to be 18 years or older, reside in a nursing home or have received community care in the Netherlands and approve receiving skin inspection. No exclusion specified.	Cross-sectional, secondary Single and multiple binary logistic regression	1.The primary aim of this study was to explore which modifiable patient-related factors are associated with the presence of category I–IV PUs on the body sites most vulnerable to PU development, the sacrum, and heels. 2.A secondary aim of this study was to explore which modifiable patient-related factors are associated with deep PUs (category III–IV).	Mean age: 82.7 yrs (9.9) Female: 70.2% (3,398/4,842) Ethnicity not specified.	Prevalence rate: 1.5% (75/4,842) Category: 1: 50.7% (38/75) 2: 16% (12/75) 3: 16% (12/75) 4: 1.7% (8/75) Unstageable: 2.7% (2/75) DTI: 4% (3/75)	**Category 1–4** Malnutrition 0.7; 2.0 Braden mobility 0.4; 0.8 Braden moisture 0.8; 1.3	0.5 0.001 1	OR: 1.2 OR: 0.6 OR: 1
Braden friction and shear	<0.001	OR: 0.3		0.2; 0.5						
Category 3–4										
Braden friction and shear	Not reported	OR 0.32		0.17; 0.62						

All variables are reported in the table using the same descriptions as in the original articles, CSE-Combined spinal and epidural; MD- Mean difference; MNS-Modified Norton Scale; PNB-peripheral nerve block OR-odds Ratio, †values calculated by review authors.

addition to descriptive statistics [29–31,33]. The rest of the eligible studies either performed parametric or non-parametric analyses (chi-squared, *t*-test and Whitney Mann-U tests) or just reported ORs as appropriate. Not all studies that reported on measures of association included CIs or p-values as appropriate; where adequate data was reported, reviewers attempted to calculate these based on the extracted data, as highlighted in Table 1.

Only three studies ([31,33,42] were classed as high quality, seven were of moderate quality [29,30,32,35,38,40,41]and three were of low quality [36,37,39] (see Table 2). Two high quality studies [31,42] and three moderate quality studies [29,35,38] reported on their sample size assumptions and/or calculations. Of the four eligible studies that performed additional multivariable analysis, only Delmore et al. (2019) (31) and Manderlier et al. (2019) [33] had sufficient numbers of HPUs (events) per risk factor (i.e.10 events per risk factor) in their final logistic regression model.

The main issues contributing to high risk of bias and consequently rendering 10/13 studies moderate to low quality: were their retrospective study design, lack of comparator group, study participants only being high risk patients and already experiencing HPUs, lack of sample size calculations, selection bias, inadequate reporting and statistical analysis issues. All of these issues may have influenced the accuracy of the study results, interpretation and generalisability. As a result, the evidence from low quality studies could not be utilised to inform the decision as to whether to accept or reject these variables as potential risk factors for developing HPUs. It was evident from the review that most of the eligible papers did not follow the STROBE recommendations. STROBE recommendations were developed to facilitate critical appraisal, interpretation of results and consequently enable direct translation of research into clinical practice [28]. As a result, most of the studies were rated as manifesting moderate risk of bias across the six subdomains of the QUIPS tool.

4.4. Risk factors

In total, 51 different variable names were identified from the 13 eligible studies. These were categorised into 16 risk factor domains as summarised in Table 3. Although some studies used standardised measures (e.g., validated risk assessment tools), there was still a lack of consistency across the tools utilised, measurement scales, or classification of diseases investigated. The Braden scale (PU a risk assessment tool) was the most used validated measurement scale. All variables identified in this review are listed in Table 3 according to the specification in each of the eligible studies. Table 3 highlights the heterogeneity of variables utilised across different studies. Lack of consistency in measuring and reporting of variables made it difficult to synthesise review results using quantitative methods.

Nine risk factors (body mass index, smoking status, pre-albumin, blood urea, creatinine, systemic infection, end-stage renal disease, vasopressor and corticosteroid use) were only investigated in one low quality study [39].Thirty two other remaining variables were examined in at least one or more moderate quality studies [29,32,35,40] as potential contributory factors for HPU development using descriptive and univariate analyses. Haemoglobin, respiratory rate and the use of HPU preventative measures emerged as significant in one moderate quality study [38] which involved patients undergoing either elective orthopaedic or hip surgery.

The MNS subscales: physical activity and incontinence emerged as significant in the Muntlin-Athlin et al. (2016) [32] study only however this study did not adjust for another potential confounders in their analysis. Mental status, although measured differently in the Campbell et al. (2010) [38] and Muntlin-Athlin et al. (2016) [32] (moderate quality) studies, emerged as significant in both studies. Length of surgery and perioperative analgesia were considered in moderate to low quality studies only [30,35,39] and results were either statistically insignificant or not reported.

Sensory neuropathy as defined by the Braden subscale [29] or using the neuropathy symptom score (NSS) and neuropathy disability score (NDS) [40] were also found to be significant in univariate analysis. Only the Braden subscale 'sensory perception' item was further considered in a multivariable analysis, however did not emerge to be statistically significant [29]. Overall, almost all moderate quality studies did not adjust for confounding factors (with the exception of [29]. The studies were also inconsistent in reporting measures of association, and inadequately reported on sample size assumptions, statistical analysis plans, p-values, and CIs. All of these factors impacted on the review authors' ability to fully assess the studies' potential risk of bias and interpretation of results. Consequently, there is no conclusive evidence to support whether these variables are risk factors for HPU development, given that the studies were of moderate quality.

A total of 10 potential risk factors were examined in at least one high quality study [31,33,42] that involved hospital, nursing home, community-dwelling, and rehabilitation patients. A disease status of either diabetes or lower limb vascular disease emerged as statistically significant in more than one high quality study. The Delmore et al. (2015) [30] (moderate quality) and Delmore et al. (2019) [31] (high quality) studies found that hospital patients with diabetes were at least 1.4 times (95%CI: 1.0; 7.2) more likely to develop a HPU compared to those without diabetes.

