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Review Article

The prevalence of bleeding after percutaneous coronary interventions: A systematic review and meta-analysis

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ABSTRACT

Background: Bleeding is a common complication associated with percutaneous coronary intervention (PCI). The aim of this study was to determine the prevalence of bleeding after PCI through a systematic review and meta-analysis.

Methods: The systematic review and meta-analysis covered the period from 1989 to 2023. Multiple databases, including Embase, PubMed, Scopus, Web of Sciences (WoS), MagIran, Scientific Information Database (SID), and Google Scholar, were searched using validated keywords with MeSH and Emtree. The I^2 index was used to check for heterogeneity among studies.

Results: The review of 8 studies, with a sample size of 397,298 participants, showed high heterogeneity (I^2: 97.8 %). Therefore, the random effects method was used to analyze the results. The prevalence of bleeding after intervention in percutaneous coronary arteries was reported to be 4.4 % (95%CI: 2–9.1).

Conclusion: This meta-analysis showed a significant prevalence of bleeding after PCI, highlighting the need for health policymakers to pay more attention to the complications associated with PCI. Interventional cardiologists should consider the effective factors in these bleeding and how to treat and control them due to the importance of this complication.

1. Background

Coronary artery disease (CAD) is a serious health problem worldwide and the most significant cardiovascular disorder.[1] It is estimated that by 2025, cardiovascular disorders will cause nearly 7.8 million premature CVD deaths.[1–3] The most important risk factors for coronary artery diseases are high cholesterol, high blood fat, smoking, high blood pressure, diabetes mellitus, obesity, and inactivity.[4–6] Therefore, timely diagnosis and treatment of coronary artery disease is essential to reduce mortality and complications in patients.[6] PCI is a non-surgical method used to treat coronary artery stenosis.[7–12]

Local side effects can vary from painful hematomas that heal on their own to life-threatening retroperitoneal bleeding.[13–15] Retroperitoneal bleeding can occur if access is too proximal, while hematoma, false aneurysm, and arteriovenous fistula can occur if access is too distal (relative to the inguinal fold).[16,17] Bleeding is the most common non-cardiac complication in patients who undergo percutaneous coronary intervention and is associated with increased risks of death, myocardial infarction (MI), stroke, and longer hospital stays.[18,19] The difference in the amount of bleeding after PCI is related to the access site (radial versus femoral), the skill of the operator and the way of prescribing antiplatelet and anticoagulant drugs. Given the high prevalence of cardiovascular disorders that require percutaneous coronary interventions and the fact that bleeding is the most common complication caused by this procedure, it is important to conduct a general statistical study of the prevalence of bleeding after PCI. Different studies around the world have reported the prevalence and different and heterogeneous values of the prevalence of bleeding after PCI, and according to the

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growing trend of the prevalence of cardiovascular complications and the need for intervention in this field, as well as to homogenize the information and values of the reported prevalence. The aim of this study is a systematic review and meta-analysis of the overall prevalence of bleeding after PCI in the world and to reduce the heterogeneity of studies.

2. Methods

The present study was conducted using the systematic review and meta-analysis methods in accordance with the PRISMA 2020 guidelines (http://www.prisma-statement.org/), including the steps of identification, screening, eligibility, and inclusion. In order to minimize potential errors, inaccuracies, and publication bias, all stages of searching, evaluating, identifying, and selecting articles, as well as extracting data, were independently carried out by two researchers. In the event of discrepancies, a supervisor was consulted to facilitate consensus.

2.1. Identification of studies

To identify relevant records for the research question - "What is the prevalence of bleeding after PCI?" - we conducted a comprehensive search of both Persian information databases, including Scientific Information Database (SID) and MagIran, and international databases such as PubMed, Embase, Scopus, and Web of Science (WoS). The search strategy in each database was determined by using validated keywords and Medical Subject Headings (MeSH) for PubMed and Emtree (Elsevier's authoritative life science thesaurus) for Embase. The keywords were combined using OR and AND operators to identify all relevant studies.

The search was not restricted by language or time frame and included all relevant articles available until February 2023 (1989 to 2023). In order to ensure the completeness of the search, additional records were identified by manual searching in the Google Scholar search engine and reviewing the reference lists of retrieved papers (supplementary).

