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Cost-Effectiveness of Topical Prophylaxis Against Tympanostomy Tube Otorrhea: An Economic Decision Analysis

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Abstract

Objective. To evaluate the cost-effectiveness of various topical prophylaxis strategies against posttympanostomy otorrhea using a break-even analysis.

Study Design. An economic decision analysis of data collected from purchasing records and the literature.

Setting. An academic center.

Methods. Costs of various strategies were calculated by querying our institution's pharmacy as well as GoodRX.com drug prices. Posttympanostomy otorrhea rates were acquired from a review of the literature. Costs for treatment of otorrhea were based upon our institution's self-pay patient charges. A break-even analysis was performed to determine the required absolute risk reduction (ARR) in otorrhea rate to make prophylactic treatment cost-effective.

Results. The most expensive strategy ciprofloxacin/hydrocortisone otic ($626.83) was not cost-effective unless the rate of postoperative otorrhea was greater than 92% or if the cost of otorrhea treatment exceeded $4477.36. The cheapest antibiotic/steroid combination, ciprofloxacin/dexamethasone otic ($72.25) was cost-effective (ARR 10%). Using a conservative initial otorrhea rate (14%) and weighted cost of treatment ($683.39), the most expensive cost-effective prophylactic intervention possible was $95.67.

Conclusion. Prophylaxis against posttympanostomy otorrhea can be cost-effective. Physicians should consider the cost of prophylaxis at their institution as well as the patient's postoperative risk of otorrhea when making treatment decisions.

Keywords

cost-effectiveness, postop otorrhea, tympanostomy

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Tympanostomy tubes are an effective treatment modality for otitis media with effusion. In the United States, bilateral myringotomy with tympanostomy tube placement (BMT) is the most commonly performed ambulatory surgery performed on children under 15 years of age.[1] The most common complication following BMT surgery is otorrhea seen in 67% of children within the year after tube placement.[2]

Tympanostomy tube otorrhea can be classified as early postoperative otorrhea (within 4 weeks), delayed otorrhea (4 weeks postoperatively), chronic otorrhea (most than 3 months of continuous duration), and recurrent acute otorrhea (3 or more discrete episodes).[3] For the purposes of this paper, we will define postoperative otorrhea as otorrhea that occurs within 4 weeks of tympanostomy tube placement.

There are multiple prophylactic strategies seeking to decrease the rate of posttympanostomy otorrhea, including oral antibiotics, topical antibiotic and steroid combination drops, saline irrigation, and oxymetazoline drops. Though recent studies show topical drop prophylaxis as an effective modality for decreasing the rate of postoperative otorrhea, results vary as to which drops are the most effective.[4-7] The 2022 clinical practice guidelines on tympanostomy tubes in children by the American Academy of Otolaryngology–Head and Neck Surgery Foundation recommends against routine postoperative antibiotic ear drops to avoid unnecessary antibiotics, save costs, and reduce local side effects.[8] This statement was based on a Cochrane systematic review that showed no added benefit from routine antibiotic ear drops after surgery compared with intraoperative saline washouts.[9]

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While studies have examined the costs of treating acute otorrhea, there is limited information regarding cost-effectiveness of intervention in preventing postoperative otorrhea.[10] Break-even analysis has been utilized by orthopedic surgeons examining the cost-effectiveness of prophylactic antibiotic use for shoulder surgery.[11] A similar adaption was used by otolaryngologists evaluating the cost-effectiveness of various *Staph aureus* decolonization protocols in cochlear implantation.[12,13]

The aim of this study is to investigate the cost-effectiveness of various prophylaxis regimens against early posttympanostomy otorrhea using a break-even analysis. Given the high burden of disease, we hypothesize that the less expensive prophylactic protocols can be cost-effective.

Methods

Institutional review board (IRB) exemption was obtained from the University of Texas Medical Branch (IRB 21-003).