Lower limb vascular disease emerged as statistically significant in two high quality studies [31,42] and two moderate quality studies [30, 41]. Participants diagnosed with lower limb vascular disease were at least 3.1 times (95%CI: 1.3; 60.2) more likely to develop a HPU compared with those without lower limb vascular disease. There is some evidence to suggest that diabetes and vascular disease are risk factors for HPU. However, this evidence comes from only one high quality study for diabetes and two high quality studies for lower limb vascular disease. The second high quality study to report on lower limb vascular disease as statistically significant [42] was a small explorative study and its analysis did not adjust for other potential risk factors.

Physical conditions: age >65years, Braden subscales 'moisture, friction and shear', immobility/mobility (Braden and MNS subscales), nutritional status, perfusion issues, mechanical ventilation and surgery, all emerged as statistically significant in at least one high quality study. Age merged as an independent risk factor in only one high quality study [31]. Patients older than 65 years were more likely to develop HPUs compared to younger patients (OR: 3.3; 95%CI: 2.4–4.6). Malnutrition/impaired nutritional status was considered in two high quality studies [31,33],however, the two studies involved different study populations (hospital inpatients and nursing/community care patients, respectively). Malnutrition only emerged as statistically significant in one of the two high quality studies [31], in this study, hospitalised patients suffering from malnutrition had an increased risk of developing HPUs by a factor of 6.9 (95%CI: 4.1–11.5). The Manderlier et al. (2019) [33] study was only aimed at examining what they considered 'modifiable patient-related risk factors', defined as patient characteristics that are sensitive to interventions used by HCPs to prevent HPU development'. Therefore, differences in study populations and variables examined could have contributed to some of the disparities between the Delmore et al. (2019) [31] and Manderlier et al. (2019) (33) study results.

Perfusion issues, mechanical ventilation and surgery were examined in only one high quality study [31] involving hospitalised patients; all three variables emerged as highly significant (p-value< 0.001). Perfusion issues were defined by the presence of conditions that affect blood to peripheral extremities - excluding vascular disease, which was considered separately. Patients that had evidence of perfusion issues (e.g., cardiovascular disease, myocardial infarction, hypovolemic shock) were at least 2.8 times more likely to develop HPUs compared to patients without perfusion issues.

Participants on mechanical ventilation were at least seven times more likely to develop a HPU compared to those not on mechanical

Table 2
Quality appraisal for individual studies (n = 11).

Study Name	1.Selection Bias	2.Attrition Bias	3.Risk Factors measurement bias	4.Outcome measurement bias	5.Bias due to Confounders	6.Analysis and Reporting Bias	Overall study quality	Details of Concerns
Author(s) (year)	*Clear eligibility criteria, method used to identify population, adequate study participation, Recruitment period, Presence of control group, baseline characteristics of participants,*	*Response rate, attempts to collect information on dropouts, Reasons for loss to follow-up provided,*	*Clear RF definition, method and setting of measurement, proportion of risk factor data available for analysis*	*Clear outcome measure definition, valid and reliable measurement of outcome, method and setting of outcome measurement, proportion of outcome measurement data available for analysis*	*Clear definition of confounding factors, valid and reliable measurement of confounding factors, method and setting of confounding factors, Method used for missing data, appropriate accounting of confounding factors*	*Use appropriate statistical analysis, pooled or individual reporting. Selective reporting, accuracy of reporting.*	*High/ moderate/ low*	
Tourtual et al (1997)	Low	Low	Moderate	Moderate	Moderate	Moderate	Moderate	1. Do not specify missing data 2. Lack of quality assurance processes for outcome measurement based on skin assessment 3. Collect data on numerous factors however only used multivariable logistic regression in their validation study 2 to adjust for confounding factors 4. Lack of full information in statistical analysis plan 5. Authors only report significant results from their multivariate analysis in study 2. 6. Insufficient number of events- logistic regression analysis
Demers (2005)	Low	Low	High	Moderate	High	High	Low	1. Retrospective design-reviewing records 2. Subjective nature of lack of quality assurance processes for risk factor measurement. 3. Subjective nature of staging tool and lack of quality assurance processes for outcome measurement. 4. Descriptive analysis with no consideration of potential confounders 5. Methodological limitations- sample size, low incidence rate
Duncan et al (2003)	Mo derate	Moderate	Moderate	Moderate	Moderate	High	Moderate	1. No clear sampling frame and recruitment processes reported.

(*continued on next page*)

Table 2 (*continued*)

Study Name	1.Selection Bias	2.Attrition Bias	3.Risk Factors measurement bias	4.Outcome measurement bias	5.Bias due to Confounders	6.Analysis and Reporting Bias	Overall study quality	Details of Concerns
								2. Not specify number eligible or withdrawals. 3. Subjective nature of staging tool and lack of quality assurance processes for outcome measurement. 4. Only provide overall mean age for study population. 5. Lack of reporting on missing data and reasons. 6. High levels of missing data on reported risk factors also do not report for 2 other risk factors. 7. Not specified statistical tests used.
Edwards et al. (2006)	Low	Low	Medium	Medium	High	High		1. Retrospective design reviewing medical records. 2. No clear eligibility criteria. 3. Lack of validation of outcome measure 4. Inadequate reporting of results as a result unable to clearly follow results extract appropriate data. 5. Descriptive analysis with no consideration of potential confounders 6. No statistical analysis plan reported and evidence of selective reporting
Meaume and Faucher (2008)	Moderate	Low	Low	Low	Moderate	Moderate	Moderate	1. Lack of reporting do not specify population details, no exclusion criteria. 2. Recruitment summary not provided to assess generalisability of studies. 3. No confounders considered however authors acknowledges in limitations. 4. Partial reporting of statistical analysis used. 5. No effect size, confidence interval reported.
Clegg et al (2009)	Moderate	Low	Low	Moderate	High	High	Low	1. No adequate information on how subjects were

(*continued on next page*)

Table 2 (*continued*)

