



Efficacy of Povidone Iodine Solution in the Prevention of Surgical Site Infections in Minimally Invasive Instrumented Spinal Fusion Surgery

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Abstract

Study Design: A retrospective case-controlled study.

Objectives: To evaluate overall infection rate and adverse event after harvesting bone graft soaking and surgical wound irrigation by povidone iodine solution (PVI) in the minimally invasive instrumented spinal fusion surgery. In order to reduce the rate of surgical site infection in spinal surgery, surgical wound irrigation by povidone iodine solution has been well-established. However, the efficacy of autologous bone graft soaking by PVI has not been evaluated before.

Methods: This is a retrospective cohort study. 120 patients were enrolled in the PVI group and compared with 124 patients in the historical cohort. In the PVI group, the harvesting autologous bone graft was soaking and the surgical wound was also irrigated by diluted PVI solution. The outcome measures were overall infection rate, superficial wound infection and deep infection. In addition, the delayed union of the fusion mass was also evaluated through the radiograph evaluation.

Results: Both groups shared similar patient demographics instead of body mass index. The use of PVI solution had decreased the overall infection rate (0% versus 4.03%, $p = 0.026$) and deep infection rate (0% versus 3.23%, $p = 0.047$). In addition, there was no delayed bone healing in the PVI group after autologous bone graft soaking.

Conclusions: In this study, we conclude that harvested autologous bone graft after PVI soaking in spinal fusion surgery can decrease the incidence of deep infection.

Keywords

povidone, lumbar interbody fusion, infection

Introduction

Surgical site infection (SSI) is a common postoperative complication in spinal surgeries, leading to both poor outcome and increased medical cost. The incidence of SSI in spinal surgery was reported diversely, ranging from 1% to 14% in open procedure and 0.6% to 4.6% in minimal invasive spine fusion procedure respectively.¹⁻⁶ Specific risk factors were identified, increased blood loss, diabetes, obesity, prolonged operation time, posterior spinal approach, instrumentation and fusion have all been reported as risk factors in previous literatures.¹⁻⁴

In order to reduce rate of SSI in spinal surgery, intrawound prophylaxis with antibiotics or antiseptics were proposed, including intrawound vancomycin powder and povidone-iodine (PVI) solution irrigation,⁷⁻¹⁰ result in reduced SSI rates

without reported adverse events.^{11,12} Povidone-iodine is well known as a low-cost but effective antiseptic agent and has been widely used in wound disinfection, preoperative skin preparation for decades. Its broad antimicrobial spectrum, including methicillin-resistant *Staphylococcus aureus* (MRSA) and

