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Topical antibiotic prophylaxis in Lichtenstein hernia repair and comparison of three methods: A prospective randomized clinical trial

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Abstract:

INTRODUCTION: Lichtenstein hernia repair is a clean surgical intervention and one of the most frequently applied operation worldwide. Despite guidelines, benefit of antibiotic prophylaxis in hernia surgery has been considered questionable and prophylaxis usage is not infrequent. Here, in this clinical randomized trial, we aimed to compare three different prophylaxis regimens to find out which one is more effective.

METHODS: In this prospective study, patients were divided into three groups. First group (G1) received cefazoline, second group (G2) received topical gentamicin, and third group (G3) received combination of cefazoline and topical gentamicin. On 1st, 7th, and 30th postoperative days, surgical sites were examined for the signs of infection according to the definitions of Centers for Disease Control. Furthermore, effectiveness of infection prevention in patients with comorbid diseases was also analyzed.

RESULTS: Totally 276 patients were analyzed. In G1 three, in G2 two, and in G3 0 infections were recorded. Total, infection rate was 1.8%. There was no any difference in infection rates between three groups ($P = 0.285$). Comorbidities did not rise infection rates under prophylaxis coverage ($P > 0.05$).

CONCLUSION: All three methods are equally effective in surgical site infection, but combination method seems better with "0" ratio. Prophylaxis coverage also prevents surgical site infection even in the presence of risk (comorbidities).

Keywords:

Anti-bacterial agents, hernia, infection, prevention and control, wounds

Introduction

Open hernia repair with mesh implantation is a clean surgical intervention. It is well documented that antibiotic prophylaxis is needed in selected clean surgical interventions where a prosthesis is implanted. Arthroplasties such as hip or knee replacement and cardiac or vascular graft implants are clean procedures, in which antibiotic prophylaxis has been shown to be beneficial and clearly indicated.^[1,2] However, the benefit

of antibiotic prophylaxis in hernia surgery has been considered questionable. Last updated Cochrane meta-analysis concluded that administration of antibiotic prophylaxis for elective inguinal hernia repair cannot be universally recommended.^[3] It must be kept in mind that this study includes herniorrhaphies (with no mesh), hernioplasties (with a mesh), different hernioplasty techniques, and different antibiotics for prophylaxis. In our study, only mesh (a foreign body and potential infection cause) repairs were included. European Hernia Society guideline states that "in clinical settings with low

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rates (<5%) of wound infection, there is no indication for the routine use of antibiotic prophylaxis in elective open inguinal hernia repair in low-risk patients.^[4] Antibiotic prophylaxis is still used for high-risk patients in many centers and in the institutions with high rate of surgical infection. International guidelines for groin hernia repairs, published in 2018, state a significant benefit from antibiotic prophylaxis in a high-risk environment with higher than 5% incidence of wound infection there. Furthermore, there are reports, contrary to guidelines, saying that antibiotic prophylaxis is beneficial to reduce surgical site or deep infection in open hernioplasty.^[5-8] When prophylaxis is needed or preferred as a surgeon's choice, it can be applied intravenously (iv), topically, or in combination. Typical antibiotic prophylaxis for an inguinal hernia repair is the intravenous application of first- or second-generation cephalosporins before skin incision.^[8,9] Topical antibiotic prophylaxis is also a reliable alternative for open inguinal hernia repair.^[10,11] According to the Deysine report, topical gentamicin can help to reach 0 infection rate with the help of a strict aseptic and antiseptic protocol.^[11] The presence of these three alternative application methods (iv, topical, and combination) spontaneously emerges the question of "Which method is most effective in preventing or decreasing the postoperative infection?" In this double-blind prospective randomized trial, our objective was to compare the effectiveness of three different antibiotic prophylaxis regimens in a large volume reference hospital.

Methods

This prospective randomized trial was conducted at University of Health Sciences Diskapi Yildirim Beyazit Training and Research Hospital, Ankara, Turkey. The local ethics committees approved the study. All patients gave informed consent. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. The trial was registered on <http://www.clinicaltrials.gov> (NCT01273818).

A sample size of 300 patients (100/group) was calculated. The candidate patients were the ones with primary or recurrent unilateral inguinal hernia who were scheduled for elective open mesh repair during the study period. The patients who underwent contralateral hernia repair previously were also included in the study. Exclusion criteria were age under 18, incarcerated, or strangulated hernias requiring emergency intervention, simultaneous bilateral hernia repair, history of allergic reaction to antibiotics used in the trial, usage of any antibiotic within 1 week before surgery for any reason, and history of any kind of immunosuppressive disease.

All operations were performed by the same group consisting of senior residents and staff surgeons. Skin was shaved just before the operation in the operating room and prepared by povidine-iodine. All patients underwent open hernioplasty using a standard heavy polypropylene mesh (Trulene mesh-sutures, Bangalore, India) in a standardized Lichtenstein technique.

