# Cover Letter

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# **Manuscript:**

Title Page: Intra-Wound Application of Vancomycin Powder For Instrumented Deformity, Trauma and Degenerative Spine Patients.

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Vancomycin, spondylolisthesis, deformity, instrumented, spinal infection

#### Abstract:

Objective: To evaluate the use of an intra-operative placement of 1 gram of Vancomycin powder into the wound of instrumented spinal patients with spondylolisthesis, deformity, trauma and degenerative disk disease.

Methods: Since July of 2010, 46 patients had consent prior to their lumbar surgery. These 46 patients had lumbar spinal surgery with instrumentation by 2 different surgeons at three different facilities. All patients received either 2 grams of IV Cefazolin one hour prior to the incision or 1 gram of IV Vancomycin one hour prior to the incision if they had a Penicillin allergy. Near the end of the surgery the wound was thoroughly irrigated with normal saline. Standard fusion techniques were performed. Postoperatively, patients continued to intravenous antibiotics for up to twenty-four hours. All patient underwent routine postoperative surgical care including physical therapy, routine radiographs, and routine weaning of pain medications. Braces were prescribed for the patients with a prior unstable spondylolisthesis, trauma or revision surgery.

Results: During the course of follow up that has ranged from two months to thirteen months, there have been no wound infections with this surgical technique. No patients were lost to follow up. No allergic reactions or adverse outcomes were reported from the use of 1 gram of Vancomycin power prior to closure. All patients that were more than 6 months postoperative had signs of fusion. One pseudo-arthrosis in a high-grade spondylolisthesis was appreciated at three months when his interbody device started backing out. This patient required a revision surgery.

Conclusions: Although there have been a myriad of recent techniques to minimize the risk of spinal wound infections, it seems that intra-wound application of Vancomycin is a reasonable and simple technique to minimize infections, even in the complex of cases such as trauma and deformities.

#### Introduction:

Lumbar spine surgery with instrumentation continues to be a successful procedure, especially for deformities and trauma. Infection, however, is always a potential vulnerability during these procedures. To minimize the risk of infection an accepted standard has been the use of preoperative antibiotics within an hour of skin incision and the utilization of postoperative antibiotics for up to twenty-four hours. Medical doctors have relied on additional preventive treatments such as nasal cultures for evaluating and treating methicillin-resistant *Staphylococcus aureus* (MRSA) rates, as well as the use of intra nasal Bactroban ointment (mupirocin). Surgeon's dependence on these treatments has led to a much-increased use, but unfortunately we are unsure as to how such treatments translate in their ability to limit postoperative wound infections. In certain situations, spine surgeons have even used plastic surgery to perform muscle flaps in order to reduce the risk of infection after spinal surgery. 12

Even with these regimens, spinal infection rates from .4% up to 10% continue to be reported, especially for deformity and trauma patients. In order to prevent spinal infections, surgeons have utilized multiple preoperative, intraoperative, and postoperative methods of prophylaxis. Most prominently, intrawound application of antibiotics seems to have been overlooked. There has been little to no attention given to the intrawound application of antibiotics to reduce or even eliminate the risk of instrumented lumbar fusion, even with such a high-risk population.<sup>7</sup>

Although surgeons may adopt several of the adjunctive measures mentioned, the 0.4%–3.5% incidence of infections. It is our belief that the use of intraoperative placement of 1 gram of Vancomycin powder into the wound of instrumented spinal patients with spondylolisthesis, trauma and degenerative disk disease would be less than the accepted national average of 3.5%.<sup>3,11</sup>

### Material and Methods:

All patients had consent prior to their lumbar surgery. Since July of 2010, 46 patients had lumbar spinal surgery with instrumentation by 2 different surgeons at three different facilities. Preoperatively, all patients received an alcohol preparation, followed by 3M<sup>TM</sup> DuraPrep<sup>TM</sup> Surgical Solution (Iodine Povacrylex [0.7% available Iodine] and Isopropyl Alcohol, 74% w/w) patient preoperative skin preparation. Additionally, all patients received either 2 grams of IV Cefazolin one hour prior to the incision or 1 gram of IV Vancomycin one hour prior to the incision if they had a Penicillin allergy. No patients had a known Vancomycin allergy.

