ORIGINAL ARTICLE

Topical vs Combination Ofloxacin in the Management of Discharging Chronic Suppurative Otitis Media

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ABSTRACT

Aim: To assess the effectiveness of topical ofloxacin ear drops in comparison with combination of topical and oral ofloxacin as the first line management among patients with chronic suppurative otitis media.
Methods: It was prospective randomized interventional clinical trial in which 50 patients with severe episode of chronic suppurative otitis median (CSOM) visiting outpatient department were included.
Results: Among 100 patients, 60.0% were males and 40.0% were females. Pseudomonas aeruginosa was most prevalent organism isolated from forty five patients and Klebsiella from thirty patients. These all organisms were sensitive to Ciprofloxacin.
Conclusion: During systemic infectivity absence or acute underlying disease, the topical antibiotics alone comprise first line therapy for most of the patients with CSOM, finding no confirmation that systemic antibiotics alone or in combination with topical preparations enhance treatment outcomes compared with topical antibiotics alone.
Keywords: Ofloxacin, Topical, Oral, CSOM

INTRODUCTION

The prevalence of CSOM seems to depend upon the race as well as socioeconomic factors. The socioeconomic factors, for example, overcrowding, poor living environment, poor nutrition and hygiene are considered leading factors for extensive prevalence of chronic suppurative otitis media[1].

Transformations in microbiological flora after introduction of the sophisticated synthetic antibiotics boost the significance of reevaluation of current flora in chronic suppurative otitis media and their sensitivity pattern of in vitro antibiotic is most significant for doctor to design treatment broad outline for patients with persistently discharging ear[2].

There is an increasing concern regarding systemic antibiotics use and bacterial resistance development. The doubt continues as to whether ototopical medicines could also encourage antibiotic resistant bacteria in ear on local level. This research was carried out due to antibiotics resistance increasing rates in the country.

The current study is intended to find out the organisms lead to chronic suppurative otitis media through acquiring ear swab for the culture and sensitivity and through treating patient with topical or combination ofloxacin. Response to therapy is investigated and examined.

MATERIALS AND METHODS

It was a time bound cross-sectional study in which 50 patients visiting ENT (Ear Nose Throat) OPD (Outpatient Department) of Avicena Medical College were included. The study was carried out from January 2016 to June 2016 among patients with severe episode of chronic suppurative otitis media. The patients were selected according to inclusion and exclusion criteria. The respondents with active ear discharge were counseled regarding their health condition and informed consent was taken before conducting the study.

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Inclusion criteria

- Patients aged 15 years and above
- Mucopurulent ear discharge >4 weeks with central TMP (tympanic membrane perforation).
- Participants with sensitivity to ofloxacin (Tested by culture sensitivity of the discharge).

Exclusion criteria

- Acute perforation (< 28 days) of the tympanic membrane (severe otitis media)
- Recognized allergy to benzalkonium chloride or quinolone (preservative)
- Major chronic diseases, for example, tuberculosis and diabetes mellitus
- Immunodeficiency known cases
- Atticoantral kind of CSOM
- Impending difficulties
- Otomycosis
- In middle ear, presence of large aural polyp
- Have taken antibiotic treatment in the target ear during last month
- Ear surgery during last year
- Severe traumatic perforation
- Grommet presence
- Pregnant/lactating women
- Recognized hepatitis and severe or persistent renal failure
- Symptomatic conditions, for example, chronic sinusitis, otitis externa, chronic pharyngitis needing systemic antibiotic treatment that may impede with the assessment of the study drugs

After that patients were divided into two groups through random sampling technique:

Group-A: Topical ofloxacin ear drops treatment for 2 weeks.

Group-B: Combination of oral ofloxacin and topical for 2 weeks

To record proper data of each patient during his first visit, a pretested proforma was utilized. Aural discharge was taken with conservative sterile swab avoiding contact with external auditory canal utilizing an uncontaminated aural speculum. Immediately, the collected samples were taken to microbiology test lab. These samples were first put in a glucose broth and then inoculated in the Mac Conkey agar (differential medium) and blood agar (enriched medium) and after that were cultured for twenty four hours. Primary colony of cultured bacteria was recognized through biochemical and gram stain tests. The isolates culture and sensitivity was assessed through Kirby–Bauer disk diffusion technique.

