

The evidence of effectiveness and safety of peripheral intravenous catheter dressings and securement devices: a systematic review and meta-analysis protocol

Afina Chaerunnisa*¹, Auxillia Madhuvu¹, Danielle Najm¹, Ensieh Fooladi¹, Victoria Team¹

¹School of Nursing and Midwifery, Monash University, Level 1, 10 Chancellors Walk, Wellington Road, Clayton, Melbourne VIC 3800 Australia.

*Corresponding author email acha0222@student.monash.edu

ABSTRACT

Background Peripheral intravenous catheters are widely used worldwide. Intravenous catheterisation is one of the most common medical procedures in hospitals. Despite their widespread use, peripheral intravenous catheters exhibit concerning failure rates. Peripheral intravenous catheter dressing and securement devices can be protected against factors that cause the development of peripheral intravenous catheter failures.

Aim The primary objective is to review the evidence of effectiveness and safety of peripheral intravenous catheter dressings and securement devices in terms of post-insertion peripheral intravenous catheter failures; dislodgement, occlusion, extravasation, infiltration, phlebitis, and catheter-related bloodstream infection in hospitalised adult and paediatric patients. The secondary objective is peripheral intravenous catheter dwell time.

Inclusion criteria This review included randomised controlled trials or cluster randomised trials. Cross-over trials are considered for inclusion where data from the initial treatment period was available.

Methods The study performed methodical searches in the following electronic databases: CENTRAL, CINAHL, Ovid EMBASE, and Ovid MEDLINE from 1959 to 2024. The review will use standard methodological procedures expected by Cochrane. Methodological quality will be appraised using the revised version of the Cochrane risk of bias tool for randomised trials (RoB2). A fixed effect models meta-analysis will be conducted where appropriate. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool will be used to determine confidence levels of findings from the studies.

Keywords intravenous catheter devices, intravenous catheter dressings, intravenous catheter dwell time, intravenous catheter failure, intravenous catheter securement, peripheral intravenous catheter

For referencing Chaerunnisa A, et al. The evidence of effectiveness and safety of peripheral intravenous catheter dressings and securement devices: a systematic review and meta-analysis protocol. *Journal of Wound Management*. 2025;26(1):29-38.

DOI <https://doi.org/10.35279/jowm2025.26.01.08>

Submitted 13 September 2024, Accepted 21 January 2025

KEY MESSAGES

- This systematic review protocol aims to investigate the evidence of effectiveness and safety of peripheral intravenous catheter (PIVC) dressings and securement devices in terms of post-insertion PIVC failures or unplanned removal of PIVC before completion of therapy.
- The review is centered on assessing critical clinical outcomes related to PIVC usage, specifically post-insertion PIVC failures or unplanned removal of PIVC before completion of therapy for any causes such as dislodgement, occlusion, infiltration, extravasation, phlebitis or catheter-related bloodstream infection (CRBSI).

AUTHORSHIP

Afina Chaerunnisa
Conceptualisation, methodology, investigation, writing of the original draft.

Victoria Team
Conceptualisation, methodology, writing (review and editing).

Auxillia Madhuvu

Conceptualisation, methodology, writing (review and editing).

Danielle Najm

Conceptualisation, methodology, writing (review and editing).

Ensieh Fooladi

Methodology, investigation

INTRODUCTION

A peripheral intravenous catheter (PIVC) is a thin, flexible tube that is inserted in a vein for blood sampling or the delivery of intravenous fluids and medications.¹ PIVC is one of the most common medical procedures performed in hospital environments. Almost 2 billion PIVCs are employed annually worldwide, and of this figure, 1.8 million PIVCs are used in paediatric patients.^{2,3} Approximately, 200 million PIVCs are used annually in the United States of America, and nearly 30 million in Australia.^{1,4} A cross-sectional study conducted in both low- and high-income countries reported that 40,620 PIVCs in 38,161 patients were used in 406 hospitals between

2014 and 2015 (Asia, Africa, Australia/New Zealand, Europe, the Middle East, North America, South America, and the South Pacific).²

The PIVC is usually inserted into the lower part of the arm and the back of the hand or foot. The insertion site is considered a wound, which needs to be appropriately dressed to prevent the development of PIVC failures, such as dislodgement, occlusion, infiltration, phlebitis, and PIVC-associated infections or catheter-related bloodstream infection (CRBSI), and ensure the device remains securely within the vein during the therapy.^{1,5}

Despite their widespread use, PIVCs exhibit a concerning failure rate ranging from 21% to 69% in both high- and low-income countries, such as Australia, Japan, and Spain.^{1,6,7} The reported prevalence of dislodgement is in 7–10% of adult patients in medical-surgical non-ICU settings, and 8.8% of paediatric patients.^{10–12} The incidence rate of occlusion was 23%.¹⁶ The incidence rate of infiltration and extravasation was between 7.7% and 17.8% in adult patients.^{7,18} The incidence of phlebitis was 10% to 12% in adult patients, while it was 5% in paediatric patients.^{16,18,21} CRBSI is an uncommon, but a significant complication. The authors of an observational study that performed culture checks on PIVC tips to assess CRBSI reported that out of 297 failed PIVCs, 5.8% showed positive culture results.⁶

