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**Dr. Naveen Rathor**  
Assistant Professor, Department  
of Orthopaedics, American  
International Institute of  
Medical Science, Udaipur,  
Rajasthan, India

**Dr. Suresh Kumar Bhatnagar**  
Assistant Professor, Department  
of Orthopaedics, American  
International Institute of  
Medical Science, Udaipur,  
Rajasthan, India

**Dr. Momin Aadil Sumer**  
Senior Resident, Department of  
Orthopaedics, American  
International Institute of  
Medical Science, Udaipur,  
Rajasthan, India

**Corresponding Author:**  
**Dr. Naveen Rathor**  
Assistant Professor, Department  
of Orthopaedics, American  
International Institute of  
Medical Science, Udaipur,  
Rajasthan, India

## Intrawound vancomycin powder as the prophylaxis of surgical site infection after invasive lumbar spine surgery: A prospective study

**Dr. Naveen Rathor, Dr. Suresh Kumar Bhatnagar and Dr. Momin Aadil Sumer**

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### Abstract

**Objectives:** To evaluate the efficacy of locally administered vancomycin (VCM) powder for prophylaxis of SSI after invasive lumbar spine surgery.

**Material and Method:** This prospective study was conducted upon 85 patients at American international institute of medical science, Udaipur (Rajasthan). All patient were operated for invasive spine surgery from May 2019 to April 2020 and follow up was done for minimum one year of duration. In patients of the VCM group (n = 42), 1 gm VCM powder was locally administered in the surgical wound and Patients who did not receive VCM treatment were set as a control group (n = 43). We compared the patient's background, Operation time, Intraoperative blood loss, usage of implants, presence of deep SSI, and side effects between the two groups.

**Results:** There were no significant differences between the groups in age, gender, and BMI. The operation time and the intraoperative blood loss were longer and greater in the VCM group than in the control group. Implants were used in 85% of the VCM group, and in 31% of the control group ( $P < 0.001$ ). Deep SSI was observed in one patient (2.38%) of the VCM group, whereas it was observed in 3 patients (6.97%) in the control group. No systemic side effects of vancomycine were observed in any of the cases.

**Conclusion:** Administration of intrawound VCM powder might be effective to prevent SSI in cases with high risks of infection.

**Keywords:** Surgical site infection, vancomycin hydrochloride, intrawound administration, invasive spine surgery

### Introduction

Surgical site infections (SSIs) are one of the most serious complication of spine surgery. The incidence rate of deep SSI after spine surgery is reported to be 1-14%, with most of the causative bacteria being vancomycin (VCM) susceptible. Additional surgery for debridement or the removal of instrumented materials might be necessary when antibiotic therapy for SSI is not effective. However, both surgical debridement and failed antibiotic treatment result in long-term hospitalization and increased morbidity of patient. It has been reported that local application of VCM powder to wounds is effective after spine surgery. There is little evidence of local VCM application in the prophylaxis of SSI in cases with a high risk of infection. In this study, we investigated the efficacy of locally applied VCM powder in the prevention of SSIs after spine surgery.

### Materials and Methods

#### Study Design

This study was carried out after obtaining the approval from institutional ethical committee and informed consent of each participant. This prospective study was conducted upon 85 patients at American international institute of medical science, Udaipur (Rajasthan). All patient were operated for invasive spine surgery from May 2019 to April 2020 and follow up for a minimum one year of duration.

In patients of the VCM group (n = 42), VCM powder was administered in the wound before closing wound. Patients who did not receive VCM treatment were set as a control group (n = 43). patients who had surgery for existing infections and other comorbidities were excluded from the study.

### Method

All patients received identical standard operative and post-operative care procedures based on protocol of department. Patients with diabetes underwent perioperative glycemic control, which was performed by physician. Surgical sites were prepared with 10% iodine for three times and covered with iodine-containing dressing preoperatively. Cefazolin sodium (1 g) was administered as an intravenous infusion within 60 min before the start of surgery, and then every three hours during surgery. No patient was administered intravenous VCM prior to or during surgery. Normothermia was maintained in all patients. In patients who received VCM treatment (VCM group), 1 gm VCM hydrochloride powder was applied to the wound and bone grafts before the wound was closed. Patients who did not receive VCM treatment were used as a control group. We examined the following items and compared them between the two groups: patient's background, surgery duration, intraoperative blood loss, use or non-use of implants, number of fused vertebrae, presence or absence of deep SSI based on World Health Organization criteria and the occurrence of adverse effects (allergies, renal failure, red man syndrome, or auditory disorders) associated with VCM use.

For statistical analysis, we performed a Chi-square test, a Fisher's exact test, and a *t*-test. P values less than 0.05 were considered statistically significant. The data have been presented as mean  $\pm$  standard deviation.

### Results

There were 42 patients in the VCM group and 43 patients in the control group. All patients were followed more than one year. Follow up period (mean  $\pm$  standard deviation) was 18.4  $\pm$  5.2 months in the VCM group and 17.5  $\pm$  5.8 months in the control group ( $p = 0.43$ ). The primary surgeon did not differ between the groups ( $p = 0.72$ ). The demographic and surgery data of the patients are shown in Table 1 & Table 2. There were no significant differences between the groups in mean age, gender ratio, and body mass index ( $p = 0.62$ ,  $p = 0.88$ , and  $p = 0.48$ , respectively). The VCM group showed significantly higher values in the mean surgery duration and intraoperative blood loss than the control group ( $p < 0.005$  and  $p < 0.001$ , respectively). Implants were used in 85.70% and 32.5% of the patients in the VCM and control groups, respectively ( $p < 0.001$ ).