After that, every patient was allocated randomly to study group through means of a lot. For Group-A, three drops of ofloxacin ear drops were used in affected ear three times a day for fourteen days. In Group-B, three drops of combination of topical ofloxacin were used three times a day and ofloxacin tables (500mg) two times a day administered for fourteen days.

Patients were advised to avoid water entry in the affected ear and dry mopping prior to instilling ear drops. The correct method was advised to patients about instilling with intermittent tragal pressure.

On next visit, 2 weeks post-treatment, patient compliance was evaluated and described through numbers of times patients was unable to remember to use medicine during 2 weeks such as Good (0 to 3), Moderate (4 to 7) and Poor (more than 7)[4]. The patients who were non complaint (moderate & poor) were replaced with new cases to complete sample size. A complete evaluation regarding ear discharge was performed objectively and subjectively and repeat ear culture and the sensitivity test was carried out if there was still drainage.

"CURED"[4] was described as nonexistence of the otorrhea or otoscopically dormant (no discharge pooling; non swollen middle ear mucosa) or existence of serous mucous otorrhea with bacteriological culture negative after therapy period.

After 2 weeks of treatment, either group patients who cured but yet have chronic otorrhea were continued helpful anti inflammatory agents for further one week and assessed at the end of third week. The final

After 2 weeks of treatment, among group-A patients who were found uncured continued ofloxacin ear drops (if yet susceptible to the ofloxacin) or altered to a systemic antibiotic (if no longer susceptible to the ofloxacin) for further one week and assessed at the end of third week. Latter was named as "CLINICAL FAILURE". On third visit, if patients who continued ear drops and yet not alleviated of otorrhea were categorized like "CLINICAL FAILURE" and altered to a systemic antibiotic as per test report of culture and the sensitivity.

After 2 weeks of treatment, among group-B patients who were found uncured continued combination therapy (if susceptible to the ofloxacin) or altered to a systemic antibiotic (if no longer susceptible to the ofloxacin) for further one week and assessed at the end of third week. Latter was named as "CLINICAL FAILURE". On third visit, if patients who continued ofloxacin combination therapy and not alleviated of otorrhea were categorized as "CLINICAL FAILURE" and altered to another systemic antibiotic which was taken alone as per test report of culture and the sensitivity.

Keeping out the participants who cured or selected for surgical treatment, all other participants were followed up at eighth week for recurrence or resolution of symptoms. After treatment, bacteriological and clinical developments were due to adequate analysis. The categorical data was analyzed through chi square test and Z-test was applied for the proportions between both groups. The withdrawal criteria were medication intolerance and failure to follow-up during study.

RESULTS

The study was carried out among patients aged 18 years and above and found that patients were between the ages of 20-69 years. Among 100 patients, 60.0% were males while 40% were females. Among patients, 67 had unilateral chronic suppurative otitis media and 33 had bilateral chronic suppurative otitis media. Therefore, during study total 133 ears were examined. Among patients, Pseudomonas aeruginosa was most prevalent organism isolated from forty five patients and Klebsiella from thirty patients. These all organisms were sensitive to Ciprofloxacin.

Table: Comparison of various treatment options

Study	**Drugs administered**	**%age of patients with dry ears**
Kasemsuwan et al[10]	Ciprofloxacin ear drops	Ciprofloxacin-84 Controls-12.5%
Macfadyen et al[11]	Ciprofloxacin ear drops Tobramycin ear drops	Ciprofloxacin47.4% Tobramycin 23.5%
Jaya et al[12]	Ciprofloxacin ear drops Povidone iodine ear drops	Ciprofloxacin 90% Povidone iodine 88%
Eposito et al[13]	Ciprofloxacin oral Ciprofloxacin tropical	Ciprofloxacin oral 40% Ciprofloxacin tropical 85%
Present study	Ciprofloxacin ear drops Combination of oral and topical ciprofloxacin	Ciprofloxacin ear drops 6% Combination Ciprofloxacin 60%

DISCUSSION

Study found that topical antibiotics are as effectual as the oral antibiotics. A greatly higher strength of antibiotic mixture can be given to infection site through topical administration.[7] Lethality and bactericidal of bactericidal kill of the quinolones is gradually improved through third degree to which delivered intensity surpasses the MIC (minimum inhibitory concentration). The probability for emergence appears to be greatly lesser if topical administration routes are utilized as compared to drugs which are systemically administered[8]. Additionally, the topical agents usage allows for concurrent change of local microenvironment. In acidic medium, antibiotic administration helps in restoring and fortifying normal host resistance mechanism, hence antibiotics increase efficacy is used.[9] Another topical delivery systems character is

nonexistence of the systemic effects. For the reason that no substantial systemic delivery of the topically given agents takes place, the common flora in gastrointestinal and respiratory tracts is unexposed to the antibiotics.[3] Generally, the antibiotics are less costly than the systemic medicines, hence decreases the treatment cost.

