

Kumud Chapagain¹
 Rais Pokharel²
 Kumud K Kafle³
 Bimal K Sinha⁴

Department of Pharmacology, Nobel Medical College Teaching Hospital, Biratnagar¹

Department of Otorhinolaryngology, Koshi Zonal Hospital, Biratnagar²

Department of Pharmacology, Institute of Medicine, TUTH³

Department of Otorhinolaryngology and Head and Neck Surgery, IOM, TUTH⁴

Corresponding Author:

Dr. Kumud Chapagain

Department of Pharmacology, Nobel Medical College Teaching Hospital, Biratnagar

Email: kumudchapagain14@gmail.com

COMPARISON OF EFFICACY OF AMOXICILLIN AND CIPROFLOXACIN IN CLEAN CONTAMINATED EAR SURGERY DURING EARLY POST OPERATIVE PERIOD

Objective:

To compare the efficacy of amoxicillin and ciprofloxacin used in clean contaminated ear surgery during the early post operative period.

Materials and Methods:

It is a longitudinal, prospective study conducted at Department of Otorhinolaryngology and Head and Neck Surgery, TUTH from 1st April 2011 to 30th December 2011. Patient who underwent clean contaminated ear surgery were followed up on 1st, 3rd and 7th post – operative day (POD) and wounds were inspected for any signs of wound infection.

Results:

103 patients who underwent various clean contaminated ear surgeries were included in this study. Maximum patients were aged 14-29 years. Ciprofloxacin was prescribed to 80 (77.7%) patients and amoxicillin to 23 (20.3%) patients. Overall wound infection was present on 6.2% (5/80) patients receiving ciprofloxacin and on 4.34% (1/23) patients receiving amoxicillin. The most common procedure performed was MRM (53%). Wound infection was present in 9% (4/44) of patients undergoing MRM under coverage of ciprofloxacin and on 9% (1/11) patients under coverage of amoxicillin.

Conclusion:

Though the rate of wound infection was more in patient using ciprofloxacin than amoxicillin but it was not statically significant.

Key words: Efficacy, Clean-contaminated ear surgery, Antibiotics

INTRODUCTION:

Among surgical patients, wound infection is the most common nosocomial infection, accounting for 38% of all such infections.¹ The Centre for Disease Control and Prevention (CDC) for National Nosocomial Infection Surveillance (NNIS) system, reports Surgical Site Infections are the third most frequently reported nosocomial infection.¹ Prospective studies report SSI rates in range of 5-10% in clean-contaminated ear surgery.² When surgical patients with nosocomial infection died, 77% of the deaths were reported to be related to the infection and majority (93%) were serious infections involving organs or spaces accessed during the operation.¹ Patients with SSIs require a longer time in hospital, more nursing care, and additional dressings and in some cases, readmission to the hospital and further surgery.^{3,4} Prophylaxis with antimicrobials has decreased the risk, however even the best operative techniques and appropriate antibiotic have not completely eliminated this problem. There is no current evidence showing that there is any antibiotic in any regimen which can contribute to reducing complications in any type of clean contaminated surgical procedure in ear.^{5,6} In a developing country like in Nepal, the emerging trend to use higher, newer and more expensive antibiotic has not only been a financial burden to the patient but also studies regarding their efficacy is still a continuous process. Moreover, we have no data regarding the early post operative wound infection rates following the use of amoxicillin and ciprofloxacin. This study aims to determine the efficacy of antibiotics amoxicillin and ciprofloxacin in preventing early post operative wound infection and to assess whether there is any need for replacing these antibiotics with newer, higher and more expensive ones.

MATERIALS AND METHODS:

It is a prospective, longitudinal study conducted at Department of Otorhinolaryngology (ORL) and Head and Neck Surgery, Ganesh Man Singh (GMS) Memorial Academy of ENT and Head and Neck Studies, TUTH from 1st April 2011 to 30th December 2011. Patients were prescribed either amoxicillin or ciprofloxacin in early post operative period in patients undergoing clean contaminated ear surgery according to the antibiotic protocol regimen followed in otology unit. Dosage regimen was ciprofloxacin 500 mg, starting the first dose night before surgery, followed by two times a day for 7 days and amoxicillin 500 mg, starting the first dose night before surgery, followed by three times a day for 7 days. Informed consent was taken before enrolling the patient into the study. All patients were followed up in 1st, 3rd and 7th day respectively for any signs of wound infection. Data collection was done using the pre-validated proforma proposed by Cutting and Harding which was later validated by Gardner and colleagues.

RESULTS:

Total of 103 patients were included in the study. 50 patients were males and 53 were females. Table 1 shows the detailed age groups of patients.

Tab.1: Age distribution of patients undergoing clean contaminated ear surgery

Age	14-19 years	20-29 years	30-39 years	40-49 years	50-59 years
Total No:	40	32	21	8	2

Majority of our patients were within 14-29 years. Ciprofloxacin was prescribed to 80 (77.7%) patients and amoxicillin to 23 (20.3%) patients. Modified Radical

Mastoidectomy (MRM) was the most common surgery performed (53%). Table 2 shows the different surgeries performed and the respective antibiotics prescribed.

Serous discharge from the surgical site manifested as soakage of the bandage followed by pus discharge was the most common presentation of wound infection.