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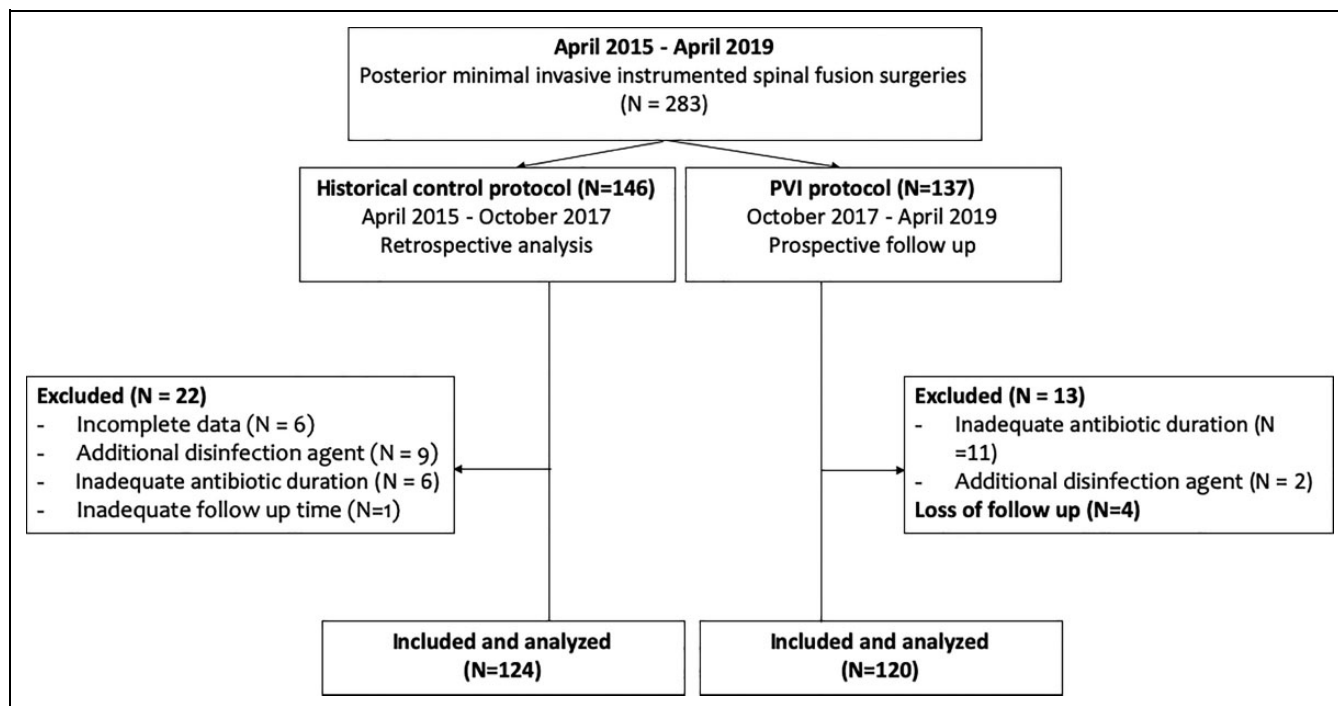


Figure 1. Consort diagram.

vancomycin-resistant *Enterococcus faecalis* (VRE), had been reported in previous literature.^{13,14}

In consideration of intraoperative contamination, both implants and autologous bone graft have been identified as potential sources of postoperative infection during spine fusion.^{15,16} A 328 cases retrospective study conducted by Lee et al.¹⁶ revealed the 4.3% microbiological contamination rate of local autologous graft in posterior lumbar interbody fusion (PLIF) procedure, which account for 62.5% of all infection cases. However, although intraoperative autologous bone graft contamination was suspected to be a source of SSI, the efficacy of PVI soaking of autologous graft has not been evaluated.

In this study, a new protocol combining autologous bone graft soaking and surgical wound irrigation with PVI solution was performed. We aim to evaluate the efficacy and safety of disinfecting autologous graft with PVI in preventing surgical site infection in minimally invasive instrumented spine fusion procedure.

Material and Method

Study Design and Patient Selection

This retrospective cohort study was conducted by orthopedic department in the single center. The patient with persisted mechanical back pain or spinal stenosis symptoms without improvement after 3-month conservative treatment, were indicated for the surgery. The diagnosis consisted of degenerative spondylolisthesis, isthmic spondylolisthesis, pathological spondylolisthesis, traumatic spondylolisthesis, spinal stenosis and revision surgery. The PVI disinfection protocol, combining

autologous bone graft povidone-iodine (PVI) solutions soaking and intrawound PVI irrigation was started on October, 2017. Patients underwent posterior minimal invasive spinal fusion surgeries under this new disinfection protocol were enrolled as the PVI cohort. Patients underwent spinal debridement surgery due to infection or with history of betadine allergy were excluded. Patient should keep postoperative follow up at outpatient department for at least 90 days, and those with inadequate follow up time would be excluded unless the SSI event occurred in 90 days. If patients receiving antibiotic or disinfection intervention other than standard disinfection protocol (as described in “surgical procedure and standard disinfection methods”), or received parenteral postoperative antibiotic for less than 48 hours, the patient would also be excluded. Until April, 2019, a total of 137 patients received spinal fusion surgeries under this new PVI disinfection protocol, while 13 patients were excluded (11 patients with inadequate postoperative antibiotics duration, 2 patient received additional antibiotics or disinfection intervention). During the 3-month follow up interval, there were 4 patients lost to follow-up. (Figure 1).

