

Factors associated with medical device-related pressure ulcers occurrence in hospital setting: a systematic review protocol



Review

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Abstract: Objective: To identify the principal factors associated with the occurrence and development of medical device-related pressure injuries (MDRPI) in adults admitted to hospitals. MDRPI, a peculiar subtype of pressure injuries (PI), result from the pressure exerted by devices (or their fixation systems) applied for diagnostic and therapeutic purposes. MDRPI represent a serious problem for patients and healthcare systems. Understanding potential risk factors is an important step in implementing effective interventions.

Methods: In this study, we will perform a systematic review; if possible, also a meta-analysis will be performed. The review will follow the preferred reporting items for systematic reviews and meta-analyses (PRISMA) reporting guidelines for systematic reviews. A rigorous literature search will be conducted both in electronic databases (Medline/PubMed, Embase, CINAHL, Web of Science, Scopus, Cochrane Library) to identify studies published since 2000 and in gray literature for unpublished studies. Pairs of researchers will identify relevant evidence, extract data, and assess risk of bias independently in each eligible study. Factors associated with the occurrence of MDRPI are considered the primary outcome. Secondary outcomes are prevalence and incidence of MDRPI, length of hospital stay, infections, and death. The evidence will be synthesized using the GRADE methodology.

Results: Results are not currently available as this is a protocol for a systematic review.

Conclusions: This systematic review will identify evidence on risk factors for developing MDRPI. We are confident that the results of this review will help to improve clinical practice and guide future research.

Keywords: incidence • medical devices • pressure injury • pressure ulcer • prevalence • risk factor

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1. Introduction

Pressure injuries (PI) are localized areas of damage involving the skin and/or the underlying tissues, generally over prominent bones. PI are primarily caused by intense and prolonged pressure or pressure in conjunction with friction and moisture.¹ Reduced mobility, advanced age, poor nutritional state, sedation, impaired perfusion, humidity, comorbidities, and the use of certain drugs are the significant risk factors for PI occurrence.² PI are a common complication in bedridden patients with an incidence rate ranging from 0.4% to 38% in acute care settings, from 2.2% to 23.9% in long-term care, and from 0% to 17% in home care.³ The term hospital-acquired pressure injuries (HAPI) refers to those PI arising during hospital stay. HAPI are a relevant indicator of the quality of nursing care⁴ and a significant patient safety issue since their negative impact on quality of life, infection risk, length of stay, and mortality.^{5–7} Moreover, HAPI contribute to increased health care expenditure with an estimated annual cost of \$9.1–\$11.6 billion in US⁸ and represent approximately 3%–5% of the total health care spending in Italy, Spain, and UK.⁹ Medical device-related pressure injuries (MDRPI), a peculiar subtype of HAPI, result from the pressure exerted by devices (or their fixation systems) applied for diagnostic and therapeutic purposes and mirror the shape and the location of the device itself.¹ MDRPI account for nearly a third of cases of HAPI^{10–12} and may interest the skin, the mucous membranes, or both (i.e. mouth/nasal passages, urethral meatus).¹ MDRPI may occur on any tissue subjected to the pressure and the humidity caused by a medical device, regardless, they are more likely to be located in “atypical” anatomical sites including the neck, face, ear, nasal bridge, nostrils, or buccal rima.^{11,12} MDRPI severity is ranked according to the National Pressure Ulcer Advisory Panel (NPUAP) classification while mucosal PU are considered unstageable.^{1,13} Skin breakdown related to medical devices is described mainly in critical care patients (incidence 0.9%–41.2%, prevalence 1.4%–21%),³ but may also occur in general wards, trauma centers, surgical units, long-term rehabilitation settings, and pediatric units (overall estimated pooled incidence and prevalence respectively 12% and 10%).¹⁴ MDRPI are often underreported or not timely recognized as shown in Apold et al.’s¹⁵ and Kim et al.’s¹⁶ contributions, in which nearly 75% of ulcers were diagnosed at very late stages (3, 4, or unstageable). These data demonstrate the need for knowledge building, raising awareness, and incorporating evidence-based acquisitions into clinical practice to reduce MDRPI burden. The prevention of MDRPI is complicated, as medical equipment is often an essential part of the treatment.

