Original Article

Does Plastic Incise Drape Prevent Recolonization of Endogenous Skin Flora during Lumbar Spine Procedures?

Abstract

Background: The aim of this study was to compare the PID with bare skin (without PID) regarding bacterial recolonization and bacterial regrowth of the adjacent skin of surgical incision in lumbar spine surgery patients. Methods: This quasi-experimental study was conducted from February to May 2018 on 88 patients who were candidate for lumbar spine surgery. Patients were assigned to one of two groups, treatment (with PID) and control (without PID). Skin sampling (adjacent of surgical incision) for bacterial culture was done in two steps, immediately after surgical skin prep (IASSP) and immediately after surgical wound closure (IASWC) by researcher. Finally, samples were sent to the laboratory. Results: The mean total bacterial count of patient's skin in stage IASSP was not significantly different between treatment and control groups (0.34 vs 0.27, P = 0.68). However, mean total bacterial count in stage IASWC in treatment group was significantly higher than control group (2.2 vs 0.93, P = 0.03). The frequency distribution of S. aureus (P = 0.04) and S. epidermidis (P = 0.02) was significantly higher in treatment group compared with control group in stage IASWC. Conclusions: The results showed that using PID is unable to reduce recolonization and regrowth of bacteria on patients' skin adjacent to surgical wound in clean lumbar spine surgeries. However, making a definite decision about using or not using of PID requires further studies.

Keywords: Bacteria, lumbar vertebrae, surgical drapes, surgical wound

Introduction

Surgical site infection (SSI) is a common problem after spinal surgery that increases the cost of surgical care, morbidity, and mortality.^[1] The majority of SSIs result from the patient's endogenous flora that originates primarily from the patients' skin.^[2,3] Human skin is a major reservoir of endogenous bacteria such as, *Staphylococcus* epidermidis, Staphylococcus aureus, Corynebacterium species, Propionibacterium acnes, and Endogenous species.^[4] Micrococcus bacteria adjacent to the surgical wound may be recolonized during the surgical procedures and migrate into the surgical wound from gap between the routine surgical drapes and surgical site and contaminate subsequently.^[5] In order to prevent wound contamination with endogenous recolonized bacteria. preventive measures are being taken for patients, including preoperative bathing and surgical skin prep.^[6] Nevertheless, even after meticulous surgical skin prep

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with standard procedures, there is still a small count of endogenous bacteria that continue to proliferate during the surgical procedures.^[7,8] Thus, skin can never completely be sterilized before surgery and gradual recolonization of bacteria will occur.^[9] The recolonization of bacteria of endogenous skin flora in the surgical site intraoperatively is a serious concern.^[10] Therefore, to prevent the problem of endogenous bacterial contamination, the patients' skin around the incision site was covered with plastic incise drape (PID) after surgical skin prep. PIDs currently are widely used to provide a barrier against lateral migration of recolonizing bacteria from the patients' skin into the surgical incision. PIDs can be used as plain or impregnated with antimicrobial agents such as iodophor.^[6] However, Falk-Brynhildsen et al. showed that recolonization of the surgical site skin in group with PID occurred faster than the group without PID.^[11] Moreover, a Cochrane review showed that PID is unlikely to reduce incidence of SSI, and

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may even increase it.^[12] Another study of Falk-Brynhildsen *et al.* showed that PID could promote bacterial proliferation near the surgical incision.^[13] There is little evidence to support that PIDs lead to reduction of SSI.^[14] However, many surgeons routinely use PID. Therefore, the aim of this study was to compare the PID with bare skin (without PID) regarding bacterial recolonization and bacterial regrowth of the adjacent skin of surgical incision in lumbar spine surgery patients.

Methods

Study population

This quasi-experimental study was conducted from February to May 2018 on 88 patients who were candidate for lumbar spine surgery 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 intraoperatively. 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 assigned to treatment and control groups by the decussate pattern. In that way, the first patient admitted at the beginning of the workday was selected for treatment group based on the inclusion criteria, and the next patient was selected for control group. Informed consent was obtained from all patients before starting the study.

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.^[15] Subsequently, 1 g of cefazolin was administered for prolonged surgeries (>4 h). All patients were under general anesthesia. After induction of anesthesia, the patients were placed in 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 PID (Mehr Teb-e Jey Co., Isfahan, Iran) with a size of 28×30 cm² was also adhered

on the surgical site only for the patients in the treatment group. The type of ventilation system and temperature (approx. 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 ipsilateral herniated intervertebral disc involvement) or bilateral (for spinal canal stenosis and spondylolisthesis). After the exposure of the vertebrae, laminotomy and discectomy were performed for the patients with ipsilateral herniated intervertebral disc involvement (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.

