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In-Office Tympanostomy Tube Placement in Children Using Iontophoresis and Automated Tube Delivery

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Objectives/Hypothesis: Evaluate technical success, tolerability, and safety of lidocaine iontophoresis and tympanostomy tube placement for children in an office setting.

Study Design: Prospective individual cohort study.

Methods: This prospective multicenter study evaluated in-office tube placement in children ages 6 months through 12 years of age. Anesthesia was achieved via lidocaine/epinephrine iontophoresis. Tube placement was conducted using an integrated and automated myringotomy and tube delivery system. Anxiolytics, sedation, and papoose board were not used. Technical success and safety were evaluated. Patients 5 to 12 years old self-reported tube placement pain using the Faces Pain Scale–Revised (FPS-R) instrument, which ranges from 0 (no pain) to 10 (very much pain).

Results: Children were enrolled into three cohorts with 68, 47, and 222 children in the Operating Room (OR) Lead-In, Office Lead-In, and Pivotal cohorts, respectively. In the Pivotal cohort, there were 120 and 102 children in the <5 and 5- to 12-year-old age groups, respectively, with a mean age of 2.3 and 7.6 years, respectively. Bilateral tube placement was indicated for 94.2% of children <5 and 88.2% of children 5 to 12 years old. Tubes were successfully placed in all indicated ears in 85.8% (103/120) of children <5 and 89.2% (91/102) of children 5 to 12 years old. Mean FPS-R score was 3.30 (standard deviation [SD] = 3.39) for tube placement and 1.69 (SD = 2.43) at 5 minutes postprocedure. There were no serious adverse events. Nonserious adverse events occurred at rates similar to standard tympanostomy procedures.

Conclusions: In-office tube placement in selected patients can be successfully achieved without requiring sedatives, anxiolytics, or papoose restraints via lidocaine iontophoresis local anesthesia and an automated myringotomy and tube delivery system.

Key Words: Iontophoresis, tympanostomy tube, myringotomy, local anesthesia, office surgery, pediatric.

Level of Evidence: 2b

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Additional supporting information may be found in the online version of this article.

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INTRODUCTION

Otitis media (inflammation or infection of the middle ear) is one of the most frequent diagnoses in children.[1] Acute otitis media (AOM; otitis media with signs of infection) affects approximately 25% of children in the first year of life and 50% of children by 3 years of age.[2] Antibiotics are often prescribed to treat AOM, representing the most common condition for which antibiotics are prescribed for children in the United States.[3,4] In addition, otitis media with effusion (OME) (otitis media with fluid in the middle ear space) has been reported in up to 90% of children before school age.[5]

Tympanostomy tubes (TTs) are surgically placed due to persistent middle ear fluid, frequent ear infections, or ear infections that are refractory to antibiotic therapy.[6] For young pediatric patients, tympanostomy procedures are almost exclusively performed in an operating room using general anesthesia. Although tympanostomy procedures are effective in resolving disease, the use of general anesthetics in very young children has raised concerns, including preoperative[7] and induction[8] distress, intra-[9,10] and postoperative[11–13] complications, and the potential for longer-term neurodevelopmental issues,[14] particularly if the child requires multiple general anesthetic exposures in childhood.[15]

In older children and adults, TT procedures are commonly performed in an otolaryngologist office setting using local anesthetics such as phenol,[16] eutectic mixture of local anesthetics (EMLA), or lidocaine injections.[17] None of these options are suitable for pediatric use, as they are associated with discomfort, a lengthy onset time, or difficult administration in a child who is not immobile. Furthermore, none of these commonly used local anesthetics have Food and Drug Administration (FDA) approval for tympanic membrane (TM) anesthesia, none have available safety data regarding local anesthesia of the TM in children, and potential ototoxic risks of phenol[18] and EMLA[19] have been reported in the literature. Risks associated with an exposed myringotomy blade in a potentially mobile child have also limited attempts at in-office pediatric tympanostomy.