Study Name	1.Selection Bias	2.Attrition Bias	3.Risk Factors measurement bias	4.Outcome measurement bias	5.Bias due to Confounders	6.Analysis and Reporting Bias	Overall study quality	Details of Concerns
								recruited or exclusion criteria. 2. Unable to ascertain generalisability of study. 3. Subjective ascertainment of outcome measure as based on clinical staff assessment of skin assessment. 4. Lacks comparator group. 5. Descriptive analysis only.
Campbell et al (2010)	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate	1. Does not specify total number of patients screened and excluded for generalisability purposes. 2. Subjective nature of outcome measurement (skin assessment and staging criteria). 3. Lack of clear definition of risk factors and how these were measured. 4. Partial reporting only p-values with no estimate of measure of association or differences.
Gaubert-Dahan (2014)	Moderate	Low	Low	Moderate	Moderate	High	Moderate	1. Partial reporting study participation unable to fully assess representation. 2. Subjective nature of outcome measurement (skin assessment and staging criteria). 3. Descriptive analysis no adjusting for confounders. 4. Conclusions are not based on reported results or research question. 5. Selective reporting making conclusion on unreported results. 6. Authors' state that they used benferroni adjustment however do not provide full details.
Delmore et al (2015)	High	High	Moderate	Moderate	Moderate	Moderate	moderate	1 Inadequate reporting. 2. Retrospective Medical record review of discharged patients.

(*continued on next page*)

Table 2 (*continued*)

Study Name	1.Selection Bias	2.Attrition Bias	3.Risk Factors measurement bias	4.Outcome measurement bias	5.Bias due to Confounders	6.Analysis and Reporting Bias	Overall study quality	Details of Concerns
								3. No specific exclusion criteria besides age for control group mentioned 4. Confusing eligibility criteria (i.e. excludes community acquired which contradicts inclusion criteria). 5. High risk of selection bias as authors don't report final no. of reviewed records especially controls. 6. Lack of reporting missing data and methods of imputation. 7. No clear prespecified sample size calculation. 8. Insufficient number of events- logistic regression analysis.
Muntlin-Athlin et al (2016)	Moderate	High	Moderate	Moderate	Moderate	Moderate	Moderate	1. Partial reporting on key characteristics however reported in RCT paper. 2. Unable to assess risk of attrition bias due to lack of reporting. 3. Unable to ascertain level of RF data collection due to inconsistencies in reporting (not clear how many patients had complete data for each RF. 4. Lack of validation of outcome measure. 5. Lack of reporting for confounders (pre-specifying RF vs confounders) at each follow-up time point. 6. Selective reporting of significant data only 7. Do not report risk estimate or mean differences and confidence intervals.
Twilley and Jones (2016)	Low	Low	Low	Low	Moderate	Moderate	High	1. No cofounding factors investigated or reported however authors acknowledge as limitation of study. 2. No p-values reported.
Delmore et al (2019)	Low	Low	Low	Low	Low	Low	High	1 Lack of validation of outcome measure
	Low	Low	Low	Low	Low	Low	High	

(*continued on next page*)

Table 2 (*continued*)

Study Name	1.Selection Bias	2.Attrition Bias	3.Risk Factors measurement bias	4.Outcome measurement bias	5.Bias due to Confounders	6.Analysis and Reporting Bias	Overall study quality	Details of Concerns
Manderlier et al (2019)								1 Lack of validation of outcome measure

ventilation (OR: 7.7; 95%CI:4.2–14.3; p-value <0.001) [31]. Participants who had surgery during their hospital stay had an increased risk of developing a HPU by a factor of 1.8 (95%CI: 1.3–2.5) compared to those who did not have surgery [31]. Types of surgery reported were divided into seven categories: vascular, orthopaedic, neurosurgery, intestinal, cardiovascular, and genitourinary and gynaecology. Cardiovascular surgery was the most common amongst those that developed HPU, accounting for 27.9% of all surgeries.

Mobility/immobility was considered in one high quality [33] and three moderate quality studies [29,30,32]. Manderlier et al. (2019) [33] defined mobility using the Braden subscale. In Delmore et al. (2015) [30] (moderate quality), immobility was associated with health conditions that impaired the ability to mobilise, for example, plegia, cardiovascular accidents, lower extremity fractures, and orthopaedic surgeries; whereas Muntlin-Athlin et al. (2016) [32] (moderate quality study) utilised the MNS subscale 'mobility' to measure patients' ability to move independently. Although mobility/immobility was measured differently across the four eligible studies, it emerged as statistically significant in all four studies. Based on the results of a high quality study, an increase in the mobility score (as measured using the Braden subscale 'mobility'), reduced the likelihood of developing a HPU (0.6; 95% CI: 0.4–0.8) [33].

The Braden subscale 'friction/shear' emerged as statistically significant in one high quality study [33] and one moderate quality [29]. An increase in the friction and shear score decreased the likelihood of developing a HPU (0.3; 95% CI 0.2–0.5) [33].

Moisture (as measured using the Braden subscale 'moisture' or MNS subscale 'incontinence'), only emerged as statistically significant in one moderate quality study each [29,32] respectively. However, the Braden subscale 'moisture' did not emerge as statistically significant in a high quality study [33]. Further high quality studies are required to investigate the impact of the identified potential risk factors in the wider patient population, in order to increase the generalisability of results and inform future practice.

5. Discussion

This is the first systematic literature review of observational studies investigating risk factors for developing HPUs. As evident from this review, there are too few studies focusing on this area, despite HPUs being the second most common type of PU. Understanding the biology and natural history of HPUs is paramount in order to optimise prevention strategies. Risk factors can be barriers to healing, and in worse case scenarios, they can instigate life threatening outcomes if they are not addressed and corrected in a timely manner. Evidence based prevention strategies, including educational programs, empower both patients and their carers to manage their risk - especially outside of care settings.

Most of the studies reviewed provided descriptive results or univariate analysis, which did not adjust for other potential risk factors or consider the impact of living with several comorbidities to their study population. There was also evidence of selective reporting, as studies mostly reported statistically significant results. The problematic use of less robust designs and analytical techniques has previously been highlighted by Clegg and Palfreyman (2014) [24] in their review on elevation devices used to prevent HPUs. These have also been common themes in this review - with serious implications on the quality and generalisability of specific study results. It was also evident that many of the studies did not follow STROBE recommendations, which made it difficult to synthesise the evidence. Despite observational studies often being criticised for their vulnerability to being influenced by unknown confounding factors, well-designed observational studies can also complement RCTs in hypothesis generation, defining clinical questions and establishing future research questions [43,44]. The results of this review can therefore be used to generate hypotheses for further research studies investigating risk factors for developing HPUs.

