Value of ciprofloxacin/dexamethasone ear drops after tympanostomy tube insertion in children: Randomized Clinical Trial

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ABSTRACT

Aims: to assess the value of ciprofloxacin/dexamethasone ear drops after tympanostomy tube insertion in children.

Settings and Design: This prospective randomized controlled trial was conducted on children who had persistent bilateral otitis media with effusion for > three months, scheduled for bilateral myringotomy and Grommet tube insertion .

Methods and Material: Myringotomy was performed using a standardized technique under general anesthesia then ciprofloxacin/dexamethasone drops were applied in three different manners, then patient were following up for three months.

Statistical analysis used: Parametric data was analyzed using the unpaired t-test, while the Mann-Whitney U test was used for non-parametric data analysis. For categorical data analysis, the Chi square test or Fisher's exact test was used as appropriate. P value of <0.05 was considered statistically significant.

Results: Within included 56 patients (112 ears); 19 with unilateral intraoperative drops application, 19 with unilateral intraoperative and postoperative drops application, and 18 with intraoperative and postoperative drops application in both ears. The incidence of otorrhea were lower in the ears that had only intraoperative ear drops than those with no ear drops, and the incidence of otomycosis were lower in the ears that had only intraoperative ear drops than those had both intraoperative and postoperative ear drops. But those differences were non-significant .

Conclusion: Application of ciprofloxacin and dexamethasone intraoperative after grommet tube insertion for persistent otitis media with effusion reduces the complication rate but this was not found statistically significant.

Key words; Ear drops, Tympanostomy tube, Persistent otitis media

INTRODUCTION

Otitis media with effusion is one of the most common ENT conditions seen all over the world. Myringotomy and grommet insertion are one of the most common surgical indications for routine hospitalization of children.[1] The most common postoperative complication associated with myringotomy and grommet insertion is otorrhea.[2,3]

Postoperative blockage has been estimated to occur in up to 10% of cases. In most instances, the blockage occurs in the early postoperative period and may be associated with transient otorrhea that occurs in 16% of patients.[4] Although a well-described clinical problem, only a few methods have been described to prevent and treat blocked tubes.[5] The combination of ciprofloxacin and dexamethasone ear drops for five days after surgery has proved to reduce early post-operative otorrhea in comparison to no treatment.[6] However, some prolonged application of ear drops ciprofloxacin and dexamethasone can cause fungal infection.[7,8] This may lead us to thinking in using of these drops as a single postoperative application, but to our knowledge, no study was conducted on the single intraoperative application of ear drops as a prophylactic agent against otorrhea and tubal blockage after myringotomy tube insertion.

Thus, the current study aimed at assessment of the value of ciprofloxacin/dexamethasone ear drops after tympanostomy tube insertion in children

SUBJECT AND METHODS

Study Population

This is a prospective randomized controlled trial conducted on 60 children with the following criteria: Egyptian, age range is three to 12 years, having persistent bilateral secretory otitis media for more than three months with failed successive medical treatment trials, admitted for doing bilateral myringotomy and

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Grommet tube insertion. We excluded unilateral cases, recurrent cases after previous myringotomy, history of otorrhea or perforated TM. Also, cases with Intraoperative finding of absence of middle ear effusion or presence of suppuration in the middle ear were excluded from the study. Ethical committee approval was obtained.

Study Design

Myringotomy was performed using a standardized technique under general anesthesia. After removal of the cerumen or debris from each patient ear canal with suction and/or crocodile, incision was made with a myringotomy knife at the antero-inferior region of the tympanic membrane, then the effusion in the middle ear cavity was suctioned. The contents were classified as thin serous or thick mucoid discharge, cases with dry middle ear or purulent effusion were excluded. Shepard tube was inserted in all cases after suction and irrigation of the middle ear content.

The ear drops used in the study are combination of ciprofloxacin 0.3%/dexamethasone 0.1%. It has been manufactured in the form of ear drops (CIPRODEX®, Alcon, Ft. Worth, TX). If the ear drops were applied intraoperatively, they were used in the form of three to four drops placed in the external ear canal after insertion of the tube and before anesthesia was discontinued. If the ear drops were applied postoperatively, the mother is instructed to apply it in the form of three to four drops three times a day for five days.

Randomization

After written consent was obtained from the parents the children, they were randomized to one of the following **three groups of patients**: 1st group, 20 patients, had applied the ear drops as a single intraoperative dose in one ear (10 right ears and 10 left ears) and no ear drops in the other ear. 2nd group, 20 patients, had applied the ear drops both intraoperatively and postoperatively in one ear (10 right ears and 10 left ears) and no ear drops in the other ear. 3rd group, 20 patients, had applied the ear drops both intraoperatively and postoperatively in one ear (10 right ears and 10 left ears). By this way, we included 120 ears in this study randomly divided into three **groups of ears**, each group is formed of 40 ears (20 right ear and 20 left ear). The first group was formed of ears without ear drops usage, the second group was formed of ears with only intraoperative application of ear drops, the third group was formed of ears with both intraoperative and postoperative application of ear drops.

