Use of non-pharmacological interventions during urinary catheter insertion for reducing urinary tract infections in non-immunocompromised adults. A systematic review

Intervenciones no farmacológicas durante la inserción de un catéter urinario permanente para reducir las infecciones en adultos inmunocompetentes. Revisión sistemática

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Abstract

Introduction: Catheter-associated urinary tract infections (CAUTI) account for up to 30% of hospital-acquired infections. In this regard, several studies have reported the use of non-pharmacological interventions during urinary catheter insertion aimed at reducing the occurrence rate of CAUTI.

Objective: To assess the safety and effectiveness of non-pharmacological interventions during urinary catheter insertion aimed at reducing the risk of contracting infections in non-immunocompromised adults.

Materials and methods: A literature review was conducted in the MEDLINE, Embase, and LILACS databases. Only randomized clinical trials comparing the use of non-pharmacological interventions to placebos, pharmacological interventions, or no intervention during catheter insertion were included.

Results: Eight studies were retrieved (8 718 participants). Based on the evidence found in the review (low-quality and very low-quality evidence according to the GRADE system), using non-pharmacological interventions reduces the frequency of asymptomatic bacteriuria episodes (RR 0.67, 95% CI 0.48-0.94; 7 studies) or mild adverse events (RR 0.84, 95% CI 0.74-0.96; 2 studies), but does not reduce the occurrence rate of symptomatic urinary tract infections (RR 0.90, 95% CI 0.61-1.35; 4 studies) or improves quality-of-life scores (MD -0.01 EQ-5D scale; 95% CI (-0.03)-(0.01), 1 study).

Conclusion: The use of non-pharmacological interventions during urinary catheter insertion does not pose any risk at all. Instead, it could help reduce the occurrence rate of infections associated with this procedure, such as asymptomatic bacteriuria and mild adverse events. However, there is very little evidence (in fact, low and very low-quality evidence) to make conclusions on the effectiveness of these interventions.

Keywords: Early Medical Intervention; Urinary Catheterization; Urinary Tract Infections; Cross Infection (MeSH).

Resumen

Introducción. La infección asociada al catéter urinario es responsable de hasta un 30% de las infecciones nosocomiales. Al respecto, se ha descrito el uso de intervenciones no farmacológicas durante la inserción del catéter urinario para reducir la frecuencia de infecciones asociadas.

Objetivo. Evaluar la seguridad y la efectividad de intervenciones no farmacológicas durante la inserción del catéter urinario diseñadas para reducir el riesgo de infección en adultos inmunocompetentes.

Materiales y métodos. Se realizó una búsqueda en las bases de datos MEDLINE, Embase y LILACS. Se incluyeron ensayos clínicos aleatorizados que compararan el uso de intervenciones no farmacológicas con el uso de placebos, el uso de intervenciones farmacológicas o la ausencia de intervención durante la inserción del catéter.

Resultados. Se encontraron ocho estudios (8 718 participantes). Con base en la evidencia encontrada (baja y muy baja calidad según la clasificación del sistema GRADE), el uso de intervenciones no farmacológicas reduce la frecuencia de bacteriuria asintomática (RR 0.67; IC95%: 0.48-0.94; 7 estudios) o de eventos adversos menores (RR 0.84; IC95%: 0.74-0.96; 2 estudios), pero no disminuye la tasa de infecciones sintomáticas del tracto urinario (RR 0.90; IC95%: 0.61 a 1.35; 4 estudios), ni mejora las puntuaciones de calidad de vida (escala MD -0.01 EQ-5D; IC95%: (-0.03)-(0.01), 1 estudio).

Conclusión. El uso de intervenciones no farmacológicas durante la inserción del catéter urinario no supone riesgo alguno y sí podría ayudar a disminuir la frecuencia infecciones asociadas a este procedimiento, tales como la bacteriuria asintomática y eventos adversos menores; sin embargo, hay poca evidencia, y de baja o muy baja calidad, para llegar a conclusiones sobre su efectividad.