Only three (27.2%) eligible studies were rated high quality [31,33,42]. Their study populations and research questions were different, which may have contributed to a difference in the risk factors that emerged as statistically significant. In total, the review identified 16 risk factor domains, however due to the small number of eligible studies, this meant that each potential risk factor was evaluated in three or less studies of high to moderate quality. In light of this review, it is not surprising that current clinical practice recommendations and guidance do not provide substantial specific guidance on risk assessment and prevention of HPUs [8,45]. It is therefore imperative that future research addresses these limitations and focuses on risk factors for HPUs in order to reduce their prevalence and incidence rates.

In this review, HPU incidence and prevalence rates were estimated as 17.4% (2.9–29.5%) and 11.7% (1.5–20.8%) respectively; however, the actual rates remain unclear due to heterogeneity of study populations, designs and quality of the studies. for instance, in this review involved retrospective review of medical notes, or they lacked quality assurance processes for their outcome measure, this affected studies that used skin assessments to diagnose HPUs. Diagnosis of HPUs remains a challenge in practice due to the misclassification of wounds affecting lower limbs; that is, many clinicians lack the ability to distinguish between diabetic foot ulcers, vascular related ulcers and PUs [20]. For retrospective studies included in this review, this could potentially have contributed to an under or overestimation of HPUs due to lack of documentation or misclassification of HPUs by clinical staff.

HPUs, like any other PU, have multifactorial contributory factors [21]. However, the actual risk factors associated with HPU development may be different due to the anatomy and anatomical position of the heel in the body, as suggested in biomechanical and other studies [18–20]. This review found that age >65 years, diabetes, malnutrition, surgery, mechanical ventilation, perfusion issues, vascular disease [31] and Braden subscales 'friction and shear', 'mobility' [33] emerged as significant risk factors in the presence of other variables using multivariable analysis from two high quality studies. These results are consistent with the aetiology of HPUs [3]. Braden subscales 'friction and shear', and 'mobility' only explained 16.6% of the variance in the prevalence of HPUs amongst nursing home patients or those receiving community care [33]. Delmore and colleagues were able to correctly identify 74% of their validation sample as either with or without HPUs using their regression model, which included: vascular disease, diabetes, malnutrition, surgery, mechanical ventilation and perfusion issues [31]. It is evident from the results of the two separate final regression models by Delmore et al. (2019) [31] and Manderlier et al. (2019) (33), that other contributory factors exist that were not explored in either study. Although both studies were the two largest, they involved different population samples.

The Braden scale has six subscales (sensory perception, moisture, mobility, activity, nutrition and friction and shear) and was the most used risk assessment tool (RAT) in the eligible studies. Subscales 'friction

Table 3
Summary of strength of evidence for identified risk factors (n = 11).

Risk factor	High quality studies	Moderate quality studies	Low quality studies
Patient Characteristics			
Age	Delmore et al. (2019)	Tourtual et al. (1997); Campbell et al. (2010)	
Height		Tourtual et al. (1997)	Clegg et al. (2009)
Weight (initial, final)		Tourtual et al. (1997)	Clegg et al. (2009)
BMI			Clegg et al. (2009)
Smoker			Clegg et al. (2009)
Vital signs			
Heart rate (highest)		Tourtual et al. (1997); Campbell et al. (2010); Muntlin-Athlin et al. (2016)	Clegg et al. (2009)
Pulse oximetry		Muntlin-Athlin et al. (2016)	Clegg et al. (2009)
Respiratory rate		Muntlin-Athlin et al. (2016)	
Blood pressure (systolic, diastolic)		Muntlin-Athlin et al. (2016) Duncan et al. (2003)	
Hypotension		Duncan et al. (2003)	
Reaction level scale		Muntlin-Athlin et al. (2016)	
Haematological measures			
Albumin (initial; final)		Tourtual et al. (1997)	Clegg et al. (2009)
Pre-albumin			Clegg et al. (2009)
Blood Urea			Clegg et al. (2009)
Creatinine			Clegg et al. (2009)
Protein- Initial		Tourtual et al. (1997)	
Haemoglobin (g/L) (initial)		Tourtual et al. (1997)	
Skin Status			
Admitted with PU		Tourtual et al. (1997)	
Moisture/incontinence			
Incontinence; Braden subscale-Moisture; MNS subscale Incontinence	Manderlier et al. (2019)	Tourtual et al. (1997); Muntlin-Athlin et al. (2016)	
Preventive measures for HPU			
Preventative ointment on heels on admission		Tourtual et al. (1997)	
Sheets tightly tucked in before development of HPU		Tourtual et al. (1997)	
HPU relief measures used		Tourtual et al. (1997)	
Disease or physical conditions			
Total number of diagnosis		Tourtual et al. (1997)	
Had a diagnosis of neoplasm		Tourtual et al. (1997); Gaubert-Dahan et al. (2013)	
Systemic infection			Clegg et al. (2009)
Limb weakness (left/right/both)		Tourtual et al. (1997)	
Diabetes	Delmore et al. (2019)	Gaubert-Dahan (2013); Delmore et al. (2015)	Clegg et al. (2009)
Perfusion issues defined congestive heart failure, MI, anaemia, dehydration, pedal oedema	Delmore et al. (2019)	Tourtual et al. (1997)	Clegg et al. (2009)
Circulatory problems of lower limb		Tourtual et al. (1997)	Clegg et al. (2009)
peripheral arterial disease/vascular disease	Twilley and Jones (2016); Delmore et al. (2019)	Meaume and Faucher (2007); Delmore et al. (2015);	Clegg et al. (2009)
venous stasis disease			Clegg et al. (2009)
Pulses (not palpable on one or the other extremity):			
Popliteal/Posterior Tibia		Tourtual et al. (1997)	Clegg et al. (2009)
Respiratory disease		Tourtual et al. (1997); Campbell et al. (2010)	
End-stage renal Disease			Clegg et al. (2009)
Nutritional Status			
Any 3-consecutive worsening of appetite/Nutrition services documented		Tourtual et al. (1997)	
Nutrition-Braden subscale/Malnutrition/impaired nutrition	Delmore et al. (2019); Manderlier et al. (2019)		
Length of stay (LOS)		Tourtual et al. (1997); Campbell et al. (2010)	
Sensory perception			
Braden subscale-Sensory perception;		Tourtual et al. (1997)	
Sensory peripheral neuropathy (NSS, NDS)		Gaubert-Dahan et al. (2013); Delmore et al. (2019)	
Friction and shear			
Braden subscale-Friction and shear	Manderlier et al. (2019)	Tourtual et al. (1997)	
Mobility/Physical activity			
Activity- Braden subscale/MNS subscale		Tourtual et al. (1997); Delmore et al. (2015); Muntlin-Athlin et al. (2016)	
Mobility- Braden subscale/MNS subscale/Immobility	Manderlier et al. (2019)	Tourtual et al. (1997); Delmore et al. (2015); Muntlin-Athlin et al. (2016)	
Risk Assessment tools			
Braden Scale total risk score		Tourtual et al. (1997); Delmore et al. (2015)	Demers (2005)
MNS total risk score		Muntlin-Athlin et al. (2016)	
Pre and post-operative risk assessments		Duncan et al. (2003)	
Medication			

