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Clinical Study

Does intraoperative antiseptic solution soaking reduce microbial contamination in spine surgery? A randomized controlled trial

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Abstract

BACKGROUND CONTEXT: Surgical site infections (SSIs) are a significant complication in spine surgery, particularly in instrumented procedures, leading to increased morbidity and healthcare costs. Despite standard preoperative disinfection protocols, bacterial contamination remains prevalent. Strategies such as intraoperative antiseptic irrigation have been explored to mitigate contamination, yet the comparative efficacy of different antiseptic solutions remains unclear.

PURPOSE: This study aimed to evaluate the effectiveness of intraoperative antiseptic solution soaking with normal saline (NS), povidone-iodine (PVP-I), and chlorhexidine gluconate (CHG) in reducing bacterial contamination in lumbar instrumented fusion surgery.

STUDY DESIGN/SETTING: A single-center, single-blinded, randomized controlled trial was conducted at a tertiary medical center in Taiwan.

PATIENT SAMPLE: A total of 105 patients undergoing posterior lumbar interbody fusion surgery were enrolled and randomly assigned to three groups: NS (n=35), PVP-I (n=35), or CHG (n=35). Patients with prior lumbar procedures, known allergies to antiseptics, previous spinal infections, trauma, or tumors were excluded.

OUTCOME MEASURES: The primary outcome was the reduction in bacterial contamination, assessed via intraoperative cultures from three sites—superficial tissues, deep tissues, and implant surfaces—before and after antiseptic irrigation. Secondary outcomes included the incidence of postoperative SSIs and clinical complications over a 6-month follow-up period.

METHODS: Patients were randomized into three groups, each receiving a 3-minute soak with the assigned antiseptic solution before wound closure, followed by normal saline irrigation. Swab samples were collected pre- and postirrigation for bacterial culture and 16S rRNA PCR analysis. Statistical analysis was performed using logistic regression and Bonferroni correction for multiple comparisons.

FDA device/drug status: Not applicable.

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RESULTS: Among 105 patients, preirrigation bacterial culture positivity rates were 49.5% in superficial tissues, 31.4% in deep tissues, and 32.4% on implants. Postirrigation, NS showed no significant bacterial reduction, while PVP-I reduced superficial contamination (55.0%, p=.015) but no significant effect in deeper tissues and implants. CHG showed the greatest bacterial reduction, significantly outperforming NS (OR: 0.06, 95% CI: 0.01–0.54, p=.011) and PVP-I (OR: 0.06, 95% CI: 0.01–0.56, p=.012) on implant surfaces. Despite these differences in culture rate, SSI rates remained low and comparable among groups (p=.72), with no reported antiseptic-related complications.

CONCLUSION: This study confirms that bacterial contamination remains high despite standard preoperative disinfection in lumbar fusion surgery. Among the tested antiseptic solutions, CHG demonstrated superior efficacy in reducing bacterial residues, particularly on implant surfaces. These findings support CHG as a promising antiseptic for intraoperative irrigation in spine surgery. Further multi-center studies are needed to validate its impact on reducing SSIs and improving long-term outcomes.

LEVEL OF EVIDENCE: Level II.

Keywords: Antiseptic irrigation; Chlorhexidine gluconate (CHG); Implant infection; Spinal surgery; Surgical site infection (SSI)

