Brief Report

Effect of Incise Drape on Contamination Rate of Surgical Wound during Surgical Procedures of Lumbar Spine

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Abstract

Background: The aim of this study was to investigate the effect of the incise drape (ID) on surgical wound bacterial contamination during lumbar spine surgical procedures in treatment group (with ID) and control group (without ID). **Materials and Methods:** The present study was conducted on 88 patients who were a candidate for lumbar spine surgery. The patients were randomly assigned to one of the two groups, treatment and control. The ID was only used in the treatment group. The surgical wound sampling for bacterial culture was done in two steps, immediately after surgical incision (IASI) and immediately prior to the surgical wound closure (IPSWC). The samples were then sent to the laboratory. **Results:** The mean total bacterial count of the surgical wound in the stage IASI was not significantly different between treatment and control groups (0.09 vs. 0.02, $P = 0.31$). However, this means in the stage IPSWC in treatment group was significantly more than the control group (18.6 vs. 0.41, $P = 0.04$). The frequency distribution of *Staphylococcus aureus* (25% vs. 3%, $P = 0.02$) and *Staphylococcus epidermidis* (36.4% vs. 9.1%, $P = 0.002$) was significantly higher in the treatment group compared with control group in the stage IPSWC. **Conclusion:** The results suggest that the use of ID is unable to reduce surgical wound bacterial contamination in clean lumbar spine surgery. Therefore, based on the results obtained in our study, the application of ID is not recommended as an essential action for the prevention of surgical wound contamination.

Keywords: *Bacterial contamination, lumbar vertebrae, surgery, surgical drapes, surgical wounds*

Introduction

The surgical site infection (SSI) is one of the most common complications after lumbar spine surgery.[1] Most of these infections are originated from the endogenous flora of the patients.[2,3] This flora originates primarily from the skin of the patients and is the main cause of the development of the SSI.[4] The bacteria of endogenous skin flora surrounding the surgical incision may be recolonized during the procedure and contaminate the surgical wound.[5] To prevent surgical wound contamination (SWC) with endogenous flora, measures have been taken for patients, such as preoperative bathing and surgical site preparation with alcohol-based chlorhexidine solution. Despite the surgical skin preparation with standard procedures, there is still a small count of resistant bacteria.[6,7] Therefore, it is impossible to sterilize the skin so that the skin bacteria can often be isolated from the surgical wound,[8] and the endogenous bacterial flora, through recolonization, can contaminate the skin that has already been prepared.[9] The endogenous skin flora includes *Staphylococcus epidermidis*, *Staphylococcus aureus, Corynebacterium* species, *Propionibacterium acnes*, and *Micrococcus* species.[10] These bacteria can migrate into the wound during surgical procedures and contaminate subsequently. The recolonization of bacteria of endogenous skin flora in the surgical site during the surgery is a serious concern[11] because SSI is nearly always the consequence of contamination that occurs at the time of the operation, and infection is most closely associated to the number of bacteria that contaminate the surgical site.[12] To prevent contact with the endogenous flora, the incise drapes (IDs) are adhered to the surgical skin.[4,9,13] These drapes can be used as plain or impregnated with antimicrobial agents such as iodophor.[14] Studies by Yoshimura *et al*.[15] and Rezapoor *et al*.[16] revealed that iodine-impregnated incision drapes are effective in preventing

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SWC with endogenous bacterial skin flora, and the National Institute for Health and Care Excellence in the UK (2008) recommended that an iodophor-impregnated ID should be used if an ID is required.[17] However, a Cochrane Systematic Review[18] showed that the IDs not only are unable to reduce the incidence of SSI but also may increase the incidence rate of SSI. Maybe this is because recolonization of the bacterial skin occurs earlier using ID compared with bare skin. In addition, a study by Falk-Brynhildsen *et al*. showed that endogenous bacterial skin significantly more positive cultures from the skin with the plastic adhesive drape than bare skin. This might somewhat explain the lack of effect on SSI rate.[19] On the other hand, the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, and the World Health Organization recommended that plain or antimicrobial-impregnated IDs should not be used routinely as a strategy for prevention of SSI.[20,21]

Most studies evaluating the IDs have focused on the effects of these types of drapes on the prevention of SSI rather than the SWC, and as there is no study to investigate the effect of the ID on the prevention of SWC in Iran, as well as since no consensus is observed among the researchers and Iranian spine surgeons about its effect, the present study aimed to investigate the effect of the ID on the rate of bacterial contamination of surgical wound.