The impact of PIVC failure imposes a significant burden on patients, their families, and the healthcare system. Treating the consequences of PIVC failures can be time-consuming for healthcare providers, often requiring the replacement of the catheter to allow for continued treatment.¹³ These failures, either individually or in combination, often necessitate the premature removal of the catheter before it reaches its intended dwell time or the traditionally recommended limit. The recommended PIVC dwell time is between 72 to 96 hours as reflected in several guidelines from China, Sweden, Australia, and the United Kingdom (UK).^{1,13–15} The re-insertion efforts and the early removal of PIVC may significantly elevate hospital expenses; for example, the average cost for replacing a PIVC and providing related care are estimated to be A\$22.79 (US\$14.11) per procedure in Australia, and US\$13.336 per procedure in the USA.^{6,16,17} Additionally, 37% of patients with CRBSI need extended antibiotic treatment, and 14% of patients with CRBSI need intensive care unit (ICU) admission due to changes in vital signs and multiple organ failures resulting from PIVC-related CRBSI.¹⁸ And, managing CRBSI is projected to incur extra expenses ranging from A\$29,500 to A\$68,983 (US\$18,262.68 to US\$42,714.27) per occurrence in Australia and approximately US\$45,000 for each episode in the USA.^{13,19}

Improving the efficiency and outcomes of peripheral intravenous catheter (PIVC) use can lead to significant cost savings and operational benefits in healthcare settings. By increasing first-attempt success rates to 96%, extending catheter dwell times to 71.4 hours, reducing complications through proper dressing and securement, and saving 37,122 nursing hours annually, a projected annual savings of US\$2.9 million in PIVC costs was achieved. Additionally, this improvement reduced costs per bed by US\$3376 across 867 beds, demonstrating the value of optimised PIVC practices in enhancing both patient care and financial performance.^{5,20}

Several guidelines exist to assist in dressing and securing the insertion site of the PIVC. PIVC guidelines from Australia, South Korea, Ireland, and the UK recommend using sterile transparent film dressing for PIVC maintenance.^{1,21,22} Furthermore, polyurethane dressings were recommended for use by the guidelines in Africa, Asia, New Zealand, Europe, the Middle East, and North and South America.^{24–25} On the other hand, the US guideline recommends the use of an adhesive securement device (ASD), integrated securement device (ISD), subcutaneous anchor securement system (SASS) and tissue adhesive (TA).⁵ The type of dressing used in the US is determined by factors such as the type of PIVC, skin turgor and integrity, anticipated duration of therapy, history of skin injury due to adhesive, and any fluid for infusion.⁵ There are no clear guidelines on types of dressings and securement that could be used to reduce PIVC failure rates. In Australia, both patient and clinician preferences are considered acceptable factors in selecting a PIVC dressing type.²³

The WHO draft guideline entitled *Global Guidelines for Prevention of Bloodstream Infection and Other Infection Associated with the use of Intravascular Catheters*²⁶ discusses the use of non-occlusive versus occlusive dressings at insertion and the use of formal sterile dressings versus no specified requirements. They also relate the outcomes to PIVC failures.²⁶

A few reviews have focused on analysing which PIVC dressing best reduces the incidence of PIVC failures.^{27,28} Several reviews, including a 2017 systematic review conducted by Marsh et al, have analysed the impact of PIVC dressings and securement devices on PIVC failure rates.²⁸ Their review included studies conducted in general surgical and orthopaedic wards.²⁸ But did not include studies conducted in emergency departments or general cancer care settings, where PIVCs are commonly used.²⁸ The authors of this review reported that transparent dressings reduced catheter dislodgement compared to gauze (RR 0.40, CI 0.17–0.92), and bordered transparent dressings showed fewer dislodgements than securement devices (RR 0.14, CI 0.03–0.63).²⁸ However, bordered dressings caused more failures than tape (RR 1.84, CI 1.08–3.11).²⁸ Ultimately, Marsh et al found no clear evidence favouring one dressing or securing method and could not assess CRBSI due to insufficient data reported in the included articles.²⁸

The objective of the planned systematic review is to systematically identify, review and synthesise evidence of effectiveness and safety of different dressing and securement methods for PIVCs in hospitalised adult and paediatric patients. Based on our preliminary search in April 2024, there have been other RCTs published that have tested the effectiveness and safety of PIVC dressings and securements against PIVC failures since the last systematic review by Marsh et al published in 2017.²⁸ The proposed systematic review will also include the following dressing/securement devices: tissue adhesive and sutureless devices, which were not included in the previous systematic review.²⁸

METHODS

This protocol is following the guidelines set by PRISMA-P statement presented in Table 1.²⁹ This review will use standard methodological procedures expected by Cochrane.³⁰ And the systematic review methodology will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2020 statement, offering updated guidelines for

reporting systematic reviews.³¹ A meta-analysis will also be conducted, if the included studies demonstrate sufficient homogeneity, consistently using the same measures or outcomes at regular intervals.³² This protocol has been registered with PROSPERO (CRD42024547483).

Eligibility Criteria

The detailed criteria for considering studies in this review, including the date of the study, exposure of interest, geographic location, language, participants, peer-review, reported outcomes, setting, study design, type of publication, and type of intervention are provided in Table 2.

Outcome measures

Primary outcome

The primary outcome of the systematic review is the evidence of effectiveness and safety of PIVC dressing and securement devices in terms of post-insertion PIVC failures in hospitalised adult and paediatric patients. The PIVC failures concept is defined as the incidence rate of dislodgement, occlusion, infiltration, extravasation, phlebitis, CRBSI or any causes of unplanned removal of PIVC before the completion of therapy or based on the catheter dwell time standard of 72 to 96 hours^{1,5} (Table 3).

