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Abstract:

Objective: To evaluate if the use of an intra-operative placement of 1 gram of Vancomycin powder into the wound of lumbar spine instrumented patients with spondylolisthesis, deformity, trauma, and degenerative disk disease has adverse effects on fusion rates.

Methods: Since July of 2010, 50 patients had consent prior to their lumbar surgery. These 50 patients had lumbar spinal surgery with instrumentation by two 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. All patients had placement of intra-operative, intra-wound application of 1 gram of Vancomycin powder. Postoperatively, patients continued on intravenous antibiotics for up to twenty-four hours. All patients 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. Plain AP and lateral radiographs, and if needed, thin-cut CT slices, were evaluated to assess posterolateral spinal fusion by looking for bridging trabeculated bone between transverse processes. Anterior-Posterior radiographs were used to evaluate lumbar interbody fusion as described by the surgical interbody research group.

Results: During the course of follow up that has ranged from six months to seventeen months, 96% of the patients experienced adequate fusion. No patients were lost to follow up. No allergic reactions or adverse outcomes were reported from the use of 1 gram of Vancomycin powder prior to closure. Two cases of pseudarthrosis were documented at three months and four months postoperative.

Conclusions: Although intra-wound application of Vancomycin is known to minimize infections, no previous studies reported if Vancomycin application adversely impacts spinal fusion. This study demonstrates that intra-wound application of Vancomycin does not adversely affect fusion rates in a deformity, trauma or degenerative spinal conditions.

Introduction:

Lumbar spine surgery with instrumentation continues to be a successful procedure, especially for deformities and trauma.[5,7] Much effort has been put into surgical techniques and preoperative and postoperative protocols to decrease failure of spinal fusion and to minimize other complications, such as infection. However, we must also carefully consider the impact our attempts to curb infection have on spinal fusion. It would not be beneficial if we are successful at decreasing infection, but are inadvertently affecting spinal fusion. To minimize the risk of infection, surgeons have utilized multiple preoperative, intra-operative, and postoperative methods of prophylaxis. Recently, it has been shown that the use of intra-wound Vancomycin application significantly decreases the risk of infection without any acute or long-term associated risks.[17] However, there are no studies that look into whether this practice affects spinal fusion. Recent large population studies have shown that 23.6% of spinal fusion surgeries needed to be revised due to failure of spinal fusion.[9] Other reports indicate that revision procedures to correct failure of spinal fusion generally have poorer results than if spinal fusion was successful on the first attempt.[10,14] Therefore it is imperative to identify what kind of impact, if any, intra-wound Vancomycin application has on spinal fusion. The goal of our study is to evaluate whether intra-wound Vancomycin application will adversely affect spinal fusion. It has been shown that infected tibial nonunion can be safely treated with Vancomycin-impregnated cancellous bone grafting without any adverse affects on fusion.[2] Based on this, our belief is that intra-wound Vancomycin application will not adversely affect spinal fusion. Understanding this relationship will allow surgeons to make better, confident decisions on how to treat patients against the risk of infection during spinal fusion procedures.

Material and Methods:

All patients had consent prior to their lumbar surgery. Since August of 2010, 50 patients, aged 19 to 71, had lumbar spinal surgery with instrumentation by two different surgeons at three different facilities. Preoperatively, all patients received an alcohol preparation, followed by 3M™ DuraPrep™ 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, which is part of standard systemic prophylaxis in these procedures. No patients had a known Vancomycin allergy.

Twenty-three patients were male, twenty-seven were female and fourteen patients had a smoking history prior to surgery. Twenty-seven patients had a preoperative diagnosis of spondylolisthesis; two with scoliosis, four with trauma and seventeen patients had the preoperative diagnosis of lumbar degenerative disk disease. Eight patients were revision surgeries. Table 1: Patient Characteristics

Near the end of the surgery, after the hardware was placed, including the interbody devices, the wound was thoroughly irrigated with normal saline. Standard fusion techniques including decortications of remaining facets, the transverse processes, and remaining lamina were performed. All patients received interbody fusion from a posterior approach with autograft and a Polyetheretherketone (PEEK) cage. Infuse (Medtronic), was used in the revision surgeries anterior to placement of the PEEK cage. Allograft combined with autograft and local bone blood aspiration were 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. Picture 1, Picture 2. For the 4 dural tears, they were primarily repaired with 6-0 prolene, followed by Dura Gen (dural graft matrix; Integra Life Sciences, Inc., and then followed by Evicel (Ethicon, Inc.). The Vancomycin powder was placed after the eveseal cured.