Twenty patients were male, twenty-six were female and twelve patients had a smoking history prior to surgery. Twenty-four patients had a preoperative diagnosis of spondylolisthesis, two with scoliosis, four with trauma and sixteen patients had the preoperative diagnosis of lumbar degenerative disk disease. Eight patients were revision surgeries. Age ranged from 11 to Seventy-one. Table 1: Patient Characteristics

Near the end of the surgery, after the hardware was placed, including the interbody devices when appropriate, the wound was thoroughly irrigated with normal saline. Standard fusion techniques including decortications of remaining facets, the transverse processes and remaining lamina were performed. Allograft combined with autograft was placed lateral to the screw heads into the lateral gutters. At this point, 1 gram of Vancomycin power was placed in the wound prior to placement of the deep drains. For the 4 dural tears, they were primarily repaired with 6-0 prolene, followed by dura gen, and then followed by eveseal (find trademarks for these). The Vancomycin power was placed after the eveseal cured.

Postoperatively, patients continued to receive 1 gram of IV Cefazolin every eight hours until the drains were removed. For the penicillin allergic patients, they received 1 gram of Vancomycin every 12 hours until the drains were removed.

All patient underwent routine postoperative surgical care including physical therapy, routine radiographs, and routine weaning of pain medications. Braces were prescribed for the patients with a prior unstable spondylolisthesis, trauma or revision surgery.

# Results:

During the course of follow up that has ranged from two months to thirteen months, there have been no wound infections with this surgical technique. No patients were lost to follow up. No allergic reactions appreciated from the Vancomycin and there were no adverse outcomes that could be attributed to the use of 1 gram of Vancomycin power prior to closure.

All patients that were more than 6 months postoperative had signs of fusion and one pseudo-arthrosis in a high-grade spondylolisthesis was appreciated at three months when his interbody started backing out. This patient required a revision surgery.

#### Discussion:

Lumbar instrumented spinal fusions are widely performed in order to reduce patients' lower back and leg pain. 13 Although instrumentation for deformities has progressed from casting, to Loque rods with sublaminar wiring, to hooks to pedicle screw lumbar instrumentation, there have also been studies confirming a direct correlation between infection rate and instrumentation.<sup>2</sup> Medical treatments for spinal disorders are known to show an increase in postoperative infection rates due to longer operative times, prolonged retraction, and internal instrumentation. There have been measures taken conforming to stringent techniques, such as copious irrigation and debridement, and having experienced operating room personnel and short operating times that were introduced in order to reduce the incidence of postoperative infections. Kim et al. did a thorough study in 2010 showing that Nasal cultures for evaluating and treating methicillinresistant Staphylococcus aureus (MRSA) rates may help to decrease orthopaedic infections.8 Another study in 2011 by Mericli AF introduced a paraspinous muscle flap technique for the reconstruction of cervical spine wounds. This 11-year, single-institution study was performed on 14 consecutive patients from 1996 to 2007 and revealed an overall complication rate of 14% after the paraspinous muscle flap surgery. The low complication rate consisted of two minor wound infections, but the study concluded that this procedure is a timely and reliable solution for complex cervical spine wounds. Although the study reported a small percentage of wound infection occurrences, such an undersized sample of patients does not have the ability to report any significant findings. This indicates the requirement for additional studies. 12

Epstein recently published a thorough review of multiple steps of reducing spinal infections including clipping the hair from the surgical site, to appropriate skin preparation to preoperative antibiotics within an hour of skin incision and postoperative antibiotics.<sup>3</sup> Although an excellent review, there was no mention of intraoperative antibiotic placement for deformity patients.