In fact, a recent NPUAP consensus statement defined some situations in which such MDRPI may be unavoidable: (a) when it is medically contraindicated to adjust, relocate, or pad underneath a therapeutic device; (b) when a life-sustaining vascular access or other medical device precludes turning and positioning; (c) when underlying edema or uncontrollable moisture under device compromises tissue tolerance to pressure/shear forces.¹⁷ Two recent systematic reviews with meta-analysis synthesized the incidence and prevalence of the problem among hospitalized adult and pediatric patients and sought to identify the medical devices mostly associated with the risk of MDRPI.^{14,18} However, the results achieved should be interpreted with caution primarily owing to the methodological limitations of the existing literature and the heterogeneity between the analyzed works.¹⁹ The literature examining risks for MDRPI remains sparse and reported risk factors vary between studies. To guide effective evidence-based interventions aimed at reducing MDRPI, it is important to increase knowledge and understanding of potential risk factors.

Given these premises, we decided to undertake a new systematic review of the existing literature regarding the phenomenon of MDRPI in hospitalized adult patients. Our principal purpose is to retrieve evidence-based acquisitions regarding MDRPI onset and possible risk factors. This work’s strength relies on an extensive and in-depth search of available scientific literature, including dissertations, theses, and conference papers. The inclusion of works irrespective of the language and country of publication allows us to overcome external validity limitations. Moreover, the rigorous methodology we are going to use warrants the retrieval of the best results for the development of clinical practice recommendations.

Primary research question is:

- What factors are associated with the occurrence and development of MDRPI in adults admitted to hospitals?

Secondary research questions are:

- What is the extent of the problem (prevalence/incidence) considering all medical devices, and, if it is possible, distinguish each device separately?
- What is the impact of MDRPI on critical outcomes including length of stay in hospital, infections, and death?
- What are the main characteristics of MDRPI (severity, anatomical location) considering all medical devices, and, if it is possible, distinguish each device separately?

The primary research question was then summarized and defined according to the PECO framework,²⁰ as shown in Table 1.

2. Methods

2.1. Protocol and registration

This study protocol is reported according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA-P).²¹ This protocol is prospectively registered in PROSPERO database under number CRD 42020167860.

2.2. Dissemination and ethics

Since this work is a systematic review, without human involvement, an ethical approval by the local ethics committee is not required. Findings will be disseminated through peer-reviewed publications, conferences, congresses, and symposia.

2.3. Eligibility criteria

2.3.1. Studies

We intend to consider all cross-sectional, case control, cohort studies, and randomized controlled trials/clinical trials/pre-post studies where they report interesting results regarding MDRPI incidence, prevalence, and possible risk.

2.3.2. Participants

Contributions involving adult patients admitted to hospitals with any type of medical equipment in use, except for beds or gurney mattresses (mats for specific therapeutic purposes, i.e. cooling systems, will be included). No restrictions are applied based on clinical conditions, current pathologies, device in use, and geographical location.

Population	Hospitalized adult patients, aged 18 years or older, with a medical device in use for preventive, diagnostic, or therapeutic purposes, applied during hospitalization.
Exposure	All factors potentially associated with the development of MDRPI during hospital stay, whether related to the patient (sociodemographic, anamnestic, clinical), treatments in progress, clinical setting (type of ward, intensity of care, time of hospitalization), the device itself and the ways in which it is managed.
Control	Not applicable
Outcome	Injuries associated with medical devices.

Note: MDRPI, medical device-related pressure injuries.

Table 1. PECO.

2.3.3. Interventions

Exposure to any factor associated with the occurrence and development of MDRPI, including patient characteristics (socio-demographic data, anamnesis, clinical conditions, drugs); clinical settings (intensity of care, hospital ward, length of stay, organization of care in general); type of device and device management.