The outcomes of the above PVI cohort was compared with historical control cohort, which applied the original disinfection protocol with intrawound normal saline irrigation in posterior minimal invasive spinal fusion procedure during April, 2015 to October, 2017. Through the electronic patient record system, 146 patients were retrospectively reviewed while a total of 124 illegible patients were finally included and analyzed (6 patients with incomplete data, 9 patients with inadequate postoperative antibiotics duration, 6 patients received addition antibiotics or disinfection intervention and 1 patient loss follow up) (Figure 1).

Surgical Procedure and Standard Disinfection Methods

All procedures were performed by 2 senior surgeons who participated in our study in standard operation rooms, without routine ultraviolet light, laminar flow, or other special air measures. Before surgical incision, aseptic technique was performed as usual, including skin preparing with PVI alcoholic solution, sterile adhesive drapes, sterile cloths and gloves. The PVI solution we used in this study were diluted from the commercially available Betadine solution with concentration of 10% PVI (0.1 g of PVI per 1 mL of Betadine solution). During preoperative preparation, 36 mL of Betadine was diluted with 1000 ml normal saline to achieve approximate 0.35% PVI solution 1036 mL and keep in the sterilized basin, covered by sterilized drapes. If extend wound size was expected, same concentration PVI solution would be prepared up to 2072 ml.

Under general anesthesia, patient was placed in prone position on the 4-poster frame. Intraoperative 3-dimensional C-arm (Vision FD Vario 3D, Ziehm Imaging, Nuremberg, Germany) and navigation system (Kick navigation system, Brainlab) were used for percutaneous pedicle screw insertions.

Intraoperative scanning was performed in both groups with CT data set automatically registered to the image guidance system. Before the skin incision was made, the spinal process was used as an anatomical landmark by navigation probe to confirm the accuracy of navigation. The ideal skin entry points were sought with the navigation probe tip in order to determine the precise skin incision based on the virtual elongated navigation trajectory on the intraoperative scanned images. Pedicle entry points were decided on navigation guidance, and pilot holes were made with a 3-mm awl. The direction of the pilot pedicle hole was rechecked with the navigation probe, and 4.5-mm tapping was done to a depth of 20 mm from the entry point. A guidewire was used for screw insertion. Rod was then placed and fixed with nuts after rechecking the position.

After microscopic decompression and preparation for transforaminal interbody fusion, the harvested autologous bone graft was collected and irrigated with 500 ml normal saline in original disinfection protocol then mixed with artificial bone material if needed. In PVI disinfection protocol, the harvested bone graft was collected and soaked in 100 ml PVI solution for 10 seconds then rinsed with 500 ml normal saline.

Transforaminal lumbar interbody fusion was then performed with cage and autologous bone graft. All ischemic tissue was debrided before wound closure. The wound was then irrigated with 500 ml normal saline in original protocol while 500 ml PVI solution was irrigated before wound closure in PVI protocol. The irrigation volume can be titrated up to 1000 ml in extended wound. The wound was closed by layers and the skin was stapled and properly dressed with gauzes as usual. Postoperative cares were identical in both groups. We did not routinely insert drainage tube for postoperative wound drainage, if inserted, the tube would not be removed until daily amount of drainage was less than 100 ml.