Materials and Methods

This is a quasi-experimental study with nonequivalent control group design. The study conducted from February 2018 to May 2018 on 88 patients who were the candidate for lumbar spine surgery in the elective operating room at Al-Zahra Hospital in Isfahan, Iran. Inclusion criteria were the absence of underlying illnesses and immune deficiency disorders, no continuous use of antibiotics and corticosteroids, no history of skin infection or disease in the surgical site, and the age of 20–60 years. Exclusion criteria were the unintentional contamination of the surgical site due to an error by the surgical team intraoperative. As quasi-experimental studies typically lack random assignment, the samples were firstly collected using continuous sampling method (i.e., enrolling all eligible participants) and finally in order to reduce effects of confounding variables (e.g., time of surgery and number of surgical team members), the samples were randomly assigned to A and B groups. In that way, the first patient was admitted at the beginning of the day work of operating room which had the criteria for entering to the study was selected for treatment group, and the next patient was selected for control group. Then, the patients were entered by the decussate pattern in the treatment and control groups. Informed consent was obtained from all patients before starting the study. This study was ethically approved by the Research Committee of Isfahan University of Medical Sciences (IR. MUI. REC.1396.3.821). This study was supported by Isfahan University of Medical Sciences (grant number: 396821).

Surgical procedures

Surgical site hairs were shortened with an electric clipper before the surgery in the ward. For all patients, 1 g of vancomycin and 1 g of ceftazidime were injected intravenously 30 min before the surgery. All patients were under general anesthesia. After induction of anesthesia, the patients were placed in the knee-chest or prone position depending on surgery type and surgeon's opinion. Primary skin preparation was performed by a neurosurgery resident using povidone-iodine 7.5% (Najo Co., Tehran, Iran) diluted with normal saline 0.9% (Samen Pharmaceutical Co., Mashhad, Iran) for approximately 3 min, followed by secondary surgical site preparation performed by surgical first assistant using povidone-iodine 10% (Tolid Daru Co., Tehran, Iran) for 2 min. After the skin preparation, the patients were draped with disposable nonwoven sheet set (Mölnlycke Health Care AB, Samut Prakan, Thailand). In addition to the nonwoven surgical drapes, the plain ID (Mehr Teb-e Jey Co., Isfahan, Iran) with a size of 28 × 30 was also adhered on the surgical site only for the patients in the treatment group. The type of ventilation system and temperature (approximately 25°C) was the same in all operating rooms. All surgical team members wore the disposable gown (Mölnlycke Health Care AB, Samut Prakan, Thailand) and a pair of gloves (Mölnlycke Health Care AB, Selangor, Malaysia). All surgical procedures on lumbar spine were performed with a posterior midline approach for patients with intervertebral disc herniation (27.3%), spinal canal stenosis (18.2%), and spondylolisthesis (54.5%) problems. Depending on the surgical diagnosis, paravertebral muscles were subperiosteally dissected as unilateral (for herniated intervertebral disc involvement ipsilateral) or bilateral (for spinal canal stenosis and spondylolisthesis). After the exposure of the vertebrae, laminotomy and discectomy were performed for the patients with herniated intervertebral disc involvement ipsilateral (L4–L5 = 76%, L5–S1 = 24%), laminectomy for spinal cord and nerve root decompression in the patients with spinal canal stenosis (L3–L4, L5 = 45%, L4–L5, S1 = 55%), and laminectomy, foraminotomy, discectomy, and interbody fusion for the patients with spondylolisthesis (L4–L5 = 65%, L5–S1 = 35%). At the end of the procedure in two groups, the wound was cleaned with normal saline 0.9%, and a Hemovac drain was placed under the fascia, and then the wound was closed. After complete skin suturing, the incision length was measured with a sterile ruler [Figure 1].