Palabras clave: Intervención médica temprana; Cateterismo urinario; Infecciones urinarias; Infección hospitalaria (DeCS).
Introduction

Catheterization is a common procedure that consists of the insertion of a latex, polyurethane, or silicone tube into the bladder to drain its contents. Urinary catheters can be indwelling or placed intermittently depending on the indications and the patient’s condition. Intermittent catheters are inserted every 6 to 8 hours, while indwelling catheters are inserted for a period of time greater than 24 hours, and are usually connected to a collection bag. Indwelling catheterization is typically used in patients with pathologies such as prostatic hyperplasia, neurogenic bladder, urinary retention, severe urinary incontinence, as well as critically ill patients and those with pressure ulcers in the sacral region, or with contaminated perineal lesions associated with incontinence.

Urinary catheterization is a minor procedure undertaken in up to 25% of all hospitalized patients. It carries substantial risks and causes high morbidity and mortality secondary to bacteremia, as well as longer hospital stays and higher resource consumption. Catheter-associated urinary tract infection (CAUTI) accounts for up to 30% of health-care associated infections. In Latin America, CAUTI is the third leading cause of nosocomial infections and its incidence is estimated at 8.9 cases per 1,000 days of exposure to this device. In Colombia, the estimated prevalence is 12% to 45%, which makes it one of the top five infections reported in the country. In Bogotá, a prevalence of 16.1% was reported for the 2012-2013 period, with an incidence rate of 3.9 cases per 1,000 days of exposure. Since urinary catheterization carries substantial risks, multiple interventions have been described with the aim of reducing the occurrence of infectious processes. Non-pharmacological interventions include staff training in catheter insertion and care. Access to guidelines and algorithms allows standardizing interventions that avoid variability among healthcare staff and guide the timely removal of unnecessary catheters.

Hand washing before and after catheter insertion and manipulation reduces non-saprophytic microflora without affecting the saprophytic microflora of the skin. Using an aseptic technique, sterile equipment and supplies during the preparation of the catheter insertion area and during the insertion, using barrier measures such as sterile gowns and gloves; and the use of antisepsics for cleaning the urinary meatus help reduce microbial load and the entrainment of microorganisms.

In addition, the lubricant applied prior to insertion contributes to bladder neck relaxation, facilitating the passage of the catheter, and also prevents urethral trauma, false passages and pain. Inserting a catheter of the smallest possible size can minimize urethral trauma and lead to a more effective drainage, while using a closed drainage system makes it more difficult for microorganisms to colonize the urethral meatus intraluminally.

Regarding pharmacological interventions, silicone catheters are recommended for patients requiring a long-term urinary catheter and in those with frequent obstruction of the device. Antimicrobial-coated catheters are used in patients with a CAUTI that does not decrease with the application of primary strategies. Finally, the consumption of blueberries, lactobacilli and Chinese herbal medicines has also been proposed to prevent urinary infections.

Since the use of catheters in clinical practice is heterogeneous and considering the frequency of adverse events and the appearance of infections associated with their insertion and use, this systematic review seeks to assess the effects of non-pharmacological interventions aimed at reducing the probability of CAUTI in the adult population. This will help develop policies designed to standardize the care of adult patients with urinary catheterization.

Materials and methods

The report was developed following the recommendations suggested by the Cochrane Handbook (CHB) and in accordance with the PRISMA statement. Review methods were established before conducting the literature search, which is detailed at http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017051553. Ethical approval was not required because this is a secondary study.

An attempt was made to identify as many relevant randomized controlled trials (RCTs) as possible, regardless of their language of publication. To this end, the Information Specialist of The Cochrane STI Group was contacted to conduct a complete search strategy, which was constructed using controlled vocabulary and text terms. The search was conducted in the MEDLINE, EMBASE, and LILACS databases. Grey literature was also consulted through the references listed in the included studies. The search was updated to September 30, 2016 (available at: https://www.crd.york.ac.uk/PROSPEROFILES/51553_STRATEGY_20161112.pdf) and citations were exported to EndNote version X6 (Thomson Reuters, New York, NY, USA). All published RCTs were included with no language restrictions.

