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Incidence of medical device-related pressure injuries: a systematic review and meta-analysis

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Corresponding author:

Ning Zhang

904193448@qq.com

Author Affiliation:

Department of ICU, The 305 Hospital of PLA, Beijing 100017, China.

Zhang, N; Li, YN; Li, XG; Li, FF; Jin, ZF; Li, T; Ma, JF.

ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 March 2024 and was last updated on 26 March 2024.

INTRODUCTION

Review question / Objective Medical device related pressure injuries (MDRPI) is common in critically ill patients and associated with negative clinical outcomes and elevated healthcare expenses. We aim to estimate worldwide incidence of MDRPI and explore associated factors through systemic review and meta-analysis. Our meta-analysis provides an updated assessment of the incidence of MDRPI since 2010, aiming to offer healthcare workers a more comprehensive understanding of MDRPI burden.

Rationale The PubMed, Web of Science, Cochrane Library, and Ovid EMBASE databases were systematically queried to identify relevant

studies published up until January 30th, 2024. Studies were included if they provided data on the incidence or prevalence of medical device related pressure injuries (MDRPI). Random-effect models were utilized to calculate the overall or domain-specific aggregated estimates of MDRPI. A meta-regression analysis was additionally performed to investigate the heterogeneity among studies.

Condition being studied With the continuous advancement of medical devices, pressure injuries related to medical equipment have gradually become an issue that cannot be ignored. Although medical devices can enhance treatment outcomes and facilitate patient survival, it is important to acknowledge that every device carries the inherent risk of pressure sore development. Medical device

related pressure injuries (MDRPI) are pressure ulcers that result from the use of devices designed and applied for diagnostic or therapeutic purposes. The morphology of the injury site typically corresponds to the configuration of the medical device. Common medical devices that cause MDRPI include endotracheal tubes, urinary catheters, nasogastric tubes and oxygen face masks. Enhanced susceptibility to pressure ulcers related to medical devices can arise from compromised sensory perception, the presence of moisture underneath the device, insufficient blood circulation, modified tissue tolerance levels, suboptimal nutritional status, and edema.

MDRPI not only reduces the quality of life of patients and increases the medical cost of patients, but also consumes the resources of hospitals. Every year, an estimated 2.5 million patients in the United States receive medical treatment for pressure injuries, resulting in costs 9.1 - 11.6 billion and an annual average of over 17,000 lawsuits are associated with these wounds. It may result in extended hospitalization periods, heightened incidence of complications, and potentially fatal outcomes. Due to the crucial role of numerous medical devices in the treatment process, refraining from utilizing medical equipment is impractical, thereby further complicating MDRPI treatment. Hospital lengths of stay, readmission rates, and hospital charges exhibit higher magnitudes in individuals who develop a pressure ulcer compared to those who remain free from ulcers. Nursing interventions for pressure injury also face serious challenges. The expertise and disposition of nurses regarding the MDRPI may influence the implementation of preventive measures in clinical practice. Hence, it is necessary for medical staff to understand the incidence and risk factors of MDRPI.

Medical device-related stress injuries occur primarily in intensive care units (ICU), but also in inpatient units such as trauma centers and pediatrics. A study conducted in Australia revealed that the pooled incidence of MDRPI can reach as high as 27.9%, with a significant proportion of cases (68%) occurring within ICU. The Norton Scale, Waterlow Scale, and Braden Scale are commonly used by healthcare providers to assess risk factors associated with MDRPI, but the results are not satisfactory.

A review conducted in 2019 tentatively revealed a incidence of MRDPI at approximately 12%. We believed that it is necessary to update the incidence in recent years and assessing the temporal trends in the incidence of MDRPI will enhance our comprehension of the detrimental impact and disease burden associated with

MDRPI. Here we conducted a systematic review and meta-analysis to estimate the worldwide incidence of MDRPI and summarize the risk factors of higher incidence.

