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# Effect of Single-Dose Prophylactic Ampicillin and Sulbactam on Wound Infection After Tension-Free Inguinal Hernia Repair With Polypropylene Mesh

## The Randomized, Double-Blind, Prospective Trial

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**Objective**

To assess the value of single-dose, intravenous, prophylactic ampicillin and sulbactam (AS) in the prevention of wound infections during open prosthetic inguinal hernia repair by a double-blind, prospective, randomized trial.

**Summary Background Data**

The use of antibiotic prophylaxis during open prosthetic inguinal hernia surgery is controversial, and no prospective trial has been conducted to examine this issue.

**Methods**

Patients undergoing unilateral, primary inguinal hernia repair electively with the Lichtenstein technique using polypropylene mesh were randomized to receive 1.5 g intravenous AS before the incision or an equal volume of placebo according to a predetermined code of which the surgeons were unaware. Patients with recurrent, femoral, bilateral, giant, or incarcerated hernias or any systemic diseases were excluded. Age, sex, body mass index, American Society of Anesthesiologists score, type of hernia, type of anesthesia, duration of surgery, and use of drains were recorded. Infection was defined according to the criteria of Centers for Disease Control. Patients were evaluated 1 week, 1 month, 6 months, and 1 year after surgery by an independent surgeon. All complications were recorded. Results were assessed using chi-square, Fisher's exact, and Student *t* tests as appropriate.

**Results**

Between September 1996 and July 1998, 280 patients (140 AS, 140 placebo group) entered the protocol. Four patients from the AS group and seven from the placebo group were excluded because of inadvertent antibiotic administration or follow-up problems. Groups were well matched for all the variables studied and postoperative complications, excluding wound infections, which occurred at a rate of 0.7% in the AS group and 9% in the placebo group ($P = .00153$). Twelve patients in the placebo group developed wound infections, requiring five repeat hospital admissions in three patients. These three patients suffered deep infections reaching the graft, which resulted in graft loss in two. The single infected patient in the AS group had his graft removed as well because of deep persistent infection.

**Conclusions**

This study documented a significant (10-fold) decrease in overall wound infections when single-dose, intravenous AS was used during Lichtenstein hernia repair. Deep infections and wound infection-related readmissions were also reduced by the use of AS. Proponents of mesh repairs may therefore be advised to use prophylactic single-dose intravenous antibiotic coverage in the light of the results of this trial. AS proved to be an effective antimicrobial agent.

The use of antibiotic prophylaxis for "clean" surgical procedures is controversial. A good example is classic inguinal hernia surgery, where reported rates of wound infections vary from 1% to 14%.[1–9] Platt et al[2] and Lazarthes et al[4] found antibiotic prophylaxis to be of benefit in classic inguinal hernia repairs, but others[7,10] failed to document any benefit in terms of prophylaxis. During the past decade, open tensionless repair of inguinal hernias by grafting has become increasingly popular as a result of the ease of the procedure and the low recurrence rates. Because the consequences of wound infection in the presence of a graft may

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**Table 1. ALL PROSPECTIVE TRIALS PUBLISHED IN THE PAST DECADE FOCUSED ON WOUND INFECTION RATES AFTER INGUINAL HERNIOPLASTIES**

| Author | Year | Study Design | Patient Number | Method of Follow-Up | Length of Follow-Up | Antibiotic Prophylaxis | Wound Infection Rate (%) |
|---|---|---|---|---|---|---|---|
| Platt et al[2] | 1990 | Prospective randomized | 301 | Telephone survey | 4–6 weeks | + | 2.3 |
| | | | 311 | | | – | 4.2 |
| Simchen et al[3] | 1990 | Prospective | 1138 | Nurse epidemiologist | 1 month | Not mentioned | 3.3 |
| Lazorthes et al[4] | 1992 | Prospective randomized | 155 | Questionnaire | 1 month | + | 0 |
| | | | 153 | | | – | 4.5 |
| Bailey et al[5] | 1992 | Prospective | 510 | Community survey | 4–6 weeks | Not mentioned | 9 |
| Holmes and Readman[6] | 1994 | Prospective | 97 | Telephone survey | 1 month | Not mentioned | 4 |
| Taylor et al[7] | 1997 | Prospective randomized | 283 | Surgical team | 4–6 weeks | + | 8.8 |
| | | | 280 | | | – | 8.9 |
| Santos et al[8] | 1997 | Prospective | 114 | Surgical team Questionnaire | 1 month | Not mentioned | 14.04 |
| Medina et al[9] | 1997 | Prospective | 454 | Questionnaire | 1 month | Not mentioned | 7 |

