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Local vancomycin in prevention of surgical site infection in spinal surgeries

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Abstract
Background: Organisms that cause surgical site infections (SSIs) can no longer be effectively prevented by antibiotic drugs due to resistance. Methicillin-resistant Staphylococcus aureus (MRSA) SSIs have become more prevalent to cure. Lyophilized vancomycin powder has been used locally as perioperative prophylactic antibiotics, right before the surgical wound is closed. The study's objective was to evaluate the local vancomycin administration to SSI prevention during spine operations.
Methods: This randomized trial study was conducted on 42 patients above 18 years old who were subjected to lumbosacral, thoracic, or cervical open spinal surgery The patients were split into 2 groups: Treatment group: this group receives local application of vancomycin and placebo group: this group not get any topical antibiotics.
Results: The ESR level at follow-up time post operatively there was no significant differences at any groups. However, there were reduction of ESR level in the treatment group. There were differences in CRP level between 2 groups at 10 days, 2weeks, and 8 weeks. In the treatment group we found most of our cases 13 (62%) with category A. There are 7 cases (33%) in category B and one case with category C. In the placebo group, we found most of our cases 11 (52%) cases with category A. There were 6 cases (29%) cases in category B and the remaining 3 cases (14%) of category C.
Conclusions: we found that old age and diabetic patient should be applied with vancomycin. Ultrasound scan and MRI are a good way to detect infections. These outcomes suggest that using vancomycin intraoperatively reduced the incidence of SSIs following spine operations.

Keywords: Surgical site infection, Vancomycin, spinal

Introduction
In spine procedures, Systemic antibiotics are already often used as surgical prophylaxis. Despite this, surgical site infection (SSI) remains a big issue in all surgeries. With systemic antibiotic prophylaxis, the risk of deep infection at the surgical site is reduced [1].

SSIs are classified as superficial or deep by the United States (US) Centers for Disease Control and Prevention (CDC) [2].

Superficial incisional SSI is a type of infection that only affects the skin in which the wound was created. A deep incisional SSI involves an infection that develops in the muscle and adjacent tissues below the site of the incision [2].

Spine surgery risk factors include diabetes mellitus (DM), transfusion, obesity, urinary tract infection (UTI), hypertension, cerebrospinal fluid (CSF) leak, and duration of operation [3]. The consequences of infection in spinal procedures include long-term hospitalisations, wound debridement, repeated readmissions, and a delay in postoperative rehabilitation [4].

Traditionally, intravenous (IV) antibiotic cover of gram-positive bacteria has been part of perioperative prophylaxis for SSIs during spinal surgery, such as clindamycin or a first-generation cephalosporin, which should be started one hour before the surgical incision and discontinued 24 hours after the surgery is finished. Due of its potent antimicrobial effects against Gram-positive bacteria, especially Staphylococcus aureus (S. aureus) and other members of the Staphylococcus species, that are the most frequent source of SSIs, cephalosporins have been employed [5].

Unfortunately, prophylaxis versus over fifty percent of all SSI-causing pathogens is no longer effective due to growing resistance to conventional antibiotic treatments; Methicillin-resistant Staphylococcus aureus (MRSA) SSIs are becoming more common and are hard to treat [5].

Considering these issues, lyophilized vancomycin powder has been administered into the surgical site prior to sealing in a number of studies as a kind of prophylactic antibiotic use during surgery. Theoretically, direct inoculation of the area with large amounts of the antibiotic will decrease the rate of SSIs by overwhelming any remaining bacterial load, including those with intermediate resistance. By reducing rapid absorption into the bloodstream, the drug's intra-site delivery may reduce negative effects associated with vancomycin [6].

The study's objective was to evaluate how using local vancomycin helps prevent SSI during spine operations.

Patients and Methods

This randomized trial study was conducted on 42 patients over 18 years old who, between April 2022 and October 2022, underwent open spinal surgery at Tanta University Hospital in the cervical, thoracic, or lumbosacral regions.

The Institutional Review Board approved the clinical trial protocol, and every one of patients provided informed consent.

Exclusion criteria were patients with a history of receiving an infection or taking antibiotics within the previous month, patients in infectious or immunodeficiency conditions (DM excluded) at the time of having surgery, vancomycin allergic reactions, history of SSI, use of immune suppressive drugs (other than steroids), radiation therapy at the site of surgery, and history of renal or liver failure.