2.2. Inclusion criteria

Original research articles, Observational articles (cross-sectional studies, cohort studies, case-control studies.), Randomized clinical trials, Access to the full text of the article, Studies that reported the percentage or frequency of bleeding after PCI.

3. Exclusion criteria

Qualitative studies, case series, case reports, Unavailability of the full text of the article after three emails to the corresponding author of the study, Repeated and overlapping studies identified in different databases.

3.1. Selection process of studies

Search strategies were devised for each database, and all retrieved records were imported into EndNote X8. The first step was to remove all duplicate and overlapping studies from different databases. Next, the names of the authors, institutions, and journals were removed from all studies. The titles and abstracts of studies were reviewed, and irrelevant studies were excluded. The full texts of the remaining records were carefully reviewed, following the inclusion and exclusion criteria, and irrelevant studies were excluded. Finally, articles that met all inclusion criteria were subjected to a qualitative assessment.

3.1.1. Quality assessment

A checklist developed for observational studies was used to assess the quality of the articles. The checklist used was the Strengthening the Reporting of Observational Studies in Epidemiology Checklist (STROBE), comprising six categories, including title, abstract, introduction, methods, results, and discussion and containing 32 items. Articles with a score of 16 or higher were considered to be of good and moderate methodological quality, and articles with a score below 16 were considered to be of poor methodological quality and therefore excluded from the study.

3.2. Data extraction

Two researchers extracted the data using a previously created checklist. The checklist consisted of the first author's name, year of publication, study location, sample size, categories and the average age of participants, the prevalence of bleeding after PCI, and study instruments.

3.3. Statistical analysis

The results extracted from this study were entered into the Comprehensive Meta-Analysis Software Version 2, and the heterogeneity of the studies was assessed using the I^2 test. To investigate publication bias, the Egger test was conducted at a significance level of 0.05, along with the use of the funnel plot.

4. Results

This systematic review and meta-analysis of studies evaluated the prevalence of bleeding after PCI according to the PRISMA guidelines. A total of 1879 articles were searched across multiple databases, and an additional record was identified through manual search, which was transferred to the reference management software (Endnote). After removing 1370 duplicates, 411 articles were excluded in the screening stage based on the inclusion and exclusion criteria. Furthermore, 60 articles were excluded through the full-text review based on the same criteria. In the quality assessment phase, the full text of the articles was reviewed, and based on the score obtained from the STROBE checklist, studies with poor methodological quality were excluded. Finally, eight studies met the inclusion criteria and were included in the final evaluation (Fig. 1). The information from these eight studies is reported in Table 1. Of these eight studies, three were clinical trials, and the remaining five were cohort studies. Most of the reviewed studies were conducted in the Americas (Table 1).

The prevalence of bleeding after PCI in the studies included in Table 1 varied, with the highest reported by Ndrepepa et al in Germany in 2014 in individuals over 75 years of age at 15.39 % and the lowest reported by Doyle et al in the state of New Hampshire in the United States in 2008 at 1.06 %.

4.1. Prevalence of bleeding after PCI

In this systematic review and meta-analysis of 8 studies with 397,298 participants, high heterogeneity (I^2: 97.8) was observed in the evaluation of bleeding after percutaneous coronary intervention. Therefore, the random effects method was used to analyze the results, and the prevalence of bleeding after percutaneous coronary artery intervention was reported as 4.4 % (95 % CI: 2–9.1) based on the meta-analysis (Fig. 2), The Egger test showed no publication bias among the studies (p: 0.960) (Fig. 3).

5. Discussion

Based on the results of the present study, the overall prevalence of bleeding after PCI was 4.4 %. Percutaneous coronary intervention is one of the most widely used methods in the treatment of coronary artery disease.[27] Studies indicate that complications such as bleeding, hematoma, and embolism may occur due to the trauma inflicted on the vessels