**Table 1:** Demographic data of the patients

	Control group	VCM group	P-value
No. of cases	43	42	
Male ratio (%)	42%	48%	0.81
Age (yr)	50.3 $\pm$ 22.2	48.4 $\pm$ 23.8	0.60
BMI (kg/m <sup>2</sup> )	22.0 $\pm$ 4.7	22.6 $\pm$ 5.9	0.81
DM	11.62%	42.85%	<0.001

**Table 2:** Surgical data of the patients

	Control group	VCM group	p-value
<b>Surgery duration (min)</b>	109 $\pm$ 43	180 $\pm$ 70	<0.005
Blood loss (ml)	250 $\pm$ 150	340 $\pm$ 250	<0.001
Implant usage	32.55%	85.70%	<0.001
No. of fused vertebrae	3 $\pm$ 2	4 $\pm$ 3	<0.001
<b>Details of spinal disorder</b>			
1) Scoliosis	06	08	
2) degenerative disease	09	11	
3) P.I.V.D	22	14	
4) Traumatic	06	09	

The incidence of deep SSI was 2.38% (one patient) in the VCM group and 6.97% (3 patients) in the control group (Table 3). All four cases of infection was associated with use of implant. The following causative bacteria were detected in the infection cases: Methicillin-resistant *Staphylococcus aureus* (1 case), Methicillin-resistant *Staphylococcus epidermidis* (2 cases), and *Escherichia coli* (1 case). All of

*Staphylococcus* strains were VCM susceptible. One of the infected patients received successful conservative treatment with antibiotics; however, in the other three cases, additional debridement surgery had to be performed. No adverse effects (allergies, renal failure, red man syndrome, auditory disorders and local soft tissue problems) usually associated with the use of VCM were observed in any of the cases.

**Table 3:** Details of patients with deep surgical site infection

group	Age(yr)/sex	Bacterial strain	Disease/surgery	Surgery duration	Blood loss	treatment
VCM group	32/M	MRSE	#L1 -L2 Vertebrae/posterior fixation	170 min	480 ml	debridement
control	52/M	MRSE	Degenerative listhesis /PLIF	210 min	400 ml	debridement
control	57/M	E.COLI	Degenerative listhesis/PLIF	260 min	450 ml	nonsurgical
control	71/M	MRSA	Degenerative Scoliosis/PLIF	230 min	290 ml	debridement

*E. coli*, *escherichia coli*; MRSE, methicillin-resistant *staphylococcus epidermidis*; MRSA, methicillin resistant *staphylococcus aureus*; PLIF, posterior lumbar interbody fusion.

### Discussion

The results showed that the duration of surgery, blood loss rate, rate of implant use, and the number of fused vertebrae were longer or higher in the VCM group than they were in the control group. We found that the surgeons tended to apply

VCM into the wounds when the surgery was or had a high risk of infection. Although there was a high risk of developing infections in many of the cases, deep SSI was observed only in one patient of the VCM group.

There is little evidence of local VCM application in the

prophylaxis of SSI in cases with a high risk of infection. Tubaki *et al.* reported that local application of VCM to surgical wound did not significantly reduce the incidence of infection after spine surgery in a randomized controlled study. In that study, there were limitations such as the lack of power analysis and a low infection rate (1.61-1.68%), which indicated that the risk of developing an infection was relatively low. Various retrospective studies have reported decreased relative risks for SSI (0.086- 0.23) and safety after intrawound use of VCM.

The biggest concern about intrawound VCM is its safety. Sweet *et al.* studied the serum level of VCM after intrawound application of 2 g VCM in 178 patients who had undergone spine surgery. The minimum sensitivity of the blood test to VCM was 0.6 µg/ml in that study. The results showed that VCM was not detected in serum in 80% of the patients. In 20% of the patients in whose serum VCM was detected, the average VCM level was 1.6 µg/ml at postoperative day 1.3) The serum level was quite low compared to the recommended safety margin of VCM (< 15 µg/ ml). The molecular mass of VCM is high; therefore, it is not easily absorbed into the blood and the risks of its side effects, such as renal failure and red man syndrome, are quite low. Although none of the case measured the serum concentration of VCM, no adverse effects were observed in the current study. Furthermore, it has been reported that an effective concentration of VCM is detected in wound drainage on the third day after surgery. Furthermore, it has been shown that VCM does not suppress *in vitro* proliferation of human osteoblasts or delay *in vivo* bone fusion in posterior lumbar fusion in rats. These indicate that intrawound VCM would not obstruct bone healing.

There were several limitations in this study. Firstly, patients' background information and surgical interventions were different between the VCM and control groups.

In addition, The surgeons tended to use VCM in cases where the risk of infection was high. Since we did not set strict criteria for the application of intrawound VCM, VCM use was the surgeon's choice. Because patients in the VCM group had a higher risk of developing infections and underwent more invasive surgeries than those in the control group. Therefore, we might have biased for the effect of VCM in preventing SSIs.

Another limitation was the small number of subjects used in the study. As a result, the statistical power was not high enough to compare the occurrence of SSIs between the two groups. we therefore plan to conduct a randomized controlled trial with an adequate number of cases.

In conclusion, the intrawound application of VCM powder might be safe and effective in preventing SSIs after spine surgeries in cases with a high risk of infection.

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