Introduction

Surgical site infections (SSIs) are significant complications of spine surgery, with reported incidence rates ranging from 0.2% to 17% [1], and even higher rates in implant-related procedures. These rates can increase to 9% in instrumented spinal surgeries for traumatic fractures and up to 19% in pediatric deformity surgeries [2,3]. SSIs result in prolonged hospital stays, increased healthcare costs, and the need for revision surgeries [4]. Previous studies have shown that even with thorough skin disinfection protocols, surgical wounds exhibit a bacterial culture positivity rate of approximately 40%. Among the identified microorganisms, Staphylococcus epidermidis and Cutibacterium acnes are the most prevalent [5]. Cutibacterium acnes has garnered increasing attention for its role in postoperative spinal infections. These infections can cause low-grade inflammation, potentially leading to severe complications such as pseudoarthrosis and spinal instrumentation issues, including loosening or failure [6,7]. These complications not only compromise patient outcomes but also pose significant challenges for revision surgery and long-term management [8]. Apart from their role in postoperative infections, Staphylococcus epidermidis and Cutibacterium acnes have been implicated in the pathophysiology of disc degeneration. Research suggests that their presence may contribute to chronic low-grade inflammation and structural degradation within intervertebral discs, potentially worsening degenerative spinal conditions and leading to adjacent segment disease [9]. This dual impact underscores the importance of improved strategies to mitigate bacterial contamination during spinal surgeries, particularly in spinal fusion procedures. Extensive research has focused on prevention strategies, emphasizing the identification and mitigation of risk factors at every stage of the surgical process [10]. Intrawound decontamination prior to wound closure has emerged as a critical area of investigation. Common methods include the application of powdered antibiotics, such as vancomycin, and irrigation with antiseptic solutions [11,12]. While normal saline (NS) irrigation is routinely performed at the end of spine surgeries, povidone-iodine (PVP-I) has also been widely utilized, with studies demonstrating its effectiveness in reducing postoperative infection rates [13,14]. However, evidence regarding the efficacy of other antiseptics remains limited.

Chlorhexidine gluconate (CHG), a cationic-chlorinated biguanide with broad-spectrum activity, disrupts bacterial cell membranes within 20–30 seconds [15]. It has been employed as an irrigation fluid in various surgeries, both preoperatively and intraoperatively [16]. This study aims to evaluate and compare the effectiveness of NS, PVP-I, and CHG as intrawound decontamination agents in minimizing bacterial contamination before wound closure in lumbar instrumented fusion surgery.

Materials and methods

Trial design

This study was conducted at a medical center in southern Taiwan. It is a single-blinded, parallel-group, randomized controlled trial registered on ClinicalTrials.gov (NCT06284174).

Patient sample

All recruited patients experienced low back pain or radicular pain caused by degenerative lumbar disorders, leading to failed conservative treatment. Their medical records, plain radiographs, and MRI studies had been previously reviewed.

Inclusion/exclusion criteria

Patients aged ≥18 years undergoing lumbar posterior decompression and instrumented fusion with pedicle screws and cages were eligible for inclusion. Fusion was performed at one to four levels using an open technique with either

posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Exclusion criteria included a history of lumbar procedures at the surgical levels (such as injections, radiofrequency ablation, or surgeries), minimally invasive surgery, previous spinal trauma, tumors, infections, allergy to PVP-I or CHG, or refusal to participate. Written informed consent was obtained from all participants. The inclusion and exclusion criteria are detailed in the study flowchart (Fig. 1).

Randomization and blinding

Patients were randomly assigned to one of three groups (NS, PVP-I, or CHG) using a computer-generated random sequence (1:1:1 ratio). Block randomization with a fixed block size of 15 ensured balanced allocation across treatment arms. Allocation concealment was maintained using sealed, opaque, sequentially numbered envelopes, which were opened only after patient enrollment to prevent selection bias. Due to the distinct characteristics of the antiseptic solutions, surgeons were aware of the assigned treatment; however, microbiologists and statisticians remained blinded to ensure unbiased culture analysis and statistical evaluation.

Intervention

All groups underwent the same preoperative preparation. A single experienced spine surgeon performed all procedures to ensure consistency in surgical technique. Before wound closure, the surgical wound was immersed in the assigned irrigation solution for 3 minutes, followed by irrigation with normal saline. In the NS group, wounds were immersed with 0.9% normal saline. The PVP-I group received a 3.5% povidone-iodine solution (SINDINE SOLUTION; SINPHAR®, Taiwan), and the CHG group received a 0.05% chlorhexidine gluconate solution (Easy Antiseptic Cleansing Solution 2%; Panion & BF Biotech Inc., Taipei, Taiwan).