To analyze the effects of the variables that influence the cost of posttympanostomy otorrhea, we evaluated the different stages of care. At our institution, the patient will be seen 4 weeks after tympanostomy tube placement. If otorrhea is identified, the patient is prescribed outpatient topical antibiotics. The patient will follow up in the clinic 2 weeks after to monitor for resolution. If otorrhea persists at the follow-up visit, an ear culture is obtained, an aural toilet is performed, and the patient is prescribed tailored topical antibiotics. If otorrhea fails medical management, the decision is made to proceed to the operating room with debridement and replacement of the tympanostomy tube.

To obtain estimated costs for treatment, we reviewed our institution's self-pay purchasing rates for established level 3 and level 4 visits, ear culture, bilateral myringotomy day surgery, and inpatient medication charges (**Table 1**). For outpatient medications, GoodRx.com was used to query for the cheapest available option in our institution's zip code (77555) on November 25, 2021.

In the literature, baseline postoperative otorrhea rate varied significantly ranging from 8.8% to 74%, for which we used a more conservative value of 14% based on a metanalysis performed by Kay and colleagues.[3,14] The risk of postoperative otorrhea requiring removal of tube

Table 1. Estimated Costs of Treatment

Medications/service	Inpatient charge[a], $	Outpatient charge[b], $	Cost of protocol C_p, $
Cipro HC Otic ciprofloxacin—hyrdocortisone	295.15	331.68	626.83
Ciprofloxacin and fluocinolone acetonide (Otovel)	16.62	250.18	266.80
Ciprofloxacin (0.3% ophthalmic drops) + dexamethasone (0.1% ophthalmic drops)	155.76	28.54	184.30
Ciprofloxacin (0.3% ophthalmic drops) + prednisolone 1% ophthalmic drops	138.61	36.82	175.43
Ciprofloxacin (0.3% ophthalmic drops)	112.99	12.54	125.53
Ciprofloxacin/dexamethasone (Ciprodex)	[c]	72.25	72.25
Ofloxacin 0.3% otic drops	45.44	10.76	56.20
Oxymetazoline 0.05%	1.27	3.99	5.26
10-d course augmentin	[d]	12.29	12.29
Self-pay Level 3 established outpatient visit		183.00	183.00
Self-pay Level 4 established outpatient visit		270.00	270.00
Self-pay ear culture		40.00	40.00
Self-pay tympanostomy tube placement (ENT charge)	3787.52		3787.52
Self-pay tympanostomy tube placement (anesthesia charge)	487.50		487.50
Cost of uncomplicated otorrhea (C_{comp}) (1 × Level 4 visit, 1 × Level 3 visit, ciprodex)			494.36
Cost of complicated otorrhea (C_{unc}) (3 × Level 4 visits, 1 × ear culture, 2 × ciprodex, 1 × augmentin, self-pay tympanostomy tube placement, self-pay anesthesia)			5220.03
Weighted cost otorrhea (C_t)[e]			683.38

[a]Charges obtained by reviewing our institution's self-pay purchasing records.
[b]Charges obtained by querying GoodRx.com on November 5, 2021 for area code 77555 and choosing the cheapest available option.
[c]Medication not available in the inpatient setting.
[d]Medication not used in the inpatient setting.
[e]$R_{comp} \times C_{comp} + R_{unc} \times C_{unc}$, where R_{comp} = risk of complicated otorrhea (%) and R_{unc} = risk of uncomplicated otorrhea (%).

(1) $S_{total} \times C_t \times IR_i = (S_{total} \times C_p) + (S_{total} \times C_t \times IR_f)$

Solving for IR_f yields:

(2) $IR_f = \frac{(IR_i \times C_t) - C_p}{C_t}$

(3) $ARR = IR_i - IR_f$

Substituting in equation (2):

(4) $ARR = \frac{C_p}{C_t}$

Cost effective prophylaxis was defined as $IR_f \geq 0$

C_{pmax} was determined by solving for C_p in equation (2) when $IR_f = 0$:

(5) $C_{pmax} = IR_i \times C_t$

Where:
S_{total} = Total annual surgical procedures
C_t = Total cost of treating an infection
C_p = Cost of protocol
IR_i = Initial infection rate
IR_f = Break-even infection rate
ARR = Absolute risk reduction
C_{pmax} = Break-even cost of protocol

Figure 1. Equations used to calculate the break-even infection rate, absolute risk reduction, and break-even cost of the protocol. Adapted from Hatch et al.[11]

and debridement was 4%.[3] The total cost of treating postoperative otorrhea was calculated using the weighted average of uncomplicated management, defined as otorrhea that resolves with conservative management, and complicated management, defined as otorrhea that requires removal of the tube and debridement.

