*Bali Medical Journal (BMJ) 2013, Volume 2, Number 2: 55-58*
*P-ISSN.2089-1180, E-ISSN.2302-2914*

# EFFECT OF PROPHYLACTIC ANTIBIOTIC ON SURGICAL SITE INFECTION AFTER TENSION-FREE HERNIOPLASTY

***[1]Saskia-Javi, Y., [1]Sudartana, I K., and [2]Raka-Widiana, I G.***

[1]Surgery Depart. Faculty of Medicine Udayana University/Sanglah General Hospital Bali-Indonesia
[2]Internal Depart. Faculty of Medicine Udayana University/Sanglah General Hospital Bali-Indonesia

**Objective**: prophylactic antibiotics were remains applied for hernioplasty treatment at Sanglah General Hospital Bali-Indonesia. On the other hand, there were no comprehensive infection incidence data gathered. This research aims to determine incidence differences of post operative infection in patients underwent tension-free hernioplasty and received prophylactic antibiotics compared to those who received placebo. The general purpose of this research is to determine the necessity of prophylactic antibiotics in the hope of setting new procedural standards in elective hernia procedures thus reducing cost and bacteria resistance. **Patients and Method**: This was an open label randomized clinical trial conducted at Sanglah General Hospital Department of General Surgery from October 2011. The target population was all patients who underwent tension-free hernioplasty procedure, in Sanglah General Hospital. The acquired data was analyzed after an independent *t* test was performed. a Mann-Whitney U test, Fisher's exact test, and Two-Sample Kolmogorov-Smirnov test were used to determine the correlations between variables, where $p < 0.05$ was regardless of significant. **Results**: From 54 subjects 3 (5.6%) of them were found to have a slight erythema around the operation wound, on the 7th,14th,21th, and 28th day no signs of erythema were found. From the three subjects two (7.4%) were from the placebo group and one (3.7%) from the antibiotic group. All clinical assessment of post operative wound was made using Southampton Wound Assessment Scale, where erythema is a grade 1C, all subjects healed primarily. **Conclusion**: An Open Label Randomized Clinical Trial comparing SSI in post tension-free hernioplasty patients who were given prophylactic antibiotics and placebo. No significant difference were found.

**Keywords: Tension-free hernioplasty, prophylactic antibiotic, SSI**

## INTRODUCTION

The incidence of groin hernias, which include inguinal and femoral hernias average at 70 per 10.000 people in the age group of 45 years to 64 years old, increasing to 150 cases per 10.000 people above 75 years old. Inguinal hernia procedures are one of the most common procedures performed. NHS data showed that it is the 10th most often performed operation in England.[1]

Prophylactic agents are antibiotics which are given before a surgical procedure with the intent of preventing infection or commonly known as surgical site infections (SSI). Out of 23 million patients who underwent surgery in the united states every year, 920.000 suffer from SSI, which increases length of stay twice as long and increases cost to 5 times higher.[2] The role of prophylactic antibiotics is still controversial as shown by Jain, *et al*. (2008) as no decrease in post operative infection were found,[3] Hernioplasty procedure in Sanglah General Hospital still uses prophylactic antibiotics, while a comprehensive infection incidence data has not been gathered. The general purpose of this research is to determine the necessity of prophylactic antibiotics in the hope of setting new standard procedure in elective hernia procedures thus reducing cost and bacterial resistance.

**Correspondence: Saskia-Javi, Y.**
**Address: Surgery Depart. Faculty of Medicine Udayana University/Sanglah General Hospital Bali-Indonesia.**
**Email: saskia@gmail.com**

## PATIENTS AND METHOD

This was an open label randomized clinical trial conducted from October 2011. The target population was all patients who underwent tension-free hernioplasty procedure, with inclusion criterias: patients with primary uni or bi-lateral inguinal hernia who underwent tension-free hernioplasty within the age group of 18-80 years old. Patients with obesity, who are immunocompromized, such as patients with HIV, Diabetes, receiving corticosteroid or chemotherapy, patients with recurrent, strangulated, and incarcerated hernias, allergic to cephalosporins, anemic, low nutritional status, who are taking antibiotics for other medical conditions, and patients with other systemic or chronic illness were

excluded from the research. the SSI scoring was based on The Southampton Wound Assessment Scale**.**

The subjects were divided into two groups using a permuted block, the first group was given with an open label an intravenous injection 1 gr of cephazolin during induction, and the second group was given a placebo (saline solution). Then a lichtenstein tension-free hernioplasty was performed using the standard operating procedure. post operative control on the 3rd,7th, 14th,21 st and 28th day, for suture removal, and evaluation of infection signs. The acquired data was analyzed after an independent t test was performed. a Mann-Whitney U test, Fisher's exact test, and Two-Sample Kolmogorov-Smirnov test was used to determine the correlations between variables, where $p < 0.05$.