Secondary Outcome

The secondary outcome is effectiveness and safety of PIVC dressings and securement devices in terms of PIVC dwell time. The PIVC dwell time is defined as time the PIVC remains intact with the vein until the completion of infusion therapy or based on a catheter dwell time standard of 72 to 96 hours.^{1,6}

Report Characteristic

This systematic review will consider studies published from 1959 to 2024. The year 1959 was chosen because the first-time tissue adhesive was successfully used in a clinical setting as a dressing.³³

Information Sources

The study will include methodical searches in the following electronic databases: The Cochrane Central Register of Controlled Trials (CENTRAL), the Cumulative Index of Nursing and Allied Health (CINAHL), Ovid EMBASE and Ovid MEDLINE. This study will also search for articles included in the systematic review conducted by Marsh and associates in 2017.²⁸

Search Strategy

The proposed systematic review will use the population-intervention-comparison-outcome (PICO) framework to guide

Table 1. Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) 2015 checklist

Section and topic	Item	Checklist item	Protocol page
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	6
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	7
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Title page
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Title page
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	5, 9
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7

Section and topic	Item	Checklist item	Protocol page
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	10–15
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10–15
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	10–15
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10–15
Outcomes and prioritisation	13	List and define all outcomes for which data will be sought, including prioritisation of main and additional outcomes, with rationale	8
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11–12
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	14–15

the search strategy³⁴ (Table 4). We plan to expand our search strategy using the Peer Review of Electronic Search Strategies (PRESS) 2015 Guideline Statement, aiming to refine and enhance the literature search process.³⁵

The university librarian will evaluate the search strategy developed by the authors for completeness and precision. The Medical Subject Heading (MeSH) terms will be used to ensure that different terminologies used by authors are well captured.³⁵ MeSH terms and Boolean operators are presented in Table 5. A preliminary search of Ovid MEDLINE was conducted in April 2024, using the developed search strategy (Table 5).

Study Selection

All studies will be imported into Endnote 20 (<https://www.endnote.com>) to remove duplicate citations and then imported to Covidence (<https://www.covidence.org>) for the management of the review process. Two review authors will independently evaluate the titles and abstracts identified through the search process.³⁶ Upon obtaining complete copies of studies that show potential relevance, these same two

authors will separately assess the eligibility of each study, adhering to the specified inclusion and exclusion criteria.³⁶ In cases where any differences of opinion still need to be addressed through consensus, the perspective of a third review author will be sought.³⁷ The results of the study selection process and the reasons for exclusion will be presented in the PRISMA flow diagram³¹ (Figure 1).

Data extraction

Two review authors will independently gather data from all the included RCTs using a pre-established data extraction template from Cochrane for RCT only then developed by the authors.³⁸ An example of extraction templates is provided in Table 6. Two review authors will extract data from the first three studies to ensure the consistency of data collection.³⁶ Discrepancies that arise between two review authors will be resolved by discussion or consulting with a third review author.³⁹ In instances where trials are published as duplicate reports (parallel publications), they will be included once in the review.⁴⁰ All relevant trial reports will be utilised to maximise the extraction of trial information, ensuring that data from the trials are not duplicated within the review.³⁶

Risk of bias in included studies

Two review authors will assess the included studies for risk of bias using the revised Cochrane risk-of-bias tool for randomised trials 2 (RoB 2).⁴¹ This tool covers five key domains:

1. bias arising from the randomisation process,
2. deviations from intended interventions,
3. missing outcome data,
4. measurement of outcomes, and
5. selection of reported results.⁴¹

Each domain includes the relevant questions that guide reviewers in making bias judgements.⁴¹ Responses to these questions lead to classifications of the trial as having a: low risk of bias; some concerns; or high risk of bias. The tool provides a systematic approach to evaluate trial reliability and helps in forming judgments about the trustworthiness of results.⁴¹

Table 2. Eligibility criteria

Criteria	Inclusion criteria	Exclusion criteria
Date	1959–2024	Study conducted before 1959
Exposure of interest	Hospitalised adult and paediatric patients in any medical conditions requiring a PIVC for therapy	
Geographic location of study	Studies conducted across all countries	
Language	All languages.	
Participants	Hospitalised adult and paediatric patients	Adult and paediatric patients who do not undergo a formal admission processes and do not occupy a hospital bed
Peer review	Peer-reviewed publications	Publications that were not peer reviewed
Reported outcomes	Primary outcome: Incidence rate of PIVC failures or a metric for unplanned removal of PIVC for any causes such as dislodgement, occlusion, infiltration, extravasation, phlebitis, CRBSI Secondary outcome: PIVC dwell time or time to PIVC completion or time to catheter failure (analysed by survival method, such as Kaplan-Meier survival curves)	
Setting	Any hospital settings providing facilities for PIVC insertion such as: medical surgical wards, intensive care units, acute care, critical care, emergency units	Aged care, nursing home, primary health care, home care clinic, community care
Study design	Quantitative research studies: randomised controlled trials or cluster randomised trials and cross over trials with available data from the initial treatment period	Quasi experimental studies, observational studies; cross-sectional studies, cohort, case study, case report, case series, cross-over trials without data from the initial treatment period, qualitative research studies
Type of publication	Research articles published in peer reviewed journals, research reports published in peer reviewed journals, grey literature from clinicaltrial.gov which already reported their findings	Grey literature, opinions, topical insights, editorials, letters to the editor, conference proceedings
Type of intervention	PIVC dressings and securement devices; tissue adhesive, bordered polyurethane, sutureless devices, antimicrobial dressings, a new generation of transparent dressing, and innovation of PIVC insertion site securement devices made of Velcro, soft fabric, and hard case compared with another PIVC dressings and securement devices; gauze, non-sterile tape, standard transparent film.	Studies that do not analyse the effectiveness and safety of PIVC dressings and securement devices