(*continued on next page*)

Table 3 (*continued*)

Risk factor	High quality studies	Moderate quality studies	Low quality studies
Vasopressor use			Clegg et al. (2009);
Corticosteroid use			Clegg et al. (2009);
Epidural (level of epidural, concentration of local anaesthesia)		Duncan et al. (2003)	Edward et al. (2006)
Surgery			
Length of surgery		Delmore et al. (2015)	Clegg et al. (2009)
Type of surgery (vascular, orthopaedic, neurosurgery, intestinal, cardiovascular, genitourinary, gynaecology,TKR,THR)	Delmore et al. (2019)	Campbell et al. (2010)	Clegg et al. (2009); Edward et al. (2006)
Mechanical ventilation	Delmore et al. (2019)		

All variables are reported in the table using the same descriptions as in the original articles. TKR-total knee replacement; THR-total hip replacement.

Table 4
Examples of database search strategies.

Database	Search Terms
CINAHL	(MH "Heel Ulcer/EP/ET/PC"); TI heel ulcer* OR AB heel ulcer*; TI (risk factors or contributing factors or predisposing factors)
Cochrane Library	MeSH descriptor: [Heel] explode all trees; MeSH descriptor: [Pressure Ulcer] explode all trees; MeSH descriptor: [Risk Factors] explode all trees
EMBASE	heel.sh. or heel*.ab. or heel*.ti.; pressure ulcer.sh. or pressure ulcer*.ab. or pressure ulcer*.ti.; limit 11 to (human and (adult <18–64 years > or aged <65+ years>))
MEDLINE	MH heel; TI heel OR AB heel; MH pressure ulcer; (MH "Skin Ulcer/EP/PC/ET") OR (MH "Foot Ulcer/EP/ET/PC") OR (MH "Pressure Ulcer/EP/ET/PC")
NICE/NHS Evidence	Heel pressure ulcer
PROQUEST Database	(su(pressure ulcer*) OR ti(pressure ulcer*) OR ab(pressure ulcer*) OR su(bedsore*) OR ti(bedsore*) OR ab(bedsore*) OR su(pressure injur*) OR ti(pressure injur*) OR ab(pressure injur*) OR su(decubitus) OR ti (decubitus) OR ab (decubitus)) AND (su(heel*) OR ti(heel*) OR ab(heel*)) AND (su(risk*) OR ti(risk*) OR ab(risk*))
PubMed	(((pressure injur*[Title/Abstract]) AND heel[Title/Abstract])) OR (((((((pressure ulcer*[MeSH Terms]) AND heel[MeSH Terms])) OR ((pressure ulcer*[Title/Abstract]) AND heel[Title/Abstract])) OR ((bedsore*[Title/Abstract]) AND heel[Title/Abstract])) OR ((decubitus ulcer[MeSH Terms]) AND heel[MeSH Terms])) OR ((decubitus ulcer [Title/Abstract]) AND heel[Title/Abstract]))
Scopus	(TITLE-ABS-KEY ("heel pressure ulcer") OR TITLE-ABS-KEY ("heel pressure sore") OR TITLE-ABS-KEY ("heel pressure injury") OR TITLE-ABS-KEY (heel W/3 bedsore) OR TITLE-ABS-KEY (heel W/3 decubitus) AND TITLE-ABS-KEY (risk AND factors))
Trip PRO	Pressure injur* heel; (decubitus heel); (bed sore heel); (pressure sore heel); (pressure ulcer heel)
Web of Science Database	TITLE: (pressure ulcer*) OR TOPIC: (pressure ulcer*) OR TOPIC: (pressure injur*) OR TITLE: (pressure injur*) OR TOPIC: (bedsore*) OR TITLE: (bedsore*) OR TOPIC: (pressure sore*) OR TITLE: (pressure sore*) OR TOPIC: (decubitus) OR TITLE: (decubitus) Indexes = SCI-EXPANDED, SSCI, A&HCI, CPCI–S, CPCI-SSH, ESCI Timespan = All years

and shear' and 'mobility' or a Braden scale 'total score ≤18' emerged as significant in high to moderate quality studies. The MNS was the only other RAT to be considered by one moderate quality study included in this review. RATs are key to PU prevention, as recommended in both national and international guidelines [3,45,46]. In clinical practice there are numerous other validated RATs (for example Waterlow, Ramstadius, and PURPOSE T) available for use, and it is up to clinicians and their employers to decide upon which one to use. Although using validated RATs is recommended, they have also been criticised in the literature for their inability to reduce PUs and have been found to be inferior compared to clinical judgement [47,48]. A possible explanation for their poor performance may include how RATs are implemented in practice. Clinicians may perhaps focus on the final risk score, rather than the individual's risk profile, as identified by the RAT.

