



RCT-based meta-analysis of povidone-iodine irrigation in spinal surgery: clarifying efficacy and safety

Chinedu Egu¹ · Rodrigo Muscogliati¹ · Weronika Nocun¹ · Hussein Akil¹ · Wasse U. Saleh¹ · Babajide Obidigbo¹ · Rebecca Aida Hakim¹ · Nasir A. Quraishi¹ · Khalid Salem¹ · Elie Najjar¹

Received: 25 June 2025 / Revised: 29 July 2025 / Accepted: 30 July 2025

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Abstract

Purpose Surgical site infections (SSIs) remain a significant complication in spinal surgery, particularly in instrumented procedures, contributing to increased morbidity, prolonged hospitalization, and healthcare costs. Intraoperative wound irrigation (IWI) using antiseptic solutions such as povidone-iodine (PI) has been proposed as a preventive strategy. This systematic review and meta-analysis evaluate the efficacy of PI irrigation against control interventions, in reducing postoperative SSIs and examines its effect on spinal fusion outcomes.

Methods Following PRISMA guidelines, a comprehensive search of Ovid MEDLINE, EMBASE, Web of Science, and the Cochrane Library was conducted through March 2025. Only randomized controlled trials (RCTs) comparing PI irrigation to control interventions (saline or no irrigation) in adult spinal surgery were included. The primary outcome was overall SSI rate. Secondary outcomes included superficial and deep SSI rates, fusion rates, and adverse events. Data were pooled using a random-effects model, and heterogeneity was assessed using the I^2 statistic.

Results Six RCTs involving 1,804 patients (901 PI group, 903 control group) were included. Pooled analysis demonstrated a significant reduction in overall SSI with PI irrigation (0.77% vs. 6.0%; RR=0.16, 95% CI: 0.08–0.34; $P<0.00001$; $I^2=0\%$). Subgroup analyses showed significant reductions in both superficial (RR=0.19; 95% CI: 0.07–0.52; $P<0.001$) and deep SSIs (RR=0.21; 95% CI: 0.08–0.52; $P=0.0009$), with absolute infection rates reduced from 2.9 to 0.33% and from 3.2 to 0.4%, respectively. Fusion rates were comparable between groups (RD=0.03; 95% CI: 0.00–0.06; $P=0.10$).

Conclusion PI irrigation significantly lowers the risk of both superficial and deep SSIs in spinal surgery without negatively impacting fusion outcomes. These findings are based on Level I evidence and support the integration of PI irrigation into routine perioperative protocols as a low-cost, effective adjunct for infection prevention.

Keywords Surgical site infection · Povidone iodine · Spine fusion · Spine surgery · Intraoperative wound irrigation · Infection prophylaxis · Complications

✉ Chinedu Egu
chinedu.brian.egu@gmail.com

Rodrigo Muscogliati
rmuscogliati@gmail.com

Weronika Nocun
weronika.nocun@gmail.com

Hussein Akil
husseinakill@yahoo.com

Wasse U. Saleh
wasse.saleh012@gmail.com

Babajide Obidigbo
obidigbobabajide@gmail.com

Rebecca Aida Hakim
rebeccaaidahakim@gmail.com

Nasir A. Quraishi
Nasquraishi@hotmail.com

Khalid Salem
kmsalem.clinic@gmail.com

Elie Najjar
elie.njjr@gmail.com

¹ The Centre for Spinal Studies and Surgery, Nottingham University Hospital NHS Trust, NG7 2UH Nottingham, UK

Introduction

Surgical site infection (SSI) is a major source of postoperative morbidity in spinal surgery, with incidence rates ranging from 0.7 to 12% depending on the procedure type, spinal level, and patient comorbidities [1, 2]. These infections are associated with prolonged hospitalization, delayed functional recovery, increased reoperation rates, and significant healthcare costs. In the United States alone, SSIs in spine surgery have been estimated to incur additional costs exceeding \$20,000 per case [3, 4].

Despite adherence to evidence-based perioperative protocols—including systemic antibiotic prophylaxis, meticulous surgical technique, and skin antisepsis—SSI remains a persistent and challenging complication, particularly in instrumented procedures [5, 6]. As such, adjunctive strategies to further reduce infection risk are under continuous evaluation.

Intraoperative wound irrigation (IWI) is one such strategy that has gained traction. Among various agents, povidone-iodine (PI) is notable for its rapid and broad-spectrum antimicrobial activity, affordability, and global availability [7]. PI has demonstrated efficacy against gram-positive and gram-negative bacteria, including multidrug-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) [8, 9]. With rising antimicrobial resistance, non-antibiotic antiseptics such as PI offer an appealing alternative in surgical infection control.