All participants received preoperative antibiotics (1 g cefazolin for patients weighing <80 kg or 2 g for patients ≥80 kg, or 300 mg clindamycin for those allergic to cefazolin) administered intravenously within 30 minutes before the skin incision. Patients were positioned prone on a Jackson table. Surgical skin preparation included scrubbing with povidone-iodine and applying povidone-iodine solutions, followed by draping with plastic adhesive surgical drapes (Steri-Drape; 3M Health Care, St. Paul, MN, USA). Surgical procedures included bilateral pedicle screw instrumentation with rods, laminectomy for nerve decompression, and

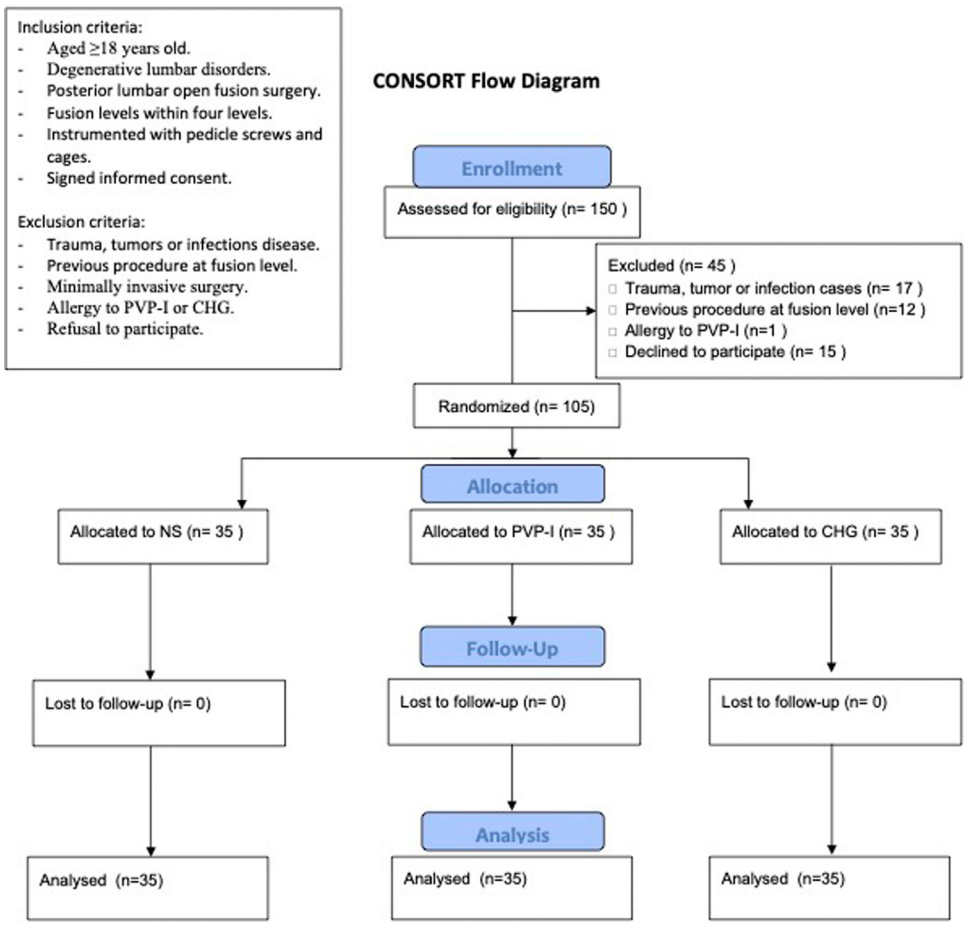

Fig. 1. CONSORT flow diagram. Flow-chart showing inclusion, randomization and participation throughout the study.

interbody fusion using the autograft and PEEK cages. Posterolateral fusion was performed using a mixture of autograft and artificial bone after antiseptic solution soaking.

Swab samples were collected from three anatomical sites: superficial tissues (skin and subcutaneous tissues), implant surfaces (pedicle screws, rods and cages), and deep tissues (vertebral endplate bone and deep muscle). Each site was sampled twice: before and after antiseptic irrigation to assess bacterial contamination reduction. Swab collection was performed by firmly rubbing a sterile swab over the designated area for 10 seconds to ensure adequate bacterial retrieval for culture and 16S rRNA PCR analysis. The sampling diagram is shown in Fig. 2.

All patients were fitted with a thoracolumbar spinal brace for 12 weeks postoperatively. Ambulation and leg muscle exercises were initiated on the first postoperative day. Clinical evaluations for signs of infection, including erythema, warmth, and excessive pain, were conducted at 14 days, 6 weeks, 3 months, and 6 months following surgery.