An economic decision analysis was conducted using the above values. We adopted the break-even equation from Hatch et al[11] to determine the cost-effectiveness of various prophylactic strategies against posttympanostomy otorrhea (**Figure 1**). The difference between the initial and final infection rates is reported as the absolute risk reduction (ARR), which is the percentage by which a protocol must reduce the initial infection rate in order to economically justify its application. The break-even cost of the protocol was defined as the maximum cost of prophylaxis (C_{pmax}) possible with a given infection rate and cost of treatment while still maintaining cost-effectiveness. This value was determined by setting the break-even infection rate to zero and solving for the cost of protocol. Prophylactic treatment strategies that were at or below the break-even cost of protocol were determined to be cost-effective.

Results

The total cost of treating postoperative otorrhea was $683.38. Using this estimated cost, we applied the break-even analysis equation in several ways (**Table 2**, **Figure 2**). **Table 2** demonstrates the results at our institution when presuming that the postoperative otorrhea rate is 14%. In this scenario, the maximum permissible cost of prophylaxis that would be cost-effective was $95.67. There were several cost-effective prophylactic protocols, including the cheapest antibiotic and steroid combination otic drops, ciprofloxacin-dexamethasone (Ciprodex) ($72.25), with an ARR of 10%. Antibiotic-only otic drops, ofloxacin, were cost-effective with an ARR of 8.22%.

Given the wide range of postoperative otorrhea rates in the literature, the break-even analysis was also applied to various initial infection rates. For these calculations, the cost of treatment was kept constant. The results of these analyses in **Figure 2A** showed that the most expensive prophylactic protocol of ciprofloxacin/hydrocortisone otic drops (Cipro HC otic) ($626.83) was not cost-effective unless the initial rate of postoperative otorrhea was greater than 92%.

We also examined the effect of varying the cost of treatment. For these calculations, the initial infection rate was held constant. **Figure 2B** shows that the most expensive prophylactic protocol was not cost-effective unless the cost of otorrhea treatment exceeded $4477.36.

Discussion

Direct and indirect costs attributed to the medical treatment of children with acute otitis media younger than 5 years of age are estimated to exceed $2.8 billion annually.[15] Not all patients with acute otitis media will progress to otitis media with effusion or become surgical candidates for tympanostomy tube placement; nonetheless, the health care costs of treating otitis media with effusion are significant. The most common complication of BMT is posttympanostomy otorrhea. This substantial burden to the patient and to the health care system underscores the importance of preventing postoperative otorrhea.

This break-even analysis demonstrated that prophylactic strategies against posttympanostomy otorrhea can be cost-effective. Based on our institution's purchasing records and postoperative otorrhea rates of 14%, multiple topical otic drops were cost-effective including Ciprodex and ofloxacin.

In this study, the cost of treatment was calculated based on self-pay patient charges and typical practice patterns within our department for the treatment of uncomplicated and complicated otorrhea, where complicated otorrhea requires frequent courses of antibiotics, aural toilet, ear culture, and ultimately removal of tympanostomy tubes in the operating room. The weighted cost of otorrhea in this scenario was $683.39. However, this estimate does not take into account other adjunct considerations that may increase the total cost of treatment including allergy evaluation and treatment, immunodeficiency workup, reflux treatment, and adenoidectomy at the time of tympanostomy tube removal.

We observed a wide range in costs between different prophylactic strategies ranging from $5.26 for oxymetazoline to $626.83 for cipro HC otic. Multiple studies have examined

Table 2. Break-Even Infection Rates (IR_f) and Absolute Risk Reduction (ARR) of Various Prophylactic Protocols

Medications/service	Cost of protocol C_p, $	IR_f, %	*ARR*, %
Ciprofloxacin hydrochloride (Cipro HC Otic)	626.83	−77.72	91.72
Ciprofloxacin and fluocinolone acetonide (Otovel)	266.80	−25.04	39.04
Ciprofloxacin (0.3% ophthalmic drops)	184.30	−12.97	26.97
Ciprofloxacin (0.3% ophthalmic drops) + prednisolone 1% ophthalmic drops	175.43	−11.67	25.67
Ciprofloxacin (0.3% ophthalmic drops) + dexamethasone (0.1% ophthalmic drops)	125.53	−4.37	18.37
Ciprofloxacin/dexamethasone (Ciprodex)	72.25	3.43	10.57
Ofloxacin 0.3% otic drops	56.20	5.78	8.22
Oxymetazoline 0.05%	12.29	12.20	1.80
10-d course augmentin	5.26	13.23	0.77
Maximum permissible cost of prophylaxis (C_{pmax})	95.67	0.00	14.00

Red values indicate not cost-effective. Presumes an initial infection rate (IR_i) of 14%. Presumes the total cost of treating an infection (C_t) is $683.38 as derived in **Table 1**.