Postoperatively, patients continued to receive 1 gram of IV Cefazolin every eight hours for a total of 24 hours. For the penicillin allergic patients, they received 1 gram of Vancomycin every 12 hours for a total of 24 hours.

All patients 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. Plain AP and lateral radiographs, and if needed, thin-cut CT slices, were evaluated to assess posterolateral spinal fusion by looking for bridging trabeculated bone between transverse processes. Anterior-Posterior radiographs were used to evaluate lumbar interbody fusion as described by the surgical interbody research group.

Results:

The course of follow-up ranged from six months to seventeen months. No patients were lost to follow up. All patients that were more than six months postoperative had signs of spinal fusion according to radiograph studies and, when indicated, thin-cut CT slices. There were two cases of spinal fusion failure, both in patients with spondylolisthesis. One case was at three months in a male with a high grade spondylolisthesis when the patient's interbody started to back out. He was treated with a revision surgery with success of fusion as identified by thin-cut CT scan. The other failure was at four months, also in a patient with spondylolisthesis, but the patient was asymptomatic.

Discussion:

Lumbar instrumented spinal fusions are widely performed in order to reduce patients' lower back and leg pain.[12] Although there has been great progress in the sophistication and effectiveness of surgical techniques to decrease failure of spinal fusion, these newer methods often require more instrumentation, which directly correlates with higher rates of infection.[3] Reasons for the higher rates of infection include longer operative times, prolonged retraction, and, of course, the use of foreign biomaterials.[3] The many techniques that have been implemented in an effort to reduce the rates on infection include generous irrigation, debridement and extra effort at shorter operating times.

Recently, a study by O'Neill showed that the application of intra-wound Vancomycin significantly reduces the risk of infection without any acute or long-term effects.[11] O'Neill et al reviewed 110 patients with traumatic spinal injuries undergoing instrumented spinal fusion procedures. Of the patients, 54 received standard systemic prophylaxis, while 56 patients received standard systemic prophylaxis in addition to Vancomycin powder application in the surgical wound. The findings showed a significant decrease in the number of infections in the group treated with Vancomycin compared to the group that was not treated with Vancomycin. This finding is very promising in decreasing the risk of infection and we predict that the use of intra-wound Vancomycin application will continue to increase.

Previously, no studies were done to assess if intra-wound application will have any adverse effects on spinal fusion. Our study reveals that intra-wound Vancomycin application has no adverse affects on spinal fusion and these findings are extremely valuable in the advancement of spinal fusion surgery.

A study by Chen et al looked into outcomes of treating infected tibial nonunion with Vancomycin-impregnated cancellous bone grafting.[2] The group followed-up 18 patients with infected tibial nonunion treated with adequate debridement, stabilization with external fixation, and staged Vancomycin-impregnated cancellous bone grafting. They found that 100% of the patients were controlled adequately for infection, and bone union was achieved in 13 of the 18 patient after an average of 5.8 months. In the remaining 5 patients, bone union was achieved by close nailing 4 patients, and plating and bone grafting 1 patient. The group concluded that Vancomycin-impregnated cancellous bone grafting is an adequate treatment option for infected tibial nonunion. These findings are consistent with our results in terms of Vancomycin not having an adverse impact on fusion.

There are numerous studies that show the greater risk of complications and poorer clinical outcomes in patients undergoing revision spinal surgeries. Revision surgeries for failure of spinal fusion can cost the patient relevant time, money, and risks not to mention the emotional stress that surgical procedures can induce even after the recovery period. A study that sampled patients undergoing spinal fusion from 2001-2005 showed that a growing number of patients undergoing spinal fusion surgery have advanced age and coexisting co-morbidites, such as congestive heart failure, chronic pulmonary disease, metastatic cancer, and renal failure.[16] Spinal fusion surgery performed in a patient population with multiple co-morbidities must be