There are isolated reports of in-office TT placement for young children,[20–23] but none have achieved widespread use. This study evaluated safety and effectiveness of in-office TT placement using a novel system of technologies designed to address the challenges of awake TT procedures in young children. Specifically, an iontophoresis system (IPS) together with an iontophoretic otic anesthesia solution were used to provide local anesthesia to the TM, and a tube delivery system (TDS) was used to rapidly create the myringotomy and deliver the tube. This system of technologies (known as Tula®) was shown to be safe and effective for TT placement in adult patients prior to the initiation of this pediatric study.[24]

MATERIALS AND METHODS

Trial Oversight

The In-Office Tympanostomy Tube Placement in Children (OTTER) study (NCT03323736) was conducted under a protocol approved by the FDA and in accordance with Good Clinical Practices. Institutional review and ethics research boards additionally approved the study protocol, and informed consent was received from patients' parents or guardians (and child assent as applicable) prior to study conduct. Adverse events (AEs) were adjudicated by two medical monitors (otolaryngologist and audiologist), and a clinical events committee (CEC) was formed consisting of an otolaryngologist, a pediatric otolaryngologist, and a physician expert in pediatric pain assessment. The CEC provided overall risk/benefit oversight for the study via regular meetings and extensive procedure/data review, and had the authority to modify or suspend the study.

Technology

The TM was anesthetized using the IPS and an iontophoretic otic solution (TYMBION™) consisting of 2% lidocaine HCl and 1:100,000 epinephrine (Tusker Medical, Menlo Park, CA), henceforth referred to collectively as IPS. The IPS accelerates tissue uptake of the local anesthetic using a submilliamp electrical current that mobilizes ions of lidocaine and epinephrine achieving local anesthesia of the TM in approximately 10 minutes (unilateral or simultaneous bilateral). The IPS system includes specialized earplugs that maintain the otic solution in the ear canal during the iontophoresis process.

Once the TM was anesthetized, the lidocaine and epinephrine solution was drained from the ear canal by gravity or wicking, and TTs were placed using the TDS (Tusker Medical). The TDS automates myringotomy and tube placement. Upon device actuation, an incision is created, and the tube is placed in <500 milliseconds. The myringotomy blade is recessed within the device except for a brief exposure during myringotomy creation. A video of TDS actions is available in the online Supporting Information (see Supporting Video S1 demonstrating the TDS actions). The implanted TT is silicone with a 1.14-mm inner diameter lumen (Fig. 1).

Population

Pediatric patients ages 6 months to 12 years indicated for unilateral or bilateral tympanostomy placement per American Academy of Otolaryngology–Head and Neck Surgery clinical

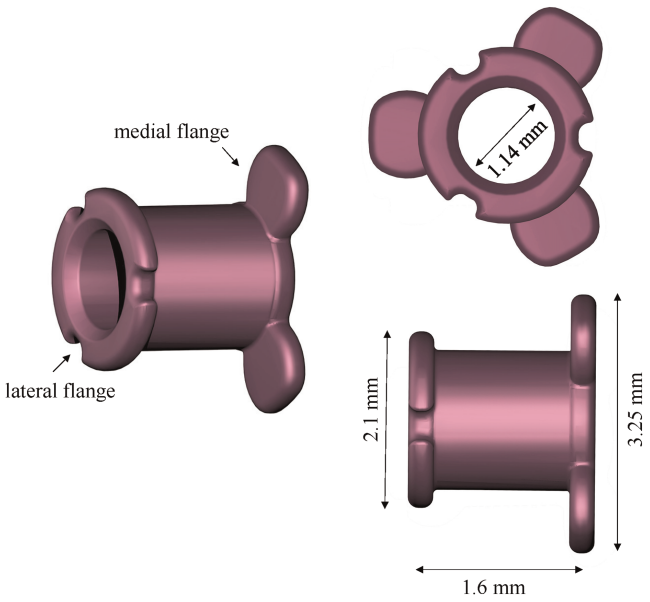

Fig. 1. Tympanostomy tube dimensions.

guidelines participated in the study.[6] Major exclusion criteria included behavioral intolerance and conditions that could impact the ability to complete the procedure such as atelectatic TM, TM perforation, damaged ear canal skin, or allergy to the drug components.

Trial Design and Endpoints

The OTTER study was a prospective multicenter study designed to assess safety and efficacy of TT placement in children in an otolaryngologist office setting using the investigational IPS, lidocaine, and epinephrine otic solution and TDS. There were three cohorts in the study: Operating Room (OR) Lead-In, Office Lead-In, and Pivotal, which was further prospectively divided into children <5 years old and 5 to 12 years old. Each investigator enrolled at least two patients into the OR Lead-In cohort, using the TDS alone with the child under general anesthesia, followed by at least two patients into the Office Lead-In cohort using the full investigational system in the office setting. Once lead-in procedures were complete, the investigator enrolled patients in the Pivotal cohort. Statistical testing is applied to the Pivotal cohort, and safety was assessed in all patients. For all office cases, no sedatives, anxiolytics, or papoose board restraints were used. Medications used intra- and postoperatively were captured.