METHODS

Search strategy We conducted the literature search in renowned databases including PubMed, Web of Science, Cochrane Library, and Ovid EMBASE until January 30th, 2024. The keywords were utilized as follows: ("Pressure Ulcer" [All Fields] or "Bedsore" [All Fields] or "Pressure Injury" [All Fields] or "Pressure Sore" [All Fields] or "Decubitus Sore" [All Fields] or "Decubitus Ulcer" [All Fields]) AND ("medical device"[All Fields] or "device-related" [ALL Fields] OR "medical device related" [ALL Fields] or "medical device-related" [ALL Fields]) AND ("prevalence" [ALL Fields] or "prevalence rate" [ALL Fields] or "incidence" [ALL Fields] or "incidence rate" [ALL Fields] or "occurrence" [ALL Fields] or "frequency" [ALL Fields]) NOT ("Meta-Analysis" [Publication Type] or "Review" [Publication Type] or "Randomized Controlled Trial" [Publication Type]). Only studies published in the English language met the eligibility criteria for inclusion in our comprehensive review.

Participant or population We involved populations spanning all age groups, including both adults and children.

Intervention NA.

Comparator NA.

Study designs to be included Observational study.

Eligibility criteria After eliminating duplicates, all full-text articles were retrieved and screened independently by two authors (Ning Zhang and Yanan Li) to determine their eligibility for inclusion in this systematic review. The primary outcome was the incidence of MDRPI, which was defined by National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP & EPUAP). Since the first edition of the guideline was published in 2009, to ensure the uniformity of the outcome of the included articles, all the included studies' publication time was after the guideline' first edition. Studies were considered eligible for inclusion in this review if they provided data on the incidence or prevalence of pressure injuries related to medical devices. We encompassed studies conducted across diverse healthcare settings and facilities, without any restrictions based on facility

type, and involving populations spanning all age groups, including both adults and children. We excluded the studies as follows: (1) Only the number of injuries was recorded, not the number of patients; (2) Experimental studies examining the efficacy of devices in preventing or managing pressure injuries, including randomized controlled trials (RCTs) and quasi-experiments; (3) Evaluation of research with low literature quality; (4) Unable to obtain the full text; (5) the same sample had already been used in an included study.

Information sources PubMed, Web of Science, Cochrane Library, and Ovid EMBASE.

Main outcome(s) We included 28 observational studies on 117624 patients in the meta-analysis. The overall incidence of MDRPI was 19.3% (95% confidence interval (CI) 13.5% - 25.2%). The incidence of MDRPI in Europe, North America, Asia, South America, and Oceania were 17.3% (95% CI 12.7% - 21.9%), 3.6% (95% CI 0.0% - 8.5%), 21.9% (95% CI 14.3% - 29.6%), 48.3% (95% CI 20.8% - 75.7%), 13.0% (95% CI 5.0% - 21.1%), respectively ($p < 0.01$). Multivariate meta-regressions revealed South America, and special inpatient (critically ill patient, etc.) were independently associated with higher MDRPI incidence.

Quality assessment / Risk of bias analysis Quality assessment entailed evaluating the risk of bias for each included study using the Newcastle-Ottawascale, a validated tool for assessing quality in observational studies.

Strategy of data synthesis A random-effects model was utilized to estimate the incidence of MDRPI and its 95% confidence interval. To assess the impact of moderator variables on heterogeneity, we employed a stratified approach for pooling outcome measures and conducted subgroup analyses. The moderating factors included study year, sex, continent, country, and population source. I^2 values exceeding 50% indicate substantial heterogeneity. All statistical analyses were carried out using the meta and metafor package in R statistics (version 4.2.2). Statistical significance was attributed to p-values less than 0.05.

Subgroup analysis Subgroup analyses and meta-regressions were performed to evaluate heterogeneity between studies based on study year, geographic locations, gender, and population source.

Sensitivity analysis Sensitivity analyses were conducted by systematically removing each study to explore its effect on MDRPI incidence.

Language restriction Only studies published in the English language met the eligibility criteria for inclusion in our comprehensive review.

Country(ies) involved China.

Keywords Medical device related pressure injury; Incidence; Factors.

Contributions of each author

Author 1 - Ning Zhang.

Email: 904193448@qq.com

Author 2 - Yanan Li.

Email: 775164880@qq.com

Author 3 - Xiaogang Li.

Email: xiaoganglee@sina.com

Author 4 - Fangfang Li.

Email: 412955615@qq.com

Author 5 - Zhaofeng Jin.

Email: mmumedic@163.com

Author 6 - Tian Li.

Author 7 - Jinfu Ma.

Email: 26637390@qq.com