Procedure of culture

Swab samples were placed in individual transport media and delivered to the microbiology laboratory within 30 minutes of collection. Samples were cultivated in liquid nutrient medium to maximize bacterial yield. Microbiology technicians, blinded to the sample groups, used liquid broth media to enhance culture sensitivity. All cultures were incubated at 35˚C for 14 days. Bacteria were identified using the VITEK MS system (bioMérieux, Marcy l'Etoile, France).

16S rRNA gene amplification and sequencing for bacterial identification

DNA was extracted from swab samples using the DNeasy Blood & Tissue Kit (Qiagen, Hilden, Germany) according to the manufacturer's protocol. The 16S rRNA gene was amplified using primers 11F (5′-GTTTGATCCTGGCTCAG-3′) and 1512R (5′-GGYTACCTTGTTACGACTT-3′) with a thermal cycler (Applied Biosystems 2720 Thermal Cycler; Applied Biosystems, Taipei, Taiwan). The PCR mixture (25 μL) contained 2.5 μL genomic DNA, 2.5 μL 10 $\times$ PCR buffer, 0.8 mM deoxyribonucleoside triphosphates (0.2 mM each), 1.5 mM $MgCl_2$, 1.0 mM of each primer, and 1 U HotStarTaq DNA polymerase (Qiagen). Thermal cycling conditions included initial denaturation at 94˚C for 3 minutes, followed by 36 cycles of amplification: denaturation at 94˚C for 30 seconds, annealing at 52˚C for 1 minute, and elongation at 72˚C for 1.5 minutes. A final extension step at 72˚C for 7 minutes was performed. The amplicons were purified and sequenced, and bacterial species were identified by comparing the sequences to those in the GenBank database using BLAST (http://www.ncbi.nlm.nih.gov/BLAST/).