Skin samples

Intraoperatively, the bacterial samples were collected aseptically from patient's skin adjacent to the surgical incision in each of the two groups in two steps, immediately after surgical skin prep (IASSP) and immediately after surgical wound closure (IASWC) by the researcher by wearing sterile gown and gloves. In the first step, the samples were taken IASSP from the skin adjacent to surgical wound edge with 1 cm distance of the middle of the surgical incision using a cotton swab from a quadrangle area of approximately $2 \text{ cm} \times 2 \text{ cm}$ (4 cm²) with a sterile swab prepared from a company. In the second step, the samples were collected IASWC, exactly after surgical wound closure with another sterile swab from the same site mentioned. Samples were taken using cotton swabs moistened with sodium chloride 0.9%, by rubbing the swab back and forth and rotating the tip for 15 s.^[13] The samples taken with sterile swabs at the two stages were cultured in a standard manner on blood agar (Merck, Germany) and MacConkey agar (Merck, Germany) media in the operating room environment. The media was then sent to the microbiology laboratory to determine the count and type of bacteria. In the laboratory, the samples were incubated under aerobic conditions at 37°C for 48 h^[16] and bacterial growth were examined after 2 days of incubation for the count and type of surgical wound contaminating bacteria and main

pathogens of SSI.^[17] The culture diagnostics were carried out for all bacteria with standard diagnostic procedures in a laboratory and one individual counted colonies. Microbial recovery was expressed as log colony forming unit (CFU) per centimeter skin (length).

Statistical analysis

Finally, the data were analyzed using SPSS software version 22.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to evaluate normality of the variables. 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 0.6 s to show the significant difference 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. 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 and McNemar test were used respectively to determine and compare the frequency distribution of total bacterial count of patient's skin between the two groups and between the two stages. In all analyses, P < 0.05 was considered statistically significant.

Results

The current study consisted of 88 patients. Both groups were similar in terms of demographic characteristics and surgical factors [Table 1]. Only the mean length of the surgical incision in treatment group was significantly higher than control group (P = 0.008), and the mean number of surgical team members in control group was significantly (P = 0.02) higher than treatment group [Table 1]. The mean total bacterial count of patient's skin adjacent to the surgical incision in the stage of IASSP was not statistically significantly different between two groups (P = 0.68) but was significantly less in the IASWC stage in control group compared with treatment group (P = 0.03). The analysis of covariance test by modifying the length of surgical incision and number of surgical team members present in the operating room showed that the mean total bacterial count of patient's skin adjacent to the surgical incision in the stage IASSP had no significant differences between the two groups (P = 0.74). However, mean total bacterial count of patient's skin adjacent to the surgical incision in treatment group in the IASWC stage had significant difference compared with the control groups (P = 0.04) [Table 2]. The mean total bacterial count of the patient's skin adjacent to the surgical incision was significantly higher in both groups between the stages IASWC compared with stage IASSP (P = 0.001). The frequency distribution of S. aureus (P = 0.04)and S. epidermidis (P = 0.02) was significantly higher in treatment group compared with the control group in IASWC stage [Table 3]. The frequency distribution of S. aureus (P = 0.002), S. epidermidis (P = 0.001), and Bacillus species (P = 0.001) in the treatment group and S. epidermidis (P = 0.06) and Bacillus species (P = 0.02) in the control group in IASWC stage was significantly higher

Table 1: Comparison of demographic characteristics of patients and surgical factors between the two groups				
Variables	Treatment Group (<i>n</i> =44)	Control Group (n=44)	Р	
Age (year), 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	
BMI (Kg/m ²), mean (SD)	27.11 (3.58)	27.06 (2.80)	0.93	
Gender				
Male, frequency (%)	23 (52.3)	21 (47.7)	0.67	
Female, frequency (%)	21 (47.7)	23 (52.3)		
Smoking				
Yes, frequency (%)	16 (36.4)	13 (29.5)	0.05	
No, frequency (%)	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 non-surgical 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	

Treatment Group=Group with plastic incise drape. Control group=Group without plastic incise drape. SD=Standard deviation. BMI=Body mass index. Student *t*-test was performed for normally distributed variables. Chi-square was used for nominal variables. *Resulted from Independent Student's *t*-test

than stage IASSP [Table 3]. The paired *t*-test was used to compare the mean total bacterial count of the SSI in each of the two groups between the two stages [Table 4].