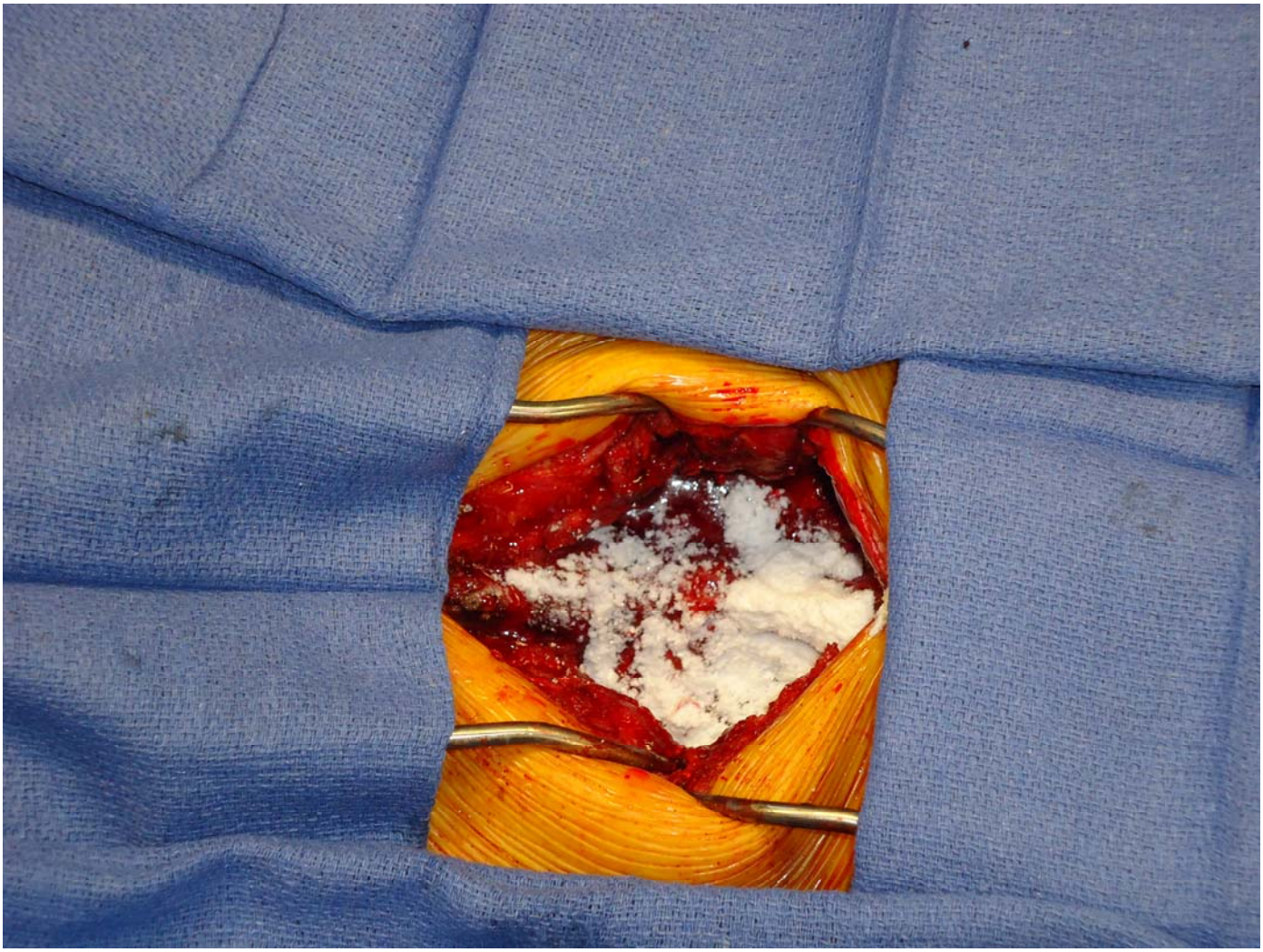
approached very carefully and extra effort must be made to ensure attempts to reduce infection do not interfere with spinal fusion, as additional surgeries may not be possible in chronically ill patients. Furthermore, it has been shown that patients with positive history of spinal surgery undergoing additional spinal surgeries are more likely to develop infections.[13] Therefore, intra-wound Vancomycin application may be used to decrease infection rates in revision surgeries without causing any adverse fusion outcomes as identified in this study.