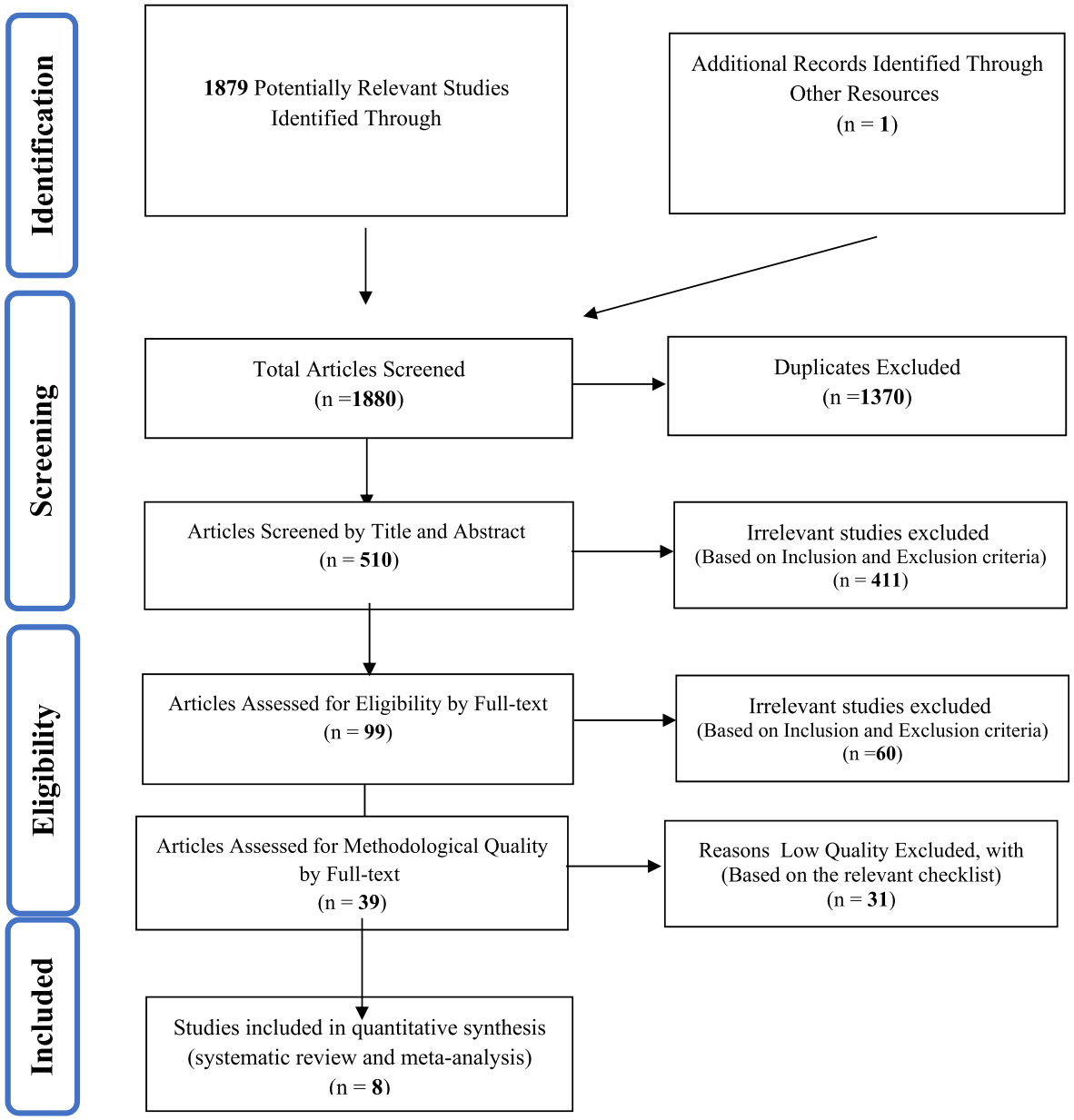

Fig. 1. PRISMA 2020 search flow diagram.

Table 1
Prevalence of bleeding after PCI.

Author	Year	Reign	Continent	Age	Type of study	Sample size			Number of patients with bleeding			Prevalence of bleeding after PCI		
						Total	Male	Female	Total	Male	Female	Total	Male	Female
Ndrepepa et al[20]	2013	Germany	Europe	–	Randomized clinical trials	6702	3351	3351	872	354	518	13.01	15.45	10.56
Numasawa et al[21]	2017	Japan	Asia	71.0 ± 10.4	cohort	13,075	–	–	402	263	139	3.07	–	34.6
Mehta et al[22]	2009	State of Missouri	USA	70 (59–78)	Cohort	302,152	–	–	7328	3437	3891	2.4	–	–
Valle et al[7]	2016	State of Colorado	USA	70 ± 11.1	Cohort	8371	–	–	391	248	143	4.8	–	–
Fuchs et al[23]	2009	Israel	Asia	66 ± 15	Cohort	831			27	13	14	3.5	–	–
Marquis et al[24]	2020	American	USA	63 (55–71)	Randomized clinical trials	45,011	–	–	1133	–	–	2.5	–	–
Doyle et al[25]	2008	State of New Hampshire	USA	–	retrospective	17,901	12,577	5324	190	–	–	1.06	–	–
Ndrepepa et al[26]	2014	Germany	Europe	>75	Randomized clinical trials	3255	2018	1237	501	255	246	15.39	–	–