In cases where discrepancies arise between the two review authors, these issues will be addressed through discussion to arrive at a consensus or, when necessary, by consulting a third review author.³⁶ The collective evaluation of the risk of bias will be visually presented in a figure, which will encapsulate all assessments in a tabular format, categorising studies by their respective entries.³⁶

Measures of treatment effect

The risk ratio (RR) and 95% confidence intervals (CI) will be used to calculate dichotomous outcomes, such as the number of patients or participants who had PIVC failure: dislodgement, occlusion, infiltration, phlebitis, and CRBSI. The mean difference (MD) along with its 95% CI will be utilised to compute continuous outcomes such as PIVC dwell time and Visual Phlebitis Score (VIP) Scale. Additionally, when dealing with time-to-event data, such as time to develop CRBSI, we

plan to analyse this data using hazard ratios. The time-to-event data that is incorrectly presented as continuous data will not be included in our analysis.

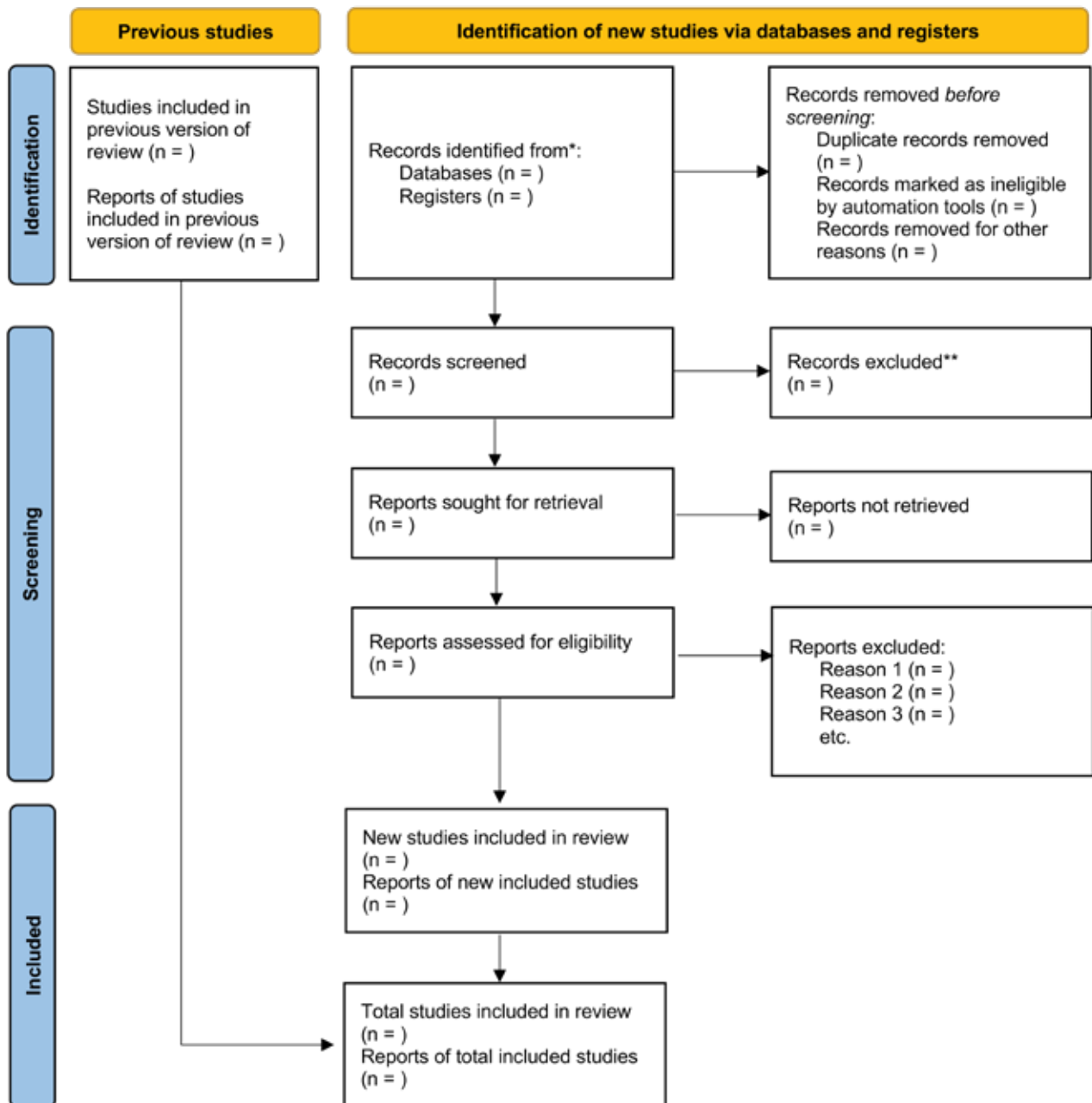
Unit of analysis

Data will be analysed using Review Manager (RevMan), a software developed by Cochrane which supports systematic reviews by helping manage references, assess risk of bias, and analyse result.⁴² In an ideal scenario, a study would be structured with randomisation and analysis at the patient level, ensuring that each participant is associated with only one device.⁴³ However, we anticipate encountering several studies where the reporting involves multiple devices per participant. These studies employed randomisation or analysis at the device level or possibly both while adjusting for clustering. In such instances, we plan to initiate contact with the study authors to obtain patient-level data or results data

and results related explicitly to one device per participant.⁴⁴ Failing that, we may secure device-level data. Subsequently, we will employ multilevel regression techniques to compute the adjusted effect.⁴⁴ We will combine the adjusted results in the meta-analysis with those from patient-level trials (using the generic inverse method), and conduct sensitivity analyses.⁴⁴ If we are unable to obtain additional data, we will exclude the study from the meta-analysis.