The size of meshes was 10 cm × 15 cm in all groups. In some patients, tailoring of mesh was needed according to the anatomical structures of patients, but in no operation mesh size was smaller than 9 cm × 13 cm. Fixation of mesh was done with polypropylene 2/0 sutures in all groups. Length of skin incision was 9 cm in all groups.

Operation details and distribution of risk factors are given in Tables 1 and 2, respectively.

Randomization

Eligible patients were assigned double-blinded randomly to each group. Randomization was done by the use of envelopes which included equal number of patients to be randomized to each arm (G1; IV cefazolin, G2: topical gentamicin, G3: IV cefazolin + topical gentamicin) of the study.

Antibiotic prophylaxis

Patients in G1 group received 1 g cefazolin (cefazolin sodium; Eczacibasi, Istanbul, Turkey) by IV bolus injection. In G2, gentamicin (gentamicin sulfate 80 mg 2%; I, E Ulugay, Istanbul, Turkey) was applied topically to surgical field just after the mesh implantation. In G3, patients received 1 g cefazolin and topical gentamicin. The anesthesiologist administered IV medication when the patient entered the operating room or at least, before the induction of anesthesia. None of the patients in either group was prescribed for any additional antibiotics.

Follow-up and data collection

Patient demographics, comorbid diseases, type of hernia, type of anesthesia, primary versus recurrent hernia, body mass index (BMI), and length of operation were recorded. All patients were discharged on the 1st postoperative day with a prescription of nonsteroidal anti-inflammatory drug. Surgical site dressing was changed in the 1st postoperative day and removed on 3rd postoperative day. Wound was inspected just before discharge and reexamined on 7, 14, and 30 days after surgery. The surgeon who was responsible the follow-up was blinded to the study. None of the visits was performed by telephone interview.

Both deep and superficial infection (infection occurring within 30 days of the operation involving only the skin or subcutaneous tissue) was followed up. Superficial and deep surgical site infection (SSI) was defined according

to the latest definition of the Centers for Disease Control.^[11] In the presence of seroma or hematoma, aspiration was performed under sterile conditions, and samples were saved for microbial culture. Examination for SSI was done on 1st postoperative day, 7th day, and 30 days after operation.

Outcome

SSI was the primary outcome of this study. Effect of comorbidities on SSI was the secondary outcome.

Statistical analysis

First, we verified that samples from all three groups came from a normally distributed population by Saphiro–Wilk test. To compare data between two independent groups, *t*-test was used, and to compare data in more than two groups, one-way analysis of variance test was used. To analyze correlation between categorical variables and differences between groups, Chi-squared and Fisher's exact test were used. The results of other demographic and group comparisons were presented as ratio in qualitative variables and as mean and standard deviation in quantitative variables. For the significance of the test, threshold for *P* value was chosen as 5%. All statistical analyses were done by SPSS 11.5 (Chicago,IL,USA).

Results

A total of 300 patients (100 for each group) were included in this study. During follow-up period, totally 24 patients were excluded due to antibiotic usage for other reasons. For final analysis, data of 98 patients in G1, 87 patients in G2, and 91 patients in G3 (total 276 patients) were used. Flow chart of the study was given in Figure 1. Groups were homogenous for age (*P* = 0.918), sex (*P* = 0.667), BMI (*P* = 0.891), length of operation (*P* = 0.570), primary and recurrent hernia (*P* = 0.867), hernia type (*P* = 0.218), and anesthesia type (*P* = 0.737). Results of the patients in all groups are given in Table 3. All patients were discharged in the 1st postoperative day. No adverse effects of the used drugs were recorded. All recorded infections were superficial surgical side infection (SSI) type, no deep infection was recorded. On 1st postoperative day, only one SSI was recorded in G2 group, whereas no infection was observed in other two groups, and this was statistically insignificant (*P* = 0.334) when compared with other groups. On 7th postoperative day, there were three SSI in G1 group and 1 SSI in G2 group but not statistically significant (*P* = 0.198). These patients with wound infection were different from the ones who had infection on 1st postoperative day. On 30th postoperative day, no further SSI was recorded in any group. Totally, there were five SSI among 276 patients (1.8%). Three of these five patients were in G1 and 2 in G2 groups. There was no infection in group G3. There was also no significant difference

among the three groups when all infections were taken into consideration totally (*P* = 0.285). In our study, statistical analysis showed that the presence of coexisting diseases (coronary, pulmonary, and endocrine diseases), BMI, anesthesia type, primary, or recurrent hernia type had no effect on SSI development (*P* = 1.000, 0.637, 0.227, and 1.000, respectively). One patient in G1 developed abscess formation during follow-up, and he was treated successfully with drainage and antibiotic (3rd generation cephalosporins) according to the wound culture and sensitivity test results.

