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Behavioral techniques to optimize success of in-office pediatric tympanostomy tube placement without sedation

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ABSTRACT

Objective: Tympanostomy tube insertion is the most common pediatric surgery, but it typically requires general anesthesia. To facilitate in-office tube placement without general anesthesia, two complementary technologies have recently been developed comprising an iontophoresis system for delivering local anesthesia and an integrated tube delivery system. The purpose of this study was to evaluate behavioral support techniques used during a clinical study of the new technology for pediatric in-office tube placement without general anesthesia or physical restraints.

Methods: As part of an IRB-approved, prospective, nine-center clinical study, pediatric patients requiring tube insertion underwent in-office treatment using the new procedure. The behavior management techniques included preparation, distraction, coaching, and reinforcement for cooperation. The entire procedure was videotaped and two independent coders used the validated FLACC (Face, Legs, Activity, Cry, Consolability) scale to code behavioral distress across five procedural phases.

Results: Seventy pediatric patients aged 8 months to 17 years (M = 7.0 years; 51% female) were enrolled in the study and 68 had video recordings available for analysis. Of the 68 recordings analyzed, 63 patients completed the procedure and had tubes placed without sedation. Mean FLACC scores ranged from 0.05 to 2.38 (M = 1.25, SD = 0.82) and median FLACC scores ranged from 0 to 1 (Mdn = 0, IQR = 0.05), which indicate "mild" distress. During iontophoresis, eardrum tap (anesthesia assessment), and tube delivery, older children displayed lower distress and girls had higher FLACC scores during the eardrum tap procedural phase.

Conclusion: When combined with the evidence-based behavioral techniques, office-based local anesthesia and tube delivery resulted in minimal distress, suggesting that the new procedure may be a viable method of conducting tympanostomy tube placement in children without having to use general anesthesia.

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1. Introduction

Myringotomy and tympanostomy tube placement for acute otitis media or chronic otitis media with effusion is the most common ambulatory pediatric surgical procedure, with approximately 667,000 performed annually in the United States [1,2]. Although this surgical procedure is relatively brief and simple, general anesthesia is routinely employed in children to control pain and avoid behavioral challenges posed by an awake child. Unfortunately, general anesthesia for any procedure is stressful for the patient and parents and introduces a host of potential complications. The majority of children experience high anxiety prior to surgery culminating during anesthesia induction [3–5]. Specifically, parent–child separation, the sterile and uninviting surgical room, and mask anesthesia induction are particularly stressful for the young patient and parents [4]. This pre-surgical distress has been found to predict a host of negative outcomes following surgery. For example, in studies of children who have had surgery with general anesthesia, approximately 18% experience post-procedure emergence delirium [6], 47% report sleep problems [7], and 60% exhibit negative behavioral changes (e.g., eating disturbances, separation anxiety, apathy, new onset enuresis) with roughly 20% of these children continuing to have negative behaviors 6 months after surgery [8,9].

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Recently, two complementary investigational technologies have been developed by Acclarent, Inc. (Menlo Park, CA, USA) that provide an alternative to general anesthesia for myringotomy and tympanostomy tube placement. The first technology is an advanced iontophoresis system intended to numb the eardrum in approximately 10–15 min and the second is an automated myringotomy and tube delivery system that allows physicians to rapidly place tubes in seconds in their offices without general anesthesia. These systems allow the procedure to be conducted in an outpatient setting without the potential medical and behavioral downsides of general anesthesia. In addition, parents and children can remain together throughout the medical procedure, which is preferable [10]. For additional details about the investigational technologies, see [11].

Even with effective local anesthesia, young patients might have heightened distress during the procedure. As part of a clinical study designed to evaluate the safety and efficacy of the new technologies, evidence-based behavioral support techniques were developed to facilitate the procedure and minimize parent and child distress. The techniques were based on a strong research foundation, incorporating methods proven to reduce child distress and parent anxiety across a range of invasive pediatric medical procedures (e.g., injections, bone marrow aspirations; for a review, see [12]). The techniques were largely based on those detailed in a review of empirically-supported treatments, which received the highest rating (i.e., "well-supported intervention" [13]). During the study, complete in-office procedures were videotaped. The purpose of this study was to retrospectively evaluate the effectiveness of the behavioral support techniques in managing distress during the procedures.