Dealing with missing data

Missing data in each study will be actively identified and the respective authors will be contacted to secure the information required for the analysis.⁴⁵ In cases where the data cannot be obtained, we will perform an analysis based on the available data, employing an available-case approach.⁴⁴ Additionally, we plan to investigate the effects of missing data on the study results through a sensitivity analysis.³⁶



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. CC BY 4.0.

Figure 1. PRISMA flow diagram.

Table 3. Primary outcomes

Term	Definition
Dislodgement	PIVC shifting out of the vein either wholly or partially due to inadequate catheter securement to the skin ¹¹
Occlusion	The inability to administer fluids and medications through a previously functioning PIVC ¹³
Infiltration	The unintentional penetration of non-vesicant intravenous fluid into the interstitial compartment, resulting in tissue swelling around the catheter site ⁵¹
Extravasation	The accidental introduction of a vesicant solution into nearby tissue, which leads to severe tissue damage, necrosis, and potential long-term complications for the patient ⁵²
Phlebitis	The irritation and inflammation of a vein wall due to the presence of a PIVC. ⁵¹ Which is identified by symptoms such as tenderness, pain, redness, swelling, warmth, palpable cord, or pus at the PIVC insertion site ¹¹
CRBSI	CRBSI characterised by a positive blood culture from a peripheral vein or there is a bacterial colonisation in IV catheter tip or there is clinical indications of infection, the absence of any other evident source for the bloodstream infection apart from the IV catheter, and a colonised IV catheter tip culture matching the organism identified in the blood ⁵³

Table 4. PICO framework and research questions

Elements	Descriptions
Population	Adult and paediatric hospitalised patients with PIVC
Interventions	PIVC dressings and securement devices; tissue adhesive, bordered polyurethane, sutureless device, antimicrobial dressings, a new generation of transparent dressing, and innovation of PIVC insertion site securement device that is made of Velcro, soft fabric and hard case
Control	PIVC dressings and securement devices; gauze, non-sterile tape, standard transparent film.
Outcome	<ol style="list-style-type: none"> 1. Primary outcome: post-insertion PIVC failures; dislodgement, occlusion, extravasation, infiltration, phlebitis, and CRBSI in hospitalised adult and paediatric patients 2. Secondary outcome: PIVC dwell time.
Research questions	<ol style="list-style-type: none"> 1. What is the evidence of effectiveness and safety of PIVC dressings and securement devices in terms of post-insertion PIVC failures in hospitalised adult and paediatric patients? 2. What is the evidence of effectiveness and safety of PIVC dressings and securement devices in terms of PIVC dwell time in hospitalised adult and paediatric patients?

Table 5. Search strategy

The following search strategy for Ovid MEDLINE will be used:	
1	exp emergency service, hospital/ or exp hospital units/ or exp hospitals/
2	exp Intensive care units/
3	hospital* or acute care or intensive care unit* or critical care
4	1 or 2 or 3
5	exp catheterisation, peripheral/
6	infusions, intravenous/
7	peripheral intravenous catheter* or peripheral intravenous or intravascular catheter* or intravenous device* or infusion* or intravenous catheterisation or peripheral venous catheterisation or PIVC or PVC
8	5 or 6 or 7
9	exp tissue adhesive/ or exp bandages/ or exp chlorexidine/
10	exp polyurethanes/
11	exp surgical tape/
12	securement dressing* or securement device* or intravenous protection device or dressing regimen* or peripheral intravenous catheter securement or dressing* or fixation device* or occlusive dressing* or tissue adhesive or skin glue or bordered polyurethane or sutureless device* or antimicrobial dressing* or transparent dressing* or transparent polyurethane film
13	9 or 10 or 11 or 12
14	4 and 8 and 13

The testing of the influence of the following study characteristics will be established in advance in sensitivity analyses: Adequate versus inadequate concealment of allocation, study size (including studies with more or fewer than 100 patients), follow-up duration (differentiating between less than 72 hours and more than 72 hours), handling of missing data, and exploration of best-case and worst-case scenarios.⁴⁴

In the best-case scenario, missing data from the treatment group will not indicate PIVC failure, while those from the control group will be presumed to signify PIVC failure. Conversely, in the worst-case scenario, missing data from the treatment group will indicate PIVC failure. In contrast, those missing from the control group will be interpreted as not indicating PIVC failure.

