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Assessment of effectiveness of prophylactic topical antibiotic vis-a-vis oral antibiotic in the prevention of surgical site infection in elective open inguinal hernioplasty

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Abstract
Background: *Reports in literature are conflicting with regard to the necessicity and effictiveness of antibiotic prophylaxis in inguinal hernia repair surgery. However, antibiotic prophylaxis is used in many centers as placement of a prosthesis (mesh) would lead to serious consequence should infection occur. Intravenous route is the most common mode of administration, but orally administered antibiotic and topical antibiotic application for prophylaxis are also used. Intravenous administration is associated with much more severe adverse effects and economic liability as compared to oral or topical prophylactic methods.*
Aim of the study : *To assess the effectiveness and compare the degree of prophylaxis between pre-operative orally administered ciprofloxacin (500 mg) and intra-operative topical application of ciprofloxacin solution (200 mg) as methods of prophylaxis against surgical site infection in elective Lichtenstein inguinal hernia repair.*
Material and method : *This is a prospective single-blind randomized study consisting of a total of 212 patients conducted over a period of four years at a tertiary care center in north eastern India. Eligible patients were allocated to two treatment arms, one group of patients (n = 107) received oral ciprofloxacin 500 mg pre-operatively and another group (n = 105) received topical ciporfloxacin delivered locally to the wound. Demographic data and relevant parameters were collated and analyzed at the end of a one year follow up period.*
Results : *Both orally administered ciprofloxacin and topically delivered ciprofloxacin appeared to be equvalent in efficacy and confer a similar degree of prophylaxis against surgical site infection in elective Lichtenstein inguinal hernia repair.*
Keywords: *Antibiotic prophylaxis, oral ciprofloxacin, topical ciprofloxacin, surgical site infection, open inguinal hernioplasty.*

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I. Introduction

Antibiotic prophylaxis for open inguinal hernioplasty is still a debatable topic. This is due to disparity among study results in this area[1]. The European Hernia Society suggested that in clinical settings with low rates (<5%) of wound infection, there is no indication for the routine use of antibiotic prophylaxis in elective open groin hernia repair in low-risk patients[2]. Although inguinal hernioplasty is traditionally considered a clean surgery where the expected risk of infection is less than 2%, several studies have demonstrated much higher rate of infection ranging from 0.06 to 5.3%[3]. Yerdel et al[4], found 9% rate of wound infection among patients who underwent Lichtenstein hernioplasty without antibiotic prophylaxis.

Lichtenstein tension-free hernioplasty is regarded as the gold standard operation for inguinal hernia repair[5]. Infection of the implanted prosthetic mesh has generated much concern since the inserted foreign material is an ideal medium for bacterial colonisation[6] .These infections respond poorly to antimicrobial treatment regimens[7].

Surgical site infections (SSIs) are the second most common cause of healthcare associated infections. SSIs account for 14-16% of all hospital-acquired infections and are among the most common complications of care, occurring in 2 to 5% of patients after clean extra-abdominal operations and up to 20% of intra-abdominal procedures. Among surgical patients, SSIs account for 40% of all such hospital-acquired infections. By reducing

SSIs, hospitals on average could recognize a reduction in extended length of stay by seven days on each patient developing an infection[8].

Administration of systemic antibiotics carries a risk of adverse reactions such as anaphylaxis and hypersensitivity, blood dyscrasias including neutropenia, thrombocytopenia, and interstitial nephritis[9]. Rinsing of the wound with an antibiotic containing solution is another technique of prophylaxis. This approach inhibits the adhesion of bacteria to the surface of the mesh, as well as their growth[10]. Lazorthes et al[11], found no wound infection following application of a single dose of cefamandole directly to the wound among patients who underwent inguinal hernia repair. Oral antibiotic administration has also been shown to be a safe and effective method for offering prophylaxis against surgical site infection [12].

A study by Terzi et al[13], found oral ciprofloxacin prophylaxis to be an attractive option with its wide antibacterial spectrum, low cost and ease of administration in patients undergoing tension-free inguinal hernia repair with polypropylene mesh. Other authors have also demonstrated the beneficial role of topical antibiotics as prophylaxis against infection [14,15].