However, despite its potential, PI's widespread adoption in spinal procedures remains controversial. Concerns about osteoblast cytotoxicity—based largely on in-vitro studies—have raised theoretical risks of impaired bone healing and compromised fusion outcomes [10, 11]. This uncertainty has led to inconsistent use in clinical practice.

International guidelines reflect this tension. The World Health Organization (WHO, 2018) discourages intraoperative antibiotic irrigation in clean wounds but endorses antiseptics such as PI when appropriately applied. Observational studies have shown encouraging reductions in SSI rates following intraoperative PI use [12–15], yet high-quality randomized controlled trial (RCT) data have only recently emerged [10, 16–20].

Previous meta-analysis [21–23] have compared different IWI solutions and techniques in spinal surgery, including retrospectively collected data in their analysis. No prior meta-analysis has synthesized only level I evidence from RCTs evaluating the efficacy and safety of PI irrigation specifically in spinal surgery. Heterogeneity in PI irrigation protocols—ranging from concentration to volume and timing—reflects not only the absence of standardization but also significant variation in current surgical practice

[21–23]. This gap underscores the need for a focused, high-quality analysis of outcomes relevant to spinal surgeons.

In this context, we conducted a systematic review and meta-analysis of randomized controlled trials to assess the efficacy of intraoperative PI irrigation in reducing SSIs in spinal surgery. As a secondary aim, we evaluated whether PI irrigation adversely affects fusion outcomes. By synthesizing the highest available evidence, this study aims to clarify the clinical utility of PI and inform standardized perioperative protocols in spinal surgery.

Methods

Search strategy and study selection

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [24]. A comprehensive literature search was performed across Ovid MEDLINE, EMBASE, Web of Science, and the Cochrane Library from database inception to March 2025. The search aimed to identify studies evaluating intraoperative wound irrigation (IWI) using povidone-iodine (PI) for the prevention of SSI in spinal surgery.

Search terms included a combination of MeSH terms and free-text keywords such as: “spine,” “spinal surgery,” “povidone-iodine,” “wound irrigation,” “surgical site infection,” “lavage,” and “disinfection.” Boolean operators and truncations were used to optimize sensitivity and specificity. Reference lists of eligible studies were screened manually for additional relevant publications.

Eligibility criteria

Studies were selected using the PICOS framework:

- **Population:** Adults undergoing spinal surgery.
- **Intervention:** Intraoperative wound irrigation with povidone-iodine.
- **Comparison:** No irrigation or alternative irrigation solutions (e.g., normal saline).
- **Outcomes:** Incidence of overall, superficial, and deep SSIs; spinal fusion rates; adverse events.
- **Study Design:** RCTs published in English.

Exclusion criteria were:

- Non-human studies.
- Non-RCT designs (e.g., observational studies, case series, reviews).

- Studies not reporting SSI outcomes as a primary or secondary endpoint.

Study screening and data extraction

Two independent reviewers screened titles and abstracts. Full texts of potentially eligible articles were retrieved and assessed for inclusion. Disagreements were resolved by a third reviewer through discussion and consensus.

Data were extracted using a pre-defined data collection sheet. The following variables were collected:

- **Study characteristics:** First author, year of publication, country, design, sample size.
- **Patient demographics:** Age, sex, spinal pathology, spinal level, instrumentation status.
- **Intervention details:** PI concentration, irrigation volume, application duration, co-interventions.
- **Outcome measures:** Rates of overall, superficial, and deep SSIs; fusion success; reported complications or adverse events.

Quality assessment

Risk of bias was assessed independently by two reviewers using the Cochrane Risk of Bias Tool [25]. This tool includes 13 domains, such as random sequence generation, allocation concealment, blinding of participants, care providers, and outcome assessors, completeness of outcome data, and selective reporting. Studies were categorized as:

- **Low risk of bias:** ≥ 9 criteria met.
- **Moderate risk:** 5–8 criteria met.
- **High risk:** < 5 criteria met.

Disagreements were resolved through consensus.

Statistical analysis

Statistical analyses were conducted using SPSS (version 30; IBM Corp., Armonk, NY, USA) and Review Manager (RevMan, version 5.4; Cochrane Collaboration). For dichotomous outcomes, relative risk (RR) or risk difference (RD) with 95% confidence intervals (CIs) were calculated. Heterogeneity was assessed using the I^2 statistic, with values of $< 25\%$ considered low, 25–50% moderate, and $> 50\%$ high heterogeneity. A random-effects model was employed for all pooled analyses to account for clinical and methodological diversity.