Standard disinfection protocols applied in both groups were identical. Routine prophylaxis antibiotics were given. Single

dose of parenteral cefazolin (1000 mg) were given 1 hour before surgery, and additional redosing of cefazolin would be given in prolonged surgery (more than 4 hours) to maintain antibiotics levels. Cefazolin 1000 mg was administered every 12 hours and lasted for at least 48 hours after surgery. Second antibiotic agent including aminoglycosides (gentamicin 80 mg every 12 hours, amikacin 500 mg every 12 hours or isepamicin 400 mg once daily), clindamycin (600 mg every 8 hours) or erythromycin (250 mg every 12 hours) was also administered as surgeon's preference. The patient was kept bed rest with brace during the first 24 hours after surgery.

Postoperative Infection and Clinical Outcome

The postoperative outpatient department follow up occurred at 2 weeks, 1 month, 2 months and 3 months after surgery. The wound condition and symptoms of SSI were record. Lumbar spine x-ray with anterior-posterior view and lateral view were performed at every visit to observe if delay callus formation or instrument malposition occurred. The fusion status of the operated level would be accessed based on Bridwell grading system¹⁷ during the last follow up. Visual analog scale (VAS) was accessed at the end of postoperative follow up.

When there were complains of symptoms and signs of suspected surgical site infection including unusual pain, induration, fever or wound discharge, C-reactive protein (CRP) level and white blood cell count with differential count would be checked. Pus-like discharge, if noted, would be collected and cultured. Advanced diagnosed tools including lumbar spine computed tomography (CT), magnetic resonance imaging (MRI) or CT-guide biopsy would be performed if needed. Once the SSI was highly suspected or diagnosed, the patient would be readmitted for intravenous empirical antibiotic therapy firstly then switched once the culture and antibiotic susceptibility test (AST) were confirmed. If the symptoms and signs of infection were not improved after antibiotic treatment after 1 week, further surgical debridement would be performed through the previous incision. Aerobic, anaerobic, fungal, and tubercular cultures would be collected if pus or discharge was noted during the debridement. After adequate debridement and normal saline irrigation, the wound was heavily sutured.

The classification and definition of superficial and deep surgical site infection was based on the Centers for Disease Control and Prevention (CDC) criteria for Surgical Site Infection (SSI), while both deep SSI and organ space SSI were classified as deep SSI in our study.

Data Extraction

All data was extracted from the electronic patient record system of our hospital by the assistant who did not involve the operation and patient care. Patient's characteristic including age, gender, body mass index (BMI), underlying disease with diabetes mellitus (DM), indication of operation, preoperative visual analog scale (VAS), preoperative American society of anesthesiologists physical status (ASA) score and habits of

smoking were recorded individually. The surgical outcomes including length of operative times, volume of intraoperative blood loss, use of artificial bone material, numbers of fusion levels, duration of postoperative antibiotic use and length of hospital stay were also recorded.

The primary endpoint of our study was comparing the rate of overall surgical site infection (SSI), superficial SSI, and deep SSI between 2 cohorts. The secondary endpoint of our study was rate of PVI related adverse effect, improvement of visual analog scale (VAS), rate of delay bone callus formation, and rate of instrument malposition or complication.

Statistical Analysis

Data was analyzed by SAS[®] 9.4 software and represented as the mean and standard deviation for continuous variables or percentages for discrete variables. The Fisher exact tests were used to compare difference between the 2 groups for each discrete variable, and the Student t test was used for each continuous variable. Univariate Logistic regression was used to evaluate the **chosen individual factors**¹¹ which may affect the outcome of SSI. **If there were 2 or more factors with significant results (p-value < 0.05), these factors would be further analyzed in multivariate Logistic regression model to evaluate if the protective efficacy of intrawound intervention would be diminished. If there was only 1 or less factor with significant result, multivariate Logistic regression model would not be performed. The 95% confidence intervals (CI) and odds ratios of each variable were calculated.** All tests were 2-tailed. Significance was set at P = 0.05 or less than 0.05 for each test.