II. Aim and objectives

i) To compare the effectiveness of single dose oral ciprofloxacin (500 mg) with topical application of ciprofloxacin (200 mg) for the prevention/reduction of post-operative surgical site infection in patients undergoing elective open mesh hernioplasty.
ii) To identify factors that may increase the risk of wound infection.

III. Materials and methods

This was a tertiary care teaching hospital based study carried out on patients admitted for inguinal hernia repair under General Surgery Department, NEIGRIHMS, Shillong, Meghalaya.

A total of 235 patients (both male and female) aged ≥ 18 years were recruited over a duration of three years and followed up to a period of one year. The study was conducted with approval of Institute Ethics Committee and consent for participation was obtained from each patient prior to enrollment.

Study Design: Prospective comparative single-blind randomized study.
Study Location: Department of General Surgery, NEIGRIHMS, Shillong, Meghalaya.
Study Duration: April 2014 to April 2018.
Sample size: 212.
Conflict of interest: Nil.

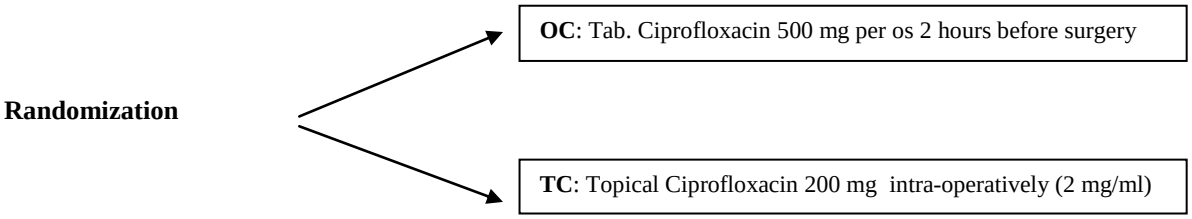
Inclusion & exclusion criteria:

All patients aged ≥ 18 years with inguinal hernia scheduled for elective open mesh hernioplasty (Lichtenstein procedure) were eligible for enrollment into the study.

Patients with one or more of the following conditions viz. refusal to give consent, age < 18 yrs, inguinal hernia requiring emergency surgery, recurrent inguinal hernia, history of chronic disease requiring antibiotic prophylaxis (e.g. RHD), uncontrolled diabetes/Hb A1c level > 7%, immunocompromised status or ongoing corticosteroid therapy, ASA class III and above, antibiotic intake in the last 48 hours prior to operation, history of sensitivity to fluoroquinolones, pregnancy/lactation and inguinal hernia repairs done under day care services were excluded from the study.

Procedure methodology:

After obtaining informed consent eligible patients received a mode of therapy as allocated into one of the study arms viz. oral ciprofloxacin group (OC group) or topical ciprofloxacin group (TC group) by block randomization using a computer generated random sequence. A medical officer not part of the research team performed the randomization of cases on admission.



Pre-operative demographic data viz. age, sex, BMI, duration of symptoms, smoking, co-morbidity and ASA class were recorded. Intra-operative characteristics viz. anaesthesia, surgeon grade, hernia type, duration of operation and post-operative parameters viz. length of hospital stay, outcome, etc. were documented.

Overweight was defined as BMI of 23.0 – 24.9 and obesity as BMI ≥ 25 based on revised guidelines for Asian Indians [16,17].
Results of the study were analyzed by calculating the rate of surgical site infection (SSI). Statistical tests of significance eg. Chi square test, Student-t test, Fischer Exact test etc. were used to evaluate the practical applicability of the study findings.