A PRISMA flow diagram was constructed to illustrate the study selection process.

Results

Study selection

The initial search identified 1,464 records. After removing 985 duplicates, 479 titles and abstracts were screened. Of these, 471 were excluded for irrelevance or failure to meet inclusion criteria. Eight full-text articles were assessed in detail, and six RCTs met the eligibility criteria [10, 16–20]. No additional studies were identified through manual reference screening. The study selection process is summarised in the PRISMA flow diagram Fig. 1.

Study characteristics

The six included RCTs comprised a total of 1,804 patients, with 901 receiving intraoperative povidone-iodine (PI) irrigation and 903 assigned to control interventions. In five trials, the control group received irrigation with normal saline, while one trial used saline supplemented with gentamicin. Sample sizes ranged from 50 to 936 participants. PI concentrations varied from 0.1 to 3.5%, and the application duration ranged from 2 to 5 min. Irrigation volume ranged from 0.2 to 2 L.

Four studies involved instrumented spinal procedures, one focused on non-instrumented surgery, and one included both. Surgical indications included degenerative disease, scoliosis, and disc prolapse, with anatomical regions spanning the lumbar, thoracolumbar, and entire spine. Detailed study characteristics are presented in Table 1.

Risk of bias assessment

Four studies [10, 16, 19, 20] were classified as low risk, having met at least nine of the thirteen evaluation criteria. Two studies [17, 18], met between five and eight criteria and were deemed moderate risk. Details of individual domain ratings are summarized in Table 2.

Meta-analysis of surgical site infection (primary outcome)

All six RCTs reported overall postoperative surgical SSI rates. Pooled analysis showed that PI irrigation significantly reduced the risk of SSIs compared to control (0.77% vs. 6.09%), yielding a relative risk (RR) of 0.16 (95% CI: 0.08–0.34; $P < 0.00001$). This corresponds to an absolute risk reduction (ARR) of 5.32%. No significant heterogeneity was detected across studies ($I^2 = 0\%$, $P = 0.62$), supporting the use of a random-effects model. These results are illustrated in Fig. 2.