be more difficult to treat than in classical repairs, antibiotic prophylaxis during graft repair of inguinal hernias may be needed. Topical[11] or intravenous prophylactic antibiotics[10] are commonly used by the proponents of graft repairs, but others do not use any form of antibiotic prophylaxis.[12] Surprisingly, there are no scientific data to justify the use of antibiotic prophylaxis during open graft repair of inguinal hernias: in other words, no study has been conducted to assess the probable advantages of antibiotic prophylaxis in such patients. In an effort to clarify this issue, the present prospective, double-blind, randomized trial was carried out to document the effect of intravenous, single-dose, preoperative antibiotics in the prevention of wound infection and associated complications after open graft repair of inguinal hernias. This paper appears to be the first work addressing this issue.

## METHODS

### Patients

A sample size of 334 patients (167 per group) was chosen to give 70% power, assuming that a 6% wound infection rate in the no-antibiotic group would fall to 1% when antibiotics were used. The 6% rate was an average derived from all the articles that were published during the past decade focused on wound infection rates after inguinal hernia surgery[2–9] (Table 1). The wound infection rates from the antibiotic arms of randomized trials were not taken into account during the calculation of this average value.

Patients with primary, unilateral inguinal hernia, electively prepared for tensionless graft repair during the study period, were candidates for our trial. Informed consent was obtained from all patients, and the protocol was approved by the institutional ethics committee.

Patients with recurrent, irreducible, strangulated, bilateral, or femoral hernias were excluded from the study for standardization. Giant scrotal hernias with massive defects were also excluded because such cases are managed by the Stoppa procedure. Also excluded were patients with systemic or advanced disease (e.g., diabetes, liver or renal impairment), patients with American Society of Anesthesiologists (ASA) scores more than II, patients receiving steroids for any reason, patients younger than 18 years, patients allergic to antibiotics, patients who were using or had used antibiotics less than a week before surgery, and pregnant or lactating women.

Randomization was accomplished by a computer-generated code by a resident who also prepared the sealed antibiotic or placebo syringes. He was unaware of the research in progress and was never involved in surgery, data collection, or patient follow-up.

Trial patients received either 1.5 g ampicillin and sulbactam (AS) (1,000 mg ampicillin and 500 mg sulbactam, Duocid 1 g IV, Pfizer Inc., Istanbul, Turkey) or an equal volume of placebo (sterile saline) by intravenous bolus injection before the incision. AS was chosen because of its long half-life and known activity against *Staphylococcus aureus* and *Staphylococcus epidermidis* as well as gram-negative cocci, historically the most common agents isolated from infected hernia incisions.

### Surgical Procedure

The skin was shaved immediately before surgery and prepared using povidone–iodine. Local anesthesia was the preferred technique, but spinal or general anesthesia was also used, depending on the patient's request or failure of local anesthesia. All procedures were Lichtenstein onlay mesh repairs and were carried out by residents under the principal author's supervision. The mesh was monofilament polypropylene (Marlex, CR Bard, Inc., Cranston, RI), and all sutures except subcuticular were 2–0 monofilament polypropylene (Prolene, Ethicon, Ltd., Edinburgh, UK). The subcutis was closed using 3–0 polyglactin 910 (Vicryl,

Ethicon, Ltd., Edinburgh, UK), and all ligatures used were also 3–0 Vicryl. The skin was closed with 3–0 interrupted Prolene. Drains were used according to the surgeon's preference; all were of the closed suction type. Patients were discharged from the hospital at the surgeon's discretion.

## Follow-Up

All wounds were inspected before discharge, and all incisions were carefully reexamined by the same surgeon during suture removal at 7 to 9 days (first follow-up visit) and during the second follow-up visit 4 to 6 weeks after discharge. Thereafter, all patients were followed up at 6-month intervals (third follow-up visit) until 1 year (fourth follow-up visit) after surgery, with special attention to wound problems. A surgeon masked to the randomization and patient details evaluated the wound during each follow-up.