Interventions:
Upon admission all patients were tested for dermal sensitivity for ciprofloxacin.
Patients with diabetes were posted for operation after control of blood sugar and their Haemoglobin A1c level < 7%.
Patients in the OC arm received a single dose of ciprofloxacin 500 mg in tablet form two hours before the operation (Ciplox – 500, ciprofloxacin Hydrochloride Tablet, I.P 500 mg, CIPLA LTD, Sikkim, India). Intra-operatively, the wounds of these patients were washed with normal saline and closure was done after ensuring satisfactory haemostasis.
Patients in the TC arm had their wounds rinsed with ciprofloxacin infusion solution (CIPROJAB, ciprofloxacin I. P 200 mg, Infutec Healthcare Limited, Punjab, India) diluted with equal volume of normal saline before mesh fixation. The mesh used for these patients was soaked in the antibiotic solution (undiluted) for at least 5 minutes. Contact period of antibiotic solution with tissues of 5 minutes was allowed during which time the wound was kept covered with sterile gauze. The wound was mopped dry of antibiotic solution and then closed after satisfactory haemostasis was achieved.

Anaesthesia and surgical technique:
The type of anaesthesia (general/spinal) was not standardized and was determined by the patient's preference or choice of the anaesthesiologist taking into account the patient's age, co-morbid factors etc.
Local anaesthetic infiltration was not used in any patient.
The skin was shaved immediately before surgery and prepared with 10% povidone iodine.
Operations were performed either by a consultant surgeon or a supervised resident who were blinded to the study group allocation.
A standard Lichtenstein hernia repair was performed. Monofilament polypropylene mesh (DOLPHIN Mesh PM 1515-1, Futura Surgicare, Bangalore, India) was used and fixed in place with 2-0 monofilament polypropylene suture (DURACARE TS 841, Futura Surgicare, Bangalore, India). Subcutaneous fat was closed with interrupted sutures using 3-0 Polysorb^{TM} (SL-632, 93% polyglycolic and 7% polylactic, COVIDIEN^{TM}). Skin was closed with interrupted sutures using 3-0 Nylon (CENTLON CNW 3328, CENTENIAL Surgical Suture Ltd. Thane, India).
No drain was placed.

Endpoints:
The primary endpoint was to measure the wound infection (SSI) rate in the two groups at the end of one year as per definition of SSI by Centers for Disease Control and Prevention Guidelines 1999[18].
A superficial incisional surgical site infection (SSSI) is described as infection that occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision. A deep incisional SSI is described as infection that occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision[18].
Secondary endpoint was to determine factors related with post-operative complications.

Sample size:
Our sample size was based on 2 antecedent studies. One is case-control study that studied the role of prophylactic antibiotic use in elective inguinal hernioplasty[19] and another is a single blinded prospective randomized trial comparing local antibiotics to intravenous antibiotics in the prevention of superficial wound infection in inguinal hernioplasty[20].

Follow up:
Wound examination for SSI and monitoring of co-existing disease were performed daily up to time of discharge. Only non-steroidal anti-inflammatory agents with continuation of other medications for co-existing disease (non-antimicrobial) were prescribed. Dressings of the surgical incision site were changed 24 hours after the operation and sutures were removed at the first follow up visit.
Patients were followed up by a non-investigative surgeon/resident at intervals of one week after discharge from hospital and at one month after the first visit. Subsequent follow up was done at three monthly intervals till

completion of one year follow up period. Follow up consisted of standardized history taking and examination. The target objective of clinical examination at follow up was to detect surgical site infection (SSI) using the criteria defined by the Center for Disease Control and Prevention [18,21]. Patients were educated regarding signs and symptoms of wound infection and were advised to report to the surgical OPD anytime they experience a wound problem as cited in the information leaflet. Patients who did not return for follow up were contacted by telephone and called for physical examination.

Satistical analysis:

Data was presented as mean with standard deviation and analyzed using applicable statistical test viz. Chi-square test, Student *t*-test, Fischer exact test and multiple regression analysis as appropriate computed with IBM SPSS Statistics software for Windows®.

III. Results:

All patients gave informed consent for participation. Originally, 262 patients were enrolled into the study. Twenty seven patients were excluded from the study due to presence of one or more exclusion criteria.
Randomization was successful and baseline parameters viz. age, sex, duration of symptoms, hernia type, co-morbid factors etc. were similar between the study groups (Table 1).