Specimen collection from the surgical wound

The wound samples were obtained aseptically from the patients in each of the two groups in two steps, immediately after surgical incision (IASI) and immediately prior to the surgical wound closure (IPSWC) by wearing

sterile gown and gloves. In the first step, the samples were obtained IASI and subcutaneous exposure from the surgical wound edge (epidermis, dermis, and hypodermis) at a range of approximately 2 cm × 2 cm (4 cm^2) in the middle of the surgical incision with a sterile swab prepares from a company [Figure 2]. In the second step, the samples were obtained IPSWC, exactly after lumbosacral fascia closure with another sterile swab from the same site mentioned [Figure 3]. All samples collected from the wound edge were obtained from the same site by a technique of five horizontal movements (left and right) and two vertical movements (up and down).[22] The samples taken with sterile swabs at the two stages were cultured with a standard manner on blood agar (Merck, Germany) and MacConkey agar (Merck, Germany) media [Figure 4] in an operating room environment.[22,23] The media was then sent to the laboratory to determine the count and type of bacteria. In the laboratory, the samples were incubated at 37°C for 48 h[22] and were examined for the count and type of surgical wound contaminating bacteria and main pathogens of SSI.[24]

Statistical analysis

To calculate the number of samples, considering the 95% confidence coefficient and 80% test power, the mean total bacterial count considered to be at least 0.6s to show the difference significant between two groups. Accordingly, 44 participants were selected for each group. Thus, the sample size in this study was generally 88 participants. Descriptive statistics were used to show the number, percentage, mean and standard deviation, and independent Student's *t*-test was used to determine the differences in the count and type of bacteria, and to detect and compare the features of the surgical procedures between the two groups, as well as analysis of covariance test was used to modify confounding variables related to surgical procedures. Independent Student's *t*-test (for quantitative variables) and Chi-square (for qualitative variables) were used to compare the demographic characteristics between the two groups and paired *t*-test for comparing the mean total bacterial count of the SSI in each of the two groups between the two stages. Fisher's exact test was used to determine and compare the frequency distribution of surgical wound

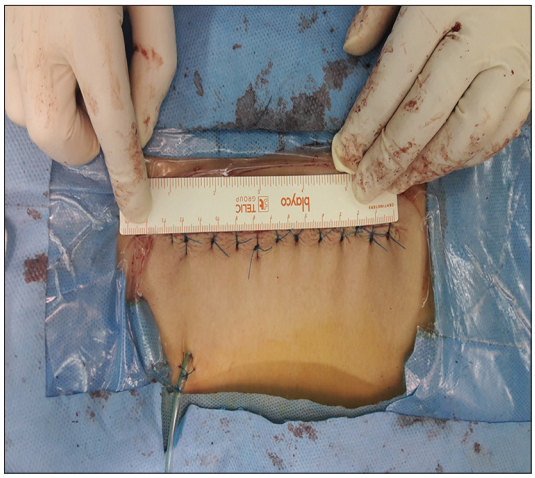

Figure 1: Measuring the length of surgical incision at the end of surgical procedures