Discussion

Because of inconsequent evidences, there is no consensus on whether or not antibiotic prophylaxis is effective or not in inguinal hernia repair, but it is obvious that mesh infection is the most challenging early complication both for the health carers and the patient. Recently, Cochrane Collaboration review concluded that usage of antibiotic prophylaxis in inguinal hernia repair was inconclusive.^[3] On the other hand, a separate meta-analysis including six of the 11 randomized control trials identified by Cochrane review, it was concluded that antibiotic prophylaxis is beneficial.^[5] Furthermore, two other recent meta-analysis support the use of antibiotic prophylaxis in patients undergoing mesh hernioplasty.^[12,13] A previous study of our own center reported no difference in infection between prophylaxis and placebo groups.^[14]

Table 1: Operative details of the groups

	Group 1	Group 2	Group 3	<i>P</i>
Operation time (min)	32±7	34±5	35±6	>0.05
Indirect hernia	64	58	60	>0.05
Direct hernia	34	29	31	>0.05
Primary case	84	76	80	>0.05
Recurrent case	14	11	11	>0.05
Left sided herhia	50	45	47	>0.05
Right sided hernia	48	42	44	>0.05

Table 2: Distribution of risk factors among groups

	Group 1 (n=98)	Group 2 (n=87)	Group 3 (n=91)	<i>P</i>
Coronary disesase	6	4	5	>0.05
Pulmonary disease	12	9	11	>0.05
Endocrine disease	23	19	20	>0.05
BMI	25±7	27±6	24±5	>0.05

BMI: Body mass index

Table 3: Results of patients

	Group 1 (n=98)	Group 2 (n=87)	Group 3 (n=91)	<i>P</i>
1 st day infection	0	1	0	0.334
7 th day infection	3	1	0	0.198
30 th day infection	0	0	0	-
Total	3	2	0	0.285

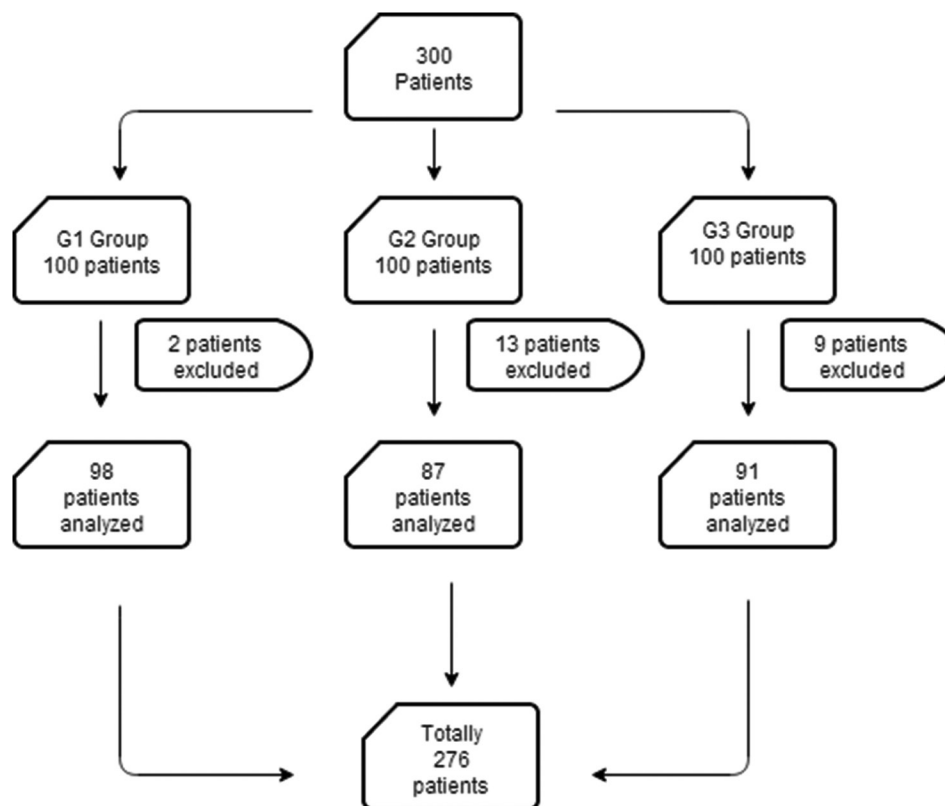


Figure 1: Flow chart of patients participated in the study

There is also inconsistency between clinical guidelines: the National Institute of Clinical Excellence (NICE) recommends the use of antibiotic prophylaxis in clean surgery with implanted material but guidelines issued by the Scottish Intercollegiate Guideline Network (SIGN) state that antibiotic prophylaxis is not needed in inguinal hernia repair with or without implanted mesh.^[15,16] Although the European Hernia Guidelines advise that there is no indication for the routine use of antibiotic prophylaxis in elective open or laparoscopic groin hernia repair in low-risk patients but that prophylaxis should be considered for patients with risk factors for wound infection, there seems to be an inconsistency in country-based surgical practices such as conflict between NICE and SIGN guides.^[4]