Result

Characteristic of Patients

The characteristic of patients in both groups were compared in Table 1. The mean age of the patients was 67.75 years (range 27-91 years, SD = 12.20 years) included 76 (61.3%) patients elder than 65 years old in control cohort and 67.14 years (range 21-98 years, SD = 12.01 years) with 72 (60.0%) patients elder than 65 years old in PVI cohort. The mean BMI of the patients was 26.1 kg/m² (SD = 4.27kg/m²) in control cohort and 27.1 kg/m² (SD = 4.85 kg/m²) in PVI cohort respectively. In control cohort, 31 patients (25.0%) had underlying diabetes mellitus and 13 (10.5%) patients were smokers, while 36 patients (30.0%) with diabetes mellitus and 15 patients (12.5%) were smoker in PVI cohort. There were no significant differences in age, gender, BMI, ASA scores and underlying medical condition (diabetes mellitus and smoking) between 2 groups. The initial diagnosis was divided into 6 subgroups, consisted of degenerative spondylolisthesis, isthmic spondylolisthesis, pathological spondylolisthesis, traumatic spondylolisthesis, spinal stenosis and revision surgery. There was no difference of the proportion of diagnosis subgroups between 2 cohorts (Table 1).

Table 1. Patient Demographic Data.

	Control cohort (n = 124)	PVI cohort (n = 120)	P-value
Gender (Male)	36 (29.03%)	44 (36.67%)	0.204
Age (year)	67.75 (SD = 12.20)	67.14 (SD = 12.01)	0.695
ASA score			0.354
1	9 (7.26%)	4 (3.33%)	
2	80 (64.52%)	77 (64.17%)	
3	34 (27.42%)	39 (32.50%)	
4	1 (0.81%)	0 (0.00%)	
Diabetes mellitus	31 (25.00%)	36 (30.00%)	0.382
Habits of smoking	13 (10.48%)	15 (12.50%)	0.621
Body mass index	26.07 (SD = 4.27)	27.05 (SD = 4.85)	0.095
Fusion Levels			0.236
1	68 (54.84%)	76 (63.33%)	
2	45 (36.29%)	40 (33.33%)	
3	10 (8.06%)	4 (3.33%)	
4	1 (0.81%)	0 (0.00%)	
Diagnosis			
	Control cohort (n = 124)	PVI cohort (n = 120)	P-value
Degenerative spondylolisthesis	63 (50.81%)	55 (45.83%)	0.437
Traumatic spondylolisthesis	6 (4.84%)	2 (1.67%)	0.164
Spinal stenosis	36 (29.03%)	49 (40.83%)	0.053
Pathological spondylolisthesis	1 (0.81%)	1 (0.83%)	0.981
Isthmic spondylolisthesis	17 (13.71%)	8 (6.67%)	0.070
Revision of previous operation	1 (0.81%)	5 (4.17%)	0.090
Surgical outcomes			
	Control cohort (n = 124)	PVI cohort (n = 120)	P-value
Blood loss (ml)	377.9 (SD = 201.9)	373.3 (SD = 244.8)	0.873
Operation time (hour)	4.27 (SD = 1.27)	4.09 (SD = 1.12)	0.224
Length of hospitalization (day)	8.40 (SD = 6.63)	7.02 (SD = 4.30)	0.055
Drainage tube insertion	15 (12.10%)	9 (7.50%)	0.228
Artificial bone material use	58 (46.77%)	70 (58.33%)	0.071
Postoperative antibiotics duration (day)	3.18 (SD = 1.13)	3.42 (SD = 1.45)	0.154

Abbreviation: ASA = American society of anesthesiologists physical status classification system, BMI = body mass index, DM = diabetes mellitus.

Disinfection Efficacy and Primary Endpoint

In terms of postoperative surgical site infection (SSI), there were totally 5 patients diagnosed with SSI (4.03%) in control

Table 2. Infection Cases of Control Cohort (N = 5).