Wound infections were categorized as superficial incisional surgical site infection and deep incisional surgical site infection (DISSI), according to the latest definitions of Centers for Disease Control.[13] Superficial incisional surgical site infection was defined as an infection occurring within 30 days after surgery involving only the skin or subcutaneous tissue. DISSI was defined as an infection occurring within 1 year after surgery involving fascial and muscle layers and also the graft. The exact criterion for the definition and surveillance of wound infection is well established and can be found in Centers for Disease Control reports.[13,14]

Patient demographics, body mass index (patient weight in kilograms per square of height in meters), ASA scores, type of anesthesia, duration of surgery, type of hernia (Rutkow modification of Gilbert classification[15]), and use of drains were recorded. In addition to wound infection, all postoperative complications were also carefully recorded throughout the follow-up period.

Because of the high rate of wound infections, the code was broken after the discharge of patient 280 (140 patients in the placebo group and 140 in the antibiotic group). At that point, the results revealed an extreme discrepancy in favor of antibiotic prophylaxis; therefore, the study was prematurely stopped before reaching the previously established sample size of 334 patients. All data were analyzed using chi-square, Fisher's exact, and Student *t* tests as appropriate after the completion of the fourth (1-year) follow-up visit of all patients.

## RESULTS

Between September 1996 and July 1998, by strict adherence to the exclusion criteria, 280 patients having 280 primary, unilateral inguinal hernias were initially included in this trial. Half of these patients represented the study group and the other half represented the control group. Four patients from the antibiotic group and seven from the placebo group were excluded, leaving 269 patients for evaluation (antibiotic group 136, placebo group 133). Reasons for exclusion are summarized in Table 2. None of the patients who inadvertently received antibiotics developed wound infections during their follow-up. All patients lost to follow-up were contacted by phone, and none had any wound problems during the year after surgery. The patient who died at 6 months of myocardial infarction had no wound problems at his second follow-up visit.

**Table 2. REASONS FOR LATE EXCLUSIONS**

| Group | Reason | n |
|---|---|---|
| Antibiotic | Inadvertent antibiotic administration | 2 |
| | Lost to follow-up | 2 |
| Placebo | Inadvertent antibiotic administration | 4 |
| | Lost to follow-up | 2 |
| | Death from an irrelevant cause 6 months after surgery | 1 |
| | **Total** | 11 |

Groups were well matched for age, sex, body mass index, ASA scores, type of hernia, type of anesthesia, duration of surgery, and use of drains (Table 3).

The distribution of postoperative complications among groups is shown in Table 4. With the sole exception of wound infections, all complications were evenly distributed in the placebo and antibiotic groups. Hyposthesia overlying the incision was the most common postoperative complaint, but this subjective problem gradually subsided in all patients. Late postoperative pain, which occurred in several patients, was easily managed with short-term nonprescription pain medication in all patients, and no inguinal neuralgia or nerve entrapment syndrome was observed. All seromas were diagnosed by fine-needle aspiration of clear-serous fluid in the presence of a well-healing incision. All samples were double-cultured, and sterility was confirmed. The seromas of two patients in each group were confined to the peritesticularly left indirect sac remnant, and these were managed expectantly without sequelae. Four seromas (three from the antibiotic group and one from the placebo group) required multiple aspirations without further problems, except for the patient from the placebo group. This patient eventually developed DISSI, which became evident on postoperative day 28. No antibiotics were used for the treatment of seromas, except for the above-mentioned infected case, in which appropriate antibiotics were started once positive cultures were obtained. One case of ischemic orchitis was encountered in the antibiotic group; this patient was the single infected case in that group. During follow-up, this patient developed testicular atrophy. No patient had urinary retention.