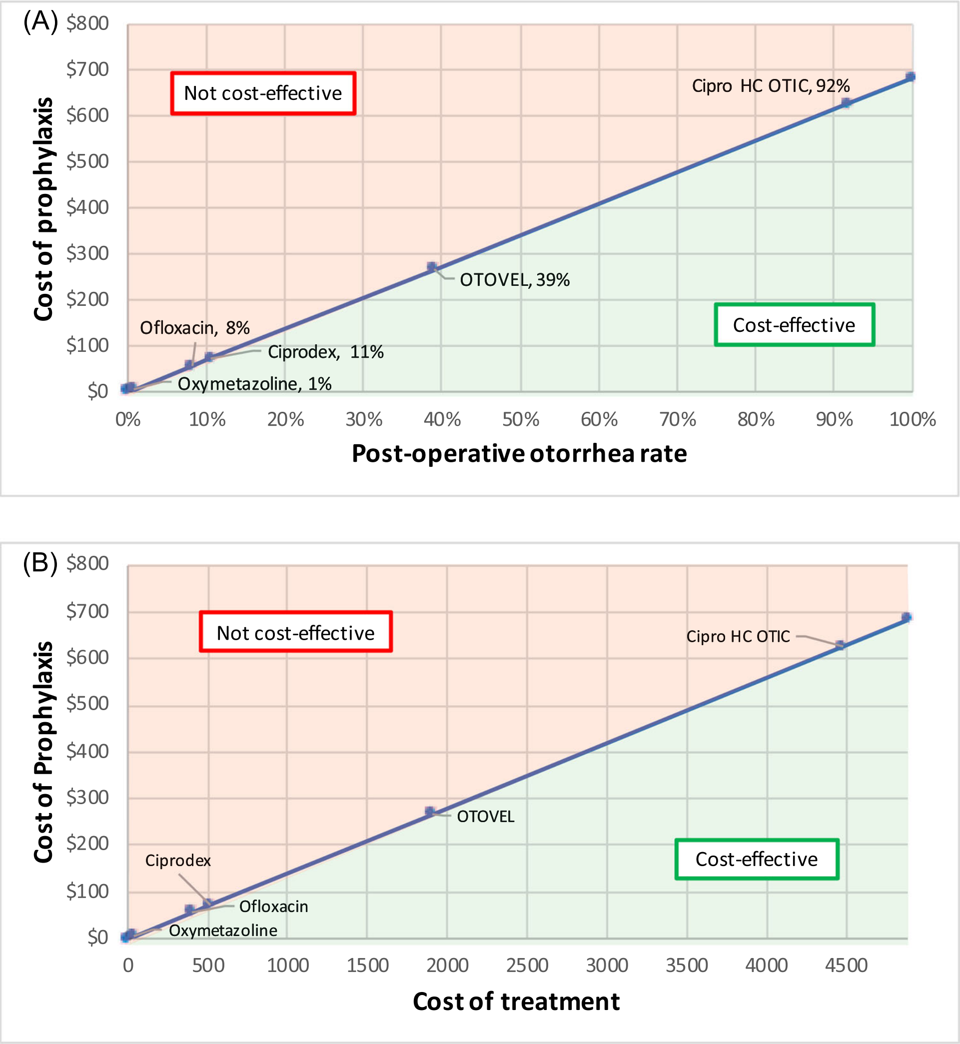

Figure 2. (A) Maximum permissible cost of prophylaxis at various infection rates. Presumes a treatment cost of $683.38. (B) Maximum permissible cost of prophylaxis at various treatment costs. Presumes an infection rate of 14%.

efficacy between different formulations of topical drops with no consensus. Thus, the cost to the patient can be reduced if clinicians prescribe the least expensive alternatives when clinically appropriate.

Further, significant cost savings could be gained using single-dose formulations. A single application of antibiotic/steroid drops in the operating room after tube insertion is routinely performed. The pharmacy at our institution provides single-dose inpatient aliquots of ciprofloxacin and fluocinolone acetonide (Otovel) at $16.62, which is substantially cheaper than any other antibiotic ear drops. Thus, at our institution, a single dose of Otovel would be the most cost- and resource-efficient otic drop to administer in the operating room.

During the course of our study, we corroborated previous findings that the costs of prescription medications varied widely based on geographic location, pharmacies, insurance coverage, and item availability.[16] We also found that the fluctuation of drug pricing affected the outcomes of the break-even analysis. For example, the GoodRx search for zip code 77555 on February 3, 2020 showed that the cheapest option for Ciprodex was $259.33, which was not cost-effective at the time. The same medication on November 25, 2021 was $72.25 and cost-effective. Clinicians should therefore consider general outpatient drug pricing trends and inpatient self-pay charges while utilizing drug registries such as GoodRx to ensure that the least expensive and most efficacious medication is provided to the patient.

The strength of the break-even analysis is that it provides a simple economic model to determine the cost-effectiveness of prophylactic protocols for postoperative otorrhea. The model can be adapted to account for the wide variation in the literature-reported rates of otorrhea. High variance in the incidence of postoperative otorrhea may be attributed to patient factors as well as the type and diameter of the tube.[17] Institutions can use their own data to determine for themselves which prophylactic strategies are cost-effective. Multiple studies have shown that postoperative otorrhea rates are higher in children with mucoid or purulent middle ear effusions at the time of tympanostomy tube placement as opposed to dry ears or those with serous effusions.[18] Regardless of the costs of treatment, the burden of responsibility should be on the prescribing clinician to ensure that the most clinically appropriate prophylactic measures are taken.

There are several limitations of this study. First, this work was an economic decision analysis and does not address the efficacy of different prophylactic strategies. A Cochrane systematic review found that saline washouts during surgery along with a single application of antibiotic/steroid drops had comparable efficacy to prolonged ear drop use. Further, the calculations performed in this break-even analysis do not account for individual intrinsic risk factors for postoperative otorrhea such as age less than 2 years old, concomitant allergic rhinitis, gastroesophageal and nasopharyngeal reflux, adenoid hypertrophy, and immunological deficiencies.[19] Nevertheless, our findings support the use of break-even analysis to study cost-effectiveness and the importance of awareness of the local costs associated with various topical prophylactic strategies against posttympanostomy otorrhea.

Author Contributions

Grant Conner, design, conduct, analysis, presentation; **Yuki Yoshiyasu**, design, conduct, analysis, presentation; **Nicholas Rossi**, design, conduct, analysis, presentation; **Brian McKinnon**, design, conduct, analysis, presentation.

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