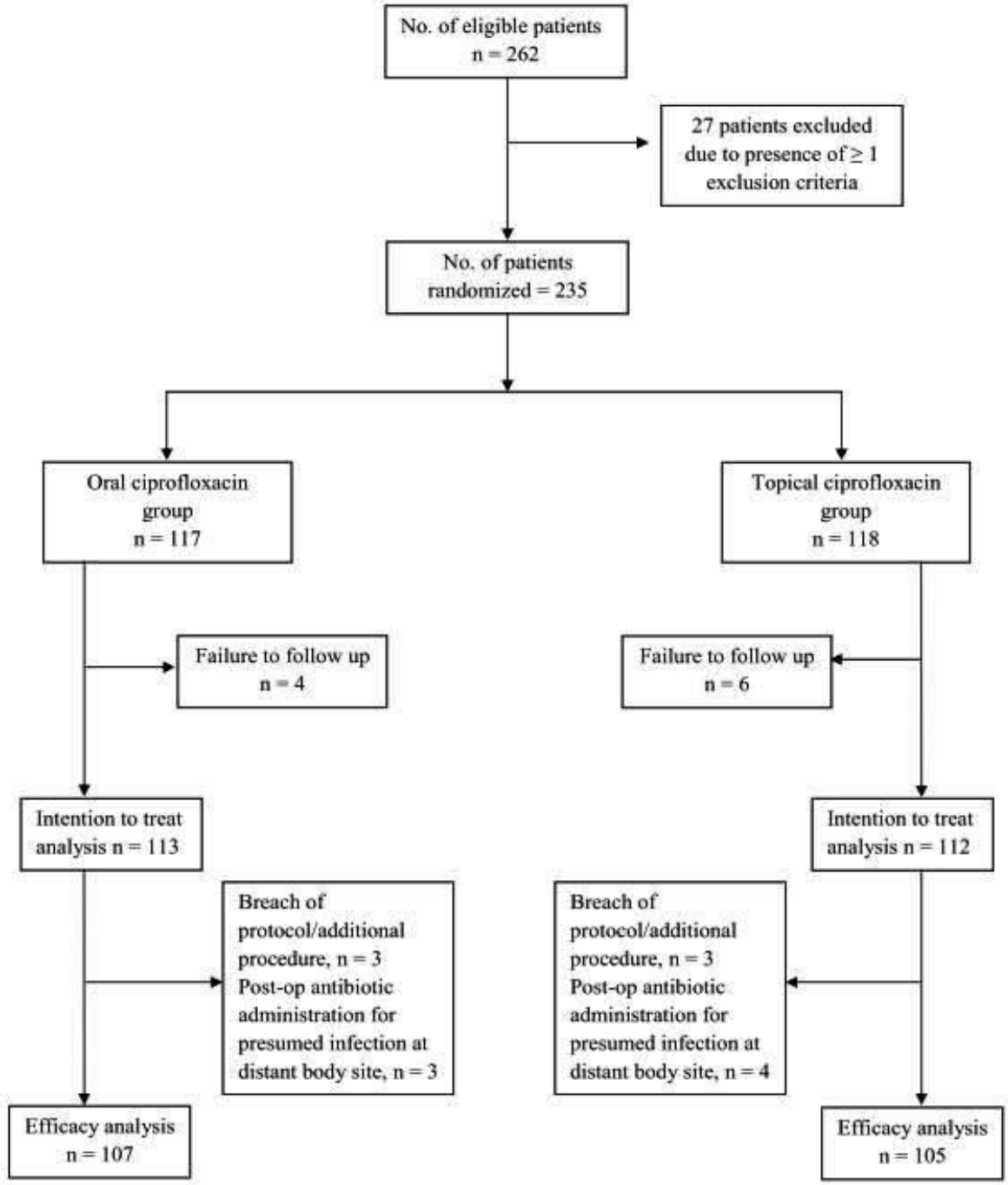
Table 1 - Pre-operative characteristics

Demographic variable	OC group (n=107)	TC group (n=105)	p value
Mean age (yrs), ± SD	53.2 ± 11.1	51.5 ± 11.4	1.14[b]
Sex (M/F)	97/10	93/12	0.619[a]
Mean BMI (Kg/M^2) ± SD	21.63± 1.76	22.05 ± 1.88	1.71[b]
Co-morbid condition	37	39	0.805[a]
DM	6	9	
HTN	14	11	
IHD	3	5	
COPD	6	8	
BPH	7	5	
Neuro. Dis	1 (post CVA)	1(PN)	
Duration of symptoms (months), ± SD	18.9 ± 2.7	19.03 ± 2.74	0.879[b]
Smoking	42	45	0.594[a]
ASA class			
I	55	57	0.764[a]
II	52	48	
Hernia localization			
Unilateral	99	101	0.248[a]
Bilateral	8	4	

SD – standard deviation, BMI – body mass index, DM – diabetes mellitus, HTN – hypertension, IHD – ischaemic heart disease, COPD – chronic obstructive pulmonary disease, BPH – benign prostatic hyperplasia, Neuro. Dis. - neurological disease, PN – peripheral neuropathy, CVA - Cerebrovascular Accident, ASA - American Society of Anesthesiologists. [a] = Chi square test, [b] = student *t* – test.

One hundred and seventeen patients were allocated to receive oral ciprofloxacin and 118 patients were allocated to receive topical ciprofloxacin.
Ten patients did not report after the first follow up visit and could not be contacted by telephone. The intention to treat population consisted of 225 patients. Two hundred and twelve patients, 107 from OCG and 105 from TCG were suitable for efficacy analysis (Figure 1).

Figure 1: Trend of patients through stages of the study



Post-randomization, 13 patients were excluded from analysis owing to violation of study protocol and development of infection at remote body site mandating antibiotic treatment (Table 2).

Table 2 - Profile of patients excluded from analysis

Reason for exclusion	**OC group**	**TC group**	**Total**
Failure to follow up	4	6	10
Post-op antibiotic administration for presumed infection at distant body site			
UTI (M:F/1:3)	1	3	4