The problem is that although these options indicate a lower infection rate, there is no significant difference to note. Ontrary to previous studies, failure to indicate a significant difference in infection rate, our aim in this prospective study was to evaluate the intraoperative placement of 1 gram of Vancomycin powder into the wound of patients with spondylolisthesis and degenerative disk disease. We hypothesized that this would significantly reduce surgical site infection rates in posterior instrumented lumbar spondylolisthesis, and to date, there have been no reported infections in a variety of diagnosis.

A study from 2007 provided a national estimate of the number of healthcare-associated infections (HAI) and deaths in United States hospitals. The authors used a multi-step approach and three data sources. The main source of their data was the National Nosocomical Infections Surveillance system containing data from 1990 – 2002. Their findings revealed that in 2002, the number of deaths associated with HAIs in U.S. hospitals was 98,987. Of these, about 20% were due to infection: 8,205 for surgical site infections, and 11,062 for infections of other sites. The findings of this study confirm that HAIs in hospitals have become a significant cause of morbidity and mortality in the United States. Surgical site infections should continue to be monitored because they remain to be a considerable problem in the treatment of traumatic spine injuries. Practitioners have found themselves in a predicament because previous treatments of traumatic spine injuries have shown no significant findings that have demonstrated a decrease in

wound infection rates. Our study is a promising first step to decrease the infections rate in these complicated cases.

In an assessment of topical antibiotic prophylaxis in neurosurgery, Haines deduced that surgical wounds with an intrinsically high risk of infection rate (greater than 15%) could be reduced substantially with the treatment of intraoperative topical antibiotics. Contrary to surgical wounds with a high risk of infection rate, he noted that there is no sound scientific evidence supported by the use of prophylactic topical antibiotics for wounds with a low risk of infection rate (less than 5%). Due to this data, Haines reported that the use of topical antibiotics in neurosurgery are either unconstrained or have a tendency to be so disconnected that no useful conclusions can be established. We tend to disagree with an arbitrary acceptance rate of 5% for infection, and feel that intrawound application of Vancomycin may reduce the risk of all spinal surgeries to a negligible number and that we should not accept a 5% infection rate.

Numerous studies have reported that prophylactic antibiotics have reduced the rate of deep wound infections. A double-blind placebo-controlled trial explored the efficacy of a single dose of one gram of cephazolin in reducing infection rates of patients undergoing lumbar spine procedures. In this 141 patient trial, 71 patients received the placebo and 70 patients received cephazolin. Nine of the 71 patients (12.7%) in the placebo group developed wound infections compared with three of the 70 patients (4.3%) in the cephazolin group. Similar results emerged in a more recent meta-analysis evaluating the efficacy of prophylactic antibiotic therapy in spinal surgery. Barker's meta-analysis study provided evidence that infection rates were 2.2% in patients treated with prophylactic antibiotics versus a 5.9% infection rate in patients without antibiotic treatment. Although these studies have produced admirable results, we feel that 4.3% spinal wound infection rate is unacceptable and that the outcomes of these infections cause a significant impact on the patient, on the hospital and on society.

There has been effort directed towards identifying preoperative, intraoperative, and postoperative risk factors that have shown a correlation to infection rate following spine surgery. <sup>1,14,16,17</sup> Regardless of all the effort to date, individual studies do not have the capability to demonstrate a significant benefit for prophylactic antibiotic therapy in spinal operations <sup>1</sup>, the efficacy of topical irrigation in preventing infections during lumbar spine surgery continues to remain unanswered <sup>15</sup>, and interventions to reduce the risk for these potentially devastating infections still needs to be developed due to wound infection rates remaining a devastating complication. <sup>14</sup>

Although there have been a myriad of recent techniques to minimize the risk of spinal wound infections, they will remain inevitable. With new research from China describing techniques of intra-wound betadine solutions to intra-wound Antibiotics, there are ways of minimizing this terrible complication. This study has shown that intra-wound Vancomycin is an adjunct to preventing infection with no acute or any long-term associated risks. There must be more double blinded studies done, especially in the high-risk population such as smokers and diabetics, but this is a good framework to begin with. Lumbar deformity as well lumbar degenerative patients seem to farewell with this described technique.







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No personal, professional or financial conflicts of interest to report.

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