Discussion

The aim of this study was to compare the PID with bare skin (without PID) regarding bacterial recolonization and bacterial regrowth of the adjacent skin of surgical incision in lumbar spine surgery patients. In the present study, PID did not decrease bacterial recolonization and regrowth of the patient's skin. The mean total bacteria count of patient's skin in stage IASSP was not statistically significantly different between the two groups but was significantly less in stage of IASWC in control group than treatment group. These findings are in concordance with Zarei *et al.* study about the effect of incise drape on contamination rate of surgical wound that showed using PID is unable to reduce surgical wound bacterial contamination in clean lumbar spine surgery.^[6] Although the present study examined the effect of PID on the bacterial recolonization and bacterial regrowth of the adjacent skin of surgical incision, not on SSI rate, it should be noted that the endogenous skin microorganisms are the most common sources of SSI that develop almost always following a surgical wound contamination occurring intraoperatively and the incidence of infection is associated with the count of bacteria that contaminate the surgical wound.^[6] Despite all the contradictory evidences regarding the effectiveness of the PIDs, many surgeons prefer to use PID to provide an added physical protection against bacterial migration from adjacent skin into the surgical wound.^[18]

Many studies have showed that PID result in a reduction in bacterial colonization, for example, Rezapoor *et al.* found that iodine-impregnated incision drapes are efficient in preventing surgical wound contamination with endogenous bacterial skin flora.^[19] In addition, Casey *et al.* showed that the use of antibiotic-impregnated PID could prevent the recolonization of microorganisms^[3] and Bejko *et al.* concluded that the PID significantly reduces the incidence of SSI.^[9] National Institute for Health and

Table 2: Comparison of the mean total bacterial count of patients' skin adjacent to the surgical incision immediately
after surgical skin prep and immediately after surgical wound closure between the two groups

Steps	Treatment	Control Group	Р	Р	
	Group (<i>n</i> =44)	(<i>n</i> =44)	Independent t-test	ANCOVA	
IASSP, mean (SD)	0.34 (0.13)	0.27 (0.10)	0.68	0.60	
IASWC, mean (SD)	2.20 (0.50)	0.93 (0.25)	0.03*	0.04**	

IASSP=Immediately after surgical skin prep. IASWC=Immediately after surgical wound closure. SD=Standard deviation. *Resulted from Independent Student's *t*-test, **Resulted from Analysis of covariance test

Bacterial species	Treatment Group (n=44)		Р	Control Group (n=44)		Р
	IASSP N _{CFU/cm} ² (%)	IASWC $N_{CFU/cm}^{2}$ (%)		IASSP N _{CFU/cm} ² (%)	IASWC N _{CFU/cm} ² (%)	
Staphylococcus aureus	3 (6.8)	13 (29.5)	0.002*	2 (4.5)	6 (13.6)	0.12
Staphylococcus epidermidis	8 (18.2)	21 (47.7)	0.001*	6 (13.6)	11 (25)	0.06
Enterobacter	0	0	1	0	0	1
Salmonella	0	0	1	0	0	1
Pseudomonas	0	0	1	0	0	1
Escherichia coli	0	0	1	0	0	1
Bacillus species	2 (4.5)	14 (31.8)	0.001*	1 (2.3)	8 (18.2)	0.02*
Klebsiella	0	1 (2.3)	0.99	0	1 (2.3)	0.99
Micrococcus	0	0	0	0	3 (6.8)	0.25
Acinetobacter	0	1 (2.3)	0.99	0	0	1

IASSP=Immediately after surgical skin prep; IASWC=Immediately after surgical wound closure; CFU=Colony-forming unit. *Resulted from McNemar test

Table 4: Comparison of the mean total bacterial count of patients' skin adjacent to the surgical incision between two
groups in two Steps

Group	Steps		Paired <i>t</i> -test	
	IASSP Mean (SD)	IASWC Mean (SD)	t	Р
Treatment Group (<i>n</i> =44)	0.34 (0.13)	2.20 (0.50)	4.35	0.001*
Control Group (<i>n</i> =44)	0.27 (0.10)	0.93 (0.25)	3.48	0.001**

IASSP=Immediately after surgical skin prep; IASWC=Immediately after surgical wound closure*,**Paired t-test

Care Excellence (NICE) in the UK (2008) recommended that an iodophor-impregnated PID should be used if a PID is required.^[20] Thus, the use of iodophor-impregnated drapes appears to mitigate colonization of endogenous flora in patient's skin. The present study examined the effect of plain PIDs, not antimicrobial-impregnated PIDs; however, Falk-Brynhildsen *et al.* showed that all plain or antimicrobial-impregnated PID have the same effect.^[13] Webster *et al.* showed that no difference was found in SSIs when either the iodine-impregnated or non-use of drape is used. On the other hand, the recent SSI prevention guidelines by World Health Organization (WHO) did not find any evidence to support the use of PIDs during surgery and recommended against its use.^[21]