The study had coprimary endpoints of procedural success and tube placement tolerability, each of which was statistically compared to prospectively defined performance goals (PGs). Procedural success was the proportion of children with successful insertion of TT in all indicated ears in a single office procedure. For bilaterally indicated patients, both ears must have received a tube for the procedure to be considered successful. Tube placement tolerability was the mean patient-reported pain score immediately following tube placement using the Faces Pain Scale-Revised (FPS-R[25]) and was only applicable to the 5- to 12-year-old Pivotal cohort, as younger children are incapable of providing reliable self-reported pain scores. The FPS-R is a validated self-report pain instrument with a range of 0 (no pain) to 10 (very much pain) and was implemented via a standardized script to ensure consistent application across sites. Safety was evaluated using audiometry, cranial nerve exam, and analysis of AEs.

Additional prospectively defined analyses included parental satisfaction, tolerability scores 5 minutes after conclusion of the procedure, and tube retention rates. Initial follow-up was at 3 weeks postprocedure and is reported in this article. Long-term follow-up to monitor tube retention and continuing safety is ongoing.

Statistical Analysis

Efficacy results were evaluated in the Pivotal cohort. Previously published results using earlier generations of the technology[26,27] suggested that younger children may be more challenging in-office patients than older children due primarily to behavior. The study was therefore designed to ensure sufficient enrollment across all ages and to evaluate results from the <5 and 5- to 12-year-old Pivotal cohorts separately.

The procedural success endpoint had to exceed a prospectively defined PG of 68% for the study to be considered successful. The PG was established via a patient preference study. A patient preference study, as defined by the FDA, assesses the relative acceptability to patients of specified alternatives or choices among outcomes that differ among alternative interventions and captures the value that patients place on the intervention accounting for differing perspectives on the associated benefits and risks. Patient preference studies can provide information about what attributes are important to patients, how important they are, and what tradeoffs patients are willing to make between attributes. A patient preference study was conducted by a health economics research firm, and indicated that parents would prefer the Tula in-office tympanostomy procedure over the alternative (traditional OR-based tube placement under general anesthesia) if the office procedure had a success rate that exceeded 68%. In the OTTER study, procedural success was evaluated in a Bayesian gatekeeping framework to control type I error. The procedural success endpoint would be met if the Bayesian posterior probability (PP) was at least 0.975, analogous to classical testing at 0.025 significance.

The coprimary endpoint of tube placement tolerability was tested against a PG requiring mean FPS-R score to be <4.2 (out of 10), tested via t test at 0.025 significance. The PG was chosen based on published FPS-R cut points for no, mild, moderate, and severe pain, where the lower 95% confidence bound of the mild pain range was 4.2.[28]

RESULTS

Demographics, Enrollment, Procedural Information

Enrollment took place between October 2017 and February 2019, with 337 children treated by 24 investigators at 18 sites (17 in the United States and one in Canada). There were 68, 47, and 222 children in the OR Lead-In, Office Lead-In, and Pivotal cohorts, respectively, with a total of 580 implanted tubes (Fig. 2). In the Pivotal cohort, there were 120 and 102 children in the <5 and 5- to 12-year-old cohorts, respectively, with a mean age of 2.3 and 7.6 years old. Table I provides demographic information for all cohorts, and a histogram of enrolled ages for office patients is shown in Figure 3. As noted in Table I, the vast majority of <5 (94.2%) and 5- to 12-year-old children (88.2%) were bilaterally indicated.

After TT placement, suction was performed in 64.1%, 12.3%, and 7.6% of OR Lead-In, Office Lead-In and Pivotal patients, respectively. For patients undergoing tube placement alone (i.e., without adenoidectomy or tonsillectomy) in the OR Lead-In cohort, opioids were used in 31.4% (17/54) of patients, whereas opioids were not prescribed for any in-office children (0%, 0/269). Follow-up compliance for all cohorts at 3 weeks was 99.4% (335/337 patients), and the overall mean length of follow-up for all patients was 4.3 months for OR Lead-In patients and 4.4 months for in-office patients.