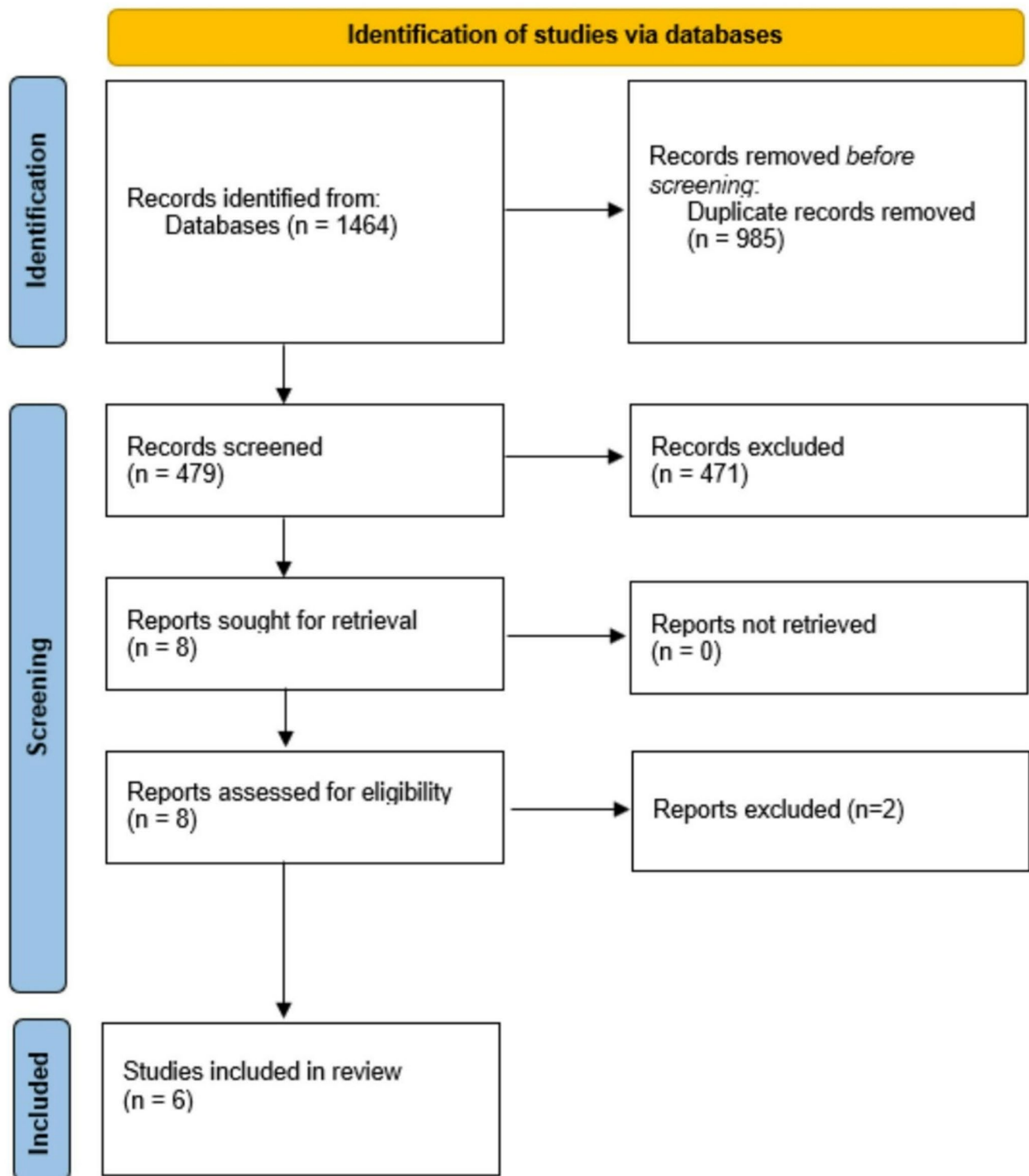


Fig. 1 PRISMA flow diagram of literature search

Table 1 Summary characteristics of included studies

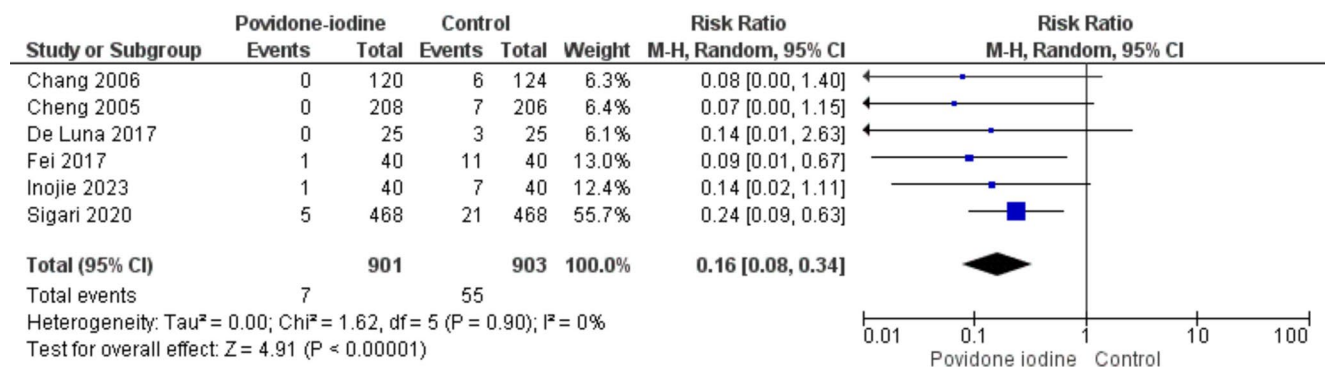
Study	Year	Country	Study design	Subjects, <i>n</i>		Population	Primary spine diagnosis	Spine location	Type of surgery
				PI Group	Control Group				
Chang et al. [10]	2006	China	RCT	120	124	Adults	Varied	Lumbosacral	Instrumented
Cheng et al. [16]	2005	China	RCT	208	206	Adults	Varied	Whole spine	Combined
De Luna et al. [17]	2017	Italy	RCT	25	25	Adults	Scoliosis	Whole spine	Instrumented
Fei et al. [18]	2017	China	RCT	40	40	Adults	Prolapsed lumbar disc	Lumbar	Instrumented
Inojie et al. [19]	2023	Nigeria	RCT	40	40	Adults	Varied	Whole spine	Non-instrumented
Sigari et al. [20]	2020	Germany	RCT	468	468	Adults	Varied	Thoracolumbar	Instrumented