The participants in the trials were non-immunocompromised men and non-pregnant women that required an indwelling urinary catheter as part of their inpatient or outpatient medical treatment. Indwelling urinary catheters are as those inserted for at least 24 hours in the urinary tract. The intervention of interest was the use of any non-pharmacological intervention during catheter insertion versus the use of placebo, or pharmacological interventions, or no intervention.

The primary outcomes were symptomatic urinary infection, time elapsed until the first episode of urinary infection, recurrent infection, bacteremia, asymptomatic bacteriuria, and major adverse effects associated with the intervention. The main secondary outcomes were satisfaction of participants, quality of life, mild adverse events, and cost-effectiveness of the intervention.

First, two authors (XSM and CFGA) selected the studies individually, and then, through consensus, they made the final selection of studies to be included in the systematic review. In addition, the other two authors (JAG and JLMV) assessed the risk of bias of the included RCTs using the tool suggested in the CHB sequence generation and allocation concealment,
blinding of participants, incomplete outcome data, selective reporting, and other risks of bias. Disagreement was resolved by consensus among all authors. All domains were assessed as low, high, or unclear risk of bias. The GRADE system was used for rating the quality of the evidence.

Results are presented as risk ratios (RR) with 95% confidence intervals (CI) and mean differences. I² statistic and Chi² test values were used to assess statistical heterogeneity, which was considered relevant if the I² statistic was greater than 40% and if there was a low p-value (less than 0.10) in the Chi² test for consistency. Statistical analyses were performed using Rev Man, with fixed-effect meta-analysis for combining data, unless there was substantial heterogeneity, while a random-effects model was implemented if there was clinical or significant statistical heterogeneity.

Results

The searches yielded 311 references, and 214 were screened after removing duplicates. Of those, the full texts of 30 references were reviewed. A total of 8 studies met the inclusion criteria; 12 papers were excluded because they were not RCTs, 6 trials implemented a different intervention and finally, 4 studies recruited a different kind of population. The following PRISMA diagram illustrates the selection process (Figure 1). For excluded RCTs and the rationale for exclusion, see Appendix A.

The selected RCTs were published from 1985 to 2012 and recruited participants from Sweden, the United Kingdom, Hong Kong, New Zealand, the USA and Belgium; 2 of those studies were funded by the industry. Retrieved studies involved 8718 men and women with an age range between 20 and 95 years, who required long-term catheterization (>24 hours) during their hospital stay due to general, cardiac, orthopedic or elective urologic surgery; 3 studies did not include information in this regard. The studies excluded patients with current or previous urinary tract infection, recent exposure to antibiotics, history of diabetes or pelvic radiotherapy, or with a recent illness (Table 1).

![PRISMA flow chart. Source: Own elaboration.](image-url)

The intervention most commonly implemented was silicone-coated latex catheter in 5 studies; 2 studies described sterile catheterization as the intervention; and the remaining trials used non-coated silicone catheters. The comparator in 6 studies was non-coated silicone urinary catheter and in the other 2 it was clean/non-sterile catheterization technique.