2.3.4. Outcome measures

Primary outcomes include identifying the principal factors associated with the occurrence of MDRPI in adults admitted to acute care hospitals. Secondary outcomes consist describing the prevalence and incidence of MDRPI considering all medical devices, and, if it is possible, distinguishing each device separately; outlining the MDRPI's impact on critical outcomes including length of stay in the hospital, infections, and death; describing the main characteristics of MDRPI (severity, anatomical location) considering all medical devices, and, if it is possible, distinguishing each device separately.

2.4. Searching methods

Multiple search strategies will be employed to retrieve primary research studies meeting the predetermined selection criteria. Medline (through PubMed), Excerpta Medica database (Embase), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science, Scopus, and Cochrane Library are searched from 1 January 2000 to identify relevant studies. A preliminary search strategy is described in Table 2.

In order to reduce the publication bias, several grey literature databases are searched as well, such as the Turning Research Into Practice (TRIP) database, Google Scholar, DART-Europe E-Thesis Portal, ProQuest, Mednar, EBSCO theses and dissertations, and Open Access theses and dissertations (OATD). Bibliographical references of the potentially relevant

#1	(injury* OR lesion* OR wound* OR sore* OR Ulcer*) AND pressure
#2	"skin injury medical device related" OR "mucosal injury medical device related" OR "pressure medical device related" OR "MDRPI" OR "MDRPU" OR "HAPI" OR "Medical device" OR "medical device related"
#3	prevalence OR incidence OR rate OR exposition OR risk
#4	#1 AND #2 AND #3

Note: HAPI, hospital-acquired pressure injuries; MDRPI, medical device-related pressure injuries.

Table 2. Preliminary search strategy in PubMed.

contributions and the systematic reviews on MDRPI occurrence are screened to complete the record research. Corresponding authors are contacted in case of unavailability of full texts or to retrieve additional information regarding potentially relevant conference papers or abstracts.

2.5. Data collection and analysis

2.5.1. Screening of the studies

Initial screening of potentially relevant contributions is based on the information contained in their titles and abstracts and is carried out by two independent authors. Screening of full texts against eligibility criteria is conducted by two independent authors. Any disagreements are solved by a third researcher with expertise in methodology. Cohen's kappa is used to measure agreement between authors.²² Zotero bibliographic management software (Creative Commons Attribution-ShareAlike 4.0 International License CC-BY-SA 4.0) is utilized to maintain a database of references related to the systematic review, store all references selected for the systematic review, remove duplicate citations, store all discarded references, create citations and bibliography when writing up the results of the systematic review. The details of the selection process are shown in the PRISMA 2020 flow diagram (Figure 1).²³

2.5.2. Data extraction

Two authors perform the data extraction according to the predefined data extraction form. Divergences between two authors are resolved by a third author to reach consensus if necessary. The extracted data consists of the first author, title, time of publication, information regarding the study (host institution of the study, study design, study aim), patient characteristics (sample size, age, gender, clinical setting, type of department and origin, and type of medical device), study methods (random methods, blind, allocation, etc.), outcome measurements (primary, secondary, and safety outcomes), ethical information, and conflict of interest. When there is unclear or insufficient information, primary authors are contacted. If such information cannot be inquired, we analyze the available data.

2.5.3. Risk of bias assessment

The assessment of risk of bias of individual studies is carried out using Joanna Briggs Institute checklists for cross-sectional, case control, cohort studies, quasi-experimental studies (nonrandomized experimental studies), and randomized controlled trials.²⁴ Risk of bias is summarized for each resulting MDRPI-associated factor as well. Two independent authors conduct this phase of the review process, with any disagreement solved by consensus mediated by a third researcher.