(1) RCT– Randomised control trial

Table 2 Quality assessment results based on Cochrane review criteria

Items	Chang et al. [10]	Cheng et al. [16]	De Luna et al. [17]	Fei et al. [18]	Inojie et al. [19]	Sigari et al. [20]
Adequate randomisation	Y	Y	N	Y	Y	Y
Concealed treatment allocation	Y	Y	U	U	Y	Y
Patient blinded	Y	Y	U	U	Y	Y
Care provider blinded	N	N	U	U	Y	U
Outcome assessor blinded	U	U	U	U	U	Y
Drop out rate described	Y	Y	N	Y	Y	Y
All randomised participants analysed in the groups	Y	Y	Y	Y	Y	Y
No reports of selective outcome reporting	Y	U	Y	U	Y	Y
Groups similar at baseline for the most important prognostic indicators	Y	Y	Y	Y	Y	Y
Cointerventions avoided or similar	Y	Y	Y	Y	Y	Y
Compliance acceptable in all group	Y	Y	Y	Y	Y	Y
Time of outcome assessment in all similar groups	Y	Y	Y	Y	Y	Y
Other sources of potential bias unlikely	Y	Y	U	Y	Y	Y
Score	11/13	10/13	6/13	8/13	12/13	12/13

(1) Y–Yes, (2) N–No, (3) U–Unclear

**Fig. 2** Forest plot of the overall postoperative surgical site infection rate between both groups**Subgroup analysis: superficial and deep SSI**

PI irrigation was associated with significant reductions in both superficial and deep infection rates:

- **Superficial SSI:** 0.33% (PI) vs. 2.9% (control); RR=0.19 (95% CI: 0.07–0.52), $P < 0.001$ (Fig. 3).

- **Deep SSI:** 0.4% (PI) vs. 3.2% (control); RR=0.21 (95% CI: 0.08–0.52), $P = 0.0009$ (Fig. 4).

The consistent findings across infection types reinforce the efficacy of PI irrigation in reducing postoperative bacterial contamination.

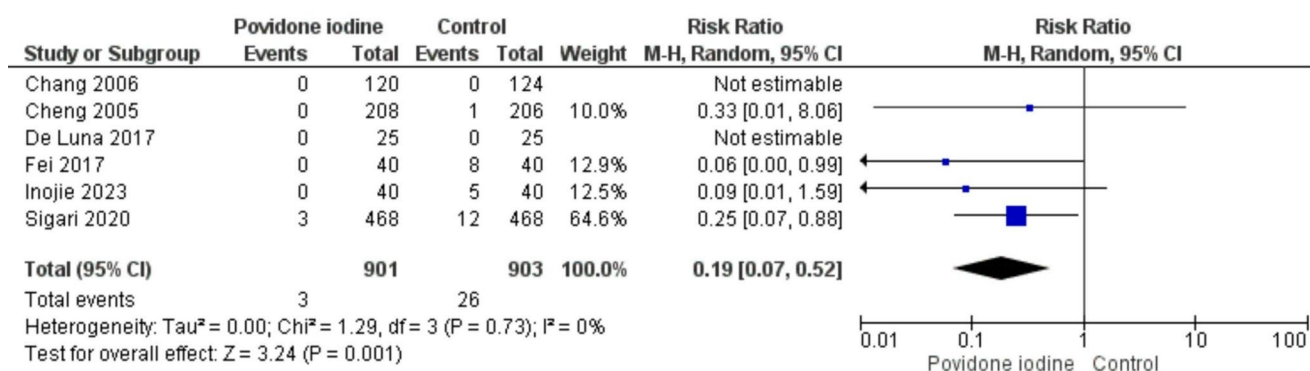


Fig. 3 Forest plot of the superficial surgical site infection rates between both groups