Sterile catheterization is the process of cleaning the urethral meatus utilizing an antiseptic aqueous solution and avoiding contact with the practitioner’s gloves. The catheter is inserted following a non-touch technique and using forceps after lubrication with sterile lignocaine gel. On the other hand, participants assigned to non-sterile catheterization used sterile water and non-sterile gloves.
Table 1. Main characteristics of the studies selected.

| Author                  | Year  | Study design | Title                                                                 | Country     | Population                   | Age (mean ± SD) | Number of participants | Intervention                                      | Primary outcomes | Secondary outcomes |
|-------------------------|-------|--------------|----------------------------------------------------------------------|-------------|------------------------------|-----------------|------------------------|---------------------------------------------------|-----------------|--------------------|
| Carappetti et al.19     | 1994  | RCT          | Water versus antiseptic periurethral cleansing before catheterization among home care patients: a randomized controlled trial | England     | Elective cardiac surgery     | 22-91           | 156                    | Sterile catheterisation                           | Bacteriuria     | Costs               |
| Cheung et al.20         | 2008  | RCT          | Silver alloy coated catheters reduce catheter-associated bacteriuria | Hong Kong   | Elective surgery             | 48-52           | 20                     | Sterile water                                    | Symptomatic bacteriuria | Microbiologically confirmed symptomatic CAUTI |
| Liedberg & Lundberg et al.21 | 1990  | RCT          | Catheter-induced urethritis: a comparison between latex and silicone catheters in a prospective clinical trial | Sweden      | Surgery or Internal medicine | 20-73           | 120                    | Sterile coated latex catheter                    | Bacteriuria     | Catheter-related symptoms |
| Nacey et al.22          | 1985  | RCT          | Antimicrobial catheters for reduction of symptomatic urinary tract infection in adults requiring short-term catheterisation in hospital: a multicentre randomised controlled trial | New Zealand | Surgery or Internal medicine | 59              | 100                    | Silicone catheter                                 | Symptomatic CAUTI | Catheter-related symptoms |
| Pickard et al.23        | 2012  | RCT          | A large randomised clinical trial of a silver-impregnated urinary catheter: lack of efficacy and staphylococcal superinfection | United Kingdom | Elective orthopedic surgery | 63.94           | 6394                   | Silver alloy-coated latex catheter                | Bacteriuria     | Time to develop bacteriuria |
| Riley et al.24          | 1995  | RCT          | Noble metal alloy-coated latex versus silicone Foley catheter in short-term catheterisation: a randomized controlled study | Salt Lake City | Elective urologic surgery    | 1309            | 1309                   | Silver coated latex catheter                      | Bacteriuria     |                    |
| Stenzelius et al.25     | 2011  | RCT          | Clinical application of the Bardex IC Foley catheter                  | Belgium     |                              | 180             | 180                    | Silver coated catheter                            | Bacteriuria     |                    |
| Verleyen et al.26       | 1999  | RCT          |                                                                                   |             |                              |                 |                        |                                                    | Bacteriuria     |                    |

RCT: Randomized controlled trial; PTFE: Polytetrafluoroethylene; CAUTI: Catheter-Associated Urinary Tract Infection.
Source: Own elaboration.

The included RCTs assessed at least one predetermined outcome, with some minor differences in the definition of the results between papers. A total of 7 studies reported bacteriuria as the primary outcome, using as threshold 10⁵ colony-forming units (CFU) per milliliter (mL), except for one study that defined a lower threshold (>1,000 CFU/mL). Three studies reported symptomatic urinary infection —defined as penile discomfort and purulent urethral discharge— reported by the patient or the caregiver, or bacterial colonization in urine, or the presence of symptoms accompanied by antibiotic prescription.

Urinespimens were collected at the time of catheterization, at the time of catheter removal, or within 7 to 14 days after catheterization. The secondary outcomes reported by the trials were quality of life (EuroQol scale; EQ-5D), mild adverse events, and costs of the intervention. For this study, data for primary outcomes (time elapsed until the first episode, recurrent urinary tract infection, bacteremia, or significant side effects), or the secondary outcome (patient satisfaction) were not collected. Finally, follow-up of participants ranged between 3 and 14 days, or 6 weeks, or 6 months.