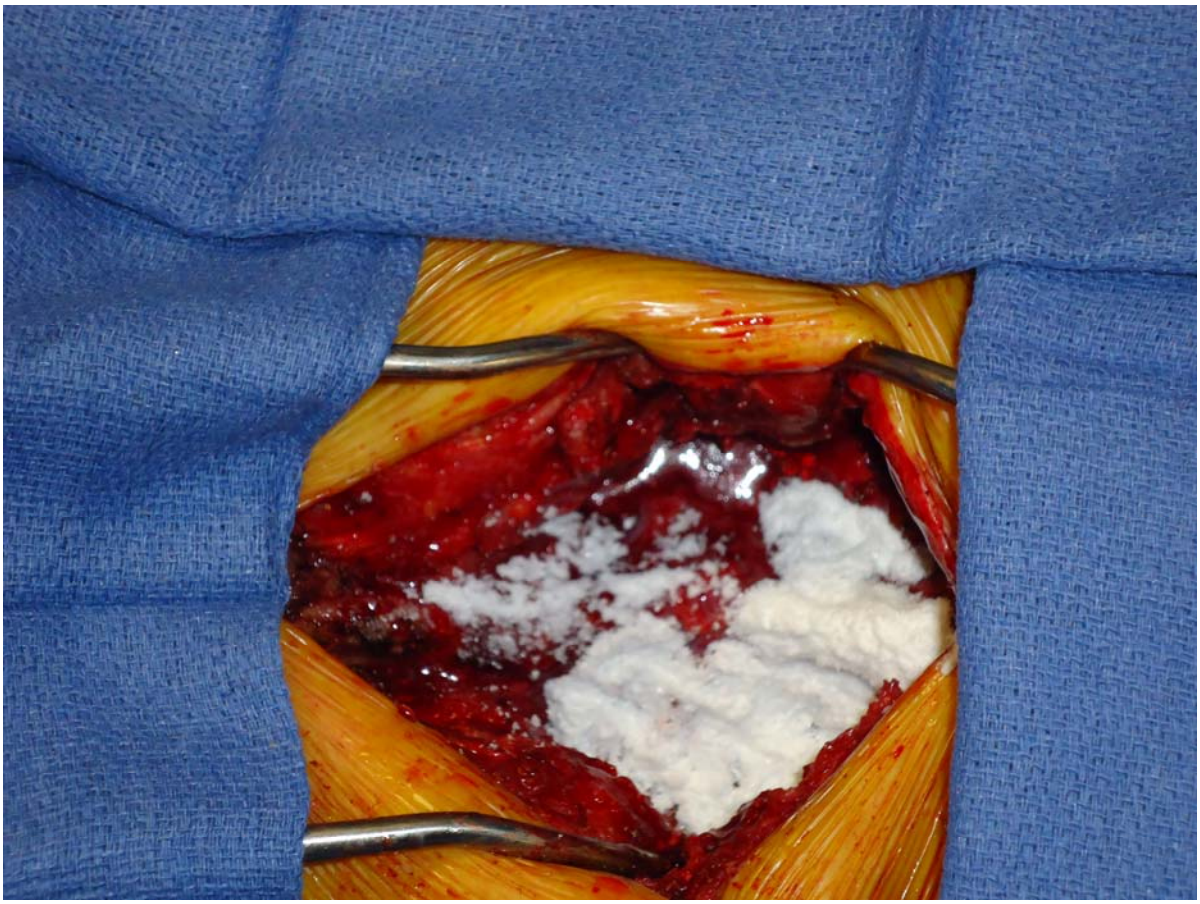
A study by Djurasovic et al looked at how well patients perform after undergoing revision spinal surgeries for various reasons, including post-decompression, adjacent segment degeneration, and failure of spinal fusion.[4] He measured post surgical improvements using 3 indices: Oswestry Disability Index, MOS short form 36, and back and leg pain numerical scores before surgery and 1 and 2 years after surgery. The results showed that 49% of post-decompression patients, 38% of adjacent spinal decompression patients, and 29% of failure of spinal fusion patients reached the minimal clinically important difference (MCID) for Oswestry Disability Index and 46% of post-decompression patients, 40% of adjacent spinal decompression patients, and 24% of failure of spinal fusion patients reached the MCID for MOS short form 36.

A study by Selznick et al aimed to examine complications between primary and revision invasive lumbar interbody fusion surgery.[15] They reviewed a total of forty-three minimally invasive transforaminal lumbar interbody fusions and posterior lumbar interbody fusions, of which seventeen cases were revision surgeries and twenty-six were primary surgeries. All of the procedures were carried out in one institution and the two groups had similar characteristics. They found no statistical significance in estimated blood loss or nerve injury between the revision group and primary group. However, they did find that the revision group had higher rates of perioperative complications, notably durotomy with leaking of CSF. In our study, dural tears were repaired with standard techniques and the addition of Vancomycin post-repair did not adversely affect spinal fusion.

Some of the limitations of this study include our retrospective database and our small sample size with our revision surgeries. Additionally, we would ideally have liked to have thin-cut CT scans on all patients to document fusion rates.

In conclusion, intra-wound application of Vancomycin is a very promising technique that will certainly be used more frequently to decrease the risk of infection in instrumented spinal procedures. Our findings suggest that this technique does not unfavorably affect spinal fusion and up until now, no other studies have been done to assess this relationship. The results of this study will enable surgeons to confidently use intra-wound Vancomycin for infection prophylaxis. We encourage more, larger sample size studies to be performed that not only look into this association, but also the relationship between other prophylactic measures and how they impact spinal fusion.





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