

The Role of Antibiotic Prophylaxis in Elective Tension-Free Mesh Inguinal Hernia Repair

Dr. Dutt Chandrakala MS^{1*}, Dr. Anand Tanmay MBBS²

¹Associate Professor, Department of Surgery, G.R.M.C, Gwalior, India

²3rd year Post-Graduate student, Department of General Surgery, G.R.M.C, Gwalior, India

Original Research Article

*Corresponding author

Dr. Dutt Chandrakala

Article History

Received: 03.08.2018

Accepted: 06.08.2018

Published: 30.08.2018

DOI:

10.36347/sasjs.2018.v04i08.002



Abstract: Surgical site infection has always been a major complication of surgery. Antibiotic prophylaxis has been widely used to reduce infection rates. The present study is aimed to assess role of antibiotic prophylaxis in hernia surgery. It consisted of 100 cases of hernia operated at G.R.M.C, Gwalior from December 2015 to December 2016. It is observed that the effectiveness of ANTIBIOTIC PROPHYLAXIS in Mesh Hernioplasty is no better than NO PROPHYLAXIS. The NO PROPHYLAXIS regimen in CLEAN procedures must be advocated as it limits antibiotic resistance and reduces cost burden. Follow up study involving multiple centres with larger sample size is needed to validate the present results and to lay down a standard protocol.

Keywords: surgical site infection, hernia repair.

INTRODUCTION

Inguinal hernia repair procedure belongs to the group of the most commonly performed procedures in General Surgery. Inguinal hernias account for around 70–75 % of all hernia operations [1]. Over the years, the number of implants used during inguinal hernia repair procedures has increased considerably, and the Lichtenstein method has become the gold standard in the management of inguinal hernia [2].

The rate of surgical site infection (SSI) following hernia repair procedures reported in the international literature ranges between 0% and 14% [3,4] and manifests anywhere between 2 weeks to 12 months [4]. The most common pathogen is Staphylococcus aureus [4,5] SSIs can increase in-hospital time and repetitive admissions to outpatient clinics.

Outline use of antibiotic prophylaxis in elective inguinal hernia repair procedures using an implant is still controversial. The use of prophylactic antibiotics seems to be empiric rather than evidence based [6].

In an effort to clarify this issue, the present prospective, randomized control trial was carried out to document the effect of intravenous, preoperative antibiotics in the prevention of wound infection and associated complications after open mesh repair of inguinal hernias. The purpose of this study is to clarify the effectiveness of antibiotic prophylaxis in reducing postoperative wound infection rates.

AIMS AND OBJECTIVES

- To evaluate infection rate in mesh hernioplasty.
- To compare infection rate in mesh hernioplasty done with and without antibiotic prophylaxis.
- To evaluate effectiveness of antibiotic prophylaxis in reducing infection rate in mesh hernioplasty.

MATERIAL AND METHODOLOGY

Study design: Prospective Randomized Control study

Sample size: n = 100

Total of 100 patients diagnosed as case of Inguinal Hernia, admitted at Department of Surgery Gajra Raja Medical College and J.A. Group of Hospitals, Gwalior, fulfilling the inclusion criteria and given consent to be part of study will be included in the study.

Study period

Study period of 12 months from December 2015 to November 2016.

Inclusion criteria

- Age ≥ 15 and ≤ 70 years.
- Diagnosis of inguinal hernia based on clinical examination or ultrasound
- Given consent to be part of study

Exclusion criteria

- Age less than 15 years or more than 70 years.
- Palpable mass on abdominal examination.

- Signs of obstructed hernia.
- Patient who are not willing for hernioplasty

After taking well informed consent, randomisation was done with a computer program and each case was assigned to one of the two wings:

- Group A (WAB) (*with antibiotics*): to be given Inj Ceftriaxone 1gm iv stat at the time of induction.
- Group B (WOAB) (*without antibiotics*): no antibiotics to be given either at induction.

Both groups were given oral antibiotics for 5-7 days post-operatively.

PRE-OPERATIVE

Shaving was done 24 hours prior to surgery. Patient was shifted to the operation theatre after applying a sterile bandage over the proposed part of surgery to avoid the contact with airborne microorganisms. In the operation theatre, sterile bandage was removed and skin preparation was done by Savlon scrub followed by Spirit and Povidone Iodine.