According to the GRADE system, publications bias should be assessed using a funnel plot and asymmetry statistical tests if 10 or more studies are included in a systematic review or a meta-analysis; therefore, since only 8 studies were included in this review, a funnel plot was not required to assess publication bias. The RCTs included had limitations regarding the use of risk of bias tools, which are detailed in Figure 2 and Appendix B. In
this regard, 4 trials\textsuperscript{19,22,23,25} implemented a valid sequence generation method and 3 established an adequate allocation concealment process (Figure 2),\textsuperscript{19,22,23,25} making selection bias unclear.

Regarding blinding, 5 studies\textsuperscript{19-21,24,26} did not report the method implemented. However, the studies were considered to be at low risk of detection and performance bias since the results were objectively appraised (i.e., culture) and, therefore, the lack of blinding is unlikely to affect confidence in the results. One study\textsuperscript{22} was masked to the allocated intervention because of the similarity of the interventions, making performance and detection bias unlikely. Finally,\textsuperscript{23,25} the participants of 2 trials were not masked to the intervention because of the distinctive appearance of the catheters; based on the subjective nature of some outcomes (i.e., mild adverse events of the intervention), these RCTs were considered as having high risk of performance and detection bias.

With respect to possible attrition bias, 2 RCTs\textsuperscript{22,24} appropriately mentioned the exclusions (<20%) and the reasons were balanced between the arms, making incomplete outcome data bias unlikely. For 6 studies, trial protocols were not available and were assessed as having unclear risk of bias.\textsuperscript{19-22,24,26} Finally, all RCTs were at low risk of other potential sources of bias. Table 2 presents a detailed description of the quality of the evidence.

### Table 2. Quality of the evidence regarding non-pharmacological interventions at the time of insertion of an indwelling catheter for reducing urinary tract infection in non-immunocompromised adults.

| Outcomes                              | Absolute effects* (95% CI) | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) |
|---------------------------------------|-----------------------------|--------------------------|-----------------------------|--------------------------------|
| Symptomatic urinary infection         | 136/1000 (83-184)           | RR 0.90 (0.61-1.35)      | 4762 (4 RCTs)               | VERY LOW *, †, ‡               |
| Asymptomatic bacteriuria              | 175/1000 (84-164)           | RR 0.67 (0.48-0.94)      | 5810 (7 RCTs)               | LOW *, **                      |
| Mild adverse events after the intervention | 193/1000 (143-186)       | RR 0.84 (0.74-0.96)      | 4157 (2 RCTs)               | LOW *, ††                      |
| Quality of life                       | MD - 0.01 (-0.03-0.01)     | -                        | 3672 (1 RCT)                | LOW ‡, ‡‡                      |

* Two trials have high risk of detection, attrition and reporting bias.
† Heterogeneity $I^2=63\%$.
‡ CI overlaps the line of no difference and failed to exclude appreciable benefit or harm.
** Relevant heterogeneity $I^2=71\%$.
†† Heterogeneity $I^2=0\%$.
‡‡ High risk for detection, attrition, and selective reporting.
Source: Own elaboration.

Low-quality evidence showed that, compared to the control group, the use of non-pharmacological intervention does not seem to decrease the frequency of symptomatic urinary infections\textsuperscript{19,22,23,25} (RR 0.90, 95% CI: 0.61-1.35; 4 762 participants, 4 RCTs; 12 statistic: 63%), or improve quality-of-life scores (MD –0.01 EQ-5D scale; 95% CI: -0.03 - 0.01, 1 RCT) (Figure 3). However, there was evidence of differences between groups in terms of asymptomatic bacteriuria episodes\textsuperscript{19,21,23-26} (RR 0.67, 95% CI: 0.48-0.94; 5 810 participants,
Interventions for reducing CAUTI

7 studies; I² statistic: 71% (Figure 4) and the rate of mild adverse events \(^2,25\) (RR 0.84, 95%CI: 0.74-0.96; 4 157 participants, 2 trials; I² statistic: 0%) (Figure 5).

