Prophylactic ciprofloxacin drops after tympanostomy tube insertion

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ABSTRACT

Objective: To evaluate the effectiveness of prophylactic ciprofloxacin drops in decreasing the incidence of post-tympanostomy otorrhea, and the relation between middle ear content and post-tympanostomy otorrhea.

Methods: One hundred and fifty patients aged 3-14 years underwent tympanostomy and tube insertion at the Prince Rashid Ben Al-Hasan Hospital, Al-Husn, Jordan during the interval between February 2000 to January 2003. The patients were randomized into 3 groups: group 1 (control group) received no antibiotic drops, group 2 received a single dose of ciprofloxacin drops intraoperatively and group 3 received an intraoperative dose followed by 5-day postoperative course.

Results: Application of topical ciprofloxacin after tympanostomy tube insertion was associated with a significantly lower incidence of early post-tympanostomy otorrhea. The rate of otorrhea for the control group was 16.5% and the treatment groups were (group 1) 8.4%, (group 2) 8.2% and p=0.011. A single dose of antibiotics was effective when patient's middle ears were dry or had serous effusions. For those whose ears had mucoid or purulent content a 5-day course was indicated.

Conclusion: Topical administration of a single dose of ototopical ciprofloxacin after surgery is an effective treatment for the prevention of early post-tympanostomy otorrhea, and a prolonged course (5 days) may be indicated for those whose ears had purulent or thick mucoid contents, and the content of middle ear are important in predicating postoperative otorrhea.

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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] In the United States of America, one million myringotomy and grommet are performed annually.[2] The most common postoperative complication associated with myringotomy and grommet insertion is otorrhea, which reportedly occurs in 6-40% of cases.[3,4] Ciprofloxacin, a fluorinated quinolone antibiotic is available for oral, ophthalmic and intravenous use. Apart from having the greatest activity against pseudomonas, is effective against staphylococcus aureus, the other major pathogen in chronic media.[5] Our study is designed to assess the efficacy of prophylactic ciprofloxacin drops after tympanostomy tube insertion.

Methods. All patients who underwent tympanostomy and tube placement at the Prince Rashid Ben Al-Hasan Hospital, Al-Husn, Jordan during 3 years interval (February 2000 to January 2003) were entered into the study. Patients who underwent concomitant adenoidectomy, tonsillectomy or both were included. The indications for tympanostomy tube insertion were chronic serous otitis media, recurrent acute otitis media that did not respond

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to antibiotic therapy and antibiotic prophylaxis or a combination of both conditions. Informed consent was obtained for all patients before surgery. Patients were randomized into 3 groups: Group 1 (control group) received no prophylactic antibiotic drops, group 2 received a single dose at the time of tube placement, and group 3 received antibiotics drops at the time of tube insertion and 3 times daily for 5 days postoperatively, no one received oral antibiotics. All myringotomies were performed using a standardized technique under general anesthesia. After removal of the cerumen or debris from each patient ear canal with suction and crocodile, incision was made with a myringotomy in the antero-inferior region of the tympanic membrane, then the middle ear cavity was suctioned. The contents were classified as dry, thin serous, thick mucoid or purulent. One of the 3 standard tympanostomy tubes (Armstrong, Shepard and T-tube) was inserted after suctioning the middle ear content. Before anesthesia was discontinued 3-4 drops of ciprofloxacin solution (ciprofloxacin HC1 eye drops 0.3%) were placed in the external ear canal of patients in group 2 and 3. The parents of the patients in group 3 were instructed to continue the drops 3 times a day for the next 5 days. They were instructed to call the clinic if otorrhea occurred before the program. Postoperative visit and patients were seen in our clinic 2 weeks after tube placement and the presence or absence of otorrhea was recorded. Statistical analysis was performed with x^2 analysis.