The ability of certain bacteria to colonize the human skin is dependent on a host of contributing factors, such as availability to moisture, temperature, etc. Warm and moist environments are believed to be characteristics in the pathogenesis.^[4] On the other hand, quantitative culture showed that high temperature and high humidity are associated with increased numbers of bacteria on the back and other part of body.^[22] Theoretically, the PIDs could create a "greenhouse effect" that enables quick bacterial recolonization and regrowth.[11] Therefore, the PID may increase the formation of moisture and accumulation of sweat beneath or around the incised edge of the PID and formation of air bubbles or pockets of bodily fluids with a high mass of bacteria formed beneath the PID may be entered into the surgical site, especially subsequent removal of the drape for the wound closure.^[8] The present study showed that the frequency distribution of S. aureus and S. epidermidis on the patient's skin was significantly higher in the treatment group compared with control group in the IASWC stage. In line with our study, Falk-Brynhildsen et al. showed at 120 min after the beginning of surgery frequency distribution of P. acnes and S. epidermidis on the patient's skin were significantly higher in the PID group than without PID group.^[11] In the present study, the exact time of bacterial recolonization of patients' skin adjacent to the surgical incision did not record. However, the result of paired *t*-test showed in two groups in stage IASWC and the mean total bacterial count of patients' skin adjacent to the surgical incision was significantly higher than stage IASSP. Therefore, it can be concluded that prolonged surgical procedures may associate with a higher rate of bacterial recolonization [Table 4]. Furthermore, our data showed that although the duration of the surgery in treatment group was longer than the control one, there was no significant difference between them (P = 0.10).

The results of the present study showed one possible explanation why a Cochrane Systematic Review showed no reduction of SSI rate with PID. Webster and Alghamdi revealed a higher incidence of SSIs in surgical patients in whom PIDs had been used than those without drapes.^[12] Therefore, whenever PIDs are used, surgeons

should be aware that adherence of PIDs can itself recolonize or regrowth the skin flora such as *S aureus* and *S. epidermidis*, etc.

All PIDs lift from the wound edges about 30 min after beginning of procedures in present study. Regarding this situation, Alexander et al. revealed that PID lift or pull-back from the wound edges was associated with a six times increase in the infection rate compared with surgical procedures in which the incise drape was not lifted.^[23] This situation may allow skin organisms to contaminate the surgical wound secondary to migration of bacteria from near to skin or contaminated instruments with endogenous skin flora, which recover several hours after preoperative skin preparation into the surgical wound.^[5,24] Hence, PIDs do not appear to be useful for decreasing the wound contamination rate by preventing intraoperative contamination with skin bacteria. Falk-Brynhildsenet et al. demonstrated skin recolonization or regrowth of bacteria, after 30 min with PID and after 60 min without PID (bare skin); there were significantly more positive cultures with the PID than without PID.^[11] In line with the above study, present study showed the increase bacterial regrowth and bacterial recolonization 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 patients' skin bacteria in treatment group in two stages was less than control group; however, the results of the present study were the opposite. The present study showed that using PIDs did not decrease bacterial recolonization in the lumbar spine surgeries and this study does not support the hypothesis that PIDs prevent from migration of bacterial recolonization into surgical wound.

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 patients' skin bacteria count and their frequency distribution between the two groups, while Olsen et al. showed that the presence of more than one resident during spinal surgery was one of the factors for surgical wound contamination and the incidence of SSI.^[25] The length of the surgical incision is an independent factor for the surgical wound contamination and SSI. The longer the surgical incision, the greater the damage to the vessel and the negative effect on the wound healing process.^[26-28] The longer the length of the surgical incision, the greater the chance of SSI with endogenous flora. In the present study, the mean length of surgical incision in the treatment group was significantly higher than the control group. However, the analysis of covariance test by modifying the 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 patients' skin bacteria in any of the two stages.

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Study 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, the risk of airborne contamination of the skin, which were out of the control of the researchers. Another limitation of this study is that we did not evaluate the need for blood transfusion during the surgery because the blood loss can mostly affect the infection rate post-operatively, not the recolonization rate intraoperatively.

Conclusions

The results showed that using PID is unable to reduce recolonization and regrowth of bacteria on patients' skin adjacent to the surgical wound in clean lumbar spine surgeries. These drapes may stimulate the endogenous bacterial flora to recolonize by providing a moist environment between the skin and their plastic layer, and thereby predisposing the SSI. However, making a definite decision about using or not using of incise drape requires further studies.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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