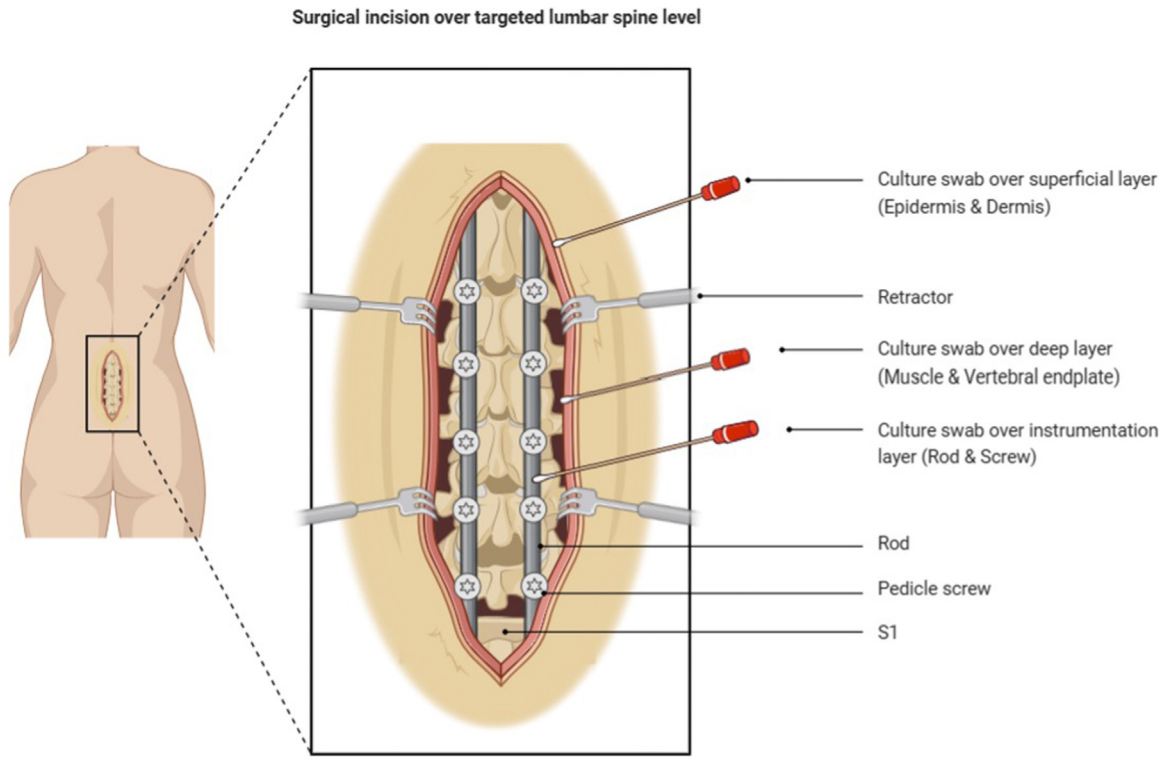

Fig. 2. Swab samples were obtained from three anatomical locations: superficial tissues (including the skin and subcutaneous layers), implant surfaces (pedicle screws, rods and cages), and deep tissues (comprising vertebral endplate bone and deep muscle). Each site was sampled twice: before and after antiseptic irrigation.

The sampling was performed by firmly rubbing a sterile swab over the designated area for 10 seconds to ensure adequate bacterial collection for culture.

Sample size calculation

Sample size estimation was based on bacterial culture results from a pilot study evaluating bacterial contamination reduction in implant sites. In this pilot study, 30 patients were randomized into three groups: 12 in the NS group, 9 in the PVP-I group, and 9 in the CHG group. The preirrigation bacterial culture positivity rates were 33.3% (NS), 44.4% (PVP-I), and 33.3% (CHG), with postirrigation reductions to 25.0%, 22.2%, and 11.1%, respectively. A chi-square test was used to determine the required sample size. Based on the expected bacterial reduction, we assumed a medium-to-large effect size (Cohen's w=0.35) to detect meaningful differences among groups. A power analysis was conducted using G*Power (version 3.1.3, Heinrich Heine University of Düsseldorf, Germany), indicating that a minimum of 30 patients per group was required to achieve 80% power (1-β=0.80) at an α level of 0.05. To ensure robust statistical power and account for potential data variability, we increased the final sample size to 35 patients per group (total N=105).

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics, version 22 (IBM, Armonk, NY, USA). Baseline characteristics were summarized descriptively. Between-group differences in bacterial culture reduction were analyzed using logistic regression, adjusting for baseline contamination levels. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated to compare the effectiveness of different antiseptic solutions. Bonferroni correction was applied to account for multiple comparisons. In addition, an analysis of covariance (ANCOVA) was conducted to further assess the adjusted effect of antiseptic solution on postirrigation bacterial contamination, using preirrigation bacterial status as a covariate. SSI rates were analyzed using Fisher's exact test. A p-value <.05 was considered statistically significant.

Results

From January 2021 to March 2024, a total of 150 patients scheduled for posterior lumbar fusion surgery were screened for eligibility. Among these, 45 patients were excluded based on the exclusion criteria: trauma, tumor, or infection cases (n=17); previous procedures at the fusion level (n=12); allergy to PVP-I (n=1); and refusal to participate (n=15). Ultimately, 105 patients were enrolled and randomly assigned to one of three groups: normal saline (NS, n=35), povidone-iodine (PVP-I, n=35), or chlorhexidine gluconate (CHG, n=35). All participants completed the assigned interventions, and no dropouts were reported during the follow-up period. The demographic characteristics of the participants are summarized in Table 1.

Effectiveness of different rinsing agents

The positive culture rates for the samples in each group are summarized in Table 2. PCR testing was used to confirm bacterial species and improve the detection rate of residual bacteria. The overall bacterial culture rates before irrigation were as follows: 49.5% (NS 42.8%, PVP-I 57.1%, CHG 48.5%) for the superficial area, 31.4% (NS 22.8%, PVP-I 48.5%, CHG 22.8%) for the deep area, and 32.4% (NS 28.5%, PVP-I 42.8%, CHG 25.7%) for the implant area. After NS irrigation, culture-positive rates remained unchanged across all areas. PVP-I significantly reduced bacterial contamination in the superficial area (55.0%, p=.015), but showed no significant effect in the deep or implant areas. CHG irrigation demonstrated the greatest bacterial reduction, with a 94.1% reduction in superficial contamination (p<.0001) and 88.9% reduction in implant contamination (p=.02). Logistic regression