RTI (M:F/3:0)	2	1	3

Breach of protocol			
Local anaesthetic infiltration	1	-	1
I/V antibiotic at induction	-	1	1
Different mesh material used	1	-	1
Additional procedure			
Circumcision	-	1	1
Hydrocoelectomy	1	1	2
Total no. of patients excluded			23

UTI – urinary tract infection, RTI – respiratory tract infection.

Majority of patients belong to the age group of 50 – 60 years. The types of hernia operated were, 51 direct hernias (24.05%), 154 indirect hernias (72.6%) and 7 (3.3%) combined hernias.
Eighteen percent (38/212) patients belong to overweight category. The shortest and longest durations of hernia were 3 months and 42 months respectively.
At operation, 46% (97/212) of hernial sacs were empty, 39% (83/212) contained omentum, 8% (18/212) contained small bowel along with omentum and 7% (14/212) contained only small bowel. Omentum adherent to the sac was seen in 16% (34/212) of cases for which partial omentectomy was performed along with primary hernia repair. No bowel resection was performed.
A total of 17 surgeons (6 consultants and 11 residents) and one medical officer were involved in the study. Almost 70% of the operations were performed by residents.
The mean operating time was 65.22 ± 17.51 minutes for OC group and 73.01 ± 15.56 minutes for TC group. This difference in length of operative time between the two groups was noted to be significant (Table 3, $p < 0.05$)
The mean in-hospital stay was 1.63 ± 0.59 days for OC group and 1.77 ± 0.54 days for TC group.
Operative characteristics were similar for both groups (Table 3).
Primary outcome (SSI) occurred in 13 patients (6 OC group + 7 TC group) and overall infection rate was 6.13%. All 13 patients had superficial SSI and none progressed to deep SSI or required wound debridement/re-exploration.
Twelve patients were males and only one female patient developed SSI. Four patients who developed SSI belong to overweight category.