Oral antibiotics may be of great use if systemic effect of the drug is required like among CSOM patients with associated chronic or acute rhinosinusitis, pharyngitis, adenotonsillitis, and URTI (upper respiratory tract infection).[14]

CONCLUSION

Study concluded that Pseudomonas aeruginosa was most prevalent organism isolated followed by Klebsiella while the topical ciprofloxacin was an effective combination of the topical and oral ciprofloxacin ear drops, hence the probability of reemergence was found to be more when the topical ear drops were utilized as sole agent in first line administration of discharging persistent supportive otitis media.

REFERENCES

1. M Kiris, M Berktas, E Egeli, et al. The efficacy of topical ciprofloxacin in the treatment of chronic suupurative otitis media. Ear Nose Throat J. 1998;20(77):904–5. [PubMed]
2. SM Wintermeyer. Efficacy of ototopical ciprofloxacin in paediatric patients with otorrhea. American Academy of Otolaryngology – Head and Neck Surgery. 1997;116(4):450–3. [PubMed]
3. GH Ettehad, S Refahi, A Neemati, A Pirzadeh, A Daryani. Microbial and antimicrobial susceptibility patterns from patients with chronic otitis media in Ardebil. International Journal of Tropical Medicine. 2006;1(2):62–5.
4. JM Loy, AL Tan, PKS Lu. Microbiology of chronic suppurative otitis media in Singapore. Singapore Medical Journal. 2002;43(6):296–99. [PubMed]
5. AA Gul, L Ali, E Rahim, S Ahmed. Chronic suppurative otitis media – frequency of pseudomonas aeruginosa in patients and its sensitivity to various antibiotics. Professional Medical Journal. 2007;13(3):411–15.
6. VK Poorey, A Iyer, R Kalra. Study of bacterial flora in CSOM and its clinical significance. Indian Journal of Otolaryngology and Head and Neck Surgery. 2002;54(2):91–5. [PMC free article] [PubMed]
7. P Supiyaphun, K Tonsakulrungruang, L Chochaipanichnon, et al. The treatment of chronic suppurative otits media and otits externa with 0.3 % ciprofloxacin otic solution: a clinicomicrobiological study. J Med Assoc Thai. 1995;78:18–21. [PubMed]
8. N Micro, HS Sharma. Controlled multicenter study on chronic suppurative otits media treated with topical applications of ciprofloxacin 0.2% solution in single dose containers or combination of polymyxin B, neomycin and hydrocortisone suspension. Otolaryngol Head Neck Surg. 2000;123:617–23. [PubMed]
9. Dohar, C M Alper, A Elizabeth, W J Doyle. Treatment of Chronic Suppurative Otits Media with topical Ciprofloxacin. Ann Otol Rhino Laryngol. 1998;107:865–71. [PubMed]
10. L Kasemsuwan, P Clongsuesuek. A double blind prospective trial of topical ciprofloxacin versus normal saline solution in the treatment of otorrhea. Clin Otolaryngol Allied Sci. 1997;22(1):44–6. [PubMed]
11. CA Macfadyen, JM Acuin, Gamble, et al. Systemic antibiotic versus topical treatments for chronically discharging ears with underlying eardrum perforations. Cochrane Database Syt Rev. 2006;1 [PubMed]
12. C Jay, A Job, E Mathai, B Antonisamy. Evaluation of topical povidoneiodine in chronic suppurative otitis media. Arch Otolaryngol Head Neck Surg. 2003;129(10):1098. [PubMed]
13. S Eposito, S Noviello, G D'Errico, C Montanaro. Topical and oral treatment of chronic otitis media with ciprofloxacin. Arch Otolaryngol Head Neck Surg. 1990;116(5):557. [PubMed]
14. C Nawabusi, FE Ologe, PKS Lu. Pathogenic agents of chronic suppurative otitis media in Ilorin Nigeria. East African Medical Journal. 2002;79(4):202–05. [PubMed]