Data synthesis

When/if all included studies share sufficient similarity, such as the population being studied, intervention being explored and comparisons being made, and all included studies use the same measures or outcomes consistently and simultaneously at regular intervals, a meta-analysis will be conducted.³²

Data will be pooled for meta-analysis as a fixed effects model. The chi-squared test will be used to assess statistical heterogeneity and a cut-off significance level of 0.10 will be used. Since statistical tests for heterogeneity lack robust power, employing a higher P value than the one typically used is advisable.⁴⁶ The I² is calculated to measure heterogeneity across studies, and heterogeneity is declared at >50%.⁴⁷ If substantial heterogeneity (exceeding 50%) is detected, potential sources of heterogeneity will be investigated, and a random-effects methodology will be applied to the analysis.⁴⁶

Subgroup analysis and investigation of heterogeneity

The following subgroup analyses were pre-specified in our protocol:

1. Children (under 18 years old) and adults.
2. Additional bandaging versus dressing or securement device alone.

Summary of findings

The interpretation of the findings from the meta-analysis will

Table 6. Data extraction template

Study:	
Methods	Study design: Methods of randomisation: Concealment of allocation:
Participants	Country: Number: Age: Inclusion criteria: Exclusion criteria:
Interventions	
Comparisons	
Outcomes	
Result	

use forest plots. Typically, a forest plot contains six columns, including studies, intervention group, control group, weight, outcome of effect measure in numeric format, and outcome of measure in graphical presentation.⁴⁸

The primary findings of this review will be summarised in the summary of findings tables. GRADEpro will be used to create these tables.⁴² The tables will provide essential information, ensuring a comprehensive description of the studies and meta-analysis to support their content.⁴⁹ This description encompasses an evaluation of the certainty of the evidence, which includes an assessment of the quality of evidence and confidence in the estimates of the intervention effects, as well as an amalgamation of the available data on the primary outcomes.⁴⁹

The summary of findings tables will include an overarching assessment of the evidence associated with each primary outcome, using the Grading of Recommendations Assessment, Development and Evaluation (GRADE).⁴⁹ The GRADE approach quantifies the quality of a body of evidence based on the degree of confidence that an effect estimates or association closely aligns with the specific quantity of interest.⁵⁰ The assessment of evidence quality considers factors, such as the risk of bias within the trials (methodological quality), the directness of the evidence, heterogeneity, precision of effect estimates, and the risk of publication bias.⁴⁹ Within this project's scope, the summary of findings tables will encompass the following outcomes for all comparisons: the proportion of PIVC failure and PIVC dwell time.

DISCUSSION

The effectiveness and safety of dressing and securement methods for PIVCs are critical components in reducing complications and ensuring optimal patient outcomes in hospitalised adult and paediatric patients. Despite their routine use, PIVCs are associated with high rates of failure and complications, such as phlebitis, infiltration, infection, and dislodgement, often linked to inadequate securement and dressing practices. The objective of the planned systematic review is to systematically identify, review and synthesise evidence of effectiveness and safety of different dressing and securement methods for PIVCs in hospitalised adult and paediatric patients.

By systematically reviewing and analysing the current literature, this protocol provides a structured approach to addressing key gaps in knowledge related to PIVC dressing and securement methods. This review will adhere to rigorous methodological standards, including the PRISMA-P guidelines, to ensure transparency and reproducibility. The meta-analysis, if conducted, will allow for quantitative synthesis of data, offering robust conclusions where sufficient homogeneity exists among the included studies.

The results will be valuable to health planners in developing standard operating procedures to secure PIVCs and reduce failure rates. Additionally, they will help healthcare professionals to better understand how PIVC dressings and securement devices influence PIVC failure and dwell time. Ultimately, the findings will contribute significantly to enhancing PIVC failure prevention strategies and improving patients' outcomes.

IMPLICATIONS FOR CLINICAL PRACTICE

- Healthcare professionals' improved understanding of the impact of PIVC securement on PIVC failure and dwell time will improve the quality of care and subsequently patients' outcomes.
- Findings of the proposed systematic review will equip healthcare professionals with the latest evidence on and guide their decision of PIVC dressing and securement devices selection for hospitalised adult and paediatric patients.

ETHICS AND DISSEMINATION

Since the data will come from publicly accessible sources, ethical considerations are unnecessary. Findings of this systematic review will be published in a peer-reviewed journal and presented at conferences.

AUTHOR CONTRIBUTION

Afina Chaerunnisa: conceptualisation, methodology, investigation, writing of the original draft. Victoria Team: conceptualisation, methodology, writing (review and editing). Auxillia Madhuvu: conceptualisation, methodology, writing (review and editing). Danielle Najm: conceptualisation, methodology, writing (review and editing). Ensieh Fooladi: Methodology, investigation. We acknowledge Olivia Thompson, Subject Librarian for MNHS (Medicine, Nursing, Health Science) at Monash University, for her dedicated assistance in developing search strategies.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

FUNDING

The first author is sponsored by Indonesia Endowment Fund for Education. The sponsor provides a Masters program scholarship, including production of a thesis by the first author. This review protocol is a requirement for the thesis.

