Balloon Dilation Of The Cartilaginous Portion Of The Eustachian Tube: Initial Safety And Feasibility Analysis In A Cadaver Model

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ABSTRACT

Background: Balloon catheter dilation of sinus ostia has demonstrated efficacy and safety in the treatment of chronic sinus disease with two years follow-up. Similarly, studies of partial resection of inflamed mucosa from within the cartilaginous Eustachian tube (ET) have demonstrated efficacy and safety in the treatment of medically refractory otitis media with effusion (OME). Therefore, balloon dilation of the cartilaginous ET was investigated as a possible treatment modality for OME.

Methods: A protocol for sinus balloon catheter dilation was evaluated in each of the cartilaginous ETs in eight fresh human cadaver heads. CT scans and detailed endoscopic inspections with video or photo documentation were performed pre- and post-treatment and cross-sectional anatomical dissections were done to analyze the effects of treatment and to look for evidence of undesired injuries.

Results: Catheters successfully dilated all cartilaginous ETs without any significant injuries. There were no bony or cartilaginous fractures and three specimens showed minor mucosal tears in the antero-lateral or inferior walls. Volumetric measurements of the cartilaginous ET lumens showed a change from an average of 0.16 to 0.49 cm3 (SD 0.12) representing an average increase of 357% (range 20 – 965%).

Conclusions: Significant balloon catheter dilation of the nasopharyngeal orifice of the ET was feasible and without evidence of untoward injury. A clinical study is now indicated to determine whether balloon dilation will demonstrate lasting benefits and safety in the treatment of otitis media.

INTRODUCTION

Dilation of sinus ostia was introduced with the hypothesis that it could provide lasting patency of ostia along with the advantages of minimizing tissue trauma, bleeding, and scarring. Patency rates have been reported at 91.6%1 and two year patient satisfaction results of 85% with significant symptom improvement and objective reduction of disease.2

Partial resection of inflamed ET luminal mucosa and submucosa from the postero-medial wall has been beneficial in early results, supporting the concept that enlargement of the valve of the ET may facilitate the dilatory efforts of the TVP muscle and provide effective benefit for chronic OME.3

Widening of the tubal valve could be accomplished by balloon dilation. It would circumferentially compress and stretch the mucosa and submucosa and rotate the posterior cushion medially. No attempt would be made to dilate the bony-cartilaginous isthmus as it is usually patent4, even with OME and the dense bone would be largely unaffected. The purpose of this study was to investigate the feasibility and safety of performing balloon dilation of the cartilaginous ET prior to consideration of a human trial.

METHODS AND MATERIALS

The sinus balloon dilation system (Acclarent, Inc., Menlo Park, CA) was employed off-label to dilate the cartilaginous portion of both ETs in 8 fresh cadaver heads, 6 of which were sagittally split.

Procedure: A curved guiding catheter was passed through the nasal cavity and the tip placed into the ET nasopharyngeal orifice. A 6 or 7 mm diameter x16mm length Relieva Solo™ sinus balloon catheter containing a guidewire protruding 5 mm from the distal tip were of the catheter were introduced through the guide catheter. Once in position, the guidewire was removed to avoid overpressure injury to the middle ear and the guide catheter maintained in position to stabilize the balloon. The balloon was inflated to 12 atm for one minute, after which it was deflated and removed.

Analysis: Post dilation endoscopic inspection of the tubal lumen was done for any evidence of injury. ½ heads underwent pre and post dilation high resolution CT scans including the introduction of contrast agent into the dilated tubal lumens. OsirIX software (Geneva Switzerland) was used for pre & post dilation measurements and volume calculations. Dissections were performed on ½ heads to inspect for any evidence of adverse effects.

RESULTS

Successful balloon dilation was achieved in all ETs without any major adverse effects. The guide catheter, guidewires, and balloon catheters were all inserted into the ET without difficulty. Dilation of the 12 ETs in the ½ heads was accomplished with a 7 mm diameter balloon in 8 (66.7%) and with a 6 mm balloon in 4 (33.3%). In most cases, the inflated balloon locked securely into position leaving approximately one-third of the 16 mm length protruding distally (inferiorly) out of the orifice, but stable.

Average intraluminal volumes of the cartilaginous ET increased from pre-dilation 0.16 cm3 to post-dilation 0.49 cm3 (increase of 357 %), which was statistically significant (p < 0.001).

There were minor adverse effects in three ½ head specimens, all of which were lacerations of the luminal mucosa. There were no other soft tissue injuries, no fractures of the cartilage of the ET or separation from the basis phenoid, and no bony fractures detected on palpation or on post dilation CT images.

DISCUSSION

Balloon dilation of the cartilaginous portion of the ET has been proposed as a minimally invasive novel method for treating refractory OME. The present study has demonstrated that the procedure is feasible and safe to the best extent that can be judged from a cadaver trial. There was significant dilation of the lumen without any significant adverse effects. There was no significant effect at the tubal orifice, where the medial cartilaginous lamina is most mobile, or near the bony cartilaginous junction where the cartilage becomes circumferentially fixed. The greatest dilatory changes occurred between 6 – 24 mm from the orifice, where the cartilage is less mobile and the balloon was forced to expand into the soft space of the antero-lateral wall, toward Ostmann’s fat pad, TVP muscle, and pterygoid fossa.

Risks of the balloon dilation could be circumferential stricture, fracture of the medial cartilaginous lamina, injury to the TVP muscle, and patulous ET.

If balloon dilation of the ET were ultimately demonstrated to be effective with the benefits sustained over time, it would be a useful and minimally invasive alternative to tympanostomy tubes in patients with chronic OME.

CONCLUSIONS

This study demonstrated that balloon dilation of the cartilaginous portion of the ET was feasible and appeared to be safe in a cadaver trial. The hypotheses for this study were supported by the significant dilation of intraluminal volumes and cross-sectional areas within the middle section of the cartilaginous ET. No significant adverse effects were encountered.

On the basis of this study, it is reasonable to proceed with a human pilot study to judge safety and efficacy in patients with medically refractory dilatory dysfunction of the Eustachian tube.

REFERENCES


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