Patient	Indication	Date	SSI diagnosis criterion	Treatment
59 year-old Female	L4-5 Degenerative spondylolisthesis	POD 14	Superficial SSI (Criterion d)	Parenteral antibiotics Teicoplanin (16 days) Daptomycin (13 days)
60 year-old Female	L4-5 Degenerative spondylolisthesis	POD 46	Organ space SSI (Criterion c)	Parenteral antibiotics Vancomycin (19 days)
62 year-old Female	L4 Pars fracture with L4-5 isthmic spondylolisthesis.	POD 12	Deep incision SSI (Criterion c)	Parenteral antibiotics Vancomycin (7 days) Fosformycin(7 days) Linezolid (14 days) Wound debridement (POD 19)
84 year-old Male	L2-5 spinal stenosis	POD 81	Organ space SSI (Criterion c)	Parenteral antibiotics Teicoplanin (14 days) Ceftazidime (14 days) Debridement and L3, L5 screws revision (POD 89)
58 year-old Female	L4-5 Degenerative spondylolisthesis	POD 4	Deep incision SSI (Criterion b)	Parenteral antibiotics Teicoplanin (37 days) Ceftazidime (21 days)

Abbreviation: POD: Postoperative date.

Table 3. Postoperative Infection Rate of the 2 Groups.

	Control cohort (N = 124)	PVI cohort (N = 120)	P-value
Overall Infection	5 (4.03%)	0 (0.00%)	0.026*
Superficial wound infection	1 (0.81%)	0 (0.00%)	0.324
Deep wound infection	4 (3.23%)	0 (0.00%)	0.047*

*Significant results (p-value < 0.05).

cohort, consisted of 1 superficial infections (0.81%) and 4 deep infections (overall rate = 3.23%, including 2 deep incision SSI and 2 organ space SSI). The cases of SSI were listed (Table 2). Nevertheless, there was no infection incident in PVI cohort. Both overall infection rate (0% versus 4.03%, $p = 0.026$) and deep infection rate (0% versus 3.23%, $p = 0.047$) were significant lower under the intervention of PVI use while no similar significant disinfection efficacy was seen in superficial infection (0% versus 0.81%, $p = 0.324$) (Table 3).

Surgical Outcomes and Pain Improvement

There were no significant differences in intraoperative blood loss ($p = 0.873$), length of hospital stay ($p = 0.055$), drainage tube insertion rate ($p = 0.228$), artificial bone material use ($p = 0.071$), operation time (4.27 hours in control cohort versus 4.09 hours in PVI cohort, $p = 0.224$), or postoperative antibiotics duration (3.18 days in control cohort versus 3.42 days in PVI cohort, $p = 0.154$). There was no significant difference in preoperative visual analog scale (VAS) (p value = 0.293), postoperative VAS ($p = 0.311$), or the range of VAS improvement ($p = 0.095$). During the last follow up, through the X-ray evaluation by the surgeon, all patients were graded as grade 2 fusion status of Bridwell grading system and there was no event of delay bone callus formation noted in both groups (Table 4).

Table 4. Postoperative Functional Outcomes and Perioperative Complications.

Functional outcome	Control cohort (n = 124)		PVI cohort (n = 120)		P-value
	Control cohort (n = 124)	PVI cohort (n = 120)	P-value		
Preoperative VAS	6.24 (SD = 1.45)	6.00 (SD = 2.07)	0.293		
Postoperative VAS	2.25 (SD = 1.85)	2.49 (SD = 1.71)	0.311		
VAS Improvement range	3.99 (SD = 2.14)	3.51 (SD = 2.27)	0.095		
Complication					
	Control cohort (n = 124)	PVI cohort (n = 120)	P-value		
Wound complication	3 (2.42%) Poor healing (3)	4 (3.33%) Prolonged discharge (3) Poor healing(1)	0.669		
Surgical Complications	10 (8.06%) Implant malposition, loosening or graft protrusion (4) Incidental durotomy (3) Residual symptom (1) Pseudoarthrosis (1) iatrogenic fracture (1)	6 (5.00%) Implant malposition or loosening (3) Incidental durotomy (3)	0.334		

Abbreviation: PVI = povidone iodine, VAS = visual analog scale.