Results. A total of 292 tubes were placed in the 3 groups of 150 patient, 97 ears in group 1, 96 in group 2 and 99 ears in group 3. In the analysis of the results, we did not differentiate between right and left ears. Patients age ranged from 3-14 years, the age distribution was similar in all 3 groups (**Table 1**). The overall incidence of otorrhea was 10.8% and the highest (16.5%) in the control group. The incidence of otorrhea was 8.4% in patients who received a single dose of antibiotics drops (group 2) and 8.2% in those who continued prophylactic treatment for 5 days (group 3). The difference in post-tympanostomy otorrhea between group 1 and the treatment group (2 and 3) was statistically significant (p=0,01). The middle ear contents were observed and recorded for 289 ears; 41 ears (14.2%) were dry at the time of surgery, thin serous effusion in 103 (35.6%), thick mucoid effusion in 139 (48.2%) and purulent effusion were noted in 6 ears (2%) **Table 1**. Three ears were not recorded as they were diagnosed as adhesive otitis media. **Table 1** also gives the incidence of post-tympanostomy otorrhea. It was the highest for ears with purulent effusions and lowest for those with a thin serous effusion. A comparison of middle ear contents with treatment category yielded mixed results for purulent middle ears, the incidence of otorrhea decreased from group 1 (33.3%) and 2 (33%) to group 3 (5-days of treatment 14.3%). Ears with thick mucoid middle ear contents, the incidence of otorrhea decreased for each treatment group: group 1 (32.4%), group 2 (13.1%) and group 3 (5.9%), this decrease was significant (p=0.02).

Discussion. Placing tympanostomy tubes is one of the procedures most often performed by the otolaryngologist. The most common postoperative complication associated with this procedure is otorrhea (6-40%).[4] The current practice is to use prophylactic drops despite the absence of data supporting their effectiveness. Several authors[6] have recommended the routine use of various topical antibiotic drops at the time of surgery to decrease the incidence of early postoperative otorrhea. In a recent prospective randomized study by Hester et al,[7] antibiotic ear drops were recommended in all patients. In our study, we tried not only to evaluate the usefulness of this agent but also to look at the issue of length of treatment. Many studies compared the results achieved without using drops with those achieved by using prophylactic drops for 2-4 days. Only one of these studies evaluated the use of a single dose in the operating room immediately after tube placement.[8] In our study, we included a control group (no antibiotics drops), a group that received a single intraoperative dose, and a final group that received 5 days of prophylactic treatment. The incidence of otorrhea in this study declined significantly between the control group (16%) and the treatment groups (8%). Only one of the studies showed a statistically significant reduction in otorrhea (19%) in control group versus 0% for a 4 day treatment.[9] The most important findings of our study was the remarkable similarity in the incidence of postoperative otorrhea between the single dose group and the prolonged treatment group (8.4%) versus (8.2%) groups 2 and 3. The only study to include a single dose group reported a 3.2% difference (8.8% for single dose treatment versus 5.6% for 2 day treatment)

Table 1 - Middle ear content versus postoperative otorrhea (N=292).

Middle ear content	Patients with otorrhea postoperatively n (%)
Dry ear (n=41)	3 (7.3)
Thin serous effusion (n=103)	7 (6.8)
Thick mucoid effusion (n=139)	19 (13.7)
Purulent effusion (n=6)	2 (33.3)

3 were not recorded as they were diagnosed as adhesive otitis media.

between these groups, showing that longer treatment may be indicated.[8] Although the incidence of otorrhea in the single dose group of the previous study (8.8%) and our study (8.3%) are identical, we did not find a significant decreased with prolonged treatment (8.2% for 5 days treatment). Multiple factors, which can affect the development of otitis media and postoperative otorrhea, need to be considered. These include age, prior treatment, bacteriology of middle ear effusion, adenoid status, allergies, preoperative antibiotics and water contamination. It has been suggested that there is a relationship between higher rates of postoperative otorrhea and the degree of middle ear inflammation at the time of surgery.[10] Some studies suggest that the presence of thick mucoid middle ear content at the time of tympanostomy is an important predictor of postoperative otorrhea.[11] Recent studies have failed to show that oral ciprofloxacin has any deleterious effects on growing cartilage in children, and the comparatively small doses used in topical application, it is likely soon to be recognized as safe for pediatric use.[12] In our study, the highest incidence of otorrhea occurred in the ears with purulent effusions (33.3%) and 13.6% in the ears with thick mucoid content. These finding suggest that both purulent and thick mucoid middle ear effusions at the time of tympanostomy may predict postoperative otorrhea and the incidence of otorrhea was significantly reduced when treatment was extended from a single dose to a 5 days course.

We conclude, that a single dose of ciprofloxacin seems to be effective when patients ears are dry or when thin serous fluid is seen at myringotomy. A prolonged course (5 days) may be indicated for those ears with purulent or thick mucoid contents, and the content of middle ear are important in predicting postoperative otorrhea.

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