**RESULTS**

Randomization was successful; there were no significant differences with respect to median age, sex, frequencies of different hernia types and location (Table 1). From 54 subjects 3 (5.6%) were found to have a slight erythema around the operation wound, on the 7th,14th,21th, and 28th day no signs of erythema were found. From the three subjects two (7.4%) were from the placebo group and one (3,7%) from the antibiotic group. All clinical assessment of post operative wound was made using Southampton Wound Assessment Scale, where erythema is a grade 1C, all subjects healed primarily (Table 2).

Table 1
Characteristics of Patients With Primary Inguinal Hernia Randomized Between Prophylactic and Placebo

| Characteristic | Antibiotic Group (n = 27) | Placebo Group (n = 27) | *p* |
|---|---|---|---|
| Sex | | | |
| -Male | 26 | 25 | 0.500* |
| -Female | 1 | 2 | |
| Age (Year) | 45,04 ± 16,803 | 44,48 ± 18,039 | 0.883** |
| Hernia Type | | | |
| -Direct | 4 | 3 | 0.500*** |
| -Indirect | 23 | 24 | |
| Hernia Location | | | |
| -Right | 14 | 13 | 0.996**** |
| -Left | 10 | 14 | |
| -Bilateral | 3 | 0 | |

*Fisher's Exact. $p < 0.05$; **Mann Whitney. $p < 0.05$; ***Fisher's Exact. $p < 0,05$; ****Two-Sample Kolmogorov-Smirnov test. $p < 0.05$

Table 2
Post operative wound assessment

| **Days** | **D3** | | **D7** | | **D14** | | **D21** | | **D28** | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Infection** | G0 | G1 | G0 | G1C | G0 | G1 | G0 | G1 | G0 | G1 |
| **Antibiotic** | 27 | 0 | 26 | 1 | 27 | 0 | 27 | 0 | 27 | 0 |
| **Placebo** | 27 | 0 | 25 | 2 | 27 | 0 | 27 | 0 | 27 | 0 |
| **Amount** | 54 | 0 | 5 | 3 | 54 | 0 | 54 | 0 | 54 | 0 |

**Description :**
D3 = Day 3 post operation
D7 = Day 7 post operation
D14 = Day 14 post operation
D28 = Day 28 post operation
GO = Normal Healing
G1 =Normal healing with erythema
G1C =Normal healing with light erythema

## DISCUSSION

Hernial repair is a clean procedure, but some surgeons still use prophylactic antibiotics in a lichtenstein procedure as a gold standard, this is assumed due to the use of a mesh as a synthetic material that may increase SSI.[4,5] This research has concluded that on elective hernioplasty, clinically using Southampton Wound Assessment Scale, no SSI was found on the post operative wound, as erythema is still considered normal wound healing. This is similar to the results achieved by another author, which states that prophylactic antibiotics are not mandatory for such cases.[3,4,6,7,8,9]

Infection signs that were found are erythema on the wound (grade 1C) on the 7th day on 1(3.7%) subject of the antibiotic group, and 2 (7.4%) on the placebo group, both cases were treated with wound care and no signs were found on the 7th,14th,21th, and 28th day, and all subjects healed primarily.

Aufenacker, *et al*. (2004) reported SSI of 1.6% on the antibiotics group, and 1.8% on the placebo group[6]; while Perez *et al*, (2005) reported SSI of 2.2% on the antibiotics group, and 1,7% on the placebo group[7]; Tzovaras, *et al*, (2007) also showed that only 4.7% placebo group and 2,6% on the antibiotic group[8]. On the other hand, Yerdel, *et al.*(2001) reported that a decrease of 8.3% infection rates were found by the use of prophylactic antibiotics.[10] A meta-analysis by Sanchez *et al.*(2003) concluded that prophylactic antibiotic use still requires further research.[11] A meta-analysis by Gravante *et al.* (2008) states that a 2.9% on the antibiotic group and 4.2% on the placebo group were found, while 1.7% on the antibiotics group and 3.7% on the placebo group were found on patients using mesh.[12]