INTRA-OPERATIVE METHODS

Operations were performed under Local or Spinal anaesthesia. Single dose of planned antibiotic was administered intravenously after diluting with required amount of distilled water at the time of induction of anaesthesia using a disposable sterile syringe for group A. group B received a placebo injection of 10mL NS. Antibiotic was administered at the time of induction of anaesthesia so as to allow the maximum concentration of the drug in the wound at the time of wound closure.

POST OPERATIVE

Wound were examined after taking aseptic precaution so that not to introduce any infection from outside. This was done on second, fourth & sixth day of operation. Wounds were looked specially for redness, swelling, temperature, tenderness and discharge. If surgical site infection is observed, it is classified as

superficial or deep infection and data is noted. If patient developed infection at surgical site, then patient was manage appropriately with iv antibiotics based on culture sensitivity report and symptomatic managed. If patient developed infection at surgical site, then patient was manage appropriately with iv antibiotics based on culture sensitivity report and symptomatic managed.

OBSERVATIONS AND RESULTS

A total of 100 patients who underwent conventional open hernioplasty in Department of Surgery, G R Medical College and J A Group of Hospitals, Gwalior were included in this study from December 2015 to November 2016.

Data for all patients who were randomly assigned to a treatment group and underwent surgery were primarily analyzed on an intention-to-treat basis. The target variables analyzed were impaired wound healing and deep infections with mesh involvement.

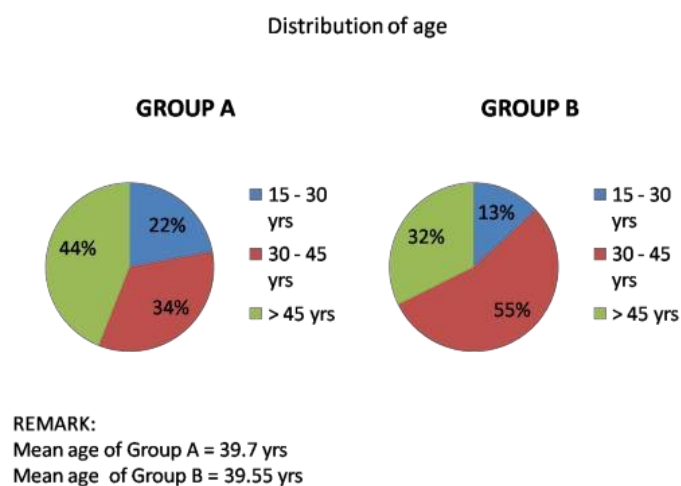
For unadjusted analysis of antibiotic influence on categorical outcome parameters, Fisher's exact test was used. In case of more than two categories, exact analysis was not possible. Here, the asymptotic Chi-square test was used. Unadjusted analysis of continuous normal distributed outcome variables was realized using the robust *t* test (Satterthwaite). All analysis were performed with the software SAS 9.2 (SAS Institute Inc., Cary, NY, USA) and intentionally calculated to a full significance level of 5 %, i.e., they were not corrected in respect of multiple tests, and each *p* value ≤ 0.05 represents a significant result.

BASELINE VARIABLES

- Age and Gender

The mean age was 39.6 years with the majority within the age bracket of 30 - 45 years.

All the patients that are part of the study are males.



Graph-01: Distribution of Age

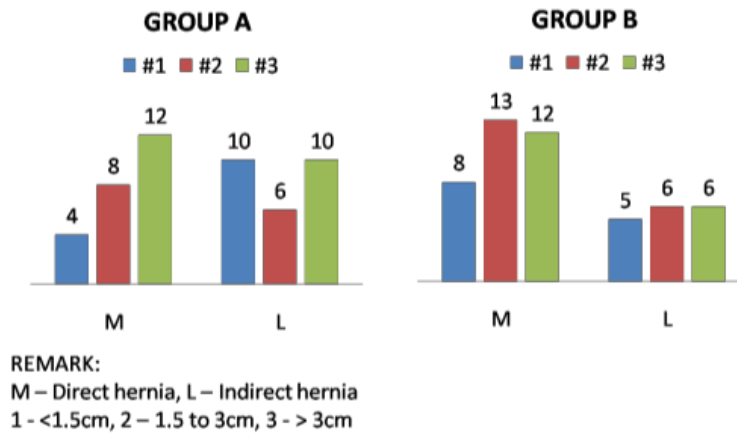
Preoperative Factors

Out of total 100 patients, 57 patients had direct hernia and 43 patients had indirect hernia. 27 patients had a defect of size < 1.5cm, 42 patients had a defect of size >3cm and 31 patients had a defect of size 1.5 – 3 cm.

Most of the patients belonged to ASA group I.

Smoking, COPD, DM and immunosuppression are identified as other important risk factors affecting wound healing. 70% of subjects from Group A have associated risk factors, whereas only 54% of subjects from Group B have risk factors.

Distribution OF SIZE OF HERNIA DEFECT



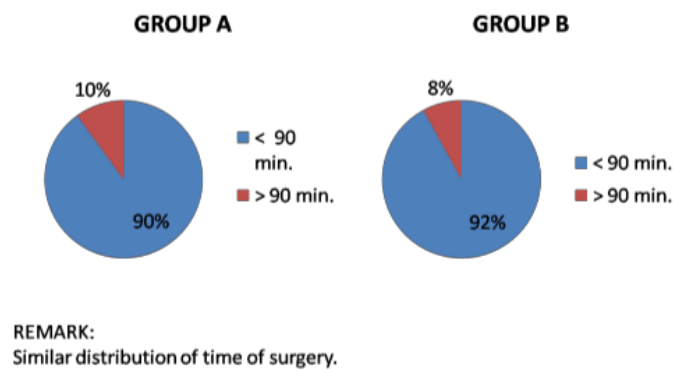
Graph-02: Distribution of Size of hernia

Duration of surgery

The mean duration of surgery was 82.5 minutes. The contents of the hernias in descending order were: empty (77.7%), omentum (18.3%), small bowel (3.4%) and small bowel with omentum (0.04%).

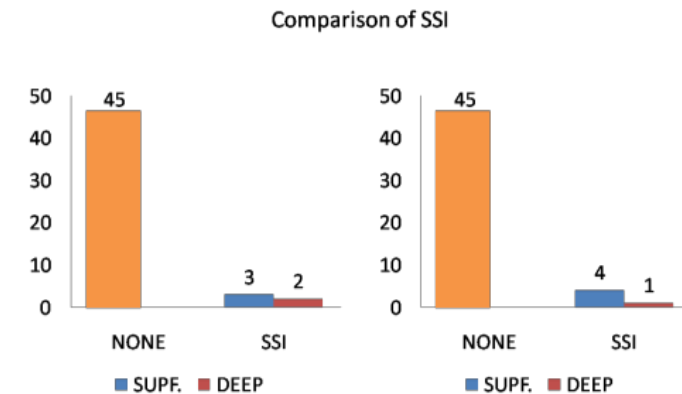
An omentectomy with primary hernia repair was performed in 4 patients. No bowel resection was done. Adhesion of the sac to the surrounding structures or to contents within such as omentum were present in 10 cases.

Distribution of Duration Of Time Of Surgery



Graph-03: Distribution of Duration of time of surgery

TESTING VARIABLES
Post-operative Infection



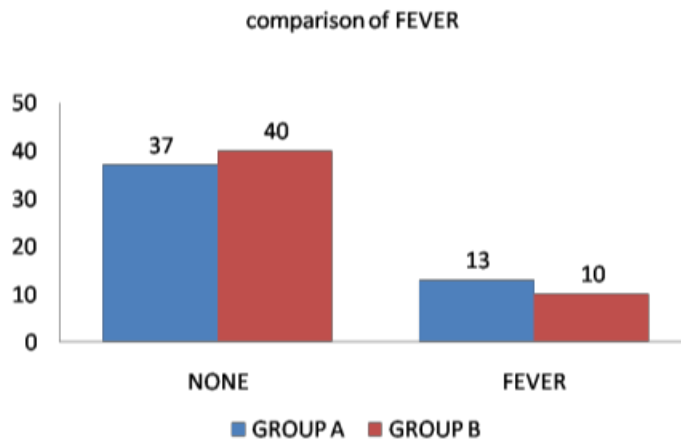
REMARK:
 p = 0.212, no statistical difference in rate of SSI.

Graph04: Comparison of SSI

Postoperative infection in study has been defined by any SSI observed within 2 weeks following surgery. Tenderness alone, scrotal swelling, etc is not considered SSI. There were a total of 10 patients with SSI, 5 in each arm. The overall SSI rate was 10%. There was no significant difference in SSI rate in between the

group which received Antibiotic Prophylaxis and the group which did not receive antibiotic prophylaxis ($p = 0.212$). There were 3 cases of Deep SSI out of which only 1 patient later required removal of an infected mesh.

Fever



REMARK:
 p = 0.131, no statistical difference in incidence of fever.

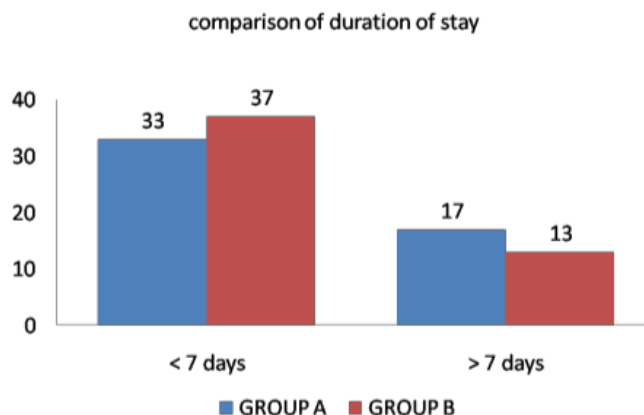
Graph05: Comparison of incidence of Fever.

13 subjects from Group A developed fever in Post OP period and only 10 subjects from Group B developed fever. Patients were managed adequately in all cases with cold sponging, antipyretics, etc.

Out of 13 patients who developed fever in Group A, only 5 later on developed SSI, whereas 5 patients out of 10 developed SSI in Group B.

Duration of hospital stay

Duration of hospital stay was studied and compared in both the groups. 70% of patients were discharged within 1 week. 10 patients who had developed SSI had a prolonged stay of greater than 1 week. Recurrence after long time follow up was studied for upto 6 months and compared in both the groups. No recurrence is observed in both groups.



REMARK:
 $p = 0.842$, no statistical difference in duration of hospital stay.

Graph-06: Comparison of duration of Hospital Stay

DISCUSSION

In present study 10 % infection rate is observed. The 10% rate of wound infections in our study 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 and

Kurzer *et al.*[6]. In Indian settings, the exposure to Operation Theatre atmosphere carries an increased risk of operative wound contamination at the time of operation. The incidence of postoperative wound infection in clean surgeries in Indian settings is as follows:

Table-01: Post-operative wound infection rate in clean surgeries in India

Year	Study by	Wound infection rate (%)
1964	CHAWLA <i>et al.</i>	18.2
1973	PRAKASH <i>et al.</i>	10.7
2006	SAHA <i>et al.</i>	7.1

The declining incidence of post operative wound infection rate in Indian settings particularly in the last decade is probably due to increased awareness of aseptic and antiseptic precautions, the dreaded diseases like AIDS and Hepatitis B have made every surgeon to be over cautious starting right from entering in to the operation theatre and then finally leaving the theatre after operation. It is needless to stress that this encompasses the washing of hands, wearing of sterile gown and gloves which all forms the important keys in keeping the patients infection free. The newer techniques of article sterilization (Autoclaving, Gamma radiation etc.), improved theatre care, and cleanliness have all led to increase in the operation theatre standard in the past few years.

ROLE OF ANTIBIOTIC PROPHYLAXIS IN REDUCING SSI

Sanchez-Manuel and colleagues performed a Cochrane meta-analysis [7] of 13 randomized trials that evaluated the benefits of antibiotic prophylaxis in inguinal hernia repair; of these 13 trials, 7 used a prosthetic material. A total of 6825 patients were included (4188 in the prophylaxis group and 2637 in the control group). The rate of infection in patients with hernioplasty was 1.4% and 2.9% in the prophylaxis and control groups, respectively.

Based on these results, the authors recommended the use of antibiotics only in cases with high rate of wound infections, and not universally for all patients undergoing elective inguinal hernia repair.