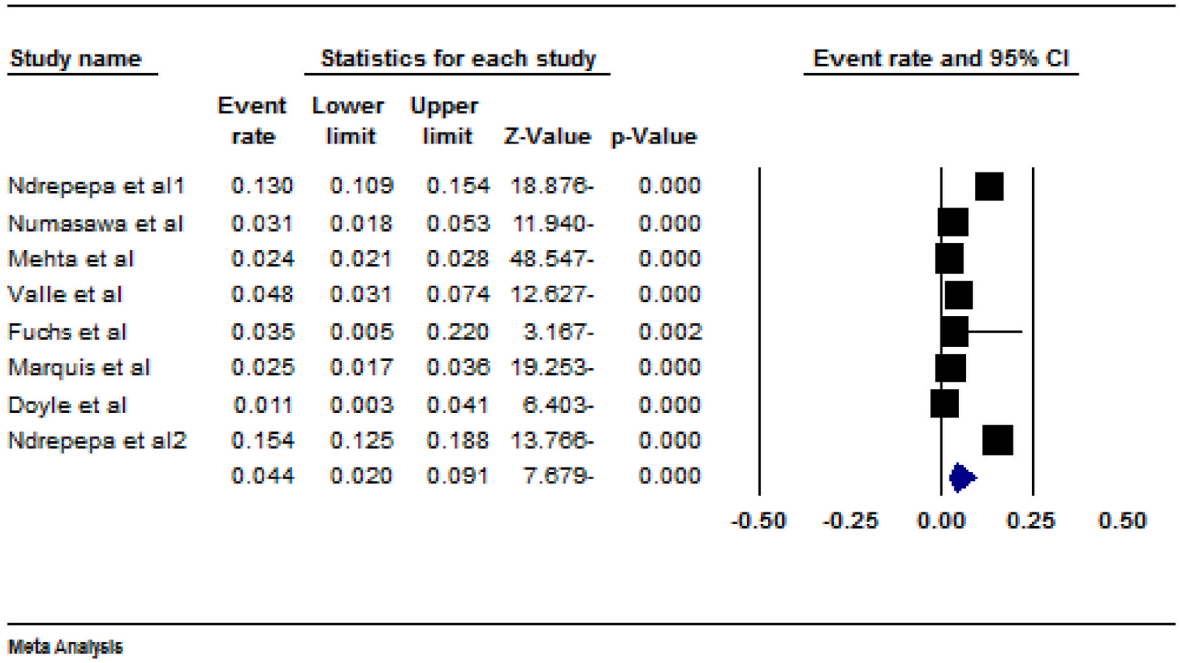

Fig. 2. Forest plot of prevalence of bleeding after percutaneous coronary intervention based on random effects method.