Outcome parameter and definition

All patients received postoperative oral antibiotics for one week and the patients were followed up weekly for a month then monthly. The family was instructed for water precautions and periodic follow up. Also, they were instructed to return if otorrhea or upper respiratory tract infections occurred. Three months after surgery, evaluation was performed clinically by oto-endoscopic examination and the following parameters were assessed in each ear: presence or absence of otorrhea, tubal blockage, otomycosis, premature tube extrusion, recurrent OME, and TM perforation. Otorrhea was considered if it was reported in any follow up visit during the period of follow up other parameters are assessed three months after surgery. Tubal blockage and recurrent OME are confirmed, when suspected clinically, by performing tympanometry.

Statistical analysis:

Parametric data was analyzed using the unpaired *t*-test, while the Mann-Whitney *U* test was used for non-parametric data analysis. For categorical data analysis, the Chi square test or Fisher's exact test was used as appropriate. P value of <0.05 was considered statistically significant.

RESULTS

Fifty-six patients completed the follow up period and four patients did not complete the follow up and so they were excluded from the study. Thus, the study included 19 cases with unilateral intraoperative application of the ear drops, 19 cases with unilateral intraoperative and postoperative application of the ear drops, and 18 cases with intraoperative postoperative application of the ear drops in both ear. So that the total number of observed ears after the follow up period was 112 divided into three groups of ears: 38 ears in the 1st group, with no ear drops, 37 ears in the 2nd group, with intraoperative application of ear drops, and 37 ears in the 3rd group, with intraoperative and postoperative ear drops (table 1). Adeno-tonsillectomy was done for all included patients.

At the end of the follow up period (three months), the incidence of otorrhea were lower in the ears that had only intraoperative ear drops than those with no ear drops, and the incidence of otomycosis were lower in the ears that had only intraoperative ear drops than those had both intraoperative and postoperative ear drops. But this difference was non-significant. No significant difference between the three ear groups in the incidence of tubal blockage, extrusion with residual TM perforations. No sensorineural hearing loss appeared postoperatively in any patient within the follow up period.

Table 1: The demographic distribution of the patients in different groups

	No ear drops	Intraoperative applications of the ear drops	Both intraoperative and postoperative	Total	P value
Number of ears	38	37	37	112	
Side (Right/Left)	20/18	17/20	19/18	56/56	0.8286 (X=0.376) NS
Age (Mean ±SD)	5.8421 1.98	5.89 1.9	6.0544 2.1	5.92 2	0.8009 (F= 0.225) NS
Sex (Male/Female)	22/16	19/18	17/20	58/54	0.58 (X=1.076) NS

NS =non-significant

Table 2: Comparison of the complication distribution of the patients in both groups

	No ear drops (n= 38)	Intraoperative ear drops (n=37)	Intraoperative and postoperative ear drops (b=37)	P value
Otorrhea	7/37	2/37	4/37	0.2 (X=3.13) NS
Blockage	4/38	1/37	0/37	0.07 (X=5.272) NS
Otitis externa and/or otomycosis	2/38	2/37	5/37	0.44 (X=1.638) NS
Persistent TM perforation	1/38	0	1/37	0.6 (X=1.005) NS

NS =non-significant

DISCUSSION

The prevalence of otorrhea ranges from 3% to 74%.[4,6] Otorrhea can cause tubal blockage, the prevalence of tubal blockage after myringotomy was reported from 1.4% to 36% of cases.[1,5,9]

Many interventions were described to reduce the risks of otorrhea and tubal blockage, such as prophylactic antibiotic,[2,10] saline irrigation,[11-13] and antibiotic ear drops.[4]

Postoperative application of ear drops has been supported by some studies. Application of aminoglycoside containing ear drops after surgery was described to prevent otorrhea.[13,14] Adding dexamethasone to aminoglycoside containing ear drops after myringotomy surgeries has been proven in some studies as an effective measure against postoperative otorrhea [13,14] but topical aminoglycosides have a theoretical risk of ototoxicity and should be used with caution.[14]

Thus, ototoxic effect of these drops is a challenge that should be considered; however, basic science and research studies have shown no evidence of ototoxicity with ciprofloxacin or ofloxacin.[13,14]

Ear drops containing quinolones and dexamethasone have been described in literature also for the same issue.[6,15,16] some described as a repeated postoperative application for 5 days.[6]

We think that single application may be sufficient and less costly and avoid the risk of contamination of ear drops or transmission of external skin infection to the ear, also may cause fungal infection. To our knowledge, no study on the effect of single application of ciprofloxacin and dexamethasone intraoperative in these surgeries, also no study focusing on the prevalence of secondary otitis externa and fungal infection after using of prophylactic antibiotic ear drops.

The results of the current study showed less incidence of Grommet tube complication with the topical ciprofloxacin/dexamethasone ear drops that are near the results of some previous studies.[6,17,18] But they did not compare in same patient in different ears.

From the results of the current randomized controlled trial, application of ciprofloxacin and dexamethasone intraoperative after grommet tube insertion for persistent otitis media with effusion decreases the complications but this was not found statistically significant. However, further multi-centers study on a large number of cases is recommended.

CONCLUSION

Application of ciprofloxacin and dexamethasone intraoperative after gromet tube insertion for persistent otitis media with effusion reduces the complication rate but this was not found statistically significant. Thus,

further multi-centers study on a large number of cases is recommended.

Key message: The most common postoperative complication associated with myringotomy and grommet insertion is otorrhea. Intraoperative application of ciprofloxacin and dexamethasone reduces the complication rate after grommet tube insertion for persistent otitis media with effusion, but this was not found statistically significant.

Declarations:

Consent for publication: Not applicable

Availability of data and material: Data are available upon request.

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