Table 3 - Operative characteristics

Parameter	**OC group (n=107)**	**TC group (n=105)**	**p value**
Anaesthesia			
GA	40	28	0.076[a]
SA	67	77	
Incision length (cm)	6.62 ± 0.34	6.73 ± 0.31	0.015[b]
Operated by consultant surgeon	37	29	0.663[a]
Operated by resident	70	76	0.30[a]
Duration of operation (mins) mean, ± SD	65.22 ± 17.51	73.01 ± 15.56	0.001[b]
Duration of hospital stay (days) mean, ± SD	1.63 ± 0.59	1.77 ± 0.54	0.064[b]

SD = standard deviation, [a] = Chi Square Test, [b] = Student *t* – test

Altogether 7 unilateral indirect hernias, 4 unilateral direct hernias, 1 bilateral direct hernia and 1 combined hernia constituted the types of hernia in patients who developed SSI (Table 4).
Almost all patients were discharged on the first or second post-operative day and all SSI were diagnosed after discharge from hospital.
With exception of one case, all SSI were seen in cases operated by residents.

Table – 4 Profile of patients with primary outcome

OCG	Age	Sex	BMI	Symptoms (mo)	Hernia type	Co-morbid condition	Anaesthesia	Surgeon	Operation (mins)	Wound character	Infection Class	Diagnosed on POD	Culture report	Length of stay (days)
1	53	M	23.13	16	ID	DM	SA	Resident	66	Haematoma	SSSI	5	*E. coli*	8
2	61	M	23.11	11	ID	HTN	GA	Resident	53	Seroma	SSSI	4	-	7
3	73	M	23.04	22	ID	NIL	SA	Resident	69	Haematoma	SSSI	5	*S. aureus*	7
4	68	M	21.14	18	D (B/L)	BPH	SA	Resident	113	Haematoma	SSSI	4	*S. aureus*	10
5	56	M	19.53	5	ID	NIL	GA	Resident	54	Cellulitis	SSSI	5	-	6
6	57	M	22.14	8	D	DM	SA	Resident	48	Haematoma	SSSI	7	*S. aureus*	6
TCG														
1	66	M	23.1	13	D	COPD	SA	Resident	67	Haematoma	SSSI	6	*Klebsiella sp*	9
2	59	M	22.72	37	D	IHD	GA	Resident	91	Haematoma	SSSI	5	-	7
3	43	F	21.09	7	ID	NIL	SA	Resident	63	Seroma	SSSI	4	-	9
4	29	M	22.83	3	ID	NIL	SA	Resident	52	Haematoma	SSSI	7	*S. aureus*	6
5	64	M	20.11	19	D	DM + HTN	GA	CS	51	Seroma	SSSI	7	*S. aureus*	8
6	71	M	20.31	23	D + ID	BPH	SA	Resident	71	Haematoma	SSSI	5	*S. aureus*	11
7	48	M	22.12	4	ID	DM	SA	Resident	57	Cellulitis	SSSI	5	*S. aureus*	8

CS – consultant surgeon, POD – post-operative day, SSSI – superficial surgical site infection

Patients classified to have wound infection were re-admitted and microbial cultures of wound discharge/aspirations were performed.

In four cases, culture yielded no growth. However, empirical antibiotic treatment was initiated based on clinical judgment. Repeated cultures were negative and all SSI resolved completely with conservative management.

The most common organism isolated from wound swab cultures was *Staphylococcus aureus.*

E. coli and *Klebsiella sp.* were other organisms isolated in our study.

Secondary outcomes occurred in 37% of patients (Table 5).

The most frequent complication was post-operative urinary retention (15%). Six patients who had SSI also experienced urinary retention. Most of the patients who had urinary retention received spinal anaesthesia, aged > 60 years or had BPH as a co-morbid factor. Urinary retention was transitory and relieved with bladder catherization.

Post – operative haematoma formation was another secondary outcome that frequently occurred with SSI. About 8% (18/212) developed wound haematoma in the post-operative period. Eight cases (4 – OC group and 4 – TC group) were classified as infected. Non-infected cases were managed conservatively with anti-inflammatory agents, daily dressings +/- drainage.