Two groups of patients were established applying the randomization technique as follows: Treatment group: this group receives local application of vancomycin (After bathing the surgical site, vancomycin was applied deep to deep fascia and muscles and superficial at subcutaneous tissues), and placebo group: wherein no local antibiotic was used (vancomycin wasn`t applied at the surgical site).

All the patients subjected to

Full history taking: Personal history: name, age, sex, smoking, drug abuse, dysuria and pregnancy history, medical history: DM, autoimmune disease and chronic diseases, and Surgical history: history of spinal surgery and history of previous SSI, full clinical examination: General examination: full general examination to detect any septic focus, and local examination: full local examination at site of surgery, pre-operative investigations: Laboratory investigation: C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and full blood count (CBC), urine analysis.

According to our department's guidelines, elective patients should shower the day before surgery and clean the operative site using 70% alcohol and povidone iodine solution.

Both groups received systemic antibacterial prophylaxes administered with 1 g or 2 g of first-generation cephalosporin. Cephazolin dosage was determined by the patient's weight 20 minutes earlier to the skin incision. Clindamycin was administered in place of cephazolin in cases of sensitivity to penicillin or the cephalosporin group of antibiotics. During the procedure, antibiotics were given again every three hours or before if there had been more than 1000 cc of blood lost during that time.

After a two-hour procedure and the administration of an image intensifier under the surgeon's guidance, Gloves were replaced in the two groups (despite using sterile cover).

Vancomycin application

The same standard prophylactic antibiotic was administered to every patient, consisting of 1 g cefazolin one hour prior to surgery and 1 g cefazolin again 24 hours after surgery. Along with IV antibiotics, the treatment group also received local application of vancomycin powder to the surgical site. 1 g of vancomycin powder was administered to patients having surgery on four spinal levels or less, Whereas 2 g of vancomycin powder was administered to patients having surgery on five or more spinal levels. All patients included in this research had surgical drains (Redivac drainage set), and the surgical site was closed in layers.

Patients' follow-up

For a minimum of three months following surgery, every patient was monitored.

There were two types of infections: superficial and profound. If an infection just affected the skin and subcutaneous tissue around the incision, it was considered superficial; if it also affected the layers of muscle and fascia, it was considered deep. Exhibiting at least one of the subsequent characteristics: redness or warmth, clinical symptoms of tenderness, localized swelling, purulent discharge caused by the incision, and a positive culture from aseptically collected fluid. Radiological assessment by ultrasound (US) scan or magnetic resonance imaging (MRI) was done to identify deep from superficial infection with good assessment to any deep pocket of pus. Based on the culture results, superficial infections were managed with wound care, local debridement, and IV or oral antibiotics. Based on culture results and surgical debridement with or without implant removal was used to treat deep infections with intravenous antibiotics. ESR, CRP, CBC were done if there is no signs of inflammation or infection every 2 weeks for three months. If there were any signs of inflammation or infection, culture from discharge, ESR, CRP, CBC were be done immediately. If there was suspicious of deep infection MRI in needed cases was done.

Assessment of clinical outcomes

The detection of deep or superficial SSI within three months following surgery was the main outcome. The secondary endpoint was using Southampton scale.

Although there isn't a globally accepted instrument to help with the assessment and treatment of surgical wounds at the moment, one of the most often used assessment methods is the Southampton Scoring System. Using this technique, one may objectively evaluate the wound by grading its healing based on predetermined criteria. It evaluates erythema, discharge, pus, bruises, and infection [7].

Southampton scale

The extent of the wound infection following surgery was assessed using this wound grading system.

The wounds are then split into 3 categories:

1. Normal healing (wounds from grade 0 to grade IC).
2. Minor complication (wounds from grade IIA TO grade IIID).
3. Major complication (wound infection - wounds graded IV or V or wounds treated with antibiotics after discharge from hospital).

Statistical analysis

We used (SPSS Corp.; Armonk, NY, USA) and MedCalc 14 (MedCalc Software Ltd., Ostend, Belgium) programs were used to analyze the variables. The quantitative variables were described as mean ± standard deviation and the median range (maximum-minimum) and categorical variables as n (%). The Levene test was used to assess variance homogeneity and the

Shapiro-Wilk test was used to determine if the data conformed to a normal distribution. To quantitatively compare the treatment and control groups, the independent sample t-test and the Mann-Whitney U test were employed using the Monte Carlo findings. On comparing the treatment and control groups regarding the categorical variables, the Fisher's exact test and the Pearson chi-square test were employed. The variables were analysed using a 95% confidence level, and significance was defined as $p<0.05$.