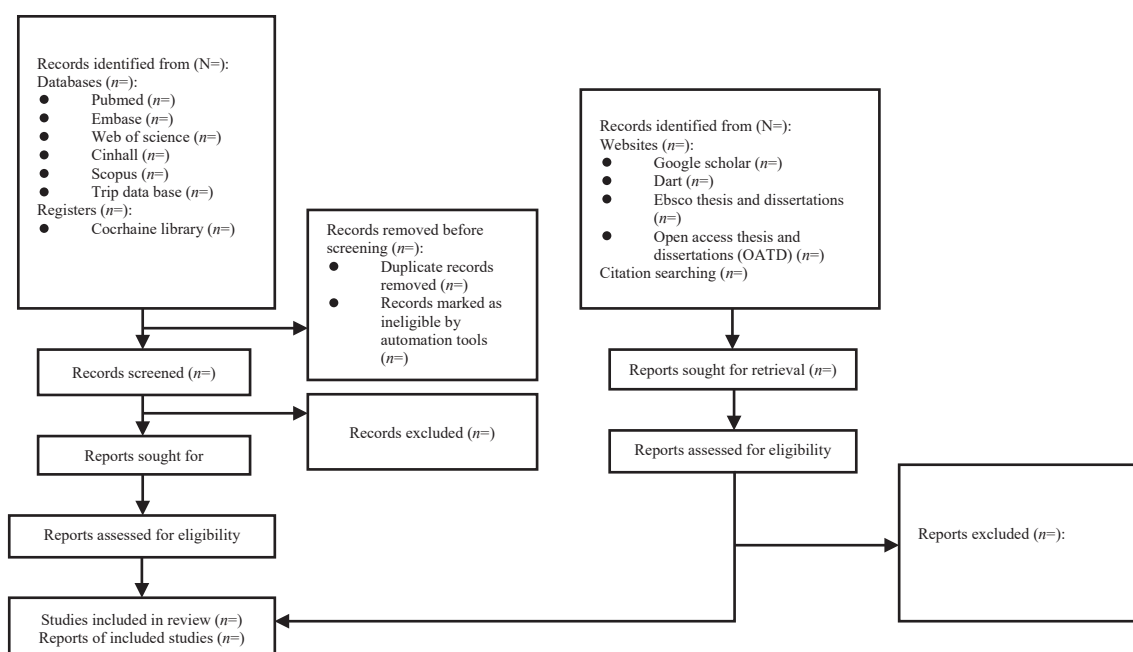


Figure 1. Search, screening, and selection of articles to include in the review.
Note: OATD, open access theses and dissertations.

2.5.4. Data synthesis

A narrative synthesis is conducted for all included studies. Pooled effect size and 95% confidence intervals for each MDRPI-associated factor are estimated. Heterogeneity between studies is assessed with forest plot and I^2 statistics.²⁵ In case of moderate to severe heterogeneity, subgroup analysis may be attempted; otherwise, random effect models (REM) may be generated. Fixed effect models are utilized in case of limited heterogeneity.

2.5.5. Subgroup analysis

We conduct subgroup analysis according to the different study or patient exposure and outcome measurements.

2.5.6. Publication bias

The presence of publication bias is evaluated with a funnel plot and Egger's test.²⁶

2.5.7. Sensitivity analysis

We conduct a sensitivity analysis to identify whether the conclusions are robust in the review according to the following criteria: sample size, heterogeneity qualities, and statistical model (REM or fixed-effects model).

2.5.8. Confidence in cumulative evidence

The strength of the body of evidence is assessed following GRADE methodology.²⁷ For each factor associated with MDRPI, overall risk of bias, inconsistency, indirectness, imprecision, and publication bias are considered.

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The magnitude of effect size, confounding impact, and dose-response gradient are also evaluated. This phase is carried out by the whole review working group. Final recommendations are drawn up after valuable counseling by experts in wound care, vascular access management, and critical and surgical care nursing.

3. Discussion and conclusion

Our protocol presents the methodological approach of a systematic review that will retrieve possible risk factors related to the occurrence of MDRPI through evidence-based acquisitions. The strengths of this work are based on an extensive and thorough search of the available scientific literature, including dissertations, theses, and conference papers. The inclusion of papers irrespective of language and country of publication allows us to overcome the limitations of external validity. In addition, the rigorous methodology we use will ensure the retrieval of the best results for the development of clinical practice recommendations. The use of systematic methods in following the PRISMA-P guidelines and the pre-specification of methods in a protocol will also be an advantage for the systematicity and transparency of the review. Therefore, we are confident that the results of this review will improve the quality of care provided and provide directions for further research.

Ethical approval

Ethical issues are not involved in this paper.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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