| Non-pharmacological intervention | Control | Risk Ratio |
|----------------------------------|---------|------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H. Random | 95%CI |
| Cheung 2008 | 0 | 12 | 0 | 8 | | Not estimable | |
| Nacey 1985 | 1 | 50 | 11 | 50 | 3.7% | 0.99 [0.01, 0.68] |
| Pickard 2012 | 263 | 2097 | 271 | 2144 | 55.6% | 0.99 [0.85, 1.16] |
| Stenzelius 2011 | 45 | 202 | 45 | 199 | 40.6% | 0.99 [0.68, 1.42] |

Total (95% CI)

Total events 309
Heterogeneity: Tau²=0.07; Chi²=5.47 df=2(P = 0.06); I²=63%
Test for overall effect: Z=0.49 (P=0.62)

Figure 3. Symptomatic urinary infection as an outcome after performing any of the non-pharmacological interventions during catheter insertion.
Source: Own elaboration.

| Non-pharmacological intervention | Control | Risk Ratio |
|----------------------------------|---------|------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H. Random | 95%CI |
| Carapeti 1994 | 7 | 12 | 0 | 8 | | Not estimable | |
| Cheung 2008 | 0 | 50 | 11 | 50 | 3.7% | 0.99 [0.01, 0.68] |
| Liedberg 1990 | 6 | 2097 | 271 | 2144 | 55.6% | 0.99 [0.85, 1.16] |
| Pickard 2012 | 310 | 202 | 45 | 199 | 40.6% | 0.99 [0.68, 1.42] |
| Riley 1995 | 85 | 745 | 73 | 564 | 23.7% | 0.88 [0.66, 1.18] |
| Stenzelius 2011 | 3 | 202 | 11 | 199 | 5.7% | 0.27 [0.08, 0.95] |
| Verleyen 1999 | 28 | 79 | 60 | 101 | 22.4% | 0.60 [0.43, 0.84] |

Total (95% CI)

Total events 2957 2853 100.0% 0.67 [0.48, 0.94]
Heterogeneity: Tau²=0.10; Chi²=20.57 df=6(P=0.002): I²=71%
Test for overall effect: Z=2.31 (P=0.02)

Figure 4. Asymptomatic bacteriuria as an outcome after performing any of the non-pharmacological interventions during catheter insertion.
Source: Own elaboration.
measured resource and capital expenditure associated with the implementation of sterile interventions compared to clean catheterization. The recruited participants underwent preoperative urethral catheterization and the direct costs were estimated based on the supplies utilized: gloves, sterile gown, catheter pack, lignocaine gel, vaginal gel, sterile water, 10-milliliter syringes, catheter bag, Foley catheter, scrub solution, and skin preparation. Compared with clean catheterization, sterile technique doubled care-associated costs, as the total cost per participant was close to GBP 7.49 versus GBP 3.06, respectively, in 1994. This study did not assess indirect or long-term intervention-related costs.

To explore heterogeneity, a subgroup analysis was performed for the asymptomatic bacteriuria outcome. The tests for subgroup effect were not significantly different when the source of heterogeneity was explored (p=0.54, data not shown). Subgroup analyses did not explain the variability in the summary effect measures for the asymptomatic bacteriuria outcome, so these findings should be interpreted with caution. The outcomes symptomatic urinary infection, time elapsed until the first episode of urinary tract infection and major adverse effects derived from the intervention were not analyzed because of the sparse information provided by the RCTs included in the present review.

### Discussion

This systematic review retrieved low-quality evidence to support the implementation of non-pharmacological interventions at the time of urinary catheter insertion to reduce the risk of infection in non-immunocompromised adults with indwelling catheterization. Regardless of the comparison, non-pharmacological interventions seem to reduce the frequency of asymptomatic bacteriuria episodes and the rate of mild adverse events.

One of the strengths of this systematic review is that its methodology was planned, developed and published at PROSPERO before conducting it, and all the methods that were established at that time were followed while doing the review, namely, a comprehensive literature search without language or date restrictions, two reviewers in charge of the selection of studies, data extraction and bias risk assessment using the tool suggested in the CHB; evidence ranking by means of the GRADE approach; and the use of subgroup analyses and methods for statistical analysis.