Perez and colleagues also performed a prospective, randomized, double-blind, placebo-controlled trial to compare single- dose 1 g intravenous Cefazolin with placebo in 360 patients undergoing open inguinal hernia using polypropylene mesh [8]. Their results also showed no benefit of antibiotic prophylaxis (1.7% vs. 3.3%, $p = 0.50$). Another double-blind prospective randomized trial in 200 patients selected to receive elective inguinal hernia surgery with mesh repair demonstrated no significant difference between the cefazolin and placebo groups (7% in the study group and 5% in the placebo group, $p = 0.38$). They concluded that antibiotic prophylaxis has no benefit in the incidence of SSI in elective repair of inguinal hernias with mesh. Similar results were documented by Jain *et al.*, Tzovaras *et al.*, and Aufenacker *et al.* which did not support the use of prophylactic antibiotics in low-risk patients with inguinal mesh hernioplasty.

LIMITATION

There were certain inadequacies of this study. In view of the small sample size ($n=100$), the calculated study power was 71.2% with significance value of 0.05.

CONCLUSION

The present study shows that there is no significant benefit of antibiotic prophylaxis in the prevention of wound infections after tension-free prosthetic inguinal hernia repairs. Even though the rates of SSI were high in both the antibiotic and control groups, the difference was not statistically significant. Based on the observed results, it is concluded that prophylactic antibiotics do not decrease the rate of SSI in mesh repair of inguinal hernias.

Hence it is recommend that the use of Antibiotic prophylaxis in elective repair surgery for inguinal hernia in low-risk patients must be avoided, but considering it in patients at a high risk of SSI.

REFERENCES

1. Aufenacker TJ, van Geldere D, Van Mesdag T, Bossers AN, Dekker B, Scheijde E, van Nieuwenhuizen R, Hiemstra E, Maduro JH, Juttman JW, Hofstede D. The role of antibiotic prophylaxis in prevention of wound infection after Lichtenstein open mesh repair of primary inguinal hernia: a multicenter double-blind randomized controlled trial. *Annals of surgery*. 2004 Dec;240(6):955.
2. EU Hernia Trialists Collaboration. Repair of groin hernia with synthetic mesh: meta-analysis of randomized controlled trials. *Annals of surgery*. 2002 Mar;235(3):322.
3. Smietanski M, Chroscicki A, Dabrowicki S, Fridiger J, Matyja A, Michalik M, Mitura K, Solecki R, Trojanowski P, Wroblewski T. Groin hernia treatment. European Hernia Society Guidelines and comments by the Polish Working Group for the guidelines' implementation. *WIDEOCHIRURGIA I INNE TECHNIKI MALOINWAZYJNE*. 2009 Jan 1;4:S13-5.
4. Mazaki T, Mado K, Masuda H, Shiono M, Tochikura N, Kaburagi M. A randomized trial of antibiotic prophylaxis for the prevention of surgical site infection after open mesh-plug hernia repair. *The American Journal of Surgery*. 2014 Apr 1;207(4):476-84.
5. Platt R, Zaleznik DF, Hopkins CC, Dellinger EP, Karchmer AW, Bryan CS, Burke JF, Wikler MA, Marino SK, Holbrook KF, Tosteson TD. Perioperative antibiotic prophylaxis for herniorrhaphy and breast surgery. *New England Journal of Medicine*. 1990 Jan 18;322(3):153-60.
6. Yerdel MA, Akin EB, Dolalan S, Turkcapar AG, Pehlivan M, Gecim IE, Kuterdem E. 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. *Annals of surgery*. 2001 Jan;233(1):26.
7. Gaynes RP, Culver DH, Horan TC, Edwards JR, Richards C, Tolson JS, National Nosocomial Infections Surveillance System. Surgical site infection (SSI) rates in the United States, 1992–1998: the National Nosocomial Infections Surveillance System basic SSI risk index. *Clinical Infectious Diseases*. 2001 Sep 1;33(Supplement_2):S69-77.
8. Kuzu MA, Hazinedaroğlu S, Dolalan Ş, Özkan N, Yalçın S, Erkek AB, Mahmoudi H, Tüzüner A, Elhan AH, Kuterdem E. Prevention of surgical site infection after open prosthetic inguinal hernia repair: efficacy of parenteral versus oral prophylaxis with amoxicillin-clavulanic acid in a randomized clinical trial. *World journal of surgery*. 2005 Jun 1;29(6):794-9.