In-Office Tympanostomy Tube Placement Under Local Anesthesia Using a Novel Tube Delivery Device

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ABSTRACT

Objectives: To demonstrate the feasibility and evaluate the safety and efficacy of in-office tympanostomy tube delivery under local anesthesia using a novel tube delivery system.

Study Design: A prospective, multi-center, single arm clinical study

Methods: 43 ears were enrolled in the study among 28 patients. Enrolled patients were at least 6 months old. Tube placement was performed in the office setting under local anesthesia using iontophoresis in conjunction with the Acclarent Tympanostomy Tube Delivery System (TTDS). All patients underwent pre- and postoperative physical exam and audiometry.

Results: 43 ears among 28 study patients were enrolled and completed the study. Of the 43 enrolled ears, 77% were in the pediatric population and 55% of those were less than 5 years old. There were no serious procedural or device related adverse events during the study. Procedural success (tube placement) was achieved in 100% of the enrolled ears and at the follow up, the tube retention rate was 97%. The postoperative audiogram demonstrated improved hearing in 84% of study patients and the remaining 16% demonstrated no change from their preoperative testing.

Conclusions: This study has shown the feasibility, safety, and efficacy of in-office tube delivery under local anesthesia using the Acclarent TTDS. The greatest potential benefit of this technique is in the pediatric population where the current standard of care for tube placement involves general anesthesia. An in-office technique to deliver tubes under local anesthesia could benefit patients, surgeons, and overall health care costs. Further improvement in device design and increased surgeon experience may reduce these incidents going forward.

RESULTS

A total of 43 ears among 28 subjects (ages 1-95 y/o) were enrolled and completed the study. Of the 28 subjects, 13 of them only required unilateral tube placement thus only one ear was enrolled. 77% (33/43) of the ears enrolled were in the pediatric population (18 or under) and of those, 55% (18/33) were 5 or under.

There were no serious procedural device-related safety events (acoustic trauma, deployment of the tube in to the middle ear, damage to middle ear structures, unintended TM perforation requiring treatment, abrasion to the canal requiring treatment, or major bleeding requiring treatment). Further, 2 week post-procedure audiology revealed improved hearing in 84% (36/43) of the ears and no change in hearing in the remaining 16% (7/43). The tube delivery device deployed the tube across the TM successfully in 88% (38/43) of the ears while the surgeon placed a tube manually in the remaining 12% (5/43). At follow up 100% (38/38) of the tubes placed with the device were retained and in position across the TM.

Clinical tolerability of the procedure was assessed using the Wong-Baker faces pain scale (0=no hurt to 5=worst) and the average level of discomfort for all subjects was 1.

DISCUSSION

Overall, this study demonstrates the feasibility, safety and efficacy of tympanostomy tube delivery under local anesthesia in the office using iontophoresis and this tube delivery device.

The results show that the system was safe, the procedure was well tolerated, and the goal of patients leaving the office with tubes delivered under local anesthesia was achieved.

Of note, there were 5 ears where a tube had to be placed manually. In these cases, the device made the myringotomy but the tube fell short of the TM or was retained in the tip of the device. The most likely cause of these incidents was a lack of proper device apposition with the TM. Further improvement in device design and increased surgeon experience may reduce these incidents going forward.

Also of note, the follow up for this study was short (2 weeks) but the audiological results and tube retention observed was consistent with expectations when placing tubes in a traditional manner. Furthermore, there was no reason to expect that, over the long term, a silicone Paparella tympanostomy tube confirmed to be in good position should behave differently based on whether it was placed manually or by an automated device and it should be noted that while not included in this study data, that assertion proved true in follow up of these patients.

Lastly, while less quantifiable, behavioral management skills and techniques used in this study were noted to be critical to procedural success in the pediatric population.

METHODS AND MATERIALS

A prospective, multi-center, single arm study was performed. 43 ears among 28 patients aged 1-95 y/o were enrolled in the study at 3 sites.

Inclusion criteria were: patients scheduled to undergo tube placement, age at least 6 months old, and behavioral capacity to undergo the procedure as judged by the physician. Exclusion criteria were: history of sensitivity to the local anesthetic used, atrophic, blemic, or atelectatic TM, otitis externa, anatomy that precludes access of the device to the TM, or anatomy that necessitates tube placement in the posterior TM.

The study design included a preliminary assessment followed by two in-office visits: a treatment visit and a follow-up visit at 2 weeks (±1 week). Audiograms and tympanograms were taken prior to treatment and at the follow-up visit.

All patients received local anesthesia with the Tula™ Iontophoresis System (Acclarent, Inc., Menlo Park, CA) using a drug mixture comprised of a 10:1 mixture of lidocaine 4%, epinephrine 1:1000, and sodium bicarbonate 8.4%. Following the anesthesia (10 minutes), the Tube Delivery System device (Acclarent, Inc., Menlo Park, CA) was used to insert a Paparella-type silicone tympanostomy tube in the anterior/inferior quadrant.

REFERENCES


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CONCLUSIONS

This study has demonstrated the initial feasibility, safety, and efficacy of in-office tube delivery under local anesthesia using a novel tube delivery device. The greatest potential benefit of this technique is in the pediatric population where the current standard of care for tube placement involves general anesthesia. An in-office technique to deliver tubes under local anesthesia could benefit patients, surgeons, and overall health care costs. Based on these results, further clinical evaluation of this system in the pediatric population is warranted and underway.