Mental status is another potential risk factor that needs further investigation given that one in three older people are living with some form of cognitive impairment (e.g., dementia, Alzheimer's or severe Parkinson's disease), and more than half have severe dementia [49]. These conditions are likely to affect individuals' concordance with HPU preventive strategies. Current national and international guidelines [8,45] recommend offloading both heels to prevent and treat HPUs. Where there are concordance issues, this strategy may be inadequate, and clinicians must use their clinical judgement on which device to use.

Perioperative analgesia (neuraxial blocks or peripheral nerve blocks; PNB) and sensory neuropathy were also considered as potential risk factors for HPU development. Patients exposed to these types of analgesia/anaesthesia are more likely to develop HPUs due to the temporary loss of mobility and peripheral sensation. For example, in pregnant women (although the incidence is rare [50,51]), and older patients the risk of developing HPU is likely to increase whilst the perioperative analgesia is still effective. Regrettably, there is a paucity of high quality evidence to support whether perioperative analgesia or sensory neuropathy contribute to HPU development, and therefore would require further elucidation.

5.1. Strength and limitations

This study has several limitations. Generalisations and inference require caution as the included studies were mostly rated as moderate quality, due to poor study designs, analysis, and reporting. Risk factors identified as independent predictors of HPUs were only examined in one high quality study [31,33]. Clinical and statistical heterogeneity of studies and poor reporting standards affected the ability to quantitatively synthesis any extracted data. A strength of this review is that it incorporated a quality assurance phase, involving a further risk of bias and quality assessment of a random selection of 50% of eligible studies by an independent third reviewer.

Finally, at least 60.0% of all reported HPUs in the eligible studies were either category 1 or 2. Only one study investigated risk factors associated with category 3 or 4. Therefore, it could be argued that the risk factors investigated or identified in this review were associated with the development of superficial HPUs. More severe HPUs are likely to have different aetiology. Furthermore, due to poor reporting and the lack of conclusive evidence, the review was not able to fully quantify the relationship between risk factors and HPU development. More people are living longer with multiple comorbidities, including those affected by cognitive impairment. It is imperative that future research studies focus on investigating risk factors, incidence, and prevalence rate for HPUs. This will help ascertain whether current HPU preventative measures are fit for purpose.

5.2. Implications for practice and future research

- Heel remain the second most common site for developing pressure ulcers, with an estimated incidence rate of at least 17% and 11% prevalence rate. The results of this review suggest that current HPU preventative interventions may require further improvement in order to reduce the incidence rates.

- Several potential risk factors for developing HPU have been identified in this review however only 3 studies were of high quality and involved heterogenous populations. Therefore, due to paucity of high quality evidence, clinicians should continue using their clinical judgement whilst reacting to individual patients' risk when evaluating and implementing HPU prevention strategies.
- This is the first systematic literature review of risk factors associated with development of HPUs, there is lack of high quality studies to inform evidence based practise. Therefore, further research is required to inform clinical practice and reduce harm.

6. Conclusions

This is the first systematic review of observational studies investigating risk factors for HPUs. There is a paucity of high quality evidence on risk factors for developing HPUs, despite being the second most common type of PU. Age, Braden subscales 'friction and shear' and 'mobility', diabetes, vascular disease, malnutrition, mechanical ventilation, perfusion issues and surgery were identified as potential risk factors, after adjusting for other factors. However, further research is required to elucidate these risk factors in addition to well-designed studies to increase the body of evidence. Other risk factors related HPU development may also exist - including age, BMI, haematological measures, comorbidities, and smoking status, which requires further investigation.

Contributions of authors

Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; AD, VS, AM, EP, SJ, ML, MR. Involved in drafting the manuscript or revising it critically for important intellectual content; AD, VS, AM, EP, SJ, ML, MR. Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; AD, VS, AM, EP, SJ, ML, MR. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. AD, VS, AM, EP, SJ, ML, MR.

Funding statement

Research was jointly funded by Birmingham City University and University Hospitals Coventry and Warwickshire, NHS Trust as part of a PhD project.

Declaration of competing interest

I can confirm that all authors have no conflict of interest to declare.

Acknowledgements

The authors thank Mrs Petra Meeson (Librarian-UHCW, NHS trust) for her contribution assisting with literature searches and data management.