In terms of wound infection rates, 1 patient (0.7%) in the

**Table 3. DEMOGRAPHICS**

| | Antibiotic Group (n = 136) | Placebo Group (n = 133) | *P* Value |
|---|---|---|---|
| Age (mean age in years) | 55.57 ± 15.1 | 55.78 ± 13.8 | .905 |
| Sex (male/female) | 123/13 | 126/7 | .179 |
| Body mass index | 24.95 ± 2.6 | 25.02 ± 3.0 | .944 |
| ASA score (patient numbers having ASA I/ASA II scores) | 97/39 | 101/32 | .500 |
| Type of hernia (patient numbers in hernia types 1/2/3/4+5/6) | 2/52/25/39/18 | 5/46/22/38/22 | .466 |
| Type of anesthesia (patient numbers having local/spinal/general anesthesia) | 56/54/26 | 55/63/15 | .163 |
| Duration of surgery (mean duration in minutes) | 64.18 ± 22.8 | 62.78 ± 19.3 | .588 |
| Use of drains (yes/no) | 29/107 | 31/102 | .694 |

antibiotic group and 12 patients (9%) in the placebo group had wound infections; this difference was highly significant ($P = .00153$). The rate of DISSI in the placebo group was higher than in the antibiotic group, although this difference was not significant (see Table 4).

The details of the infected cases are summarized in Table 5. Of the 13 wound infections, 5 were diagnosed before hospital discharge. Therefore, the in-hospital diagnosis rate of wound infections was 30.7%. In other words, 70% of the wound infections were diagnosed during the surveillance of the patients. The infectious process in three of the four patients with DISSI was first diagnosed as a superficial infection that eventually progressed to a deep infection. The fourth DISSI, however, initially became evident as a deep infection in a patient whose seroma was repeatedly aspirated as noted above. In terms of the other characteristics of the 13 infections, the mean age (56.07 years), mean body mass index (23.75), type of anesthesia (seven local and six spinal), mean duration of surgery (61.27 minutes), and use of drains (three patients) were similar in distribution to the rest of the series (see Table 3). None of the DISSI patients was drained.

The rate of recurrence was 0% at 1 year. In three patients who had undergone graft removal for persistent infection, no recurrence was noted after graft removal during their further 1-year follow-up.

## DISCUSSION

It is well documented that prophylactic antibiotic coverage of most "clean-contaminated" surgical procedures (e.g., colorectal resection) can significantly prevent infectious complications, including wound infection, thereby affecting the overall rates of death and complications.[16] There is also no doubt that antibiotic prophylaxis is needed in selected "clean" surgical procedures where a prosthesis is implanted, because the consequences of a graft infection can be severe or even fatal.[17,18] Arthroplasties such as hip or knee replacements[17] and cardiac or vascular graft implants[18] are "clean" procedures in which perioperative antibiotic coverage has been shown to be beneficial and clearly indicated.

However, the benefit of antibiotic prophylaxis in other "clean" surgical procedures, such as inguinal hernia surgery, has been considered questionable. The low rate of wound infections and the straightforward treatment if they occur at all are the main arguments against routine antibiotic coverage during inguinal hernia surgery. However, there is reasonable doubt as to the validity of these arguments. Infection in a hernia wound has been reported to be associated with a fourfold increase in the recurrence rate and therefore may indeed cause serious sequelae.[19] More importantly, wound infection rates in inguinal hernia series are frequently underreported for several reasons. First, the def-

**Table 4. POSTOPERATIVE COMPLICATIONS**

| | Antibiotic Group (n = 136) | Placebo Group (n = 133) | *P* Value |
|---|---|---|---|
| Numbness or hypesthesia overlying the incision | 11 (8%) | 8 (6%) | .507 |
| Late inguinal pain | 2 (1.4%) | 3 (2.2%) | .682 |
| Seroma formation | 5 (3.6%) | 3 (2.2%) | .723 |
| Testicular atrophy | 1 (0.7%) | 0 | .999 |
| Wound infection | 1 (0.7%) | 12 (9%) | .00153 |
| Deep surgical site infection | 1 (0.7%) | 3 (2.2%) | .367 |
| Superficial surgical site infection | 0 | 9 (6.7%) | .0015 |