Tab.2: Surgery performed and antibiotics prescribed in clean contaminated ear surgery

Surgery performed	n=103	Recommended Antibiotics	Prescribed Antibiotics	n	%
MRM	55	Ciprofloxacin Amoxycillin	Ciprofloxacin Amoxycillin	44 11	80 20
Myringoplasty with fascia with cartilage	11 24	Amoxycillin Ciprofloxacin	Amoxycillin Ciprofloxacin	11 24	31.4 68.6
PSRP Excision	6	Ciprofloxacin	Ciprofloxacin	6	100
Tympanoplasty	2	Ciprofloxacin Amoxycillin	Ciprofloxacin Amoxycillin	1 1	50 50
TORP with grafting	1	Ciprofloxacin	Ciprofloxacin	1	100
Stapedotomy	2	Ciprofloxacin	Ciprofloxacin	2	100
Ossiculoplasty	1	Ciprofloxacin	Ciprofloxacin	1	100
Mastoid exploration	1	Ciprofloxacin	Ciprofloxacin	1	100
Total	103			103	100

Same rate of wound infection, 9% (4/44) and 9% (1/11) was observed in patient receiving amoxicillin and ciprofloxacin following MRM respectively. None of the patient undergoing myringoplasty had wound infection. Table 4 shows the incidence of wound infection following the respective surgeries.

Tab. 3: Clinical feature of patients with wound infection on 1st, 3rd and 6th POD

Clinical feature	AMX n=1	Cipro n=5	Surgery performed	1st POD	3rd POD	6th POD
Serous discharge (soakage of the bandage)	0	3	MRM (n=2)	Present (n=1)	Absent	Absent
				Absent	Present (n=1)	Absent
			Mastoid exploration (n=1)	Absent	Present	Absent
Pus from wound + Wound swelling	0	1	MRM	Absent	Absent	Present
Pus from wound + Wound gap	0	1	MRM	Absent	Absent	Present
Wound gap	1	0	MRM	Absent	Absent	Present

Fishers exact test showed that wound infection following the use of amoxicillin and ciprofloxacin was statistically not significant ($p > 0.05$).

DISCUSSIONS:

In this study, 103 patients undergoing clean – contaminated ear surgery were evaluated for any signs of wound infection in the early post operative period.

Tab.4: Incidence of wound infection following different types of ear surgery

Surgery performed	Ciprofloxacin n = 80	Wound infection n = 5	%	Amoxycillin n = 23	Wound infection n=1	%
MRM	44	4	9.0	11	1	9.0
Myringoplasty	24	0	0	11	0	0
PSRP Excision	6	0	0	-	-	-
Tympanoplasty	1	0	0	1	0	0
TORP with grafting	1	0	0	-	-	-
Stapedotomy	2	0	0	-	-	-
Ossiculoplasty	1	0	0	-	-	-
Mastoid exploration	1	1	100	-	-	-
Total	80	5	6.2	23	1	4.3

Our study showed that higher proportion (70%) of these surgeries was performed among the young age groups (14-29 years). Similar reports have been reported in a study conducted by Salman A and Azhar where the majority of patients (52%) were in the age group of 16-30 years.⁷ The most common surgery performed in clean contaminated ear surgery was modified radical mastoidectomy (MRM). According to the antibiotic treatment protocol followed in otology unit, ciprofloxacin and amoxicillin were the recommended antibiotics for patients undergoing MRM. However, as the assisting surgeon decided the antibiotic to be prescribed. It was observed that the use of amoxicillin was less compared to the use of ciprofloxacin. This may be due to the fact that gram negative microbes such as *Pseudomonas pyocyanea* and *Proteus mirabilis* are commonly found in most middle ear secretions because of super infections originating from external canal. Ciprofloxacin is preferred in this situation.⁸

The most common presentation of wound infection in patients undergoing clean contaminated ear surgery was serous discharge (67%) from the surgical site manifested as soakage of the bandage followed by pus discharge (33.3%). This has been regarded as one of the most important criteria for diagnosing wound infection.⁹ This finding is consistent with the study conducted in Cleveland by Peel et al.¹⁰ Study conducted by Wilson et al¹¹ also revealed serous exudates as the most common manifestation of wound infection. Serous discharge following clean contaminated ear surgery was commonly observed on 1st, 3rd POD. This is contradictory to Mark K Wax's 13 findings where serous discharge was commonly observed on 5th–7th POD. Mark K Wax's also states that though serous discharge are commonly observed on 5th- 7th POD, any discharge from closed surgical wound after 48 hours of closure is of concern. Most of the signs of wound infection in this study were observed on the 6th POD. This is consistent with Mark K Wax's findings where most of the signs of wound infection were observed on 5th-7th POD.¹² In patient using amoxycillin, post operative wound infection rate was 4.3% in all types of clean contaminated ear surgery and 6.2% in patient using ciprofloxacin. However, wound infection rate was same in patients undergoing MRM under coverage of ciprofloxacin (9%) and amoxycillin (9%). Thus, amongst all the patients undergoing clean contaminated ear surgery, post operative wound infection was found to be

present in 5.8% of the patient. This finding is consistent with the findings of the study performed by Govaerts PJ where the wound infection rate following clean contaminated ear surgery ranged from 5% -10%.

CONCLUSIONS:

Though the rate of wound infection was more in patient using ciprofloxacin than amoxicillin but it was not statically significant. In MRM larger number of patients received ciprofloxacin than amoxycillin, however presented with the same rate of wound infection. One of the limitations of this study is small sample size and limited study period. To come to a statistically significant conclusion larger sample size over a longer duration would be needed.

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