Since there are controversial practices on usage of antibiotic prophylaxis during open prosthetic inguinal hernia surgery in contrary to some other selected clean procedures (like arthroplasties and vascular graft implants) where a prosthesis is implanted, some surgeons are still favoring usage of antibiotic prophylaxis for this procedure. A survey carried out after the publication of these three guidelines; it was observed that, in London (England), only 13% of surgeons do not use any prophylactic regimen in open hernia repair.^[17] This is an important report to see that surgeon's beliefs about the effectiveness of antibiotic prophylaxis is more

determinative than scientific data. Hence, it seems that usage of any prophylactic agent in open hernia repair with mesh is not infrequent, in addition, there is a group of selected patients (immune-compromised, critically ill, drug users, etc.), in which prophylaxis is indicated. These realities make surgeons to look forward an effective prophylactic agent. For this reason, we aimed to compare the efficiency of three different prophylaxis agents in this study.

It is generally accepted that prevention of mesh infection is best achieved by usage of systemic antibiotics and topical antibiotics often are used without convincing evidence to support their value. This long established opinion may be because of, when compared, there are very few studies reporting the effectiveness of topical antibiotic application. Favoring the topical prophylaxis or saying that topical way is as effective as intravenous way in hernia repair with mesh seems not heavily supported but in practice reality is not like this. Gentamicin irrigation had been successfully used by neurosurgeons and urologists. Cefazolin and gentamicin were also used with success by surgeons for hernia prophylaxis.^[9]

Cefazolin and topical gentamicin are well known and relatively cheap prophylactic agents used for hernia repair prophylaxis. Gentamicin irrigation is also effective in conservative management of hernia mesh

infection.^[11,17-22] Gentamicin is an aminoglycoside and acts by causing misreading of genetic code and inhibiting translocation. Topical delivery of an antibiotic has many potential advantages such as local application causes high concentration at the infection site, limited potential for systemic absorption, and toxicity. In spite of these advantages, topical application of antibiotics has not taken place in guidelines for prophylaxis. The most impressive results were reported by Deysine.^[11] He wrote that no infections were observed in thousands of mesh hernioplasties within 25 years in patients whose operative sites were irrigated with a solution of 80 mg gentamicin in conjunction with 1 g preoperative IV cefazolin. The empirical choice of a high concentration gentamicin solution may explain our results.

Probably, the closest study to the present trial was performed by Musella *et al.*^[23] They randomized a large number of cases with mesh repair for inguinal hernias: both groups received IV cephalosporin, the test group was also applied with an absorbable collagen tamponade treated with gentamicin. The test group developed significantly less SSI in comparison with the control group.

Our total SSI rate was only 1.8% with prophylaxis. This infection rate is much lower than the rate of previous study of our clinic. SSI rates were 5% and 7% in prophylaxis and nonprophylaxis groups, respectively. In the previous study, only cefazoline was used as prophylactic agent. This fall in infection rate may be because of obeying more strict aseptic rules such as opening of mesh package just before implantation. In our study, all these three agents acted with same efficiency, there was no difference in SSI among them. Prophylactic antibiotic coverage of mesh hernia repair (by all these three methods) also showed that well-known morbidity factors such as age, BMI, presence of coexisting diseases, and duration of operation did not affect the infection rate and they did not cause any increase in infection ratios. It seems that antibiotic coverage gives surgeon a power to prevent infection even in high-risk patients. Furthermore, type of anesthesia, type of hernia (primary or recurrent) did not show any negative effect on infection rates under prophylaxis coverage.

It seems that, because of conflicting meta-analysis and review reports, so many surgeons are still using prophylactic antibiotics in open mesh hernia repair despite guidelines.

As authors, we believe that the exclusion of incarcerated hernias (emergency surgery) is the only limitation of this study, because it is logic that emergency surgery may need antibiotic coverage more than elective surgery.

According to the results of our study, it seems that usage of IV cefazoline, topical gentamicin, or combination of these is a good alternative with very low SSSI rates and drug safety. Combination prophylaxis seems as more effective method with its zero ratio.

Conclusion

All three methods are equally effective in surgical site infection, but combination method seems better with "0" ratio. Prophylaxy coverage also prevents surgical site infection even in the presence of risk (co-morbidities).

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Conflicts of interest

Dr. Hakan Kulacoglu is an Editorial Board member of International Journal of Abdominal Wall and Hernia Surgery. The article was subject to the journal's standard procedures, with peer review handled independently of this Editorial Board member and their research groups.

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