Appendix

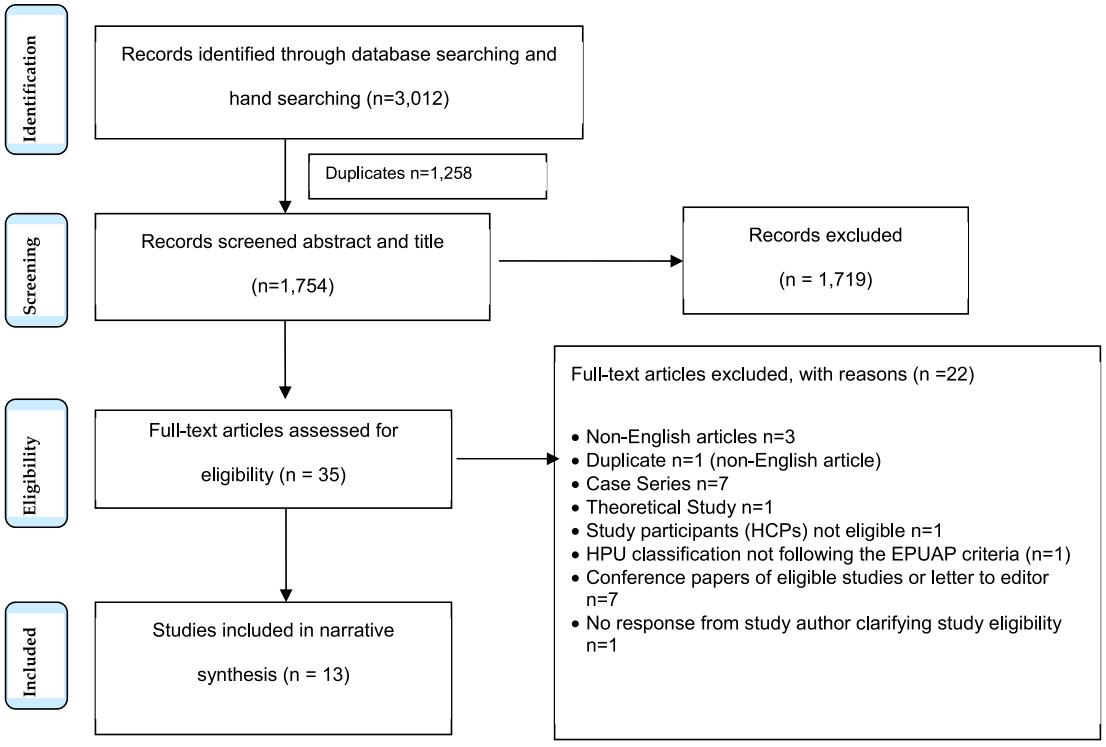

Fig. 1. PRISMA Flow chart

References

[1] NHS Digital CARM. NHS safety thermometer: patient harms and harm free care. Health and Social Care Centre; 2017. March 2016-2017.
[2] Guest JF, Fuller GW, Vowden P, Vowden KR. Cohort study evaluating pressure ulcer management in clinical practice in the UK following initial presentation in the community: costs and outcomes. Br Med J Open 2018;8(7):e021769. Jul.
[3] Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Quick Reference Guide [Internet]. In: Haesler E, editor. European pressure ulcer advisory panel, national pressure injury advisory panel. EPUAP/NPIAP/PPPIA; 2019 [cited 2020 Feb 25]. Available from: https://internationalguideline.com/static/pdfs/Quick_Reference_Guide-10Mar2019.pdf.
[4] NHS Improvement. Pressure ulcers: revised definition and measurement framework. Summary and recommendations [Internet]. Publication code: CG 73/18. London; 2018 [cited 2020 Feb 25]. Available from: https://www.england.nhs.uk/wp-content/uploads/2021/09/NSTPP-summary recommendations.pdf.
[5] Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. Infect Control Hosp Epidemiol 2005;26(3):293–7. Mar.
[6] Theisen S, Drabik A, Stock S. Pressure ulcers in older hospitalised patients and its impact on length of stay: a retrospective observational study: pressure ulcers in elderly hospitalised patients and its impact on length of stay. J Clin Nurs 2012;21(3–4):380–7. Feb.
[7] Gélis A, Dupeyron A, Legros P, Benaïm C, Pelissier J, Fattal C. Pressure ulcer risk factors in persons with SCI: part I: acute and rehabilitation stages. Spinal Cord 2009;47(2):99–107. Feb.
[8] Haesler E, editor. National pressure ulcer advisory Panel, European pressure ulcer advisory Panel, Pan pacific pressure injury alliance. Prevention and treatment of pressure ulcers: clinical practice guideline. Osborne Park, Western Australia: Cambridge Media; 2018.
[9] Vangilder C, Macfarlane GD, Meyer S. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. Ostomy/Wound Manag 2008;54(2):40–54. Feb.
[10] Reed RL, Hepburn K, Adelson R, Center B, McKnight P. Low serum albumin levels, confusion, and fecal incontinence: are these risk factors for pressure ulcers in mobility-impaired hospitalized adults? Gerontology 2003;49(4):255–9.
[11] null Suriadi, Sanada H, Sugama J, Thigpen B, Subuh M. Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit. Nurs Crit Care 2008;13(1):34–43. Feb.
[12] Vanderwee K, Grypdonck M, De Bacquer D, Defloor T. The identification of older nursing home residents vulnerable for deterioration of grade 1 pressure ulcers. J Clin Nurs 2009;18(21):3050–8. Nov.
[13] Nijs N, Toppets A, Defloor T, Bernaerts K, Milisen K, Van Den Berghe G. Incidence and risk factors for pressure ulcers in the intensive care unit. J Clin Nurs 2009;18(9):1258–66. May.
[14] Kaitani T, Tokunaga K, Matsui N, Sanada H. Risk factors related to the development of pressure ulcers in the critical care setting. J Clin Nurs 2010;19(3–4):414–21. Feb.
[15] Primiano M, Friend M, McClure C, Nardi S, Fix L, Schafer M, et al. Pressure ulcer prevalence and risk factors during prolonged surgical procedures. Assoc Perioper Rigestered Nurses J 2011;94(6):555–66. Dec.
[16] Anrys C, Van Tiggelen H, Verhaeghe S, Van Hecke A, Beeckman D. Independent risk factors for pressure ulcer development in a high-risk nursing home population receiving evidence-based pressure ulcer prevention: results from a study in 26 nursing homes in Belgium. Int Wound J 2019;16(2):325–33. Apr.
[17] [Internet] Børsting TE, Tvedt CR, Skogestad IJ, Granheim TI, Gay CL, Lerdal A. Prevalence of pressure ulcer and associated risk factors in middle- and older-aged medical inpatients in Norway. Feb [cited 2021 Sep 25] J Clin Nurs 2018;27:3–4. Available from: https://onlinelibrary.wiley.com/doi/10.1111/jocn.14088.
[18] Gefen A. The biomechanics of heel ulcers. J Tissue Viability 2010;19(4):124–31. Nov.
[19] Luboz V, Perrier A, Bucki M, Diot B, Cannard F, Vuillerme N, et al. Influence of the calcaneus shape on the risk of posterior heel ulcer using 3D patient-specific biomechanical modelling. Ann Biomed Eng 2015;43(2):325–35. Feb.
[20] Kottner J, Raeder K, Halfens R, Dassen T. A systematic review of interrater reliability of pressure ulcer classification systems: *Pressure ulcer classifications*. J Clin Nurs 2009;18(3):315–36. Feb.
[21] Coleman S, Gorecki C, Nelson EA, Closs SJ, Defloor T, Halfens R, et al. Patient risk factors for pressure ulcer development: systematic review. Int J Nurs Stud 2013;50(7):974–1003. Jul.
[22] Offord DR, Kraemer HC. Risk factors and prevention. Evid Base Ment Health 2000;3(3):70. Aug 1.
[23] Moher D, Liberati A, Tetzlaff J, Altman DG, for the PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Jul 21 Br Med J 2009;339(jul21 1). b2535–b2535.
[24] Clegg R, Palfreyman S. Elevation devices for the prevention of heel pressure ulcers: a review. Br J Nurs 2014;23(Sup20):S4–11. Nov.
[25] [Internet]. version 6.2. Cochrane. In: Higgins J, Thomas J, Chandler J, Cumpston M, Page M, Welch V, editors. Cochrane handbook for systematic reviews of interventions; 2021. Available from: www.training.cochrane.org/handbook.