Results

According to the demographic data the treatment group there were 18 (86%) males and 3 (14%) females. In the placebo group there were 15 (71%) males and 6 (29%) females. The age was distributed as follow in which mean age was 52 years (Range from 24 to 70 years) in treatment group and 43 years (Range from 24 to 71 years) in the placebo group with statistically significant difference between groups (P value = 0.08). As regards past medical history there were 4 (19%) diabetics in treatment group and 2 (10%) in the placebo group with statistically significant difference between groups (P value =0.01). As regarding smoking history there were 7 (33%) in the treatment group and 2 (10%) smokers in the placebo group with statistically significant difference between groups (P value =0.001). As regrading body mass index (BMI), the mean 26.4±1.02 kg/m2 in the treatment group and mean BMI is 27.2±1.2 kg/m2 in placebo group with no statistically significant difference between groups (P value =0.1). (Table 1)

Table 1: Patients demographic data

Patients demographics					
	Treatment group		Placebo group		P value
	No	%	No	%	
Males	18	86%	15	71%	0.15
Females	3	14%	6	29%	
Age distribution					
	Mean	Range	Mean	Range	0.08
	52	24 to 70	43	24 to 71	
DM					
	No	%	No	%	
Yes	4	19%	2	10%	0.08
No	17	81%	19	90%	
Smoking					
	No	%	No	%	
Yes	7	33%	2	10%	0.5
No	14	67%	19	90%	
BMI					
	Mean	Range	Mean	range	0.1
	26.4±1.02	24 to 28	27.2±1.2	25.6 to 32.7	

The mean operative time in both groups was nearly equal as it was 2.4±0.37 hours in the treatment group and 2.4±0.44 hours in the placebo group without statistically significant differences between both groups which means that the operative time had no rule in the infection rate in our series. The mean intraoperative blood loss was nearly equal as it was 190.47±54.7 in the treatment group and 195.2±46.04 ml in the placebo without statistical significant differences between both groups which means that the intraoperative blood loss had no rule in the infection rate in our series. (Table 2)

Table 2: Operative time, and intraoperative blood loss in both groups

Operative time	Treatment group	Placebo group
Mean	2.4	2.4
SD	0.37	0.44
Intraoperative blood loss	Treatment group	Placebo group
Mean	190.47	195.2
SD	54.8	46.04

Of the included patients we found that in the treatment group there was three patients (14.28%) suffered from infections. two of them were superficial infection with culture revealed *E.coli* positive and the other one with negative culture result, no one showing deep infection. In the placebo group, we found six patients (28.57%) suffered from infections. Two of them were superficial infection in which the culture revealed *E. coli* positive and other ones with negative culture results. Also, we found two patients suffered from deep infection and the culture revealed MRSA positive on one patient and the other one Klebsiella positive. (Table 3).

Table 3: Infection rate and culture details

No. of Patients (%), Culture		
	Treatment	Placebo
Total no. of patients	21	21
Superficial infection	2 (*E. coli*),1 (CN)	2 (*E. coli*),2 (CN)
Deep infection	0	2 (9%), (MRSA) (Klebsiella)
Total	3 (15%)	6 (30%)

CN = culture negative; *E. coli = Escherichia coli;* MRSA= *Methicillin-resistant Staphylococcus aureus;* Klebsiella.

In the treatment group, most of the patients were cured by 86% their age ranged from 24 to 70 with mean age was 52 years old. In the placebo group, the patients were cured by 71% (lower than the treatment group) most of them ranged from 24 to 71 with mean age was 43 years. The infection was present in 14.28% of the treatment group all of them were older in age than the cured group which means that the older the age the lesser cure rate. In the placebo group the infection was present in 28.57% of the patients their culture revealed multiple organisms than in the treatment group which means that the vancomycin had a rule in reducing the infection rate. Also, accidently we found the infectious organisms present in older patient age rather than younger which confirm that the older the age the more sustainability to infection. (Table 4)

Table 4: Infection rate and its relation to age

	Treatment group			Placebo group		
	No (%)	Mean age	Range	No (%)	Mean age	Range
No infection	18 (86%)	50.0	24 to 60 years	15 (71%)	38.46	24 to 47
E. coli	2 (10%)	65	60 to 70	2 (10%)	68	65 to 71
Culture negative	1 (5%)	64		2 (10%)	50	
Klebsiella	0			1 (5%)	55	
MRSA	0			1 (5%)	42	