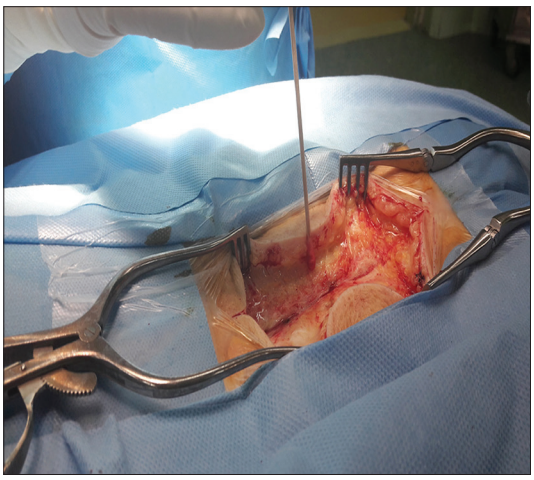

Figure 2: Sampling immediately after surgical incision

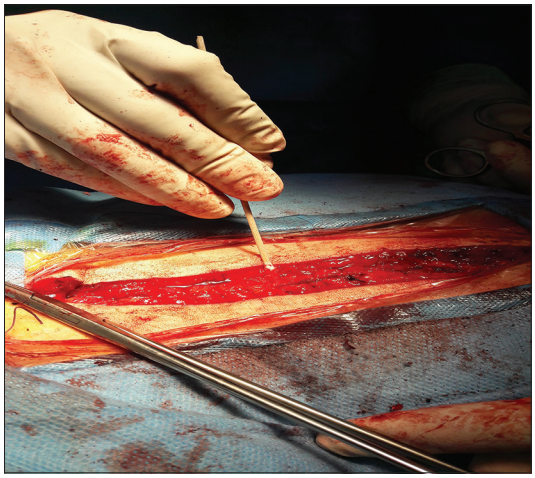

Figure 3: Sampling immediately prior to the surgical wound closure

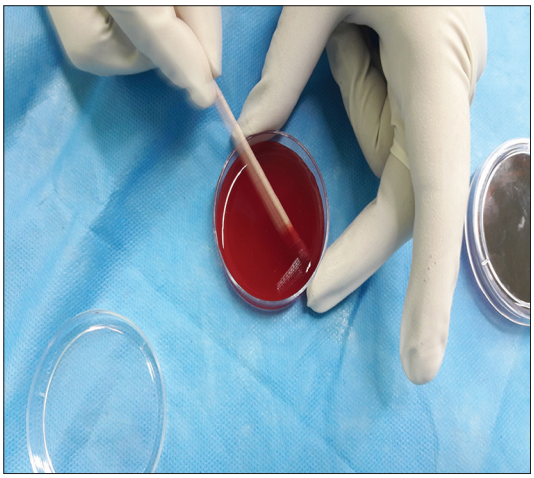

Figure 4: The culture of samples on the blood agar and MacConkey agar media

bacteria in the stage IASI and IPSWC in two groups, and McNemar's test was used to determine and compare the frequency distribution of surgical wound bacteria in two groups between the two stages Two-tailed $P < 0.05$ was considered statistically significant. Data were analyzed using SPSS version 22 (SPSS, Inc., Chicago, IL, USA).

Results

The current study consisted of 88 patients. Both groups were similar in terms of demographic characteristics and surgical factors, and only the mean length of the surgical incision in treatment group was significantly higher compared with control group ($P = 0.008$) and the mean number of surgical team members in control group was significantly more compared with treatment group ($P = 0.02$) [Table 1]. However, the analysis of covariance test by modifying the duration of surgery, the length of surgical incision, and the number of surgical team and the nonsurgical team members present in the operating room in the two groups showed that the mean total bacterial count of surgical wound in any of the two stages had no significant differences between the two groups ($P > 0.05$). The mean total bacteria count of surgical wound IASI was not statistically significantly different between the two groups ($P = 0.31$) but was significantly less in IPSWC in control group compared with treatment group ($P = 0.04$). The mean total bacterial count of a surgical wound was significantly higher in each of the two groups between the stage IPSWC compared with stage IASI ($P < 0.05$) [Table 2]. The frequency distribution of *S. aureus* ($P = 0.25$) and *Bacillus* species ($P = 0.5$) in the stage IASI was not significantly different between the two groups. The frequency distribution of *S. aureus* ($P = 0.02$) and *S. epidermidis* ($P = 0.002$) was significantly higher in treatment group compared with the control group in stage IPSWC. The frequency distribution of *S. aureus* ($P = 0.004$) and *S. epidermidis* ($P = 0.001$) in the treatment group in stage IPSWC was significantly higher compared with stage IASI [Table 3].

Table 1: Comparison of demographic characteristics of patients and surgical factors between the two groups

Variables	Treatment group (*n*=44)	Control group (*n*=44)	*P*
Age (years), mean (SD)	43.91 (10.54)	45.91 (6.64)	0.36
Weight (kg), mean (SD)	79.66 (10.36)	79.07 (9.97)	0.79
Height (cm), mean (SD)	171.70 (9.46)	170.84 (6.31)	0.62
Body mass index (kg/m^2), mean (SD)	27.11 (3.58)	27.06 (2.80)	0.93
Gender, frequency (%)			
Male	23 (52.3)	21 (47.7)	0.67
Female	21 (47.7)	23 (52.3)	
Smoking, frequency (%)			
Yes	16 (36.4)	13 (29.5)	0.05
No	28 (63.6)	31 (70.5)	
Duration of surgery (min), mean (SD)	182.55 (75.92)	156.36 (72.42)	0.10
Length of surgical incision (cm), mean (SD)	13.28 (3.72)	11.17 (3.52)	0.008*
Number of surgical team members, mean (SD)	3.70 (0.59)	3.98 (0.50)	0.02**
Number of nonsurgical team members, mean (SD)	2.75 (0.89)	2.50 (0.59)	0.12
Number of surgical instruments used, mean (SD)	32.43 (6.83)	29.91 (9.18)	0.15