REFERENCES

1. Australian Commission on Safety and Quality in Health Care. *Management of Peripheral Intravenous Catheters Clinical Care Standard*. Sydney: Australian Commission on Safety and Quality in Health Care; 2021.
2. Alexandrou E, Ray-Barruel G, Carr PJ, Frost SA, Inwood S, Higgins N, et al. Use of short peripheral intravenous catheters: Characteristics, management, and outcomes worldwide. *J Hosp Med*. 2018;13(5). doi: 10.12788/jhm.3039
3. Büyükyılmaz F, Şahiner NC, Çağlar S, Eren H. Effectiveness of an intravenous protection device in pediatric patients on catheter dwell time and phlebitis score. *Asian Nurs Res (Korean Soc Nurs Sci)*. 2019;13(4):236–241.
4. Lim S, Gangoli G, Adams E, Hyde R, Broder MS, Chang E, et al. Increased clinical and economic burden associated with peripheral intravenous catheter-related complications: Analysis of a US hospital discharge database. *Inquiry*. 2019;56:46958019875562.
5. Nickel B, Gorski L, Kleidon T, Kyes A, DeVries M, Keogh S, et al. Infusion therapy standards of practice, 9th edition. *J Infus Nurs*. 2024;47(1S Sup1):S1-s285.
6. Blanco-Mavillard I, Rodríguez-Calero M, de Pedro-Gómez J, Parra-García G, Fernández-Fernández I, Castro-Sánchez E. Incidence of peripheral intravenous catheter failure among inpatients: Variability between microbiological data and clinical signs and symptoms. *Antimicrob Resist Infect Control*. 2019;8:124.
7. Yasuda H, Rickard CM, Marsh N, Yamamoto R, Kotani Y, Kishihara Y, et al. Risk factors for peripheral intravascular catheter-related phlebitis in critically ill patients: analysis of 3429 catheters from 23 Japanese intensive care units. *Ann Intensive Care*. 2022;12(1):33.
8. Baye ND, Teshome AA, Ayenew AA, Amare TJ, Mulu AT, Abebe EC, et al. Incidence, time to occurrence and predictors of peripheral intravenous cannula-related complications among neonates and infants in Northwest Ethiopia: An institutional-based prospective study. *BMC Nursing*. 2023;22(1):11.
9. Kassahun CW, Abate AT, Tezera ZB, Beshah DT, Agegnehu CD, Getnet MA, et al. Incidence and associated factors of failed first peripheral intravenous catheters among adult patients at medical surgical wards in public referral hospitals of West Amhara, Ethiopia, 2021. *Nurs Res Pract*. 2022;2022:8261225.
10. Ben Abdelaziz R, Hafsi H, Hajji H, Boudabous H, Ben Chehida A, Mrabet A, et al. Peripheral venous catheter complications in children: Predisposing factors in a multicenter prospective cohort study. *BMC Pediatr*. 2017;17(1):208.
11. Keogh S, Mathew S. *Peripheral intravenous catheters: A review of guidelines and research*. Sydney: Australian Commission on Safety and Quality in Health Care; 2019. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/peripheral-intravenous-catheters-review-guidelines-and-research>.
12. Özkula U, Özhasenekler A, Kurtoğlu Çelik G, Tanrıverdi F, Pamukçu Günaydın G, Ergin M, et al. Tissue adhesives to secure peripheral intravenous catheters: A randomized controlled trial in patients over 65 years. *Turk J Emerg Med*. 2019;19(1):12–15.
13. Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: Peripheral Intravenous catheter failure. *J Infus Nurs*. 2015;38(3):189–203.
14. Scholey C. *Peripheral Venous Cannula (PVC) Management Guidelines*.: Doncaster and Bassetlaw Teaching Hospitals: NHS Foundation Trust; 2017.
15. Wei L, Li Y, Li X, Bian L, Wen Z, Li M. Chlorhexidine-impregnated dressing for the prophylaxis of central venous catheter-related complications: a systematic review and meta-analysis. *BMC Infect Dis*. 2019;19(1):429.
16. Tuffaha HW, Marsh N, Byrnes J, Gavin N, Webster J, Cooke M, et al. Cost of vascular access devices in public hospitals in Queensland. *Aust Health Rev*. 2019;43(5):511–515.
17. Hawkins T, Greenslade JH, Suna J, Williams J, Rickard CM, Jensen M, et al. Peripheral intravenous cannula insertion and use in the emergency department: an intervention study. *Acad Emerg Med*. 2018;25(1):26–32.
18. Sato A, Nakamura I, Fujita H, Tsukimori A, Kobayashi T, Fukushima S, et al. Peripheral venous catheter-related bloodstream infection is associated with severe complications and potential death: a retrospective observational study. *BMC Infect Dis*. 2017;17(1):434.
19. Morgan R, Callander E, Cullen L, Walker K, Bumpstead S, Hawkins T, et al. From little things, big things grow: An exploratory analysis of the national cost of peripheral intravenous catheter insertion in Australian adult emergency care. *Emerg Med Australas*. 2022;34(6):877–883.
20. Steere L, Ficara C, Davis M, Moureau N. Reaching one peripheral intravenous catheter (PIVC) per patient visit with Lean Multimodal Strategy: the PIV5Rights™ Bundle. *J Association for Vascular Access*. 2020;24(3):31–43.
21. Hallam C, Weston V, Denton A, Hill S, Bodenham A, Dunn H, et al. Development of the UK Vessel Health and Preservation framework: a multi-organisational collaborative. *J Infect Prev*. 2016;17(2):65–72.
22. Health Service Executive. *Guiding Framework for the Education, Training and Competence Validation in Venepuncture and Peripheral Intravenous Cannulation for Nurses and Midwives 2017*. Ireland: Health Service Executive; 2017.
23. National Health and Medical Research Council. *Australian Guidelines for the Prevention and Control of Infection in Healthcare*. Canberra: National Health and Medical Research Council; 2019. <https://www.nhmrc.gov.au/sites/default/files/documents/infection-control-guidelines-feb2020.pdf>.
24. Corley A, Ullman AJ, Marsh N, Genzel J, Larsen EN, Young E, et al. A pilot randomized controlled trial of securement bundles to reduce peripheral intravenous catheter failure. *Heart Lung*. 2023;57:45–53.