Safety

There were no serious AEs in any study cohorts that were associated with the study devices, drug, or procedure. AEs are shown in Table II, inclusive of all AEs possibly associated with the investigational technology, tympanostomy procedure, or disease recurrence. AEs are presented separately for patients treated in the OR (OR Lead-In cohort) and for patients treated in-office (combined Office Lead-In and Pivotal cohorts). AEs were assessed and reported by patient over the duration of the follow-up period, and if a patient experienced the same

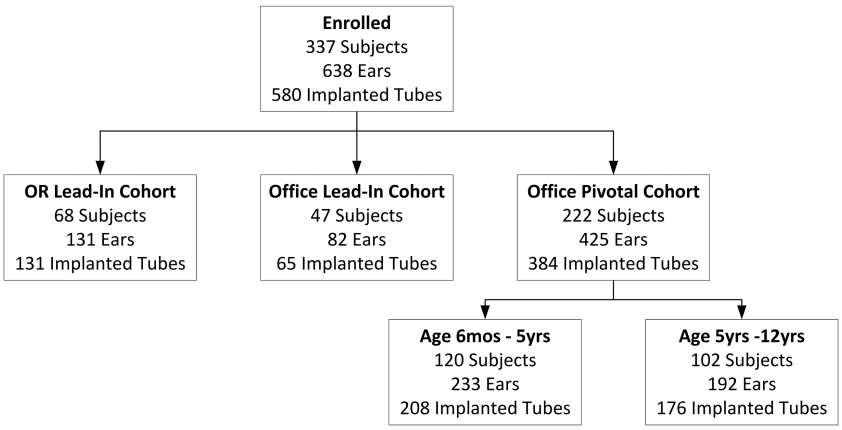

Fig. 2. Enrollment summary. OR = Operating Room.

TABLE I.
Demographics.

	OR Lead-In, n = 68	Office Lead-In, n = 47	Pivotal <5 Years Old, n = 120	Pivotal 5–12 Years Old, n = 102
Age, yr				
Mean (SD)	3.4 (2.55)	4.8 (3.10)	2.3 (1.38)	7.6 (2.10)
Median	2.4	4.7	1.6	7.0
Minimum, maximum	0.5, 11.3	0.5, 12.8	0.6, 4.9	5.0, 12.9
Sex				
Male	58.8%	57.4%	54.2%	62.7%
Female	41.2%	42.6%	45.8%	37.3%
Diagnosis				
RAOM	26.5%	12.2%	29.5%	10.8%
OME	41.2%	55.1%	33.6%	65.7%
Mixed RAOM/OME	32.4%	32.7%	36.9%	23.5%
% Bilaterally indicated	92.6%	74.5%	94.2%	88.2%
History of prior tube	19.1%	34.0%	19.2%	43.1%

OME = otitis media with effusion; RAOM = recurrent acute otitis media; SD = standard deviation.

event multiple times, the first occurrence of the event was used for the purpose of the analysis.

Common tube procedure sequelae within the first month of procedure and for the duration of the study follow-up period are described in Table II. Although otitis media and otorrhea can both describe occurrence of an ear infection, otitis media describes patients' events in which a tube had extruded and an ear infection behind the sealed ear drum had occurred, and for patients for which the parent reported a diagnosis of otitis media from a primary care or urgent care provider with no mention of ear drainage. Otitis media with otorrhea describes ear infections diagnosed by the study physician for ears with tubes in place across the TM and drainage present or a reported event from a parent in which ear drainage was present.

Otitis media with and without observed otorrhea and tube occlusion were tracked by ear within the first month after the procedure, to facilitate comparison to available literature reports commonly describing tube sequelae by ear. Otitis media with otorrhea occurred at rates of 10.7% and 6.0% of ears for OR and office patients, respectively. Tube occlusion occurred at rates of 5.3% and 3.1% of ears for OR and office patients, respectively. Otitis media with otorrhea was reported by patient over the duration of follow-up for 26.5% for OR and 17.8% for office patients. Mean follow-up period was 4.3 months for OR subjects and 4.4 months for office patients.

There were no treated ears that met the protocol-specified AE threshold of >15 dB air conduction pure tone average change from baseline to 3-week follow-up.

Twelve patients treated in-office were determined to have inadequate anesthesia for tube placement in one or both ears following iontophoresis. Anesthesia was assessed by the physician by lightly touching the TM with a dull instrument following iontophoresis. Three office patients had transient ear canal abrasions during the procedure resulting from contact of the TDS with the ear canal or anterior overhang during the procedure, and all resolved the same day as the procedure. Thirteen office patients reported mild ear pain, with six of the 13 reports within the first month postoperatively.

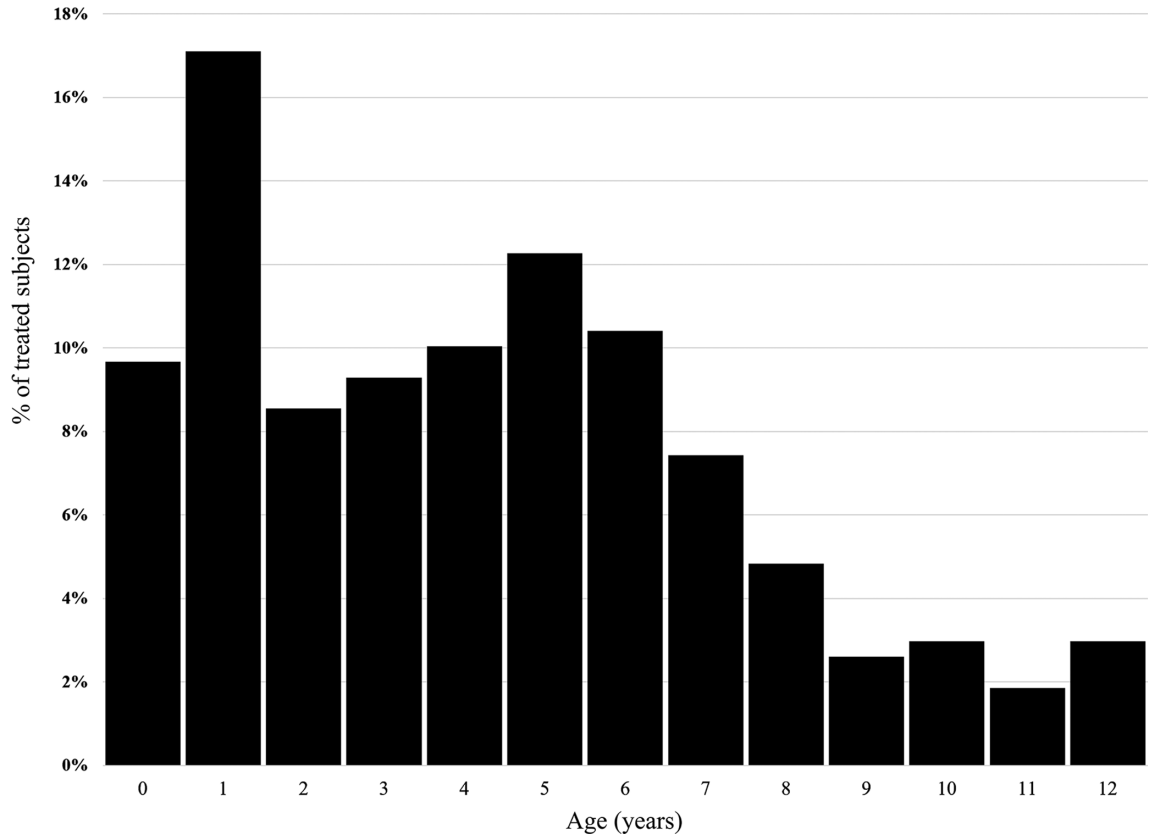

Fig. 3. Histogram of ages of children treated in the office setting.

TABLE II.
Adverse Events.

Adverse Event Within 1 Month of Procedure (by Ear)	OR Lead-In	Office Lead-In + Pivotal
Otitis media	0% (0/131 ears)	1.1% (5/449 ears)
Otitis media with otorrhea	10.7% (14/131 ears)	6.0% (27/449 ears)
Tube occlusion	5.3% (7/131 ears)	3.1% (14/449 ears)
Adverse Event for Duration of Follow-up Period (by Patient)	**OR Lead-In, Mean Follow-up 4.3 Months**	**Office Lead-In + Pivotal, Mean Follow-up 4.4 Months***
Otitis media	5.9% (4/68 patients)	5.9% (16/269 patients)
Otitis media with otorrhea	26.5% (18/68 patients)	17.8% (48/269 patients)
Ear pain	—	4.8% (13/269 patients)
Inadequate anesthesia	—	4.5% (12/269 patients)
Otitis externa	—	1.9% (5/269 patients)
Ear canal abrasion	—	1.1% (3/269 patients)
TM perforation	1.5% (1/68 patients)	0.7% (2/269 patients)
Transient medialized tube	2.9% (2/68 patients)	—

*Additional adverse events occurred at a rate of 0.4% (1/269) of in-office patients: medialized tube, partially medialized tube, tympanosclerosis, otitis externa, blood on TM, ear bleeding, TM inflammation, ear pressure, oversized myringotomy, erythema at return electrode location, pain at return electrode, transient tongue numbness, dermatographia, early tube extrusion.
TM = tympanic membrane.

TABLE III.
Procedural Success for Each Year of Age, Pivotal Cohort.