*Independent Student's *t*-test, the mean length of the surgical incision in the treatment group was significantly higher compared with the control group (*P*=0.008), **Independent Student's *t*-test, the mean number of surgical team members in the treatment group was significantly higher compared with the control group (*P*=0.02). SD: Standard deviation, Treatment group: Group with incise drape, Control group: Group without incise drape

Table 2: Comparison of the mean total bacterial count of the surgical site immediately after surgical incision and immediately before surgical incision between the two groups

Time	A	B	*P*	
			Independent *t*-test	Analysis of covariance test
IASI, mean (SD)	0.09 (0.06)	0.02 (0.02)	0.31	0.60
IPSWC, mean (SD)	1.86 (0.66)	0.41 (0.19)	0.04*	0.06

*The mean total bacterial count of surgical wound was significantly lower in the control group immediately prior to the surgical wound closure compared with the treatment group (*P*=0.04). IASI: Immediately after surgical incision, IPSWC: Immediately prior to the surgical wound closure, SD: Standard deviation

Discussion

The aim of this study was to investigate the effect of ID on the bacterial contamination rate of the surgical wound. Attained results showed that the ID could not reduce the bacterial count of the surgical wound in lumbar spine procedures with clean wounds. Cochrane Systematic Review also showed that a significant number of patients in the group with ID had more SSI compared with the group without ID.[18] Although the present study examined the effect of ID on the bacterial contamination rate of surgical wound, not on SSI rate, it should be noted that the endogenous skin microorganisms are the most common sources of SSI[3] that develop almost always following in an SWC occurring intraoperatively and the occurrence of infection is associated with the count of bacteria that contaminate the surgical wound.[12,25] According to the Cochrane study, it can be concluded that the SWC during surgical procedures in the group with ID may have been the likely cause of SSI. Falk-Brynhildsen *et al*. showed that the SWC rate during the surgical procedures was higher in the group with ID compared with the group without ID,[26] this study is in line with the findings of the present study. The intrinsic ability of flora endogenous bacteria

Table 3: Frequency distribution of various species of surgical wound bacteria immediately after surgical incision and immediately prior to the surgical wound closure in two groups

Bacterial species	Treatment group (*n*=44), *n* (%)		*P*	Control group (*n*=44), *n* (%)		*P*
	IASI	IPSWC		IASI	IPSWC	
S. aureus	2 (4.5)	11 (25)	0.004*	0	3 (6.8)	0.25
S. epidermidis	1 (2.3)	16 (36.4)	<0.001**	1 (2.3)	4 (9.1)	0.25
Enterobacter	0	0	1	0	0	1
Salmonella	0	0	1	0	0	1
Pseudomonas	0	0	1	0	0	1
E. coli	0	0	1	0	0	1
Bacillus species	1 (2.3)	4 (9.1)	0.37	0	2 (4.5)	0.50
Klebsiella	0	2 (4.5)	0.50	0	1 (2.3)	0.97
Micrococcus	0	1 (2.3)	0.97	0	1 (2.3)	0.97
Acinetobacter	0	1 (2.3)	0.97	1 (2.3)	0	1

*Frequency distribution of *S. aureus*, **S. epidermidis* was significantly higher in the treatment group in the step of immediately prior to the surgical wound closure compared with the control group ($P<0.05$), McNemar's test. IASI: Immediately after surgical incision, IPSWC: Immediately prior to the surgical wound closure, Treatment group: Group with incise drape, Control group: Group without incise drape, *S. aureus: Staphylococcus aureus, S. epidermidis: Staphylococcus epidermidis, E. coli*: *Escherichia coli*

for colonization on the human skin depends on host determinative factors, one of which is moisture and the endogenous flora survives using these factors.[10] Therefore, the ID may increase the moisture of the skin of the adjacent surgical wound, which in turn can facilitate the growth of the endogenous bacterial skin flora such as *Staphylococcus* species.[8] It is possible that providing favorable conditions for the growth of endogenous flora by the ID has predisposed the SWC during the surgery. In addition, the researchers believed that the patient's skin is not likely to be a primary cause of SSI if it is properly disinfected, and they concluded that attempting to isolate the skin from the surgical wound is no benefit and may create increased moisture and bacterial growth under IDs.[19] The increase surgical wound bacteria in the treatment group in the IPSWC stage compared to the IASI stage can be due to increased moisture flowing utilization of IDs which, with lasting surgical time, provided the conditions for recolonization bacterial. This may be a concerning situation because accumulated bacteria under the ID may pass into the deep of layers when the skin is sutured, and the patient is susceptible to SSI. Makki *et al*. concluded that Using IDs can regenerate the skin flora on the surface of the skin under the drapes, leading to possible SWC when the drapes are lifted off at the end of the procedure.[27]