Table 1
Demographic data of included patients

	Normal saline group (n=35)	Povidone-iodine group (n=35)	Chlorhexidine gluconate group (n=35)	p-value
Age, y, mean ± SD	68.71±10.01	64.31±12.95	66.14±12.92	.3116
Sex, male/female, n	12/23	20/15	12/23	.0818
Fusion number, n	1.74±0.75	1.40±0.55	1.83±0.79	.029*
Surgical time, min, mean ± SD	209.06±69.49	185.49±47.5	204.63±45.24	.170
BMI, mean ± SD	25.13±4.20	25.50±3.42	26.37±3.87	.385
DM, n	11	7	9	.550
Smoking, n	6	4	2	.323
Immunosuppression medication use, n	1	2	0	.357
Blood loss, mL	378.00±374.45	302.57±157.95	329.43±180.70	.463
ASA 1	2	3	2	.432
2	16	19	21	
3	16	13	12	
4	1	0	0	

SD, standard deviation; BMI, body mass index; DM, diabetes mellitus; ASA, American Society of Anesthesiologists score.
Statistical analysis is performed with One-way ANOVA and Chi-square test.
* p<.05.

Table 2
The positive culture rate in each group

	Superficial			Deep			Implants		
Rinsing status	Before	After	p-value	Before	After	p-value	Before	After	p-value
Culture positive, n (%)									
NS (n=35)	15 (42.8)	8(22.8)	.12	8 (22.8)	5 (14.2)	.53	10 (28.5)	10 (28.5)	1.0
PVP-I (n=35)	20 (57.1)	9 (25.7)	.015*	17 (48.5)	11 (31)	.22	15 (42.8)	10 (28.5)	.32
CHG (n=35)	17 (48.5)	1 (2.8)	<.0001*	8 (22.8)	2 (5.7)	.08	9 (25.7)	1 (2.8)	.02*

NS, normal saline; PVP-I, povidone-iodine; CHG, chlorhexidine gluconate.
* Significant difference (p<.05) between before and after using chi-square test.

analysis was performed to compare the efficacy of each irrigation solution. To account for multiple comparisons, statistical significance was set at p<.0167 (Bonferroni correction). The results are presented in Table 3. In the superficial area, there was no significant difference between the three irrigation fluids in bacterial decontamination. In the deep area, neither CHG nor PVP-I demonstrated superior effectiveness compared to NS. However, CHG was significantly more effective than PVP-I (OR: 0.12, 95% CI: 0.02−0.59, p=.009). For implant contamination, CHG demonstrated significantly greater efficacy than NS (OR: 0.06, 95% CI: 0.01−0.54, p=.011) and PVP-I (OR: 0.06, 95% CI: 0.01−0.56, p=.012), indicating a markedly lower risk of bacterial persistence with CHG. Since the overall bacterial culture rates before irrigation were highest in the PVP-I group across all three surgical sites, an analysis of covariance (ANCOVA) was conducted to further assess the effect of antiseptic solution, adjusted for baseline bacterial contamination status (preirrigation positivity). This analysis confirmed that, even after accounting for baseline imbalances, significant differences in bacterial reduction remained among the antiseptic groups. Specifically, CHG continued to demonstrate superior efficacy in reducing bacterial contamination compared to both PVP-I and NS groups after baseline adjustment.

Despite significant differences in bacterial decontamination, no corresponding reduction in postoperative SSI rates was observed among the groups (NS: 1 case, PVP-I: 0 cases, CHG: 1 case; p=.72).

Table 3
Effectiveness of different rinsing agents in eradicating superficial bacterial colonization

Site	Comparison	OR (95%CI)	p-value
Superficial	PVP-I vs. NS	1.12 (0.37−3.36)	.833
Superficial	CHG vs. NS	0.08 (0.01−0.74)	.025
Superficial	CHG vs. PVP-I	0.07 (0.009−0.65)	.018
Deep	PVP-I vs. NS	2.65 (0.81−8.71))	.106
Deep	CHG vs. NS	0.32 (0.05−1.78)	.194
Deep	CHG vs. PVP-I	0.12 (0.02−0.59)	.009*
Implants	PVP-I vs. NS	0.96 (0.33−2.71)	.938
Implants	CHG vs. NS	0.06 (0.01−0.54)	.011*
Implants	CHG vs. PVP-I	0.06 (0.01−0.56)	.012*

NS, normal saline; PVP-I, povidone-iodine; CHG, chlorhexidine gluconate; OR, odds ratio; 95%CI, 95% confidence interval.
* Significant difference (p<.0167) between groups using logistic regression analysis.