Age, yr	Procedural Success
<1	95.2% (20/21)
1	95.2% (40/42)
2	82.4% (14/17)
3	80.0% (16/20)
4	65.0% (13/20)
5	93.1% (27/29)
6	86.4% (19/22)
7	87.5% (14/16)
8	80.0% (8/10)
9	85.7% (6/7)
10	100% (9/9)
11	100% (3/3)
12	83.3% (5/6)

One patient had unsuccessful tube placement in-office due to oversized myringotomy possibly due to presence of acute otitis media and weakening of the TM at the time of the procedure. One patient in the office had a tube that was deployed in a partially medialized position, which was properly positioned using an otologic pick at the follow-up visit. One patient in the office had a tube

deployed medial to the TM, which could not be retrieved intraprocedurally. This patient has been followed for over 1 year with no clinical sequelae, and the investigator has decided not to intervene. In the OR Lead-In cohort, two patients had transiently medialized tubes, which were deployed medial to the TM and then immediately repositioned into proper location without sequelae.

One patient treated in-office had one tube extrude the day of the procedure. The patient presented with purulent middle ear effusion, and the tube placement procedure was uneventful; however, the tube extruded several hours postprocedure. Three patients had TM perforations. One patient had an unsuccessful tube placement attempt that created a small ancillary myringotomy, noted at 3 weeks and resolved by 6 months. Two patients had a TM defect that persisted after the tube extruded.

A small number of nonserious, transient events were associated with the iontophoresis process. One patient experienced transient (i.e., hours) tongue numbness, likely related to temporary anesthesia of the chorda tympani nerve. One patient experienced erythema, and one patient experienced pain at the return electrode location, resolving the day of procedure.

Additional AEs for in-office patients included otitis externa (1.9%, 5/269 patients), and the following occurring at 0.4% or 1/269 patients: tympanosclerosis, blood on TM, transient mild ear bleeding, transient mild TM inflammation, ear pressure, and dermatographia.

TABLE IV.
Reasons for Unsuccessful Procedures, Pivotal Cohort.

Reason	Rate
Behavior/movement	5.0% (11/222)
Inadequate anesthesia	3.2% (7/222)
Discomfort/anxiety	1.8% (4/222)
Anatomic challenges	1.4% (3/222)
Iontophoresis intolerability	0.9% (2/222)
Partial tube medialization	0.5% (1/222)