Post-operative seroma formation and cellulitis was seen in 2% and 3% cases respectively. Management approach was similar to cases of haematoma.

Other secondary outcomes managed conservatively were hydrocoele (4%), groin pain (1.5%) and orchitis (1.4%).

Table 5 - Post-operative outcomes

Complication	OC group	TC group	p value	Total	Treatment
Urinary retention	18	13	0.438[a]	31	Bladder catheterization
SSSI	6	7	0.748[a]	13	Readmission, dressings, antibiotics ± drainage
Cellulitis	3	3	1.00[b]	6	4 - conservative 2 - antibiotics
Haematoma	10	8	0.652[b]	18	10 – conservative 8 - antibiotics
Seroma	2	3	0.682[b]	5	2 – conservative 3 - antibiotics
Groin pain	1	2	0.620[b]	3	Conservative
Hydrocoele	3	1	0.621[b]	4	Conservative
Orchitis	0	1	0.425[b]	1	Conservative
Recurrence	1	1	1.0	2	Reoperation

[a] = Chi Square Test, [b] = Fischer's Exact Test.

None of the patients with groin pain were adversely affected in their daily activities or experienced sexual dysfunction. Only one patient continued to have symptoms of inguinodynia beyond 3 months. The patient was managed with analgesics, physiotherapy, and referral to pain management specialty clinic with plan for surgical re-assessment.

Recurrence of hernia (1%) occurred in 2 patients, one from each study arm. One patient presented with recurrence after 4 months of operation and another presented 5 months after the operation. Both patients did not develop SSI till the time they presented with recurrence. Repair of recurrent inguinal hernia was performed in both patients.

The mean in-hospital stay was 7.84 ± 1.57 days for patients with SSI and 1.7 ± 0.56 for other cases. This difference in length of hospital stay between straightforward patients who had uneventful recovery and patients who developed SSI was noted to be significant ($p < 0.05$).

Risk factors thought to be associated with development of SSI were age > 60 years, coexisting diabetes mellitus, prolonged operation time (> 90 minutes), presence of hernia >1 year and development of haematoma in the post-operative period.

Using multiple logistic regression, factors thought to be associated with or contribute to development of SSI were evaluated (Table 5).

Table 5 – Regression analysis of factors associated with SSI

Factor	p value	Significance
Age > 60 yrs	0.11	NS
Diabetes mellitus	0.16	NS
Duration of symptoms >1 year	0.99	NS
Duration of operation > 90 minutes	0.37	Sig.
Presence of adhesion	< 0.001	Sig.
Haematoma	< 0.001	Sig.

Sig. = significant

The presence of adhesions within/around the hernial sac and formation of haematoma were factors found to increase the risk of developing SSI significantly.

There were no intra-operative complications/ICU admissions or mortality in our study.

IV. Discussion:

Literature in the area of antibiotic prophylaxis for hernia repair is replete with opposing reports. Randomized controlled trials by Aufenacker et al[22], Tzovaras et al[23] and Ergul Z et al[19] have not recommended the use of antibiotics for hernia repair. Whereas, a meta-analysis by Sanabria et al[24] and RCTs by Platt et al[25] and Yerdel et al[4] advocate the use of prophylactic antibiotics.

In vitro studies by Scherr et al[26] and Scherr and Dodd[27]demonstrated 100% kill rates using clinically easily achieved concentrations of antibacterials in irrigating solutions after a 60-second exposure of organisms[28]. The concentration of antibiotics that can be achieved in the wound far exceeds the concentration that can be obtained by optimal parenteral administration[29]. Antibiotic prophylaxis involves the administration of a drug before bacteria adhere to host tissues or host proteins in the surgical field or the reduction of the quantity of colonizing bacteria at that site[30, 31]. A single dose of antibiotics in perioperative prophylaxis may appear harmless, but there is always a risk of causing an allergic reaction or bacterial resistance[32]. About 30 – 50 %, of antibiotics in hospitals are administered for prophylactic purposes, their unnecessary use is also significant from an economic standpoint[33].