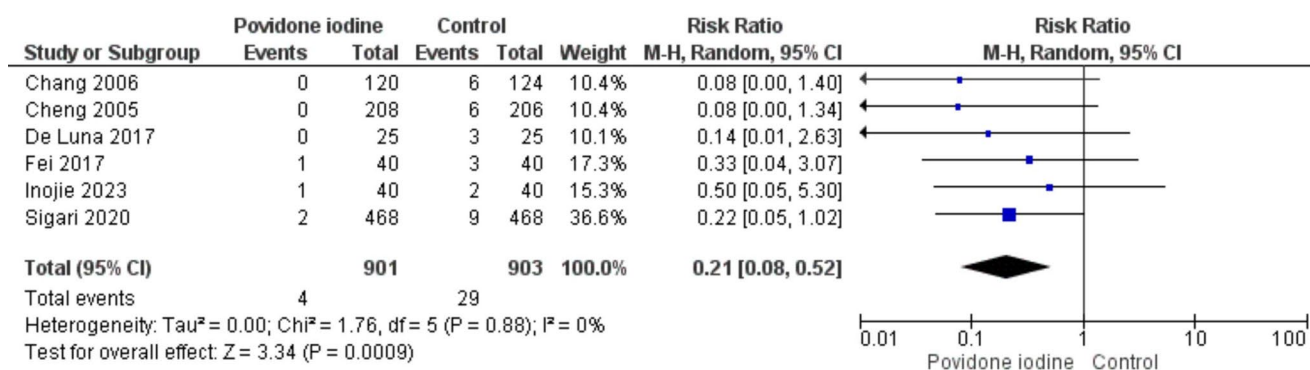


Fig. 4 Forest plot of the deep site infection rates between both groups

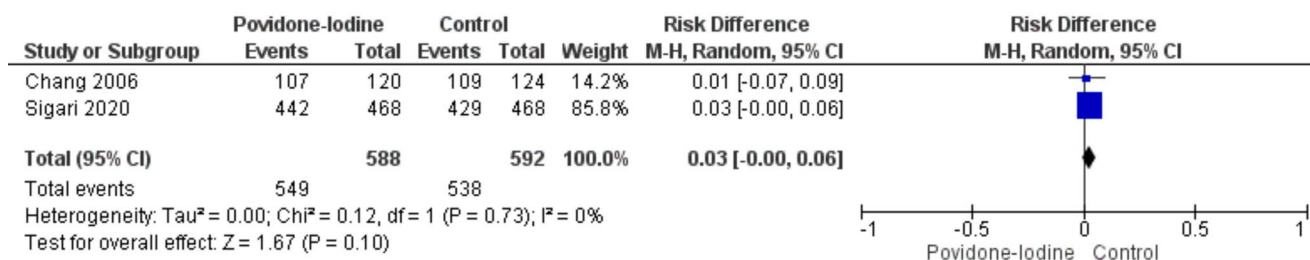


Fig. 5 Forest plot of the fusion rates between both groups

Four RCTs [10, 16, 17, 19] reported the microbial profiles of both the intervention and control groups. In the group treated with PI irrigation, only one study [19] identified *Pseudomonas* in a single surgical site infection (SSI). In contrast, the control group showed a broader range of organisms: MRSA ($n=10$, 45%), methicillin-sensitive *Staphylococcus aureus* ($n=5$, 22%), *Escherichia coli* ($n=2$, 9%), *Enterobacter* ($n=1$, 5%), *Pseudomonas* ($n=3$, 14%), and *Proteus* ($n=1$, 5%).

Fusion rates (secondary outcome)

Two RCTs [10, 20] reported spinal fusion outcomes. Meta-analysis revealed no statistically significant difference in fusion success between groups: Risk difference=0.03 (95%

CI: 0.00–0.06); $P=0.10$. Fusion rates were comparable, and there was no evidence to suggest a detrimental effect of PI irrigation on osseous healing Fig. 5.

Irrigation techniques and outcomes summary

Irrigation techniques varied across studies in concentration, volume, and timing. Most studies applied PI immediately prior to closure and followed with a saline rinse. Table 3 summarizes irrigation protocols, infection rates, and fusion outcomes.

A subgroup analysis was performed to evaluate the impact of PI irrigation concentration, volume, and duration on the overall rate of SSI. When comparing irrigation with $<3\%$ versus $\geq 3\%$ PI concentration, no statistically

Table 3 Irrigation techniques and outcomes of included studies

Study	Irrigation techniques [solution, volume (L), duration (min)]		Overall infection rate (PI vs. control group)	Superficial infection rate (PI vs. control group)	Deep infection rate (PI vs. control group)	Fusion rate (PI vs. control group)
	PI group	Control group				
Chang et al. [10]	0.35%, PI, 2 L, 3 min	Normal saline, 2 L	0% vs. 4.8%	0% vs. 0%	0% vs. 4.8%	89.1% vs. 87.9%
Cheng et al. [16]	0.35%, PI, 2 L, 2 min	Normal saline, 2 L	0% vs. 3.4%	0% vs. 0.5%	0% vs. 2.9%	n/a
De Luna et al. [17]	3%, PI, 2 L, 5 min	Normal saline, 2 L	0% vs. 12%	0% vs. 0%	0% vs. 12%	n/a
Fei et al. [18]	0.1%, PI, 0.2 L, 2 min	Normal saline, n/a	2.5% vs. 27.5%	0% vs. 20%	2.5% vs. 7.5%	n/a
Inojie et al. [19]	3.5%, PI, 1 L, 3 min	1 L saline with 80 mg gentamicin	2.5% vs. 17.5%	0% vs. 12.5%	2.5% vs. 5%	n/a
Sigari et al. [20]	3%, PI, n/a, 2 min	Normal saline, 2 L	1% vs. 4.5%	0.6% vs. 2.6%	0.2% vs. 1.9%	94.4% vs. 91.6%