25. Ullman AJ, Takashima M, Kleidon T, Ray-Barruel G, Alexandrou E, Rickard CM. Global pediatric peripheral intravenous catheter practice and performance: A secondary analysis of 4206 catheters. *J Pediatr Nurs*. 2020;50:e18–e25.
26. World Health Organizations. *Proposed members of the WHO global guidelines for the prevention of bloodstream infections and other infections associated with the use of intravascular catheters*: World Health Organization; 2023. <https://www.who.int/news-room/articles-detail/proposed-members-of-the-who-global-guidelines-for-the-prevention-of-bloodstream-infections-and-other-infections-associated-with-the-use-of-intravascular-catheters>
27. Corley A, Marsh N, Ullman AJ, Rickard CM. Peripheral intravenous catheter securement: An integrative review of contemporary literature around medical adhesive tapes and supplementary securement products. *J Clinical Nurs*. 2023;32(9/10):1841–1857.
28. Marsh N, Webster J, Mihala G, Rickard CM. Devices and dressings to secure peripheral venous catheters: A cochrane systematic review and meta-analysis. *Int J Nurs Stud*. 2017;67:12–19.
29. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4(1):1.
30. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. *Cochrane Handbook for Systematic Reviews of Interventions version 6.3*. Cochrane; 2022. www.training.cochrane.org/handbook.
31. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.
32. Grant MJ, Booth A. A typology of reviews: an analysis of 14 review types and associated methodologies. *Health Info Libr J*. 2009;26(2):91–108.
33. Carleo C, Singer AJ, Thode HC, Jr. Effect of frequent water immersion on the rate of tissue adhesive sloughing: A randomized study. *CJEM*. 2005;7(6):391–395.
34. Eriksen MB, Frandsen TF. The impact of patient, intervention, comparison, outcome as a search strategy tool on literature search quality: a systematic review. *J Med Libr Assoc*. 2018;106(4):420-31.
35. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. *J Clin Epidemiol*. 2016;75:40–46.
36. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. *Cochrane Handbook for Systematic Reviews of Interventions*. Second ed. Newark: John Wiley & Sons, Incorporated; 2019.
37. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.
38. Higgins JPT, Green S (eds.). Data collection form: Intervention review – RCTs only. In *Cochrane handbook for systematic reviews of interventions* (Version 5.1.0) 2011. <https://www.cochrane-handbook.org>.
39. Ahn E, Kang H. Introduction to systematic review and meta-analysis. *Korean J Anesthesiol*. 2018;71(2):103–112.
40. Pussegoda K, Turner L, Garrity C, Mayhew A, Skidmore B, Stevens A, et al. Systematic review adherence to methodological or reporting quality. *Syst Rev*. 2017;6(1):131.
41. Higgins J, P, Savović T, Page MJ, Sterne JAC. *Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)* [eBook]: Cochrane; 2019. <https://www.riskofbias.info>.
42. Cochrane. *Core software*. The Cochrane Collaboration; 2020. <https://training.cochrane.org/online-learning/core-software-cochrane-reviews/revman>.
43. Tawfik GM, Dila KAS, Mohamed MYF, Tam DNH, Kien ND, Ahmed AM, et al. A step by step guide for conducting a systematic review and meta-analysis with simulation data. *Trop Med Health*. 2019;47(1):46.
44. Deeks JJ, Higgins JPT, Altman DG. *Analysing data and undertaking meta-analyses*. Chichester, UK: John Wiley & Sons, Ltd; 2019.
45. Hunt NB, Gardarsdottir H, Bazelier MT, Klungel OH, Pajouheshnia R. A systematic review of how missing data are handled and reported in multi-database pharmacoepidemiologic studies. *Pharmacoepidemiol Drug Saf*. 2021;30(7):819–826.
46. Fletcher J. What is heterogeneity and is it important? *BMJ*. 2007;334(7584):94–96.
47. Schroll JB, Moustgaard R, Gøtzsche PC. Dealing with substantial heterogeneity in cochrane reviews. cross-sectional study. *BMC Med Res Methodol*. 2011;11:22.
48. Dettori JR, Norvell DC, Chapman JR. Seeing the forest by looking at the trees: How to interpret a meta-analysis forest plot. *Global Spine J*. 2021;11(4):614–616.
49. Schünemann HJ, Vist GE, Higgins JPT, Santesso N, Deeks JJ, Glasziou P, et al. *Interpreting results and drawing conclusions*. 2nd ed: Wiley-Blackwell; 2019.
50. Bezerra CT, Grande AJ, Galvão VK, Santos D, Atallah Á N, Silva V. Assessment of the strength of recommendation and quality of evidence: Grading of Recommendations Assessment, Development and Evaluation checklist. A descriptive study. *Sao Paulo Med J*. 2022;140(6):829–836.
51. Castillo MI, Larsen E, Cooke M, Marsh NM, Wallis MC, Finucane J, et al. Integrated versus non-integrated peripheral intravenous catheter. which is the most effective system for peripheral intravenous catheter management? (The OPTIMUM study): A randomised controlled trial protocol. *BMJ Open*. 2018;8(5):e019916.
52. Liu C, Chen L, Kong D, Lyu F, Luan L, Yang L. Incidence, risk factors and medical cost of peripheral intravenous catheter-related complications in hospitalised adult patients. *J Vasc Access*. 2022;23(1):57–66.
53. Webster J, Osborne S, Rickard CM, Marsh N. Clinically-indicated replacement versus routine replacement of peripheral venous catheters. *Cochrane Database Syst Rev*. 2019;1(1):Cd007798.