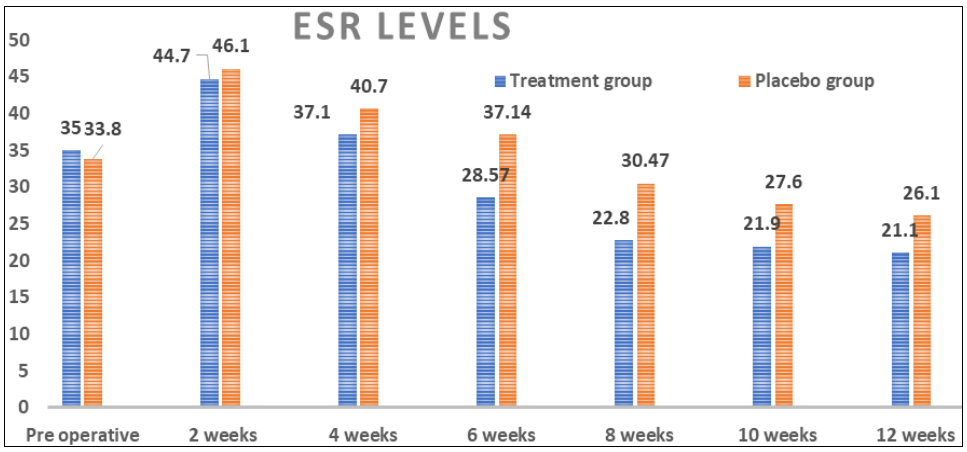
In our study the diabetic patients in the treatment group suffered from infection in 3 (14%) patients out of four all of them were superficial infection with *E. coli* in two patients and culture negative (CN) in the other one. While in the placebo group the whole diabetic patients 2 (10%) suffered from infection one of them was *E. coli* and the other was positive for MRSA.

Although there were no statistically significant differences between both groups the overall diabetic patents were susceptible to infection site more than the non-diabetic patients. In our study the all-smoker patients in the treatment group were cured without infection 7 (33%). In the placebo group the whole smoker patients 2 (10%) suffered from infection one of them was *E. coli* and the other was culture negative. (Table 5)

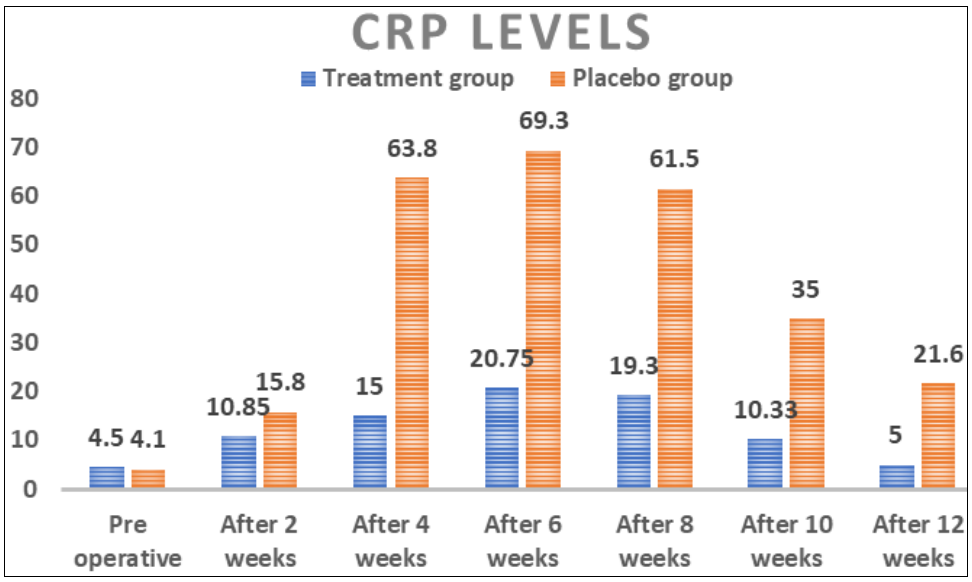
Table 5: Infection rate and its relation to DM, and smoking

Diabetes Mellitus	Treatment	Placebo	p-value
No infection	1 (5%)	0	0.2
Infection	3 (14%)	2 (10%)	
Smoking			
No infection	7 (33%)	0	0.5
Infection	0	2 (10%)	