Bacterial species detected

The bacterial species identified, based on both culture and PCR results, are summarized in Table 4. Cutibacterium acnes was the most commonly isolated species across all sample types, including superficial, deep, and implant cultures. Coagulase-negative staphylococci (CoNS) were the second most frequently identified organisms. Other species detected included those from the Corynebacterium, Streptococcus, and Lactobacillus genera.

Clinical results and complications

All patients completed at least 6 months of follow-up. Only two patients developed clinical infections, resulting in an overall infection rate of 1.9%. One patient in the CHG group experienced a superficial surgical wound infection, which was treated with antibiotics; intraoperative cultures for this patient were negative. Another patient in the NS group developed a deep infection at the L4/5 level, confirmed by magnetic resonance imaging (MRI). She was treated with antibiotics without requiring additional surgery, and blood cultures did not isolate any infectious pathogens. A review of her surgical report revealed that intraoperative cultures showed C. acnes positivity in the superficial area. All three groups showed significant improvement in functional ODI scores, with no differences observed between groups. No patient exhibited neurological deterioration or required reoperation at the latest follow-up.

Discussion

This study confirms a high risk of bacterial contamination in lumbar fusion surgery despite standard preoperative disinfection, with Staphylococcus species and Cutibacterium acnes being the most frequently identified contaminants. Our findings demonstrate that intraoperative irrigation with 0.05% CHG is significantly more effective than 3.5% PVP-I and NS in reducing bacterial residues on implant surfaces.

Postoperative spinal infections carry serious consequences, making bacterial decontamination a critical step in

Table 4
The detected bacteria species in each group

	Superficial			Deep			Implants		
	C acnes	CoNS	others	C acnes	CoNS	others	C acnes	CoNS	others
Before rinsing culture, n									
NS (n=35)	8	8	1	4	3	1	6	3	1
PVP-I (n=35)	13	7	2	10	3	4	12	4	2
CHG (n=35)	7	10	0	7	3	0	7	2	2
Total	28	25	3	21	9	5	25	9	5
After rinsing culture, n									
NS (n=35)	3	4	0	3	2	0	6	3	1
PVP-I (n=35)	7	2	0	6	2	3	6	2	2
CHG (n=35)	0	1	0	2	0	0	0	0	0
Total	10	7	0	11	4	3	12	5	3

NS, normal saline; PVP-I, povidone-iodine; CHG, chlorhexidine gluconate.

preventing infections. Previous studies have primarily evaluated antiseptic irrigation based on postoperative clinical infection rates [11]. However, the development of an infection is influenced by multiple factors, including the patient's immune function and postoperative care. Additionally, the low infection rates after spine surgery make it challenging to assess the efficacy of antiseptic irrigation fluids [1]. In this study, intraoperative sampling was used to directly measure bacterial contamination before and after irrigation. This approach allowed for a more immediate and accurate evaluation of the antimicrobial effects of CHG, PVP-I, and NS.

PVP-I, a widely used antiseptic, has shown efficacy in reducing infection rates in spine surgeries [11]. However, our results suggest that 3.5% PVP-I soaking for 3 minutes is insufficient for effectively eliminating bacteria in deep tissues or on implant surfaces. Prior studies have indicated that higher concentrations of PVP-I (eg, 10%) or prolonged soaking times (eg, 10 minutes) may achieve better bacterial reduction [12]. Factors such as dilution by blood or insufficient soaking time may have contributed to the limited efficacy of PVP-I observed in this study [17].

CHG has been widely used as a preoperative and intraoperative surgical site irrigation fluid in various surgeries, including arthroplasty [18], laparotomy [19], and cesarean delivery [20]. Its broad-spectrum activity and ability to disrupt bacterial cell membranes within 20–30 seconds make it a highly effective antiseptic. Previous studies have demonstrated that CHG effectively reduces infection rates without compromising joint cartilage or wound healing when used at a safe concentration of 0.05% [16]. However, its application in spine surgery has been rarely reported. A study by Kaliaperumal et al. utilized Savlon (chlorhexidine gluconate 0.3%, cetrimide 3%) for irrigation in microdiscectomy surgeries and observed a lower infection rate of 0.09% compared to 0.18% in the normal saline group [21]. In our study, irrigation with 0.05% CHG was more effective than NS and PVP-I on implant surfaces. This finding is particularly crucial given the increasing reliance on implants in spine surgeries, where bacterial colonization can result in serious complications such as pseudoarthrosis and implant failure [8]. Although concerns about CHG's neurotoxicity may limit its use in spine surgeries, multiple studies have demonstrated its safety at low concentrations, including in spinal anesthesia, where it has not been shown to increase the risk of neurological complications [16,22]. In this study, 35 patients who underwent irrigation with 0.05% CHG were followed for at least 6 months, and no neurological complications were observed. These findings demonstrate the safety of CHG at low concentrations in lumbar fusion surgeries.

Another key finding of our study is that, despite preoperative disinfection, there remains a high likelihood of bacterial residue in the surgical field, the results revealing a high bacterial contamination rate. The superficial area exhibited an overall positive culture rate of 49.5% before irrigation, deep tissue had 31.4%, and implant samples had 32.4%, with C. acnes and Staphylococcus species being the most common bacteria. These bacteria are also the leading causes of postoperative infections in spine surgery [23]. Furthermore, C. acnes has been reported to be prevalent in scoliosis and posterior instrumented fusion surgeries [8]. Given its abundance on the back, C. acnes plays a significant role in spinal infections, highlighting the importance of preoperative prevention. Previous studies in shoulder surgery have shown that CHG-containing cleaning solutions can effectively reduce residual bacterial contamination on both skin and implants [24]. Similarly, our study demonstrated that intraoperative CHG irrigation significantly reduced C. acnes residues in superficial and implant areas.

This study has several strengths, including its randomized controlled design and consistent surgical technique performed by a single surgeon, which minimized variability. However, several limitations should be noted. First, the relatively small sample size and single-center design may limit the generalizability of our findings. Although randomization was employed, some baseline imbalances in preirrigation bacterial contamination rates were observed, particularly in the PVP-I group. This may reflect the effects of random variation, which can occur in studies with

limited sample sizes. Future studies should consider incorporating baseline culture positivity into sample size calculations and statistical modeling to minimize such imbalances. Second, despite demonstrating significant bacterial reduction, the number of clinical SSIs was low (1.9% in 105 patients), limiting our ability to statistically assess the direct impact of irrigation fluids on infection prevention. While a direct correlation between bacterial reduction and SSI prevention remains unproven, our findings suggest that effective intraoperative irrigation may reduce bacterial colonization—a key risk factor for SSIs. Larger, multi-center trials are warranted to validate these findings and better establish the clinical implications of reduced intraoperative contamination.

Conclusion

This randomized controlled trial highlights a high incidence of residual bacterial contamination in lumbar fusion surgery, with 49.5% of superficial tissues, 31.4% of deep tissues, and 32.4% of implant surfaces testing positive for bacteria despite preoperative disinfection. CHG irrigation demonstrated superior efficacy compared to PVP-I and NS in reducing bacterial residues on implant surfaces. These findings support CHG's potential as a superior antiseptic for intraoperative wound irrigation in lumbar spine fusion surgeries. Further multi-center studies are essential to confirm its impact on reducing postoperative clinical infections and improving patient outcomes.

Declaration of competing interest

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

CRediT authorship contribution statement

Yuan-Fu Liu: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Yu-Chia Hsu:** Writing – original draft, Validation, Software, Investigation. **Po-Lin Chen:** Methodology, Conceptualization. **Hao-Jun Chuang:** Investigation, Data curation. **Ting-Yuan Tu:** Writing – review & editing, Supervision. **Chao-Jui Chang:** Investigation, Data curation. **Yu-Meng Hsiao:** Visualization, Data curation. **Cheng-Li Lin:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization.

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