**Table 5. PATIENT DETAILS OF THE INFECTED CASES**

| # | Infection was diagnosed after hospital discharge | Timing of diagnosis of initial infection (Postop. days) | Microorganism cultured | Type of infection | Other complications besides infection | Definitive treatment | Total number of in-hospital days | Outcome at 12-month follow-up |
|---|---|---|---|---|---|---|---|---|
| Antibiotic Group | | | | | | | | |
| 1 | Yes | 6 | *S. aureus* | DISSI | Ischemic orchitis | RA & graft removal at 3rd postop. month | 9 | No recurrence, testicular atrophy |
| Placebo Group | | | | | | | | |
| 1 | No | 2 | *S. epidermidis* | SISSI | No | A&D | 5 | No R & C |
| 2 | Yes | 28 | *S. aureus* | DISSI | Seroma | RA - A&D | 33 | No R & C |
| 3 | Yes | 6 | *S. aureus* | DISSI | No | RA & graft removal at 5th postop. month | 13 | No R & C |
| 4 | No | 4 | *S. aureus* | DISSI | No | RA - A&D at 3rd, 5th months. RA & graft removal at 12th postop. month | 35 | No recurrence, chronic sinus formation |
| 5 | No | 4 | *S. aureus* | SISSI | No | A&D | 28 | No R & C |
| 6 | Yes | 7 | *S. aureus* | SISSI | No | A&D | 2 | No R & C |
| 7 | No | 4 | *S. aureus* | SISSI | No | A&D | 15 | No R & C |
| 8 | Yes | 15 | *NSAI* | SISSI | No | A&D | 2 | No R & C |
| 9 | Yes | 2 | *S. aureus* | SISSI | No | A&D | 2 | No R & C |
| 10 | No | 5 | *NSAI* | SISSI | No | A&D | 7 | No R & C |
| 11 | Yes | 7 | *NSAI* | SISSI | No | A&D | 3 | No R & C |
| 12 | Yes | 12 | *S. aureus* | SISSI | No | A&D | 3 | No R & C |

A&D, antibiotic and drainage; DISSI, deep incisional surgical site infection; No R&C, no recurrence and complication; NSAI, no specific agent isolated; RA, readmission; SISSI, superficial incisional surgical site infection.

inition of wound infection is not clear in most series, thereby allowing bias in interpretation. Second, the length and method of follow-up are extremely important to establish an actual wound infection rate. Most hernias are being repaired in a day-case setting, making the in-hospital diagnosis of a wound infection impossible. The method of follow-up is also important because many patients, after being discharged, are seen by third-party practitioners for minor wound problems, including infections. The surgeon who performed the initial procedure may thus be unaware that a wound problem occurred. Therefore, the reported infection rate can be flawed because it may reflect only the in-hospital records.

When these problems regarding the definition, diagnosis, and follow-up of wound infection after inguinal hernia surgery are addressed, the actual rate of wound infection is much higher than the 1% to 2% rate previously accepted. In studies where strict surveillance after discharge was performed, the rate of wound infection after "clean" surgical procedures was 5.6% at the San Francisco University Hospital,[20] 5.2% at the Bay State University Hospital,[21] and 5.3% at the Weymouth District Hospital.[22]

Among all studies in the past decade that have specifically examined the actual rate of wound infections after inguinal hernia surgery prospectively with a proper length and method of follow-up, the rate of wound infections varies from 3.3% to 14.04%; the average rate we calculated was 5.8%[2–9] (see Table 1). Excluding the three randomized trials in Table 1, readers are not given any information about the use of prophylactic antibiotics in other reports. Therefore, there is reason to believe that these high infection rates occurred even when some surgeons used some form of antibiotic prophylaxis. Bailey et al[5] clearly demonstrated the importance of postdischarge surveillance for wound infections. In their study, a wound infection rate of 3% recorded in the hospital notes increased to 9% when additional information was obtained from community surveillance after elective inguinal hernia surgery in 510 patients. A similar observation was also made recently by Santos et al,[8] who reported an infection rate of 14.04% after inguinal hernia surgery in which the diagnosis of infection could be made only after discharge in 85% of the cases. Recently Taylor et al[7] reported a wound infection rate of almost 9% after inguinal hernia surgery in 563 patients who were properly followed up to 1 month after surgery. They even speculated that, given their 9% rate of wound infection and in view of the proximity of the groin to the perineum, open groin hernia repairs should no longer be considered a "clean" procedure. Medina et al[9] also reported a 7% wound infection rate after inguinal hernia surgery when proper follow-up was performed.