Some studies included only assessed low-risk patients, so conclusion could be applied solely to this kind of patients.[13] It should be noted that studies in which the rate of SSI are higher have reported that prophylactic antibiotis are beneficial, whereas similar conclusion could not be derived in the studies with low rates of SSI[8]. Therefore, surgeons and hospitals must assess their own SSI rates to define if prophylactic antibiotics must be widely used in all patients.[13] It is concluded the decision to use prophylactic antibiotic, therefore, must be based on balancing possible benefits against adverse effects.[14]

Clean operation is a procedure with no mistakes in sterilization, and no leaks on the digestive, respiratory and urinary tract. The four sources of infection are the medical staff, sterilization techniques, environment, and patient risk factors. A surgeon should be able to minimalize such factors. Antibiotics should not be used to replace proper aseptic and antiseptic methods, along with good surgical techniques and proper tissue handling infection can be prevented.[15]

## CONCLUSION

Based on this research and other previous research, it can be concluded that no difference were found in the occurence of SSI post tension-free hernioplasty between patients who received prophylactic antibiotics and placebo.

## REFERENCES

1. McIntosh, A., Hutchinson, A., and Roberts, A. 2000. Evidence-based management of inguinal hernia in primary care – a systematic review. Family Practice. 17: p 442-447.
2. Sunarto, R. 2007. Antibiotik Profilaksis pada Pembedahan.
3. Jain, S. K., Jayant, N., and Norbu, C. 2008. The role of antibiotic prophylaxis in mesh repair of primary inguinal hernias using prolene hernia system: A randomized prospective double-blind control trial. Trop. Doctor. 38:80-82.
4. Shankar, V. G., Srinivasan, K., Sistla, S. C., and Jagdish, S. 2010. Prophylactic antibiotics in open mesh repair of inguinal hernia – a randomized controlled trial. Int J of Surgery. 8:444-447.
5. Ijaz, A. A., et al. 2010. Post Operative Wound Infection: Prevention The Role of Antibiotic Prophylaxis in Lichtenstein. Professional Med J. p 174-179.
6. Aufenacker, T. J., Geldere, D., Mesdag, T., Bossers, A. N., et al. 2004. The Role of Antibiotic Prophylaxis in Prevention of Wound Infection after Lichtenstein Open Mesh Repair of Primary Inguinal Hernia. Annals of Surgery, Vol 240. p 955-961.
7. Perez, R. A., Roxas, M. F., and Hilvano, S. S. 2005. A Randomized, Double-blind Placebo-controlled Trial to Determine Effectiveness of Antibiotic Prophylaxis for Tension-free Mesh Herniorrhaphy. J Am Coll Surgeon. Vol 200. No 3: p 393-397.
8. Tzovaras, G., Delikoukos, S., Christodoulides, G., et al. 2007. The Role of Antibiotic Prophylaxis in Elective Tension-Free Mesh Inguinal Hernia Repair: Results of a Single-Centre Prospective Randomised Trial. Int J Clin Pract. Vol 61: p 236-239.
9. Hosseini, M., and Heidari, A. 2011. Evaluation of Prophylactic Antibiotic Prescription in Post-Operative Infection in Patients Undergone Inguinal Herniorraphy Surgery with Prolene Mesh: A Randomized Double Blind Study. Surgery Journal. Vol 6: p 21-25.
10. Yerdel, M. A., et al. Effect of Single Dose Prophylactic Ampicillin and Sulbactam on Wound Infection After Tension-free Inguinal Hernia Repair with Polypropylene Mesh. Annals of Surgery. Vol 233. No 1: p 26-33.
11. Manuel-Sanchez, F. J., et al. 2009. Antibiotic Prophylaxis for Hernia Repair; the Cochrane Collaboration. John Wiley and Sons, Ltd.

12. Gravante, G., Venditti, D., and Vincenzino, F. 2008. The role of single-shot antibiotic prophylaxis in inguinal hernia repair. Annals of Surgery. 248:496-497.
13. Sanabria, A., et al. Prophylactic Antibiotics for Mesh Inguinal Hernioplasty. Annals of Surgery, Vol 245. No 3: p 392-396.
14. Ansari, A. S., Saddique, M., and Azim, W. 2005. Antibiotic Prophylaxis in Clean Surgery. Biomedica. Vol 21: p 121-124.
15. Rose, P. A., and Matti, A. 2002. Prescribing Practices of Surgeons and Factors that Limit Adherence to the Philippine College of Surgeons Clinical Practice Guidelines on Antimicrobial Prophylaxis for Elective Surgical Procedures at the UP-PGH Surgical Wards. Phil J Micobiol Infect Dis. Vol 31: p 107-124.