On comparing the mean value of ESR level at follow-up time post operatively there was no statistically significant differences in ESR level between both groups. However, there were observed reduction if ESR level especially in the treatment group with time. There were statistically significant differences in CRP level between both groups at 10 days, 2weeks, and 8 weeks. (Figure 1)



(a)



(b)

Fig 1: Inflammatory markers ESR levels (a) and CRP levels (b)

In the treatment group we found most of our cases 13 (62%) with category A. There are 7 cases (33%) in category B and only one case with category C. In the placebo group, we found most of our cases 11 (52%) cases with category A. There were 6 cases (29%) cases in category B and the remaining 3 cases (14%) of category C. (Table 6)

Table 6: Southampton scale

	Treatment group	Placebo group
Category A	13 (62%)	11 (52%)
Category B	7 (33%)	6 (29%)
Category C	1 (5%)	3 (14%)

Discussion

AS regards past medical history there were 4 (19%) diabetics in treatment group and 2 (10%) in the placebo group with significant difference between groups (P value = 0.01).

In our study the diabetic patients in the treatment group suffered from infection in 3 (14%) patients out of four all of them were superficial infection with *E. coli* in two patients and culture negative (CN) in the other one. while in the placebo group the whole diabetic patients 2 (10%) suffered from infection one of them was *E. coli* and the other one was positive for MRSA. Despite the fact that both groups' differences were not statistically significant the overall diabetic patents were susceptible to infection site more than the non-diabetic patients and the vancomycin antibiotic powder helps to reduce incidence of SSI overall.

As regards smoking history there were 7 (33%) in the treatment group and 2 (10%) smokers in the placebo group the difference within the groups was statistically significant. (P value =0.001).

In our study the all-smoker patients in the treatment group were cured without infection 7 (33%). In the placebo group the whole smoker patients 2 (10%) were suffered from infection one of them was *E. coli* and the other was culture negative (CN).That prove our study values in reduction SSIs by applying vancomycin powder at surgical site.

The mean operative time in both groups was nearly equal as it was 2.4±0.37 hours in the treatment group and 2.4±0.44 in the placebo group without statistically significant differences between both groups which means that the operative time had no rule in the infection rate in our series. The mean intraoperative blood loss was nearly equal as it was 190.47±54.7 in the treatment group and 195.2±46.04 ml in the placebo without statistically significant differences between both groups which means that the intraoperative blood loss had no rule in our study.

Complications that detected post-operatively included the following: Three patients of treatment group showed infection. There were no other post-operative complications, such as vancomycin allergy, Redman syndrome, ototoxicity and nephrotoxicity.

In the treatment group, most of the patients were cured by 86% their age ranged from 24 to 70 with mean age was 52 years old. In the placebo group, the patients were cured by 71% (lower than the treatment group) most of them ranged from 24 to 71 with mean age was 43 years.

The infection was present in 14.28% of the treatment group all of them were older in age than the cured group which means that the older the age the lesser cure rate.

In the placebo group the infection presents in 28.57% of the patients their culture revealed multiple organisms than in the treatment group which means that the vancomycin had a rule in reducing the infection rate. Also, accidently we found the infectious organisms present in older patient age rather than younger which confirm that the older the age the more sustainability to infection.

We found that in the treatment group there was three patients (14.28%) suffered from infections. two of them were superficial infection with culture revealed Escherichia coli (*E. coli*) positive and the other one with negative culture result, no one showing deep infection. In the placebo group, we found six patients (28.57%) suffered from infections. Two of them were superficial infection in which the culture revealed *E. coli* positive and other two of them with negative culture results.

Also, we found two patients suffered from deep infection and the culture revealed MRSA positive on one patient and the other one Klebsiella positive.

In Sweet *et al*. [8] match with our study as they reported that there was a statistically significant ($p< 0.0001$) difference in infection rates between the adjunctive vancomycin group (0.2%) and control group (2.6%).

In El zahlawy *et al*., [9] decreases in SSI caused by MRSA and methicillin-resistant Staphylococcus epidermidis as a consequence of using vancomycin were documented. The percent of the pathogenic bacterium S. aureus that causes SSI decreased when vancomycin was applied. These findings also showed that vancomycin application decreased the amount of sensitive gram-positive bacteria in surgical wounds, which in turn decreased the amount of SSI brought on by strains of vancomycin-sensitive Staphylococcus. Additionally, it appears from these data that fewer SSI occurrences occurred overall. When we applied Southampton scale we found that, in the treatment group we found most of our cases 13 (62%) cases with grade developed category A, Then 7 (33%) cases in category B and only one case with category C. In the placebo group, we found most of our cases 11 (52%) cases with category A. There were 6 (29%) cases in category B and the remaining 3 (14%) cases of category C.