In light of these data, the 9% rate of wound infection found in our placebo group is in accordance with earlier reports in which strict criteria for definition, surveillance,

and follow-up were used. The 70% rate of postdischarge diagnosis of wound infections in our series underscores the importance of these criteria.

The data in Table 1 raise the question of whether antibiotic prophylaxis can be beneficial in preventing wound infections after inguinal hernia surgery. The trial by Platt et al[2] was the first effort that aimed to provide insight into this controversy. In their randomized, double-blind study, they documented a 48% decrease in infectious complications when prophylactic intravenous cefonicid (1 g) was given compared with placebo. In the hernia part of that study, the wound infection rate dropped from 4.2% to 2.3% with the use of prophylaxis. They assessed the findings of their trial retrospectively on another 4,000 patients who underwent similar "clean" surgical procedures, and this analysis also showed a 41% decrease in infectious complications when antibiotic prophylaxis was used.[23] Shortly after that study, Lazorthes et al[4] compared single-dose cefamandole (750 mg) added to local anesthetic and applied directly subcutaneously during local infiltration anesthesia with no antibiotics. Although not double-blind, this prospective study documented a significant decrease from 4.5% to 0% ($P = .007$) in the wound infection rate with local antibiotic prophylaxis. However, the results of these two trials could not be reproduced in a recent study by Taylor et al, who conducted a randomized, multicenter, double-blind prospective trial to compare single-dose intravenous coamoxiclav with placebo in 619 patients undergoing open groin hernia repair.[7] The rate of infection in both groups was almost 9%, and they concluded that antibiotic prophylaxis is of no benefit to patients undergoing open groin hernia repair. Their conclusion was criticized because the data might have shown the inefficacy of a particular antibiotic rather than "antibiotic prophylaxis in general," given the high rate of wound infections in both groups.[24] It is therefore still not clear whether antibiotic use is warranted to decrease the rate of wound infections after "nonimplant" classic inguinal hernia repairs, given the controversial results obtained from these three trials.

During the past decade, there has been an extraordinary increase in the use of implants in the repair of inguinal hernias to secure an open tensionless repair. Hypothetically, the use of antibiotic prophylaxis during such prosthetic hernia repairs might be more important than in nonimplant repairs, because the consequences of an infection that reaches the graft can be serious. Nevertheless, several recent reports of infected grafts in hernia surgery demonstrated the difficulty of managing such cases, which frequently results in graft removal.[25,26] The question of whether open prosthetic hernia repairs must be done under antibiotic coverage has been the subject of a single study published by Gilbert and Felton.[10] In this multicenter retrospective analysis, the rate of infection was approximately 1%, whether or not biomaterials or antibiotics were used. However, this study has serious shortcomings, making the results highly inconclusive. It was a retrospective analysis derived from the experience of 65 surgeons from various centers and was neither randomized nor standardized. The study entrance and antibiotic administration criteria were unclear, and different antibiotics and grafts were used. This series included patients with recurrent hernias as well as patients with concomitant diseases. The timing, duration, and dosage of antibiotics were also unknown. The method of follow-up of wound infections was also unclear. Because of all of these factors, the results of this study must be cautiously evaluated.

In contrast to Gilbert and Felton's retrospective clinical data, Troy et al reported that intraoperative topical bacitracin or preoperative single-dose intravenous cefazolin reduced the quantitative growth of bacteria in rabbit wounds implanted with polypropylene mesh.[27] This study represents the only experimental trial assessing the effect of antibiotic prophylaxis in the presence of polypropylene mesh.

No prospective randomized trial had been conducted to assess the probable effect of antibiotic prophylaxis in "open" prosthetic inguinal hernia repair. The results of our study showed a clear benefit of antibiotic prophylaxis in patients undergoing prosthetic inguinal hernia surgery, with a more than 10-fold reduction in the wound infection rate. We think that the decrease from a 9% infection rate in the placebo group to 0.7% when prophylactic AS was used is significant because our study population was well standardized and randomized, the definition of wound infection was clear, bias was avoided by the double-blind nature of the study, and strict surveillance by an independent observer was used for 1 year.