2. Methods

2.1. Clinical trial overview

The clinical study was a prospective, multicenter, single-arm study designed to evaluate the safety, efficacy, and tolerability of in-office tympanostomy tube placement in pediatric patients (defined as patients aged 6 months to <22 years) using the investigational technologies (iontophoresis and tube delivery systems). Institutional Review Board approval was obtained for each clinical site and all patients, parents or their legal guardian provided written consent (and assent if required) prior to enrollment. In addition, all patients gave written consent prior to having their procedure video recorded. Main results from the study have been reported separately as has a full description of the methodology and rationale for the study [11].

Eight physicians practicing at nine different otolaryngology practices (1 physician worked at 2 practices) participated as investigators in the clinical study over a 5-month period. All children scheduled for tympanostomy tube placement were eligible for participation. The physicians identified patients for inclusion if the patients were subjectively judged as being able to follow simple verbal directions, sit still, and cooperate during a routine ear examination and cleaning. No physical restraints (e.g., papoosing), anxiolytics, analgesics, or sedatives were permitted during the procedure.

2.2. Procedure and behavioral support techniques

The behavior support techniques included the following evidence-based components: preparation, distraction, coaching, and reinforcement for cooperation. Preparation consisted of providing parents the children's story "We're Going to the Ear Doctor". Created for the clinical study, the illustrated story details the steps of the procedure and what the patient will experience. For example, the filling of the ears for iontophoresis is described in the following way, "Dr. A puts a special headset on Jane. She feels the squish of cold medicine in her ears as the doctor fills them. It feels like a bubble bath in her ears!" Consistent with the literature, the preparation story provides procedural and sensory information and details coping skills [12,14]. Distraction was conducted by both the parent and physician and a selection of developmentally appropriate toys and games were available. As described in the literature, distraction involved multiple sensory modalities and was provided before, during, and following the procedure [15,16]. Parent coaching and reinforcement involved the parents leading the distraction when necessary as well as a "sticker chart" program. Specifically, parents were provided a sticker chart and stickers and were instructed to distribute these rewards to the child contingent on cooperative behavior (e.g., remaining still).

2.3. Measurement of distress

The FLACC (Face, Legs, Activity, Cry, Consolability) scale [17] was used to code behavioral distress. The FLACC is a valid and reliable pediatric observational measure that ranges from low (0) to high (10) distress. The FLACC is recommended in the PedIMMPACT consensus statement [18] and is a widely used observational measure of pediatric behavioral pain and distress. For the current study, a conservative decision was made to assign the highest FLACC score observed for each procedural phase as well as the highest score across both ears for bilateral procedures rather than assigning an average distress score or other measure of central tendency (Fig. 1).

2.4. Training of coders

Two independent research assistants, blind to the study aims, were trained under the direction of the second author using a subset of the study videos. During the training process, both research assistants independently coded the same videos using the FLACC scale. The second author met with the coders to discuss disagreements and improve consistency. Training concluded when research assistants demonstrated 80% FLACC score agreement with each other.

2.5. Coding process

The entire study procedure was videotaped via a discreet video camera. Subject distress was later coded by independent research assistants during each of the following five procedural phases: iontophoresis headset installation (from 30 s prior to the iontophoresis headset first touching the child's head until the headset is placed), filling (from initiation of the first ear fill of numbing solution until filling is complete for the second ear),

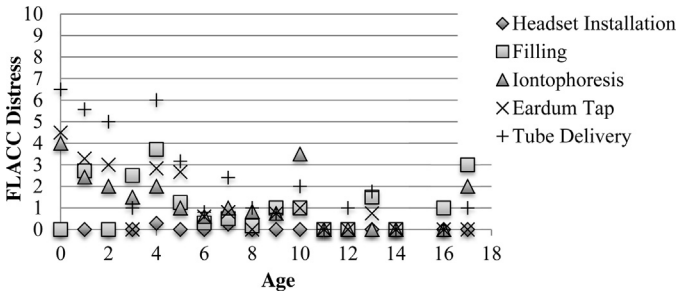

Fig. 1. Scatterplot of distress by age across procedural phases. *Note*: Distress and age were negatively correlated during the iontophoresis, eardrum tap, and tube deliver phases. Distress and age were not correlated during the headset installation or filling phases.