Falk-Brynhildsen *et al*. showed that the ID can facilitate the recolonization rate of endogenous bacterial skin flora after the skin preparation.[26] The advantage of the ID is when adhered tightly to the edges of the surgical wound throughout the surgical procedures,[5] while all IDs in the present study were lifted from the surgical skin in the first 30 min after surgery and retracted from the edges of the surgical wound. Alexander *et al*. reported that the ID separated from the skin surface is associated with a sixfold increase in the infection rate compared with when it is not separated from the skin.[28] Among the compatible studies, there were also studies that claimed the use of ID was effective in reducing the SWC and preventing the SSI. Studies by Fairclough *et al*.[25] and Rezapoor *et al*.[16] showed that the iodine-impregnated incision drapes are effective for prevention of SWC with bacteria of endogenous skin flora.

Artz *et al*. concluded that the use of ID has unique advantages and these drapes should be added to other preventive measures of SSI.[29] Casey *et al*.[4] showed that the use of antibiotic-impregnated ID could prevent the recolonization of microorganisms. Bejko *et al*.[30] concluded that the ID significantly reduces the incidence of SSI. The results of this study are inconsistent with the results obtained in our study. The present study examined the effect of plain IDs, not antimicrobial-impregnated IDs; however, Falk-Brynhildsen *et al*.[8] showed that all plain or antimicrobial-impregnated ID have the same effect, and the Centers for Disease Control and Prevention does not recommend using the plain or iodophor-impregnated ID for the prevention of SSI.[31] Cochrane study showed that there was no significant difference in the incidence of infection between the groups with iodophor-impregnated IDs and the group without this drape.[18] Therefore, the use of antimicrobial-impregnated IDs not only has no effect on the prevention of infection but also imposes treatment costs on the patients. A significant proportion of SSI occurs due to bacterial contamination of the wound during the surgical period.[26] Based on previous studies, there is a correlation between increasing the duration of surgery and the high rate of SWC and SSI.[32,33] The present study showed that the increase in surgical wound infection in the two groups is an unavoidable event and may increase with the passing of time due to the reactivation of endogenous flora. Nevertheless, we expected that the mean and frequency distribution of surgical wound bacteria in the treatment group in two stages was less compared with the control group; however, the results of the present study were the opposite. At the center under the study, the

majority of lumbar spine surgeries were performed by two residents with the presence of an attending. Although the mean number of surgical team in the control group was significantly higher compared with the treatment group, it did not affect the total bacteria count and their frequency distribution between the two groups, while Olsen *et al*.[34] showed that the presence of more than one resident during spinal surgery was one of the factors for SWC and the incidence of SSI. The length of the surgical incision is an independent factor for the development of SWC and SSI.[35,36] The longer the surgical incision is the greater the damage to the vessel and the negative effect on the wound healing process.[36] The longer the length of the surgical incision appears the greater the chance of surgical wound infection with endogenous flora. In the present study, the mean length of surgical incision in the treatment group was significantly higher compared with the control group. However, the analysis of covariance test by modifying the variable length of surgical incision showed that the difference in the mean length of surgical incision between the two groups did not affect the count and the frequency distribution of surgical wound bacteria in any of the two stages.

Limitations

The present study has some limitations. The ventilation system in the operating rooms of the study environment was the same, and the room's temperature was approximately 25°C; however, due to the teaching nature of the research environment, some factors such as operating room traffic, closing of the operating room doors, and the electrical equipment lit up in the operating room might affect the ventilation systems and the temperature of the operating room, which were out of the control of the researchers.

Conclusion

The results suggest that the use of ID is unable to reduce surgical wound bacterial contamination in clean lumbar spine surgery. According to the results of this study, making a decision on the use of ID is an important step that should be taken into consideration by health-care providers because the ID has not been able to reduce endogenous bacterial flora. These drapes may, by providing a moist environment between the skin and their plastic layer, stimulate the endogenous bacterial flora to recolonize, and thereby predisposing the SSI. Therefore, we do not recommend the ID as a preventive measure of SWC and as a basic step required to control the SSI in the patients undergoing surgery.

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Conflicts of interest

There are no conflicts of interest.

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