In a systematic review conducted by El zahlawy *et al.* [9] revealed that a dose of 1-2 g of intra wound vancomycin was found to significantly reduce SSIs in spinal surgeries; however, in two of the included studies, the rate of SSIs in the vancomycin group was higher than that in the control group, but not statistically significantly. Data from the more thoroughly investigated topical vancomycin in spine support its safety, and Shan *et al*.'s meta-analysis [10] research that included 7627 individuals who received topical vancomycin for spine procedures only found two instances of major side effects associated with the drug's use: an allergic reaction and an epidural seroma. The absence of any systemic side effects, including thrombophlebitis, eosinophilia, "red man syndrome," ototoxicity, and nephrotoxicity, associated with IV vancomycin usage. Is because serum vancomycin concentrations produced by topical vancomycin treatment are well below the toxicity threshold. Reducing SSIs with topical vancomycin will improve quality measures including readmission rates that impact hospital referral and payment patterns, as well as reduce direct and indirect cost burdens [11, 12].

In El zahlawy *et al.* study [9]. Revealed that Vancomycin was administered intrawound, and the total adverse event rate that was reported thereafter showed very little, if any, adverse events, so confirming the safety of the medication. In Sweet *et al*. [8] study they reported some complications. In contrast, there was no statistically significant variation in the rate of perioperative problems including deep vein thrombosis (DVT), implant failure, neuritis, spinal fluid leakage, or the narcotic requirements. Patients receiving vancomycin powder for local adjunctive prophylaxis did not experience hypotension or renal damage. These reported side effects may be due to relatively larger sample size compared to ours.

Similarly,a study done by Xiao *et al*. [13] 1512 surgeries involving intraoperative vancomycin usage reported a single case of temporary renal failure. It was unknown how long renal failure would take to progress, how creatinine would fluctuate over time, and how much vancomycin was in the serum, even though all patients got 1 g of the antibiotic. Prior studies done by Bokhari *et al*. [14] showed that following intra-wound dosing, serum vancomycin seldom rises to supra-therapeutic levels and is almost undetectable within 24 hours. Moreover, using vancomycin intrawound did not have any

negative consequences. A meta-analysis revealed no adverse effects linked to intra wound vancomycin, although the authors also noted that the quality of the available data was currently inadequate. An outlier with supratherapeutic vancomycin levels and no systemic toxicity was seen, according to a retrospective research on vancomycin usage.

A recent systematic review reported by Martin and his collages. [15] found Among over 1400 children receiving posterior spinal surgery for early onset scoliosis, there was just one instance of an adverse medication response (transient rash), representing just 0.072% of cases. Furthermore, individuals in this research who had previously had adverse pharmacological responses to intravenous vancomycin did not exhibit any negative reactions to intrawound vancomycin powder that reported in Remschmidt *et al*., study [16].

Strengths of our study included that it is the prospective design. It is of relatively long follow up period with several laboratory and clinical assessment every other two weeks to assess the improvement and complications. Good quality follows up by clinical assessment, laboratory and scoring system. Use of MRI and ultrasound to detect infections.

Limitations of our study include the using of one scoring system only. The small number of patients is not enough to show a significant results and accurate feedback about possible complications Patient co-morbidities needed to be assessed well This has a significant impact on the frequency of SSI after surgery.

Conclusions

SSIs are major problem affecting spine surgeries and consume medical resources. Lowering infection rates is the aim of local vancomycin powder administration. Applying vancomycin locally reduces the number of microbes present in the surgical site, which in turn reduces SSIs. Because of the exceedingly low risk of side effects associated with its usage and the challenges of treating SSI, we felt that its use was worthwhile. From follow up of patient in our study, we found that old age and diabetic patient should be applied with vancomycin at their surgical sites to reduce risk of infections (mainly deep infection). Ultrasound scan and MRI are a good way to detect site and depth of infections. Infection if happened it will be superficial and easy to treat. These results suggest that administering vancomycin intraoperatively reduced the incidence of SSIs following spine operations.

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