

# Oxymetazoline is Equivalent to Ciprofloxacin in Preventing Postoperative Otorrhea or Tympanostomy Tube Obstruction

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**Objective:** To compare the effectiveness of ciprofloxacin and oxymetazoline solutions instilled after tympanostomy tube placement in the prevention of postoperative otorrhea and tube occlusion. **Study Design:** Prospective cross-sectional series. **Methods:** We reviewed all bilateral myringotomy and tube placement operations performed by two full-time attending pediatric otolaryngologists during a 9 month period. Data from 488 patients who underwent surgery for otitis media were collected. Demographic and clinical variables including age, sex, number of tube insertions in the past, previous adenoidectomy, type of effusion present at surgery, and type of drop prescribed postoperatively were recorded. All patients were evaluated in the office 2 to 4 weeks postoperatively. Multivariate logistic regression analysis was used to estimate the relationship of these variables with the occurrence of otorrhea and tube patency. Odds ratios were calculated. **Results:** No significant differences in postoperative otorrhea or tube patency were found between ciprofloxacin (Ciloxan) and oxymetazoline solutions (Afrin, Visine LR). **Conclusion:** Oxymetazoline and ciprofloxacin solutions are equivalent in the prevention of postoperative otorrhea and tube occlusion after tympanostomy tube placement. The implications for medication cost and potential adverse reactions are discussed. **Key Words:** Ciprofloxacin, otitis media, postoperative otorrhea, oxymetazoline, tympanostomy tubes, ototopical preparations.

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## INTRODUCTION

More than 2 million sets of tympanostomy tubes are placed annually for the treatment of chronic or recurrent otitis media in children (personal communication, Reilly

JS, based on survey of U.S. tympanostomy tube manufacturers). As such, choice of surgical setting and technique and anesthetic and perioperative medications have important financial and public health implications. The most common complications in the first weeks after surgery are otorrhea and occlusion of the tube lumen. Otorrhea occurs in approximately 10% of children within 2 weeks after surgery.<sup>1</sup> In an attempt to minimize postoperative infection, sterile operative technique, antiseptic canal preparation, middle ear irrigation, silver oxide-impregnated tympanostomy tubes, and perioperative systemic or ototopical antibiotics have been advocated.<sup>2–7</sup> A few studies have compared one antibiotic preparation with another, but none has compared antibiotic with nonantibiotic drops. We undertook this study to compare an expensive broad-spectrum antibiotic preparation (ciprofloxacin) to oxymetazoline solutions as prophylaxis against postsurgical otorrhea and to examine their effect on tympanostomy tube obstruction.

## MATERIALS AND METHODS

We prospectively recorded data from all bilateral myringotomy and tube placement operations performed by two full-time pediatric otolaryngologists operating with residents from October 2000 to June 2001. The Institutional Review Board of Temple University approved analysis of these data. Indications for tympanostomy tube insertion were either chronic or recurrent acute otitis media. Children who underwent concurrent adenoidectomy or adenotonsillectomy were included. Patients were excluded if they did not complete a follow-up appointment within 4 weeks of surgery. Fluoroplastic Armstrong beveled grommet tympanostomy tubes were inserted while the children were under general anesthesia. Middle ear effusions were cleared with suction and saline irrigation of the ear canal. Any bleeding was stopped before the placement of ear drops. Topical solutions were applied intraoperatively and prescribed for 3 days postoperatively. Families were instructed to telephone if otorrhea occurred before their follow-up appointment. Information collected from chart reviews included age, sex, number of previous tympanostomy tube placements, history of adenoidectomy, date of operation, type of middle ear effusion present at surgery, type of ear drops used at surgery, incidence of postoperative otorrhea by first follow-up appointment, and tube patency at first follow-up. Middle ear status was classified as dry (no fluid), mucoid, serous, or purulent effusion present. Both middle ear clefts had to be free of effusion for a

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patient to be categorized as “dry.” Topical preparations used were ciprofloxacin drops (Ciloxan) or oxymetazoline solution (Afrin, Visine LR). Multivariate logistic regression analyses were performed to estimate the relationship of demographic, clinical, and intraoperative findings with the occurrences of postoperative otorrhea and clogged tubes.

## RESULTS

Data from 488 patients were recorded. Patient ages ranged from 6 months to 14 years. Ciprofloxacin solution was used with 219 patients. Two hundred sixty-nine patients received oxymetazoline drops. One hundred eighty-seven patients had bilateral dry middle ear clefts (38%) at the time of surgery. Mucoïd effusions were found in 41% of patients. Serous and purulent effusions were recorded in 16% and 4% of patients, respectively (Table I). One patient was on oral antibiotics for otitis media at the time of surgery.

The incidences of postoperative otorrhea for patients who received oxymetazoline drops and ciprofloxacin drops were 10% and 7%, respectively (Table II). There was no difference found between ciprofloxacin and oxymetazoline solutions and the occurrence of postoperative otorrhea (odds ratio 1.4, 95% confidence interval [CI] 0.718–2.725,  $P = .32$ ). The overall incidence for postoperative otorrhea was 8.9%. The other demographic and clinical variables discussed were not found to be significant in predicting probability of postoperative otorrhea. Although age was not found to be positively predictive of ear drainage, 72% (29/40) of the patients with otorrhea were 2 years or less in age.

The probability of having a patent tube decreased with the presence of serous and purulent effusions (94.8% and 87.5%, respectively) (Table III). Dry middle ear clefts or mucoïd effusions at surgery were less likely to lead to clogged tubes, with patency probabilities of 96.7% and 94.8%, respectively. The trend in the predicted probabilities was not found to be significant ( $P = .11$ ) however.

There was no statistically significant difference between tube patency rates with different drop types. Ciprofloxacin solution had a probability of tube patency of 96.7% and oxymetazoline solution of 94.5% ( $P = .18$ ).

TABLE I.  
Effusion Type at Time of Surgery.

	Effusion	Total	Percent
Ciloxan	None	70	32.0
	Mucoïd	87	39.7
	Serous	47	21.5
	Purulent	15	6.8
	Total	219	100.0
Afrin	None	117	43.5
	Mucoïd	115	42.8
	Serous	34	12.6
	Purulent	3	1.1
	Total	269	100.0

TABLE II.  
Presence of Absence of Otorrhea at the First Postoperative Visit.

	Effusion	Dry	Percent	Otorrhea	Percent
Ciloxan	None	67	32.8	3	20.0
	Mucoïd	79	38.7	8	53.3
	Serous	45	22.1	2	13.3
	Purulent	13	6.4	2	13.3
	Total	204	100.0	15	100.0
Afrin	None	106	43.4	11	44.0
	Mucoïd	102	41.8	13	52.0
	Serous	34	13.9	0	0.0
	Purulent	2	0.8	1	4.0
	Total	244	100.0	25	100.0

Rates for tympanostomy tube obstruction for ciprofloxacin and oxymetazoline solutions were 3% and 5%, respectively ( $P = .18$ ). Drop type was not predictive of tube obstruction (odds ratio 0.55, CI 0.22–1.39,  $P = .21$ ).

## DISCUSSION

Otopical antibiotic drops have been advocated as effective local agents to prevent otorrhea and assure patency after tympanostomy tube placement (personal communication, Reilly JS, based on survey of U.S. tympanostomy tube manufacturers). Several authors have shown that the use of otopical drops after tympanostomy tube placement decreases the incidence of postsurgical otorrhea, especially in young children and in grossly infected ears.<sup>8</sup> Different antibiotic preparations appear to have similar efficacy.<sup>9</sup> They are superior to no treatment or saline drops.<sup>10</sup>

Broad-spectrum antibiotic drops have been associated with the development of fungal otitis<sup>11</sup> and emergence of resistant microbial pathogens.<sup>12</sup> Aminoglycoside drops have the theoretic risk of causing hearing

TABLE III.  
Patency Rates of Myringotomy Tubes at the First Postoperative Visit.

	Effusion	Patent	Percent	Plugged	Percent
Ciloxan	None	68	32.1	2	28.6
	Mucoïd	85	40.1	2	28.6
	Serous	45	21.2	2	28.6
	Purulent	14	6.6	1	14.3
	Total	212	100.0	7	100.0
Afrin	None	113	44.5	4	26.7
	Mucoïd	107	42.1	8	53.3
	Serous	32	12.6	2	13.3
	Purulent	2	0.8	1	6.7
	Total	254	100.0	15	100.0

loss if they enter the middle ear. In response to these concerns, one of our pediatric otolaryngologists (G.I.) began using oxymetazoline nasal spray (Afrin or Nasal Relief Spray) or eyedrops (Visine LR) in place of antibiotic drops in 1998.  $\alpha$ -adrenergic agents have been shown to decrease the incidence of tube occlusion secondary to bleeding.<sup>13</sup> Oxymetazoline, unlike other similar agents, has potent  $\alpha$ -adrenergic effects but causes minimal increases in heart rate even when applied to mucosal surfaces. Furthermore, the preservatives in the commercial preparations (Afrin, povidone, benzalkonium chloride, and ethylenediaminetetraacetic acid or edetate disodium; Visine LR, sodium borate) have considerable activity against the common pathogens of otitis media.<sup>14</sup>

Given that some ototopical preparation is to be used, many authors caution that potentially ototoxic agents should be avoided. In animal models, of the commonly used ear drops, ciprofloxacin has the least adverse effect on cochlear outer hair cells. Currently, only ofloxacin (Floxin otic) and ciprofloxacin-dexamethasone (Ciprodex) are approved by the U.S. Food and Drug Administration for topical use in ears with tympanostomy tubes or tympanic perforations. Recent studies by our group have shown that neither USP oxymetazoline nor its common commercial preparations (Afrin nasal spray, Visine LR) is ototoxic in a standard guinea pig model.<sup>14</sup>

Cost must be considered in the choice of ototopical preparation after tube placement. A 10 mL bottle of Ciloxan costs approximately \$90, whereas a 15 mL of Afrin or Visine LR is approximately \$5. Generic oxymetazoline costs even less. We estimate that if generic oxymetazoline has been used for all tube placements in the last 30 years, almost \$1,000,000,000 would have been saved with no change in clinical result.

Our study examined the effects of antibiotic and non-antibiotic drops used after myringotomy and tube placement before the first postoperative visit. Our study showed no difference between ciprofloxacin solution and oxymetazoline solution in prevention of either postoperative tube obstruction or otorrhea. With more than 219 patients in each arm of the study, there was adequate statistical power to detect a difference of 50% in each category with 95% confidence.

Ototopical drops help reduce incidences of postoperative otorrhea and obstructed tube lumens. Choice of ototopical preparation should be based on the surgeon's preference, risk of ototoxicity, and cost.

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