One of the weaknesses of the present review is that the quality of the evidence found was very low according to the GRADE system; therefore, further research is highly likely to change the conclusions presented here. On the other hand, the RCTs included were heterogeneous and publication bias was not assessed using a funnel plot due to the recommendation of the GRADE system regarding the detection of this type of bias when less than 10 studies are included in a meta-analysis or a systematic review.

There were no other systematic reviews evaluating the impact of non-pharmacological interventions for catheter insertion in cases of urinary tract infection that require long-term catheterization. Consistent with this review, a Cochrane review concludes that the use of silver-coated catheters reduces the frequency of asymptomatic bacteriuria, but the studies reviewed there only assessed short-term catheterization.

### Conclusion

Very low-quality evidence shows that non-pharmacological interventions at the time of urinary catheter insertion in non-immunocompromised adults could reduce the frequency of asymptomatic bacteriuria episodes and mild adverse events, without reducing the rate of symptomatic urinary infections or improving quality-of-life scores.
Conflicts of interest

None stated by the authors.

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Appendix A. Characteristics of the excluded studies.

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Supplemental Digital Content

Appendix B. Summary of risk of bias according to the authors of this review for each included study

| Random sequence generation (selection bias) | Four trials\(^{19,22,23,25}\) adequately reported the random sequence generation method by using a computer-generated randomization list or flipping a coin, making selection bias at entry unlikely. The remaining trials\(^{20,21,24}\) did not report the random sequence generation method, making the risk of selection bias at entry unclear. |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |

| Allocation concealment (selection bias) | Three studies adequately implemented an allocation concealment method by using sequentially numbered sealed envelopes,\(^{25}\) a central randomization,\(^{23}\) or flipping an unbiased coin,\(^{19}\) making selection bias at entry unlikely. The other 5 trials\(^{20-22,24,26}\) did not report the allocation concealment method used, so the risk of bias for this domain was deemed unclear. |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |

| Blinding (performance and detection bias) | Five studies,\(^{19-21,24,26}\) did not report the implemented methodology to blind study participants, outcome assessor and personnel from knowing what intervention was given to the participant. However, the studies were considered to be at low risk for performance or detection bias because the outcomes were objectively assessed (i.e., culture), so the lack of blinding would be unlikely to affect results. One study\(^{22}\) was masked to the allocated intervention because of the similarities of each catheter, making performance and detection bias unlikely. Finally, in two trials,\(^{23,25}\) participants, clinicians and trial team were not masked to the allocated intervention because of the distinctive characteristics of each catheter, making performance and detection bias unlikely. |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |

| Incomplete outcome data (attrition bias) | Two trials\(^{22,24}\) appropriately reported the attrition and exclusions at each stage; the reasons were balanced across groups and the level of missing data was not more than 20%, making attrition bias unlikely. Four studies\(^{20-22,25,26}\) had a discontinuation rate and follow-up loss greater than 20%, so they were appraised as high risk of attrition bias. Finally, 2 trials\(^{19,20}\) did not have enough information to permit judgment of “yes” or “no” (rated as unclear risk of bias). |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |

| Selective reporting (reporting bias) | Some outcomes were not pre-specified in the protocol stage in two of the trials included,\(^{21,23}\) but they were reported in the manuscript. These trials were considered to be at high risk of selective reporting bias. For 6 studies,\(^{19-22,24,26}\) the trial protocol was not available, and it is unclear whether the published reports presented all the expected outcomes, including those that were pre-specified. The report had insufficient information to permit judgment of “Yes” or “No” (rated as unclear risk of bias). |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |

| Other potential sources of bias | All retrieved trials seemed to be free from other sources of bias and were rated as low risk of bias for this domain. |
|---|---|
| Risk of Bias | Low | Unclear | High |
| Reference | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |