Post-Tympanostomy Tube Otorrhea Rates: Data From a Claims Analysis and a Phase 3b Clinical Trial

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Abstract

Objectives: Otorrhea is the most common sequela following tympanostomy tube placement (TTP). However, the impact of otorrhea on clinical outcomes and healthcare utilization (HU) are not well understood. Objectives of two studies were to evaluate rates of otorrhea-related post-TTP emergency department (ED) visits (HU study) and post-TTP otorrhea between Medicaid-enrolled versus commercially-insured populations in patients who received OTO-201 (OTIPRIO®), ciprofloxacin otic suspension, Phase 3b study).

Study Design: HU: Retrospective analysis of insurance claims databases. Phase 3b: 8-week, prospective, multicenter, open-label study of OTO-201 in pediatric patients with a history of otitis media requiring TTP.

Methods: HU: Patients ≤17 years old undergoing TTP between 1/1/10 and 12/31/13 were identified. ED encounters within 30 days post-TTP, all-cause, ear-related, and otorrhea-related were compared. Phase 3b: During TTP, a single 6 mg OTO-201 was administered to each ear in patients at 40 US sites. Safety, efficacy and quality of life (QOL) assessments were evaluated at Weeks 4 and 8.

Results: HU: 128,472 Medicaid-enrolled; 240,375 commercially-insured. Within 30 days following TTP, rate of all-cause ED visits was twice as high in Medicaid-enrolled compared with commercially-insured (8.0% versus 3.9%, p<0.0001). Ear-related and otorrhea-related ED visits were three- to four-fold higher (p<0.0001) in Medicaid-enrollees. Phase 3b: Enrollment completed in 501 patients. Full data analysis underway.

Conclusion: Based on the HU study, ED visits within 30 days following TTP was significantly greater among Medicaid-enrolled pediatric patients than commercially-insured, regardless of cause. Initial Phase 3b data suggests Medicaid and commercial otorrhea rates are similar. Additional clinical and QOL data from Phase 3b will be presented.

Introduction

Children with recurrent acute otitis media (AOM) or chronic otitis media with effusion (OME) are often referred to otolaryngologists (ENTs) for TTP. TTP is the most common pediatric ambulatory surgery in the United States with over 840,000 procedures performed in 2012, and an estimated 40% of patients covered by Medicaid.[1] While it is well documented that patients enrolled in Medicaid utilize more healthcare resources, are less compliant, and have poorer health outcomes than those with commercial insurance,[2,3,4,5] this effect has not been documented specifically in pediatric patients following TTP.

Otorrhea is the most common sequela that may arise after TTP[6] which may cause patients (and caregivers) to seek physician follow-up and utilize additional healthcare resources. Also, otorrhea decreases the quality of life for both patients and caregivers.[7] To reduce otorrhea post-TTP, antibiotic otic drops are applied by ENTs intraoperatively during TTP and by caregivers postoperatively for up to 10 days,[8] although no antibiotic otic drops have been approved by the US Food and Drug Administration (FDA) for this use. OTO-201, given as a single administration by the ENT intraoperatively during TTP, has been demonstrated to significantly reduce the rate of post-TTP otorrhea in clinical trials,[9] however its effectiveness in the Medicaid population compared to non-Medicaid population is unknown.

Objectives

HU Study: To evaluate the rate of ED visits (all cause, ear-related, otorrhea-related) within 30 days of TTP in pediatric patients with Medicaid vs. Commercially insurance.
Phase 3b: To assess the rate of post-surgical otorrhea in a pediatric population requiring TTP with Medicaid and non-Medicaid insurance.