Safety and Complication

There was no iodine related adverse event including iodine allergy or thyroid function abnormality reported during the

Table 5. Univariate Logistic Regression of Overall Infection.

Variate	Odds ratio	Confidence level	p-value
Age	0.982	0.917-1.051	0.593
ASA score = 3 or higher	0.568	0.062-5.175	0.616
Gender	0.506	0.056-4.605	0.545
DM	1.785	0.292-10.924	0.530
BMI	1.152	1.024-1.296	0.019*
Fusion levels	0.809	0.176-3.711	0.785
Operation time	1.844	0.974-3.491	0.601
Drainage tube	2.348	0.252-21.902	0.454

Abbreviation: ASA = American society of anesthesiologists physical status classification system, BMI = body mass index, DM = diabetes mellitus.

*Significant results (p-value < 0.05).

90-day interval of follow up. There was also no significant difference of wound complication (p = 0.669) or surgical complication (p = 0.334) (Table 4).

Efficacy or Risk Factor Analysis

The univariate Logistic regression was performed to evaluate the potential relation between overall infection events and different variates, revealing only the variate BMI as significant harmful factors (odds ratio = 1.152, p = 0.019) of overall SSI. Multivariate Logistic regression was not performed due to the variate BMI was the only significant harmful factors in univariate Logistic regression. (Table 5).

Discussion

In the present study, patients operated with PVI disinfection protocol showed significant decreased both overall and deep postoperative surgical site infection (SSI) rate during the 90 days follow up period comparing with the historical control group. The difference of infection rate was statistically significant in overall SSI rate (P = 0.026) and deep SSI rate (P = 0.047), while no same efficacy was seen in superficial SSI rate (P = 0.324).

The similar disinfection efficacy with same PVI concentration was also mention in previous literature. Cheng et al.⁷ reported the disinfectant efficacy of betadine irrigation in spinal surgery in a 414 spinal surgery patients prospective study. The surgical wound irrigated by 3.5% Betadine solution (0.35% PVI solution) before wound closure, resulted in 0% of overall SSI in PVI-irrigated wounds, while still 3.4% of overall SSI in the saline-irrigated wounds. In instrumented spinal surgery, Chang et al.¹² also reported same disinfection efficacy of wound irrigation and soaking with 0.35% povidone iodine solution for 3 minutes. Similar efficacy was also seen in preventing deep periprosthetic joint infection. A retrospective study reviewed disinfection efficacy of dilute Betadine wound lavage (0.35%) for 3 minutes before wound closure in total hip (THA) and knee (TKA) arthroplasty, showing significant reduction in the infection rate (0.15% versus 0.97%, P = 0.04).¹⁸

Previous literatures have identified some common strains of bacteria in spinal surgeries SSI^{4,19} or intraoperative bone autograft contamination.¹⁶ The bactericidal sensitivity to povidone-iodine in some strains, including *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli* and methicillin sensitive *Staphylococcus aureus* (MSSA) and methicillin resistant *Staphylococcus aureus* (MRSA) have been identified.^{13,14,20} The remained bactericidal effect of PVI on Vancomycin-resistant *Enterococcus faecalis* (VRE),¹⁴ and multi-resistant Gram-negative bacilli have also been revealed on previous literature.¹³ The broad spectrum antimicrobial efficacy of povidone-iodine made itself a reasonable agent not only in surgical wound but also bone autograft disinfection, which can be the explanation of the lower SSI rate of PVI protocol in the present study.