[26] Hayden JA, van der Windt DA, Cartwright JL, Côté P, Bombardier C. Assessing bias in studies of prognostic factors. Ann Intern Med 2013;158(4):280. Feb 19.
[27] Altman DG. Systematic reviews of evaluations of prognostic variables. In: Egger M, Smith GD, Altman DG, editors. Systematic reviews in health care [internet]. London, UK: BMJ Publishing Group; 2001 [cited 2021 Sep 24]. pp. 228–47. Available from: https://onlinelibrary.wiley.com/doi/10.1002/9780470693926.ch13.
[28] von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Int J Surg 2014;12(12):1495–9. Dec.
[29] Tourtual DM, Riesenberg LA, Korutz CJ, Semo AH, Asef A, Talati K, et al. Predictors of hospital acquired heel pressure ulcers. Oct Ostomy/Wound Manag 1997;43(9):24–8, 30, 32-34 passim.
[30] Delmore B, Lebovits S, Suggs B, Rolnitzky L, Ayello EA. Risk factors associated with heel pressure ulcers in hospitalized patients. J Wound, Ostomy Cont Nurs 2015;42(3):242–8. May.
[31] Delmore B, Ayello EA, Smith D, Rolnitzky L, Chu AS. Refining heel pressure injury risk factors in the hospitalized patient. Adv Skin Wound Care 2019;32(11):512–9. Nov.
[32] Athlin Å Muntlin, Engström M, Gunningberg L, Bååth C. Heel pressure ulcer, prevention and predictors during the care delivery chain – when and where to take action? A descriptive and explorative study. Scand J Trauma Resuscitation Emerg Med 2016;24(1):134. Dec.
[33] Manderlier B, Van Damme N, Verhaeghe S, Van Hecke A, Everink I, Halfens R, et al. Modifiable patient-related factors associated with pressure ulcers on the sacrum and heels: secondary data analyses. J Adv Nurs 2019;75(11):2773–85. Nov.
[34] Bååth C, Engström M, Gunningberg L, Athlin ÅM. Prevention of heel pressure ulcers among older patients – from ambulance care to hospital discharge: a multi-centre randomized controlled trial. Appl Nurs Res 2016;30:170–5. May.
[35] Duncan F, Haigh C, Bailey S. An analysis of epidural related pressure sores in a specific patient population. Acute Pain 2003;5(1):11–5. Aug.
[36] Edwards JL, Pandit H, Popat MT. Perioperative analgesia: a factor in the development of heel pressure ulcers? Br J Nurs 2006;15(Sup1):S20–5. Mar.
[37] Demers CA. Using the braden scale to predict heel pressure ulcer development IN hospitalized patients with peripheral arterial disease, vol. 42. ProQuest Inf Learn Co; 2005.
[38] Campbell KE, Woodbury MG, La T. Heel ulcer incidence following orthopedic surgery: a prospective, observational study. Ostomy/Wound Manag 2010;8.
[39] Clegg A, Kring D, Plemmons J, Richbourg L. North Carolina wound nurses examine heel pressure ulcers. J Wound, Ostomy Cont Nurs 2009;36(6):635–9. Nov.
[40] Gaubert-Dahan M-L, Castro-Lionard K, Blanchon M-A, Fromy B. Severe sensory neuropathy increases risk of heel pressure ulcer in older adults. J Am Geriatr Soc 2013;61(11):2050–2. Nov.
[41] Meaume S, Faucher N. Heel pressure ulcers on the increase? Epidemiological change or ineffective prevention strategies? J Tissue Viability 2008;17(1):30–3. Feb.
[42] Twilley H, Jones S. Heel ulcers – pressure ulcers or symptoms of peripheral arterial disease? An exploratory matched case control study. J Tissue Viability 2016;25(2):150–6. May.
[43] Song JW, Chung KC. Observational studies: cohort and case-control studies. Plast Reconstr Surg 2010;126(6):2234–42. Dec.
[44] Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction—GRADE evidence profiles and summary of findings tables. J Clin Epidemiol 2011;64(4):383–94. Apr.
[45] NICE. Pressure ulcers: prevention and management [Internet]. Royal College of Physicians of London; 2014. Available from: https://www.rcplondon.ac.uk/guidelines-policy/pressure-ulcers-prevention-and-management-nice-guideline.
[46] National Pressure Ulcer Advisory Panel. European pressure ulcer advisory Panel, Pan pacific pressure injury alliance, haesler E. Prevention and treatment of pressure ulcers: etiology and risk factors – an extract from the clinical practice guideline. Osborne Park, Western Australia: Cambridge Media; 2014.
[47] Moore ZE, Patton D. Risk assessment tools for the prevention of pressure ulcers. Cochrane Database Syst Rev [Internet]. 2019 Jan 31 [cited 2021 Sep 25]. Cochrane Wounds Group; 2019. p. 1. https://doi.org/10.1002/14651858.CD006471.pub4. Available from:.
[48] Pancorbo-Hidalgo PL, Garcia-Fernandez FP, Lopez-Medina IM, Alvarez-Nieto C. Risk assessment scales for pressure ulcer prevention: a systematic review. J Adv Nurs 2006;54(1):94–110. Apr.
[49] Wittenberg R, Hu B, Barraza-Araiza L, Rehill A. Care policy and evaluation centre, London School of Economics and Political Science. :79.
[50] Armstrong L, Stevenson K, Hignett R. Pressure sores in labouring women: a national OAA approved survey. Int J Obstet Anesth 2013;22:S46.
[51] NHS resolution. Did-you-know-Maternity-Pressure-Ulcers.pdf [Internet], cited 2020 Sep 28]. Available from: www.resolution.nhs.uk; 2018. https://resolution.nhs.uk/wp-content/uploads/2018/10/Did-you-know-Maternity-Pressure-Ulcers.pdf.