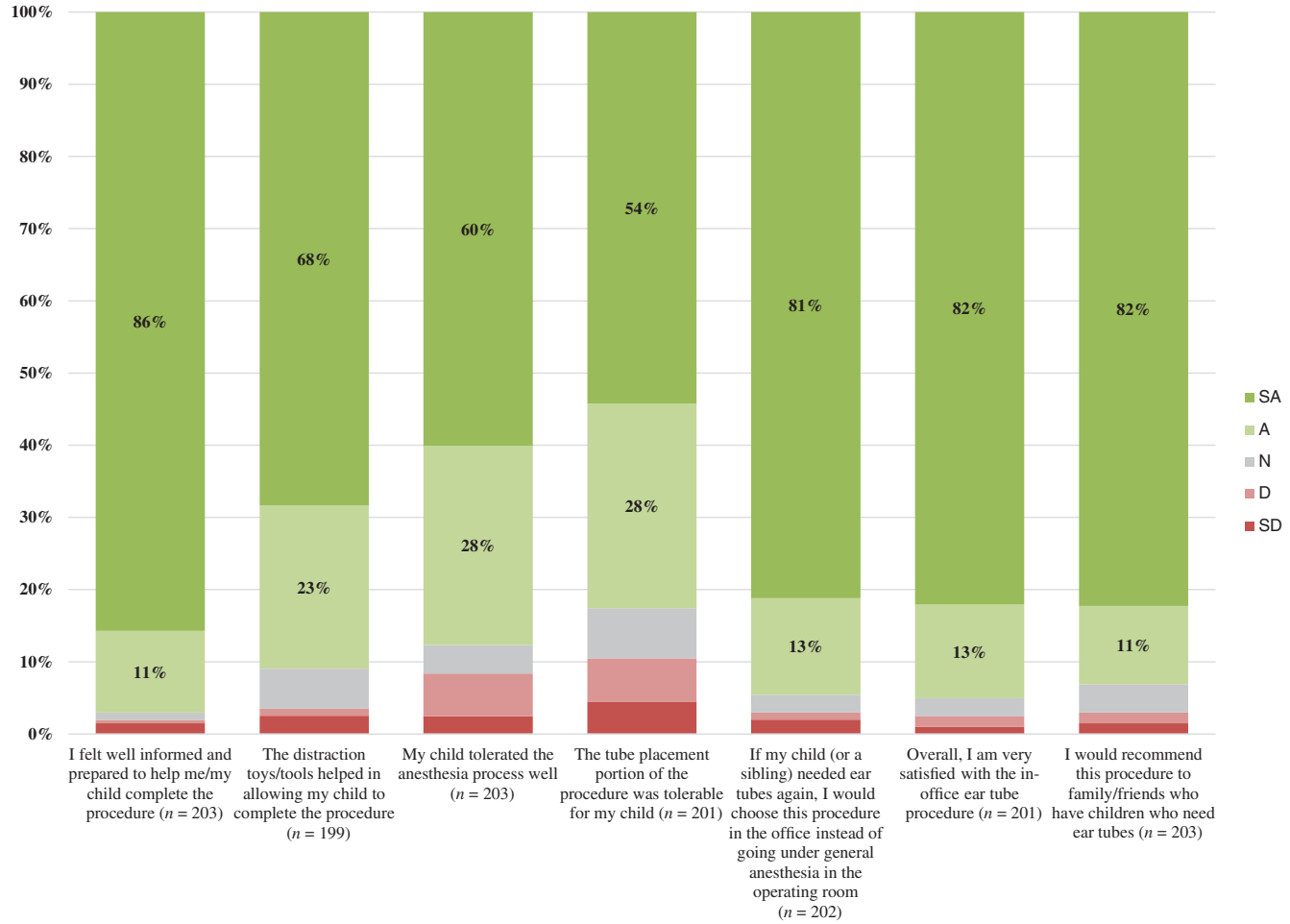

Fig. 4. Parent survey conducted at 3-week follow-up visit, Pivotal cohort. A = agree; D = disagree; N = neutral; SA = strongly agree; SD = strongly disagree.

Coprimary Endpoints

The study successfully met both coprimary endpoint statistical tests for Pivotal cohort patients. Procedural success rate was 85.8% (103/120) for the <5 and 89.2% (91/102) for the 5- to 12-year-old groups (PP = 0.9999 for each group). Procedural success for each year of age is provided in Table III, although the study was not powered for analysis in each individual year of age. As anticipated, the procedure was not successful in all children, with reasons for nonsuccess described in Table IV.

The mean (standard deviation) tube placement FPS-R score for the 5- to 12-year-old group was 3.30 (3.39) on a scale of 0 to 10, significantly lower (P = .0072, 95% confidence interval: 2.6-4.0) than the PG. The median tube placement FPS-R score was 2.0. Although not tested statistically, the mean FPS-R score 5 minutes after conclusion of the procedure was 1.69, with a median of 0.0.

Additional Analyses

Effusion type was determined at time of procedure after tube placement. Among 57.9% (259/447) ears treated in-office with effusion at the time of the procedure, 46.3% were serous, 44.4% mucoid, and 10.8% were purulent effusion type. Ears could be scored with more than one effusion type; therefore, percentages totaled slightly more than 100%. Effusion resolution and tube patency rates were similar for ears observed having mucoid or serous effusions at baseline despite low suction rates. At 3 weeks postprocedure, no effusion was present for 94.0% (109/116) of treated ears previously observed with serous effusion and 96.5% (111/115) of ears with mucoid effusion. Tube patency rate at 3 weeks was 91.5% (108/118) for ears previously observed with serous effusion and 93.0% (107/115) for ears with mucoid effusion. For the 34.7% (155/447) of ears with no effusion at time of TT placement, 3-week follow-up patency was 96.8% (150/155), and no effusion was observed in 94.8% (147/155) of ears, similar to rates observed for ears with effusion at the time of the procedure.

Tube retention in the pivotal cohort was 99.5% (380/382 tubes) at 3 weeks and 91.8% (314/342 tubes) for patients evaluated at the 6-month follow-up (not all patients have reached the 6-month follow-up window). Parental satisfaction was high, evidenced by results obtained from 203 pivotal cohort patients' parents during the 3-week follow-up visit (Fig. 4), with 94% of parents agreeing (13%) or strongly agreeing (81%) with the statement, "Overall, I am very satisfied with the in-office ear tube procedure." Parents reported that 76% of children returned to normal activity immediately at the conclusion of the procedure. Nineteen pivotal cohort patients' parents did not provide a survey, including seven with successful procedures and 12 with unsuccessful procedures.

DISCUSSION

The OTTER study demonstrated that the IPS with 2% lidocaine, 1:100,000 epinephrine solution, and TDS enabled safe and successful placement of TT in children in an office setting without the use of sedatives, anxiolytics, or papoose restraints. The most common reason for an unsuccessful procedure was behavioral compliance, which was expected for office-based procedures in young children (e.g., cerumen removal, nasal endoscopy, and foreign body extraction). Cerumen removal was an appropriate behavioral screening test but had limitations, as the child's behavior can change between screening and procedure, and screening is not as procedurally intense as TT placement. It is important to ensure the child is well-rested and fed, and to appropriately prepare both the parent and child. Age-appropriate distractions such as electronic games/videos, toys, and bottles (for infants) are essential, as well as properly trained staff.

Safety was demonstrated by absence of device, drug, or procedure-related serious AEs. Nonserious AEs were of type and rate consistent with expectations for tympanostomy procedures. For in-office patients, otorrhea (6.0%) or tube occlusion (3.1%) rate by ear within the first month after the procedure was similar to rates reported in the literature,[29–31] despite infrequent suction of effusion. This result is consistent with the literature suggesting that suction is not necessary to ensure a patent tube or reduce otorrhea rate.[32–36] Resolution of effusion and tube patency rates at the 3-week follow-up were similar for ears that had serous or mucoid effusions at baseline.

The FPS-R tube placement mean score of 3.30 is in the mild range of the FPS-R scale.[28] Although studies reporting FPS-R results differ in design and population, the mean tube placement FPS-R score appears not materially different from mean FPS-R scores for other very common pediatric inventions (e.g., immunization [3.0–6.6],[37,38] dental injection [3.0–6.3],[39–41] intravenous cannulation [3.9],[42] venipuncture [3.3–6.5],[43,44] and ear piercing [3.9]).[45]

An unanticipated benefit of the in-office technology was the avoidance of additional medications often administered in concert with general anesthesia during TT procedures. The most common intraoperative medication observed in the OR cohort in this study was fentanyl. In the OR Lead-In Cohort, 31.4% (17/54) of children who had tube placement only in absence of adjunctive adenoidectomy or tonsillectomy were given an opioid medication, primarily fentanyl or morphine. No children (0%, 0/269) in the OTTER Office Lead-In or Pivotal cohorts were given opioids intraprocedurally or to address postprocedure pain related to their Tula procedure. Correspondingly, return to normal activity was immediate for the large majority of the in-office patients.

This study was conducted using investigational devices and drugs via an FDA-approved investigational device exemption (IDE), with the aim to provide study results for FDA review to permit marketing. The iontophoresis and tube delivery systems and Tymbion drug received FDA approval on November 25, 2019 for in-office tube placement for pediatric (aged 6 months and older) and adult patients.

Strengths and Limitations

This study was a large multicenter study with a robust and prospectively defined statistical plan.

Investigators included a mix of private and academic practice, and included general otolaryngologists, pediatric otolaryngologists, and otologists, enhancing the generalizability of the results. Furthermore, the age of enrolled children matched what would be expected in clinical practice, with a peak in the 1-year-old range, but also significantly inclusive of children in the 2- to 4-year-old range, which are generally considered to be the most behaviorally challenging. In addition, over 88% of children in the Pivotal cohort were indicated for bilateral tube placement, reflective of the anticipated patient population and appropriately challenging the iontophoresis process and the ability to place tubes in both ears. The full profile of tube retention characteristics are not yet fully known, as follow-up is ongoing. However, 91.8% (314/342) of implanted tubes were present at the 6-month follow-up. There are limited reports in the literature regarding the time course of tube retention for comparison purposes. Kim et al.[30] reported mean time to extrusion for Medtronic Paparella silicone 1.14-mm tubes (Jacksonville, Florida USA) as 7.4 months. Soderman et al. demonstrated that 39% of Donaldson silicone 1.10-mm tubes (Atos Medical AB, Hörby, Sweden) were extruded at 12 months,[46] and Gordts et al. reported an average extrusion time of 11.3 months for Donaldson 1.10-mm tubes.[47] Not all parents answered the survey, as there were 19 parents (out of 222 total pivotal patients) who did not respond. Parent satisfaction did not appear to be materially different when analyzed for the full set of respondents (n = 203, 94%) compared to respondents with successful procedures only (n = 187, 97%), suggesting the impact of the 19 parents who did not complete the survey (including 12 with unsuccessful procedures) is unlikely to have had a significant impact on conclusions.

CONCLUSION

Using the IPS, lidocaine and epinephrine solution, and TDS, TTs were successfully and safely placed in pediatric patients in an ear, nose, and throat office setting without requiring the use of sedation, anxiolytics, or papoose restraints.

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