(1) PI–Povidone iodine, (2) L–Liters, (3) min–minutes, (4) n/a–no available data, (5) mg–milligrams, (6) vs.–versus

significant difference in SSI rates was observed (0.8% vs. 1.4%, $P=0.30$). Similarly, there was no significant difference based on the volume of irrigation used, with trials employing <2 L versus ≥ 2 L showing SSI rates of 1.3% and 0%, respectively ($P=0.20$). Additionally, irrigation duration of <3 min compared to ≥ 3 min yielded no significant difference in SSI rates (1.4% vs. 0.8%, $P=0.30$). Despite the absence of statistical significance, a favourable trend was observed in studies utilising $<3\%$ PI concentration, ≥ 2 L irrigation volume, and ≥ 3 -minute duration. Lastly, when stratifying by type of surgery, PI irrigation did not result in a statistically significant difference in infection rates between instrumented and non-instrumented spinal procedures (1% vs. 2.5%, $P=0.30$).

Regarding adverse events, only two studies [16, 18] reported on their occurrence. Cheng et al. [16] did not specify the types of adverse events but stated there was no significant difference between the PI and control groups. In contrast, Fei et al. [18] reported significantly higher rates of wound effusion (67.5% vs. 20%, $p=0.001$) and post-operative pain (77% vs. 50%, $p=0.01$) in the saline group compared to the PI group, suggesting a potential protective effect of PI irrigation against these complications.

Discussion

This meta-analysis of six randomized controlled trials involving 1,804 patients provides level I evidence supporting intraoperative PI irrigation as an effective adjunct for reducing SSIs in spinal surgery. The pooled relative risk of 0.16 corresponds to an absolute risk reduction of 5.3%, indicating a clinically meaningful decrease in postoperative infection rates. Notably, this benefit was observed across both superficial and deep SSIs, with no statistical heterogeneity ($I^2 = 0\%$), suggesting a consistent and reproducible effect across varied surgical settings and study methodologies. Subgroup analyses revealed no significant differences in SSI prevention based on PI concentration ($<3\%$ vs. $\geq 3\%$), irrigation volume (<2 L vs. ≥ 2 L), or duration

(<3 min vs. ≥ 3 min). Furthermore, no adverse impact on fusion outcomes was reported in the two studies [10, 20] that specifically assessed this parameter.

SSIs remain a significant and persistent complication in spinal surgery, particularly in instrumented procedures. Despite adherence to established perioperative protocols—including systemic antibiotics, aseptic technique, and skin antisepsis—SSI rates continue to pose a challenge, leading to prolonged hospital stays, increased reoperation rates, and considerable healthcare costs [26, 27].

Our findings align with the current World Health Organization [28] recommendations, which advise against the use of intraoperative antibiotic irrigation in clean surgical fields but endorse antiseptic agents such as PI. Several of the included studies reported *Staphylococcus aureus*, particularly MRSA, as the most common organism found in surgical site infections—especially in the control groups. This highlights an important benefit of PI irrigation: its ability to target a broad range of microbes—gram positive and negative bacteria, fungi, viruses, including antibiotic-resistant bacteria [8,9]. PI works through a chemical mechanism that damages microbial cell walls, which means it remains effective even against tough, drug-resistant organisms like MRSA [29]. Unlike antibiotics, it's not prone to resistance [29]. The consistent reduction in infection rates across studies suggests that PI may be especially useful in today's surgical environment, where antimicrobial resistance is a growing concern. Its ability to reduce the risk of infection from these difficult-to-treat pathogens makes it a valuable and practical addition to spinal surgery protocols.

Concerns regarding PI's potential cytotoxicity to osteoblasts and its hypothetical negative impact on bone healing have limited its widespread adoption, especially in fusion procedures [10, 11]. However, our analysis of fusion outcomes from two high-quality RCTs [10, 20] revealed no evidence of adverse impact on fusion rates, reinforcing the safety profile of appropriately applied PI irrigation. However, more studies would help substantiate this finding.

