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Does Soaking Synthetic Mesh with Vancomycin Solution Reduce Infections in Open Hernia Repairs?

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I. Introduction

Mesh infections following open hernia repair pose a daunting postoperative challenge given the sheer number of cases involved, the severity of consequences to the patient, and the attendant cost to the healthcare system. Mesh infections following hernia repair are known to increase re-operation rates, morbidity, financial cost, as well as hernia recurrence (which, in turn, leads to all of the aforementioned factors. [1,2] In many circumstances, this implies the need for a third, if not fourth or more, operation for redo repair of the hernia with reintroduction of synthetic mesh at some point in the patient's course. This is because the second operation will typically be limited to removal of the infected mesh without reintroduction of further synthetic material in an infected field. The cost of repeat physician and hospital visits; as well as that ofre- operations, readmissions, and the potential clinical complications thereof; may mount to very significant levels. It is, therefore, not surprising that a great deal of interest has been shown in preventing infections of synthetic mesh following hernia repair.

Our current sterilization protocols as well as the practice of prophylactic antibiotic administration are examples of the efforts applied in this regard. However, prophylactic antibiotic therapy has not proven to be sufficient on its own in reducing SSIs (surgical site infections) to negligible levels[3]. As such, mesh infections following hernia repair surgery remain a significant problem and have been documented to occur in up to 13% of cases when the use of synthetic mesh is involved[4-9]. Mesh infections or SSIs are a significant predictor for the recurrence of hernias[10]. Soaking meshes in antibiotic solutions in order to prevent potential infection and adhesion of the bacteria to the mesh, and as such prevent biofilm formation, is an idea that has long been contemplated and experimented with by General Surgeons[10, 11]. Although this practice today is not that uncommon, there remains a lack of solid data with human clinical trials to demonstrate its efficacy.

A recent trial in a rat model found that pre-soaking synthetic mesh in a 10mg/ml Vancomycin solution resulted in significantly lower mesh bacterial counts[10]. In this study, soaking the mesh for 15 minutes prior to surgical implantation inside the body significantly reduced the chance of bacterial adherence and biofilm formation on composite meshes, subsequently reducing bacterial growth[10]. Others have explored the possibility of coating meshes with affinity-based drug delivery polymers and then soaking the mesh with vancomycin in an attempt to deliver vancomycin in slow release linear fashion in an animal model; This successfully prevented *staphylococcus aureus* infections at 2 and 4 weeks post-operatively[12]. In a 2015 study performed by Perez-Kohler et al., it was found that pre-soaking mesh in Vancomycin solution not only prevented the adherence of bacteria to the surface of the pre-soaked meshes, but also resulted in no toxicity in an *in vitro* animal model. Whether this translates into lower rates of clinically significant mesh infections, for example, those requiring re-hospitalization and re-admission, is unknown. In addition, whether the results found in this animal model are applicable to human subjects is also unknown.

Based on the preceding information, we can conclude that pre-soaking mesh in antibiotic solution with certain parameters has shown to be useful in reducing bacterial infestation of mesh in an animal model. The evidence to demonstrate that this is applicable in humans and leads to clinically important outcomes (namely, reduced mesh infection rates) is lacking. In this study, therefore, we set out to explore whether pre-soaking mesh in an antibiotic solution (with the parameters set out in the aforementioned animal studies) results in lower rates of mesh infections in human subjects. To this end, we designed and carried out a randomized controlled trial to test whether soaking synthetic mesh in a 10mg/ml solution of Vancomycin would lead to a significant reduction in infection rates with open hernia repair surgeries.

II. Methods

Both inguinal and ventral hernias performed via the open surgical approach were included in this study. All procedures were done under standard sterile field precautions at Moose Jaw Union Hospital in Saskatchewan, Canada. All patients received weight-based Cefazolin intravenous injection within one hour of skin incision as a prophylactic measure. Patients who were allergic to Cephalosporins or Penicillin were given intravenous Clindamycin injection instead as a prophylactic antibiotic. Inguinal hernia repair surgeries were all performed using the standard Lichtenstein tension-free repair method utilizing synthetic mesh and non-absorbable sutures for mesh fixation. Patients were randomized to one of two groups: Vancomycin group (where mesh is soaked in a 10mg/mL Vancomycin solution for 15 minutes prior to fixation within the body) and placebo group (where the mesh is soaked in a Normal Saline solution for 15 minutes prior to fixation within the body). This was done using the block randomization technique. Both the patient as well as the surgical team were blinded as to the patient's group assignment within the study. Both the Vancomycin and Normal Saline solutions were clear and appeared identical to the naked eye. Both the surgeon and office staff remained blinded to the patient's group assignment on follow up which was uniformly arranged at 6 weeks after the operation.