Mazaki et al[34], found that antibiotic prophylaxis is significantly effective for low risk patients and that antibiotic prophylaxis also decreased the incidence of other complication, whereas Aufenacker et al[22], opined that antibiotic prophylaxis is not indicated in low-risk patients. Both these authors followed up their patients for 3 months.

Wittmann et al[35] opined that the infection rates published in surgical series with focus on technique may underestimate infections rate by 50% and that the infection rates reported in most surgical studies are low and probably reflect the bias introduced by surgeons analyzing their own data.

Unclear definition of wound infection, bias and deficient post-discharge surveillance method are probable factors causing underreporting of infection rates.

With diminishing duration of inpatient stay and the increasing trend towards day and short-stay surgery, the incidence of infection after operation becomes difficult to determine and monitoring of SSIs after

patients have left hospital presents two challenges: first, to follow up all eligible patients and, second, to diagnose wound infection accurately in these patients[36].

The importance of an effective follow up process cannot be overemphasized.

A study on self-reported adverse events after groin hernia repair by Ulf Fränneby et al[37] where patients who underwent groin hernia were sent a questionnaire asking about complications within the first 30 postoperative days showed that 7.3% patients reported infection and 23.8% patients reported adverse events in the questionnaire whereas only 5.2% were affected according to the national hernia register.

In our study, patients were followed up to 1 year and prior to discharge they were given an information/instruction leaflet with contact details to report any symptom they experience. Ciprofloxacin has been used as an oral prophylactic agent in various types of surgery[13]. Orally administered antibiotics have variable absorption and hence less predictable serum bioavailability[38]. However, oral prophylaxis needs to be reconsidered following introduction of fluoroquinolones that are completely absorbed in the small intestine after oral intake[39-41].

Topical ciprofloxacin (ointment) has been validated to have antimicrobial properties. We supposed that ciprofloxacin solution also would possess similar antimicrobial property akin to other intravenous antibiotics as shown by some authors using locally applied gentamicin[20] and locally applied amikacin[42].

To the author's knowledge, this is the first study evaluating effectiveness of oral antibiotic in comparison with topical antibiotic for prophylaxis of SSI in open inguinal hernioplasty.

In our study, the time taken for operation was longer in the TC group as compared with OC group. We believe the additional 5 minute hiatus for allowing contact of antibiotic solution with tissues explains the prolonged operating time. Taylor et al[36] suggested that extended operating time and surgeon's experience does not influence the incidence of SSI.

In this study, we did not find female sex to be an independent risk factor for SSI as observed by Aufenacker et al[22]. Our study contained fewer female patients as compared to the study by Aufenacker et al. The number of female patients got further reduced after 3 patients were excluded from analysis due to antibiotic treatment in the post-operative period.

The drawbacks of our study were limited sample size; single center study and majority of patients being operated by residents. The infection rate of 6.13 % and recurrence rate of 1% reflected in this study may not be representative if equal number of patients were operated by consultant surgeons and residents or exclusively by consultant surgeons.

An audit on SSI after groin hernia repair by Taylor et al[36], showed infection rate ranging from 0 to 14·6 percent. O' Connor et al[9], pointed out that postoperative wound infections are costly, requiring antibiotic therapy, extra physician visits, time lost from work and even readmission to the hospital and Davey et al[43], showed that infection represents a significant problem in terms of health care expenditure. In our study, we did not carry out a cost benefit analysis between oral ciprofloxacin (tablet) and topical ciptofloxacin (infusion solution) because no financial expenditure was incurred by any patient since all medications and surgical materials used were hospital supplied resources.

History of smoking was documented, but smoking as an accompanying risk factor for SSI was not assessed due to unreliable history regarding duration of smoking and number of cigarettes smoked per day. Moreover, many patients used conventional cigarettes while others used *'bidi'* (a type of herbal cigarette made of unprocessed tobacco wrapped in leaves). These facts created a difficulty in determining and comparing the magnitude of impact of smoking on health.

This was a non-funded study carried out during routine practice. We speculate that return to follow up would have been enhanced if conveyance fee for follow up visit was compensated.

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