The overall infection rate in our control group (4.03%), which was comparable to previous literature. Mattheew et al reported a 5170-patient retrospective comparative analysis of perioperative surgical site infection between minimally invasive versus open posterior or transforaminal lumbar interbody fusion in 2011, showing SSI rate of 4.5% in single level and 4.6% in 2 level minimally invasive fusion procedure respectively.⁶ Another 298-case prospective comparative analysis between MI-TLIF and open TLIF also reported the rate of 4.2% in overall SSI among 144 MI-TLIF cases.²¹

According to some in vitro studies, potential harmful effect on bone cell may be caused after irrigation with dilute PVI solution. Newton et al. reported the rapid and detrimental effect of PVI on human osteoblast cellular proliferation, metabolic function, and bone nodule mineralization after 0.35% PVI exposed for 3 minutes.²² Another in vitro study conducted by van Meurs et al.²³ reported that only diluted PVI remained bactericidal at a cell-viable concentration, comparing with other antiseptics including hydrogen peroxide, and chlorhexidine digluconate. They concluded that 1.3 g/L (0.13%) diluted PVI could be the optimal antiseptic for intraoperative irrigation. In vivo study, however, no similar adverse effect has been reported. The safety of wound irrigation with 0.35% PVI in spinal surgery was evaluated by Chang et al.¹² in a 244 patients prospective study, concluding that wound irrigation with diluted PVI solution followed by normal saline irrigation before the bone-grafting procedure exerted no adverse effects on spinal bone fusion, clinical outcome and wound healing, which revealed the same conclusion of the safety of PVI in related literature.^{7,8,10} The real wound environment contains certain factors including proteins and other organic compounds that may dilute and neutralize the PVI molecule, which may diminish both the cytotoxic and bactericidal effect of PVI, resulted in both higher cytotoxic and bactericidal concentration of PVI when clinically used.

According to another in vitro study, the bactericidal effect of PVI onset immediately on contact, suggesting that PVI exposure time is not the key factor of bactericidal efficacy.²⁰ In present study, under 0.35% diluted PVI solution, we shorten the PVI exposure time of bone graft soaking to 10 seconds, and the remained disinfection efficacy was revealed. There were no

iodine allergies or other betadine related adverse effect noted during the 3-month follow-up. Moreover, based on VAS score improvement, clinical condition, length of hospital stay, reoperation and readmission rate, there was no difference of post-operative outcome between 2 cohorts.

There were several limitations of our study. First, the results of PVI cohort was compared with historical control group instead of concurrent control group. Consequently, the higher SSI rate in historical control group may be inevitably contributed to the learning curve of MIS fusion procedures for surgeons and operative team members. However, we also comparing other surgical outcomes including blood loss volume, surgical complication or length of hospital stay between the 2 groups, but no significant difference was found. Furthermore, all the data of the control group was retrospectively extracted from the electronic patient record system, which may lead to potential bias of data interpretation. Inadequate description of mild infection symptoms or signs of the outpatient department record may also lead to underestimate the actual rate of SSI event.

Besides, the follow up interval was set with only 90 days and the fusion process was accessed through the dynamic view of lumbar spine x-ray instead of lumbar CT. The longer follow up duration may be needed to evaluate the solid bone fusion condition through CT image, in order to monitor the long-term effects of PVI. Last but not least, the procedure in our study was limited to minimal invasive fusion spinal procedures, and further studies were needed to evaluate if the identical efficacy and safety can be seen in other spinal procedure.

To the best of our knowledge, this is the only study in the English language literature evaluating PVI-soaked autogenous bone graft in spine surgery. Our report is the first to propose the protective efficacy and safety of combining PVI soaked autogenous bone graft and PVI intrawound irrigation as a standard disinfectant protocol in spinal fusion procedures.

Conclusion

Harvested bone graft soaking and intrawound irrigation with diluted PVI solution showed significant efficacy in decreasing overall SSI rate and deep SSI rate. No PVI-related adverse effect or delayed bone callus formation was noted during the 90-day follow up duration.



Declaration of Conflicting Interests

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