The ventral hernia repairs within this study were all done with the standard open technique using synthetic mesh in a tension free fashion. As with the inguinal hernias, the patients were randomized into the same two groups of Vancomycin and Normal Saline. The same sterile, prophylactic antibiotic administration method, blinding, as well as follow ups principles were adhered to as described above.

Statistical Methods

Non-parametric statistical methods were used for analysis in this study. The primary outcome in this study was postoperative mesh infection following open hernia repair. Secondary outcomes were postoperative pain, hernia recurrence, bleeding, and medical complications in the immediate postoperative period. We calculated descriptive and summary statistics for all recorded variables. We performed univariate analyses using t tests for continuous variables and $\chi 2$ tests for categorical variables. Multivariate logistic regression analysis was performed to control for potential confounding factors, and odds ratios and 95% confidence intervals were generated. We generated descriptive statistics (means, medians, frequencies, standard deviations) for all variables. We used logistic regression models to delineate the relation of each variable with (primary outcome). The $\chi 2$ test was used to calculate the statistical significance of the differences between the groups with regard to the variables. The odds ratios and 95% Wald-based confidence intervals were also calculated. Because of the limited data available, we performed multivariate regression analysis using only the factors that were significant in the univariate analysis. We used a significance level of $p < 0.05$ throughout the study.

III. Results

We successfully managed to recruit and randomize 115 participants in this study. Of the 115 research subjects, 80.8% were over the age of 45 at the time of the surgery. The majority of the subjects were male (92 subjects or 80%) and 20% (23 patients) were female. There was no statistical difference in age between the male and female subjects. Inguinal, umbilical and incisional hernias were included in the study as demonstrated in Table 2. 48.2% of the surgeries preformed were on inguinal hernias and 42.9% were umbilical, the remaining 8.9% were on incisional hernias.

Of the 115 hernia repairs performed, 14 patients (12.3% of the total study population) experienced complications. Complications included pain, seroma, infection, swelling and recurrence, as demonstrated in Table 3. Of the 14 cases that experienced complications, 8 (57.1%) were on inguinal hernia repairs and 6 (42.8%) were on umbilical hernias. It is interesting to note that 35.7% of those that experienced complications had diagnosed type-two diabetes, 50.0% were alcoholics and 71.4% were smokers as demonstrated in Table 4.

Overall, the rate of postoperative infection was very low in patients undergoing open hernia repair in this study. Out of the 114 participants who underwent hernia repair surgery only three of them developed an infection (less than 3%). Although this outcome of roughly 2.6% was within the current normal range (0 - 9%)[15], it is not possible to infer the efficiency of soaking meshes in antibiotic solutions, as three infections is a small sample. It is evident, that the occurrence of infection post-hernia repair surgery with meshes is rare in MUH. This may indicate that regular mesh use, without soaking in antibiotic, has little infection complications in MUH.

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IV. Discussion

Hernia repairs are one of the most common procedures performed by general surgeons.
[14,15] Overall, infection rates for open hernia repairs are quite low, with previous research indicating rates anywhere between 0% to 9%, with varying definitions of what an infection includes.[15] As hernia repairs are done as a day surgery, infections are not recognized within the setting of the hospital, but rather in the out-patient setting.[14] Additionally, there are independent predictors of infection within the patient population that have been previously identified such as smoking, prolonged operative time, and chronic steroid use.[16] These characteristics will largely impact the infection rates reported and should be identified prior to surgery.

It is highly likely that the surgical methodology and the surgeon technique was superb and had resulted in few complications such as infections or seromas. Some centers have reported higher rates of infections than were obtained at MUH throughout this study. It is important to document and assess how the surgeries were performed in order to disseminate best practice for preventing infections through an operative procedure.

Many studies have been done looking at the efficacy of reducing post-operative infections utilizing antibiotic prophylaxis prior to open hernia repair. These studies have had similar results to our study, in that the overall infection rate was low, and therefore no statistically significant difference between groups was detected.[17]

V. Conclusions

This study demonstrated that soaking pre-soaking mesh in Vancomycin solution for open hernia repair was practical, feasible, and safe in a community surgery setting. No significant difference in outcomes, however, was detected in this trial between the vancomycin and placebo groups. It is likely this was the case due to the very low incidence rates of mesh infections and other postoperative complications. A larger sample size would be necessary to definitively elucidate the effect of soaking mesh in Vancomycin solution on open hernia infection rates.

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