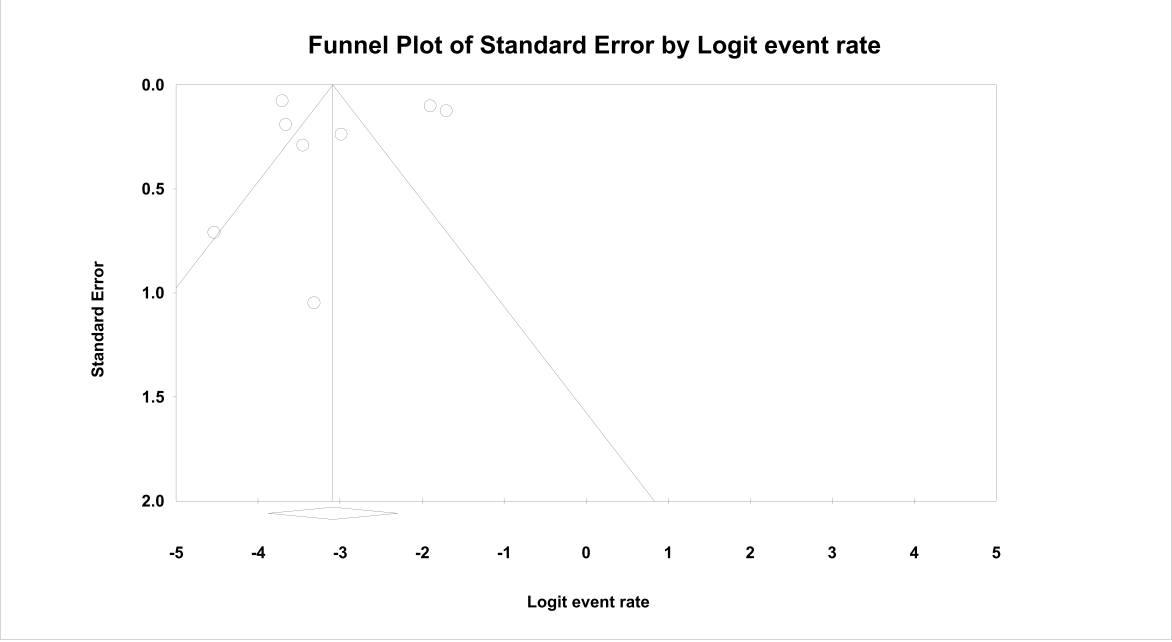

Fig. 3. Funnel plot of the publication bias in the reviewed studies.

during this procedure. Among these complications, bleeding is the most common complication of percutaneous coronary intervention (PCI), which is associated with an increased risk of adverse events, including death, myocardial infarction (MI), and stroke, as well as an increased length of hospital stay and costs.[28–32]

Similarly, Numasawa et al (2017) reported a 3.07 % prevalence of bleeding after PCI in a six-year prospective cohort study of 13,075 patients in Japan titled "Incidence of bleeding complications after percutaneous coronary intervention".[21] In most studies, there is a statistically significant correlation between bleeding after PCI and female gender[33–38] but Patti et al.'s study in Australia did not find a significant association, suggesting the larger vessels in men and easier access to these vessels may be possible reasons for this difference.[39] Sabo and colleagues showed a significant relationship between age and bleeding, attributing increased blood vessel fragility to ageing.[40] Al-Sadi et al's study found that high systolic blood pressure is also a related factor for vascular complications,[41] while Shemirani and colleagues concluded that high systolic blood pressure is associated with bleeding after coronary interventions due to chronic vascular changes caused by high blood pressure.[42]

The incidence of bleeding after intervention varies due to differences in the strategies used to prevent complications, such as vascular blocking devices in the post-coronary intervention phase.[43–46] Cantor et al found a direct relationship between the duration of sheet removal and

the severity of complications, especially bleeding, suggesting that delaying sheet removal leads to higher bleeding rates and intensity.[47] Prolonged coronary intervention weakens vascular tone, contributing to vascular complications such as bleeding.[48]

5.1. Limitations

One limitation of this meta-analysis is that it only included studies published in English, potentially resulting in the exclusion of relevant studies published in other languages. Furthermore, several studies were excluded due to inadequate quality, such as those with small sample sizes or those that did not report prevalence.

6. Conclusion

The findings of the present study indicate that the incidence of bleeding after PCI is 4.4 %, which is a significant result. Therefore, these results can serve as a crucial criterion for developing appropriate prevention and treatment strategies. Health policymakers can also utilize the results of this meta-analysis to prioritize research on the complication of bleeding after PCI and its outcomes and implement effective measures to prevent and manage this complication.

Ethics approval and consent to participate

Ethics approval was received from the ethics committee of deputy of research and technology, Kermanshah University of Medical Sciences (IR.KUMS.MED.REC.1402.145).

Consent for publication

Not applicable.

Availability of data and materials

Datasets are available through the corresponding author upon reasonable request.

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Authors'contributions

RHM and AHA contributed to the design, MM statistical analysis, participated in most of the study steps. MM and AHA and AM prepared the manuscript. MM and AM and NS and SHSH assisted in designing the study, and helped in the, interpretation of the study. All authors have read and approved the content of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ihj.2024.01.009.

Abbreviation

PCI	Percutaneous Coronary Intervention
CAD	Coronary artery disease
SID	Scientific Information Database
STROBE	The Strengthening the Reporting of Observational Studies in Epidemiology
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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