Methods

HU Study
Study Design: Retrospective , observational, healthcare claims study.
Data Source: Truven Health's MarketScan and Commercial Claims and Encounters data from >100 large employers and 12 unique health plans; MarketScan Multi-State Medicaid data for 11 states.
Patient inclusion criteria: At least one claim for TTP (CPT code 69436 or ICD-9-CM procedure code 20.01) from 1/1/10 to 12/31/13, the first of which defined as the patient's index date; age ≤17 years; continuous health plan enrollment for a period of ≥180 days prior to and ≥30 days following a patient's index date.
Study Measures: Patients' baseline demographics; all-cause ED visits (associated with any primary ICD-9 diagnosis code); otorrhea-related ED visits (associated with ICD-9 codes for otorrhea); and ear-related ED visits (associated with ICD-9 codes that may have been used by physicians to characterize middle ear disease as we suspect otorrhea to be under-coded). Otorrhea-related ICD-9 included 388.6x. Ear-related ICD-9 included 381.x-384.x; 385.0x; 385.3x; 388.6x; 388.7x; 389.0x; 389.9 (e.g., otorrhea, OM, otalgia). Data was analyzed for Medicaid vs. Commercial patients. T-tests for continuous variables and chi-square tests for categorical variables were used.
Phase 3b Study
Study Design: Prospective, multicenter, 8-week, open-label study.
Intervention: During TTP, one dose of 6 mg OTO-201 given intratympanically in both ears. Safety and efficacy assessments at Weeks 4 and 8. Subjects who developed otorrhea on/after 3 days post-TTP (Day 4) were instructed to return for assessment and treated with antibiotic ear drops for 7 days if deemed necessary.
Patient inclusion criteria: Age 6 months to 17 years, inclusive; with history of otitis media requiring bilateral TTP; caregiver is willing to comply with the protocol.
Study Measures: Otorrhea rates in Medicaid and non-Medicaid patients at Day 15, Week 4, and Week 8.

Results

HU Study
128,472 Medicaid-enrolled and 240,375 commercially insured patients met all study inclusion criteria. Mean age 3.2 years; 59% male; in Medicaid group, 64% white, 19% black, 17% other (this information not available for Commercial patients). Results were previously reported at major medical and scientific conferences.[10,11] Within 30 days following TTP, the rate of all-cause ED visits was twice as high in Medicaid-enrolled compared to commercially insured patients (8.0% versus 3.9%, p<0.0001). Furthermore, ear-related and otorrhea-related ED visits was 2.7 and 3.8 times higher, respectively, in Medicaid vs. Commercial patients, p<0.0001.

Results (continued)

Phase 3b Study
A total of 501 pediatric patients were enrolled. In the per-protocol population (N=410), approximately one-third of patients were Medicaid-insured. The incidence of otorrhea through Day 15, at Week 4, and at Week 8 was 8.1%, 17.0%, and 17.8%, respectively in Medicaid patients, and 7.3%, 14.5%, and 21.8% in non-Medicaid patients (Table 1).

Table 1. Phase 3b: Incidence of Otorrhea by Medicaid vs. Non-Medicaid Patients

	Medicaid (n=135)	Non-Medicaid (n=275)
Patients with Otorrhea Through Day 15		
Overall (%)	8.1%	7.3%
95% Confidence Interval	(4.1%, 14.1%)	(4.5%, 11.0%)
Patients with Otorrhea at Week 4		
Overall (%)	17.0%	14.5%
95% Confidence Interval	(11.1%, 24.5%)	(10.6%, 19.3%)
Patients with Otorrhea at Week 8		
Overall (%)	17.8%	21.8%
95% Confidence Interval	(11.7%, 25.3%)	(17.1%, 27.2%)

Discussion

The HU study is the first report showing a significantly higher rate of ED utilization (all-cause, ear-related, and otorrhea-related) in Medicaid patients who had undergone TTP within 30 days compared to Commercial patients. This finding is consistent with a previous report where those with the lowest socioeconomic status (i.e., urban children) experience higher rates of otorrhea after TTP.[12]
The Phase 3b study is the first clinical study that evaluated the incidence of post-TTP otorrhea in Medicaid and non-Medicaid (or Commercial) patients following treatment with OTO-201 during TTP. Results show that efficacy of OTO-201 was similar in both Medicaid and non-Medicaid patients. OTO-201 administered once by the ENT during TTP ensures compliance with antibiotic therapy, and thus may result in the similar efficacy observed in both Medicaid and non-Medicaid populations.

Limitations

In the HU study, variability or inaccuracies in coding for diagnoses may have occurred. The Phase 3b study was an open-label, single-arm study.

Conclusions

Medicaid patients visit the ED within 30 days of TTP significantly more often than those with Commercial insurance. OTO-201 given during TTP resulted in otorrhea rates that were similar in both Medicaid and non-Medicaid patients. These data suggest that OTO-201 administered during TTP may avoid the risk of non-compliance associated with antibiotic otic drops prescribed post-operatively and may be an effective treatment for children regardless of Medicaid status. The clinical benefit seen with OTO-201 may be especially important given that Medicaid patients are generally at risk for poor compliance, poor health outcomes, and higher utilization of healthcare resources.[2,3,4,5]

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