Parameters that may be associated with an increased risk of infection that we cannot control during the enrollment phase of the study, such as the use of drains and seroma formation, were also evenly distributed in the groups. Seroma, which occurred in three patients in the antibiotic group and five patients in the placebo group, preceded wound infection in only one patient and therefore did not seem to be associated with a greater risk of wound infection. None of the DISSI patients was drained.

The benefit of the decreased infection rate was also reflected in the postoperative costs and the complication rate. Prophylaxis with AS, besides reducing the overall infection rate by 10-fold, reduced the number of DISSIs from three to one and repeat admissions from five to one. The average number of in-hospital days in patients without infection was 1.2; this number increased to an average of 12 days in patients with wound infection. No patients without infections required any more physician visits or any medications, but the situation in those with infections was quite different (see Table 5). The management of DISSI patients was difficult and eventually required repeat admissions in all such patients. One patient in the placebo group required repeat readmissions until the mesh was finally explanted.

DISSI of mesh-implanted hernia wounds has always been a grave complication.[25,26] Mann et al[25]and Taylor and O'Dwyer[26] recently reviewed the literature about the fate of

infected inguinal hernia grafts and concluded that this condition frequently necessitated complete removal of the grafts. Their conclusion is in accordance with our 75% rate of inevitable graft loss in DISSI patients. Three of the four DISSIs in our series became evident as superficial infections that eventually developed into deep infections, further emphasizing the importance of decreasing the overall number of wound infections.

Recent data have noted a new problem associated with the occurrence of "late onset of deep prosthetic infection," which becomes evident months after surgery under a well-healed wound and frequently requires in explantation of the mesh for definitive cure. The incidence of this condition is probably very low (approximately 0.1%[25]), and we experienced no such case in this series. Nevertheless, our study provides no data as to whether late prosthetic infections can be prevented by prophylactic antibiotics.

An interesting observation from our series is in contrast to previous knowledge about the recurrence-increasing effect of hernia wound infections. It has been shown that wound infection in a nonimplant hernia puts the patient at a fourfold increased risk for recurrence.[19] The presence of a prosthesis may have a preventive role in avoiding this risk, as long as the infection is eliminated and the prosthesis remains in place. We did not observe a recurrence, even in the three patients in whom the grafts were removed because of persistent infection. Although only 1 year of follow-up is available, avoidance of a recurrence in these patients may be explained by the dense fibrotic reaction around the posterior wall of the inguinal canal.

The 9% rate of wound infections in our placebo group is quite high compared with the rates reported by tension-free hernia repair experts who do not use any form of antibiotic prophylaxis, such as Robbins[12] and Kurzer et al.[28] However, besides being experts in the field and having very short surgical times (15 to 20 minutes for Robbins), their reports' main focus has never been infectious complications, and the definition, method, and length of follow-up for infection have never been mentioned in their publications. As stated by Bailey et al,[5] outcome measurements apart from death are often difficult to define in an objective manner, and defining a complication is easy at the extremes but often becomes subjective for minor problems such as wound infection. Bearing in mind the consistently high rates of hernia wound infections in all prospective trials specifically focused on postoperative wound infections with proper definitions and methods, there is reason to believe that our 9% infection rate may reflect a common problem in training centers, where nonexpert residents are performing the procedures. The good news is that this high infection rate can be prevented, and infection rates similar to those obtained by experts can be achieved with proper use of antibiotics, as shown in our trial. The question of whether local antibiotics or newly developed antiseptic-impregnated meshes[29] are as effective as intravenous prophylaxis in the prevention of wound infections remains to be answered by similar prospective trials.

In conclusion, our results showed a significant benefit of intravenous, single-dose, prophylactic 1.5 g AS in the prevention of wound infections after tension-free prosthetic inguinal hernia repairs. The importance of a 10-fold decrease in the overall wound infection rate, a 5-fold decrease in the wound infection-related readmission rate, and a 3-fold decrease in the occurrence of DISSI cannot be overemphasized. In light of our results, we believe that routine use of single-dose intravenous antibiotics is warranted during open mesh repairs of inguinal hernias. AS acted as a very efficient agent for this purpose.

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