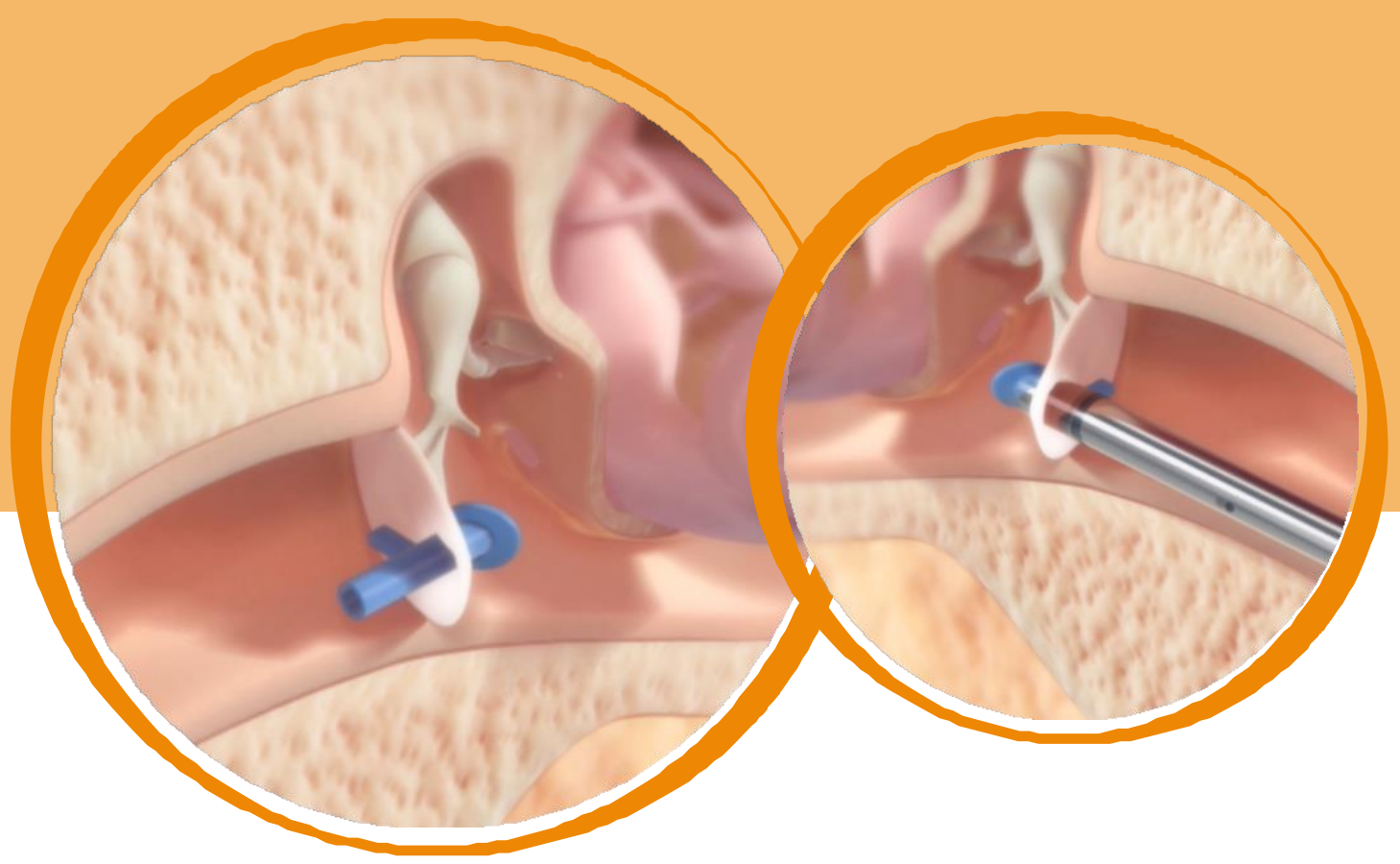
SPECIALTY AREA

PEDIATRIC OTOLARYNGOLOGY



MAYO CLINIC

INTRODUCTION

To investigate the tolerability profile of in-office tympanostomy tube insertion (O-TTI) in young children with a single-pass delivery instrument using a standardized methodology encompassing audio-video (A/V) recording, developed in coordination with the FDA.

METHODS

In a prospective multi-site single-arm clinical study of O-TTI in 211 children 6-24 months old using a single pass delivery instrument, a sub-study of thirty (30) children were consecutively enrolled to undergo A/V recording of O-TTI between February 2020 and May 2020. The procedures were uniformly recorded; children were restrained with swaddling and/or papoosing and Phenol was used as a topical anesthetic. Recordings were reviewed by 3 independent pediatric clinician experts, and patient response was studied at 5 different stages of the procedure: patient enters room, papoose/swaddling, ear wax removal, phenol application and tube insertion, and 3 minutes post procedure. The level of tolerability was determined using a standardized scale. Analyzed features included crying patterns, facial expression, interaction with the environment and body position. Response patterns were divided into four categories: No patient response (baseline state), mild response, moderate response and significant response. The reviewers also opined as to whether the child tolerated the procedure adequately. Finally, a 3-question survey was distributed to parents to assess their overall satisfaction with the procedure, and the surgeon and staff assessed child recovery.

RESULTS

Thirty (30) patients had bilateral O-TTI A/V recorded. 1st and 2nd surgical pass success rates were 93% and 100%, respectively. Median procedural time was 236 seconds (range 120-592 seconds). A total of 90 A/V reviews were performed. The highest moderate or significant patient response was reported during phenol application and tube insertion, with ear wax removal similar in response. At the final stage of the procedure, patient response rates were almost similar to the initial stage of the procedure. The experts judged that 30/30 (100%) children tolerated the procedure adequately. Per the parental survey, 93.3% strongly agreed or agreed that an alternative to general anesthesia is necessary in tube insertion, and 93.1% would recommend O-TTI to other parents. Per surgeon/staff assessment, 27/30 (90%) children were considered recovered once back with parents, and 3/30 (10%) were recovered before leaving the clinic.

CONCLUSION

We present data that provides objective evidence of clinically reasonable patient tolerability of O-TTI in children age 6-24 months with a single pass delivery tool, restraint and Phenol as a topical anesthetic. O-TTI with this methodology was also very well perceived by both healthcare providers and parents.