Although this meta-analysis consolidates the highest level of available evidence, variability in the irrigation

technique across studies presents a limitation to standardized clinical adoption. PI concentrations ranged from 0.1 to 3.5%, with irrigation volumes varying between 0.2 L and 2 L, and application durations spanning 2 to 5 min. Subgroup analyses revealed no statistically significant differences in SSI rates based on PI concentration, volume, or irrigation duration, this may reflect the broad-spectrum efficacy of PI even at dilute concentrations. In vitro evidence shows that PI remains bactericidal at concentrations as low as 0.1–0.3% [30], potentially explaining the comparable outcomes between $<3\%$ and $\geq 3\%$ solutions. Similarly, the absence of differences with respect to volume and duration may indicate a threshold effect, where adequate lavage and exposure—rather than maximal volume or time—are sufficient for antimicrobial action. The timing of application, typically just prior to wound closure, may also play a critical role in maximizing efficacy. While some studies suggest repeat irrigation during prolonged surgeries or prior to grafting, these practices remain inconsistent [13, 17]. Overall, the data suggest that PI irrigation is technique-sensitive rather than strictly dose-dependent. Based on current evidence, using $\leq 3\%$ PI in ≥ 2 L volume for approximately 3 min followed by saline rinse appears to be a safe and practical approach, though further research is needed to define an optimal standardized protocol.

Despite variations in surgical indication, anatomical location, and procedure type, intraoperative PI irrigation consistently demonstrated efficacy in reducing surgical site infections across both instrumented and non-instrumented spinal procedures. Moreover, no significant difference in effectiveness was observed between complex, prolonged surgeries such as those for scoliosis correction and shorter procedures such as simple decompressions for prolapsed disc. These findings highlight the broad applicability of PI irrigation as a preventive measure against SSIs in diverse spinal surgical contexts.

Previous meta-analyses [21–23] have examined PI irrigation across broader surgical contexts, with the inclusion of observational studies. By narrowing our inclusion criteria to randomized controlled trials, this study provides the most rigorous assessment to date of PI's efficacy and safety in spinal procedures.

From a practical standpoint, the absolute risk reduction of 5.3% is both statistically and clinically significant. PI is an inexpensive, widely accessible, and easy-to-use adjunct, making it particularly advantageous in both high-resource and resource-limited healthcare settings. Notably, its efficacy was comparable across studies conducted in low-income regions [19] and high-income countries [10, 16–18, 20]. Given the substantial burden of SSIs and the consistent benefit observed across diverse clinical environments, our findings support the routine incorporation of PI irrigation

into spinal surgery protocols, especially in instrumented procedures where the risk of infection is higher.

It's worth noting that while most studies used plain saline as the control irrigation, Inojie et al. [19] used saline mixed with gentamicin, an antibiotic. This creates a small difference in how the control groups were treated. However, our results showed no statistical variation between studies ($I^2 = 0\%$), which suggests that this didn't significantly affect the overall findings. If anything, using an antibiotic in the control group could make it harder to show a benefit for PI, so the fact that PI still performed better supports the strength of our conclusions.

Limitations

This meta-analysis is limited by the relatively small number of included randomized controlled trials and significant variability in PI irrigation protocols—particularly with respect to concentration, volume, and duration of application. The absence of a standardized methodology across studies limits the ability to make direct comparisons and weakens the foundation for definitive clinical recommendations. Future research should aim to establish the optimal PI concentration, timing, and technique of irrigation to support protocol harmonization and widespread clinical adoption. Additionally, data on long-term outcomes, microbiological profiles of infections, and spinal fusion status were inconsistently reported. Only two studies evaluated fusion outcomes, and while the available evidence suggests no adverse impact from PI irrigation, further studies with long-term follow-up are necessary to confirm its safety in this regard. Finally, incomplete reporting of blinding and allocation concealment in several trials raises the potential for performance and detection bias, which may affect the internal validity of the findings.

Conclusion

This meta-analysis of randomized controlled trials provides level I evidence that intraoperative povidone-iodine irrigation significantly reduces the incidence of surgical site infections in spinal surgery. The intervention demonstrated consistent benefit across both superficial and deep infections without evidence of harm to spinal fusion outcomes. Despite some variability in technique, the overall safety, affordability, and antimicrobial efficacy of PI support its integration into perioperative protocols, particularly for instrumented spinal procedures. Future research should focus on standardising irrigation protocols to optimise efficacy and facilitate broader clinical adoption.

Author contributions C.E, R.M, W.N, H.A, W.U.S, B.O, R.A.H was involved with abstract and full article screening, and data collection. C.E, R.M, E.N was involved with data analysis. C.E, N.A.Q, K.S, E.N was involved with manuscript writing. All authors reviewed the manuscript.

Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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