National Institute for Health and Care Excellence

IP914/2 Balloon dilation for chronic eustachian tube dysfunction

IPAC date: 10/10/19

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Patient	**General**	As a a sufferer of this condition for countless years, and numerous grommet procedures, I welcome this and cannot wait until it is approved for use, the symptoms are very debilitating, and whilst grommets help they are not a good long term solution.	Thank you for your comment.
2	Consultee 2 Company Minim Healthcare Ltd	**Page 31**	Re Company Engagement: Page 31 Overview Document IP914/2 My company, Minim Healthcare Ltd is the UK supplier of a balloon eustachian tuboplasty device (TubaVent - manufactured by Spiggle & Theis) that is perhaps the most widely used currently in the UK. I have checked with the manufacturers and to their knowledge and our knowledge, nothing has been received in terms of an information request. We are keen to help the process of review; if it is not too late, is it possible to have the survey resent to us? If there is anything we can add, we would be happy to do so.	Thank you for your comment. According to our records, a structured information request was sent to Spiggle & Theis with a deadline for completion of 16 March 2019. We did not receive a response.

3	Consultee 3 Company Stryker ENT (Stryker acquired Entellus Medical)	**1.1**	Interventional Procedures Programme (IPP) IP914/2 Balloon dilation for eustachian tube dysfunction Dear Dr. Thomas Clutton â€“ Brock and committee, We appreciate the opportunity to submit comments back on the draft guidance. We thank the committee for conducting a detailed review of the evidence submitted, the analysis performed by the external assessment center as well as listening to stakeholdersâ€™ feedback. We are in agreement with the committeeâ€™s draft recommendation on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure under standard arrangements. Additionally, since the committeeâ€™s review of the evidence, there has been an additional relevant paper published which supports the draft guidance for consideration. It includes long-term follow-up data on the efficacy of balloon dilation for treating patients with persistent Eustachian tube dysfunction (ETD) since there was a lack of literature on treatment efficacy beyond 12-months. We extended the long-term follow-up of the participants who had undergone balloon dilation in our randomized trial, Meyer et al. A total of 47 participants enrolled in the extended follow-up study which ranged from 18-42 months with the mean follow-up was 29.4 months. Participants demonstrated substantial reduction in the mean overall ETDQ-7 score compared with baseline. Middle ear assessments were also significantly improved at the long-term follow-up period. Eustachian tube balloon dilation results in a long-term improvement for patients with persistent ETD.	Thank you for your comment. The additional paper (Cutler et al., 2019) was identified in the updated literature search and has been added to table 2 of the overview.

			The paper is published online currently. Information regarding the paper: "Address correspondence and reprint requests to Jeffrey L. Cutler, M.D., Colorado Sinus Institute, 850 Harvard E. Ave, Suite 505, Denver, CO 80210; E-mail: jeffrey.cutler@hotmail.com Entellus Medical designed and sponsored this study. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/MAO.0000000000002396 " I will also send a copy to NICE via email since I can not upload with my comments. With the introduction of Eustachian tube balloon dilation, patients now have access to a safe, effective, and durable treatment that addresses the actual condition. Moreover, balloon dilation procedures with XprESS can be performed in the ambulatory setting under local anesthesia, providing cost savings to the patient and providers over procedures performed in the OR. Also,when performed under local in the ambulatory setting, it benefits the patient the ability to rapidly return to work and other normal daily activities. Thank-you again for allowing stakeholders to comment on this draft recommendation.	

			Kind regards, [redacted] Consultant for Stryker ENT	
4	Consultee 4 Private Sector Professional	General	First, I want to thank the NICE organization for the guidance provided across all areas of healthcare and specifically for the guidance info related to ETDB (Eust Tube Balloon Dilation). I also appreciate the opportunity to submit comments on this most important technology. I believe the body of literature available supports the safety and efficacy of ETBD. There are 2 randomized, controlled trials with excellent results: Poe et al Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial.Laryngoscope. 2018 May;128(5):1200-1206 and Meyer et al, Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction with 1-Year Follow-Up. Otology & Neurotology: August 2018 - Volume 39 - Issue 7 - p 894â€“902. I have been using the XprESS device to treat my patients with ETD for over 2 years now and have performed several hundred dilations in both the operating theatre and under local anesthesia in an ambulatory setting. I also participated in a clinical research ETBD registry study to further enhance the clinical data available. My patients' outcomes have been very similar to the RCT's; >80% symptom resolution rate, well-tolerated in operating theatre or ambulatory setting, no complications, no pain issues. ETBD is simple, safe and comfortable to perform under local anesthesia by performing a sphene-palatine block. This reduces cost and avoids the risks of general anesthesia. My patients return to work/school the next day and only	Thank you for your comment.

			require acetaminophen or ibuprofen for discomfort. The learning curve for using the XprESS device is very short; usually just 2-3 cases. In summary, based on the similarity in patient inclusion and exclusion criteria and the consistency of the positive outcomes achieved between studies, there is sufficient evidence to demonstrate that health improvement is attainable in routine clinical practice. Balloon dilation is a safe and effective minimally invasive procedure for patients with ETD who otherwise have very limited options for treatment.	
5	Consultee 5 Professor of Otolaryngology, US	General	Thank you very much for extending this opportunity to comment on the proposed IP above. I have been traveling a great deal this past month, including today and I missed the 17:00 BST deadline for comment, although it is currently 15:15 PDT locally. I apologise for missing the deadline and I hope that it may still be possible to include my comments as I have been involved in the development of this procedure and I was the lead investigator in designing the Acclarent device and lead PI for the FDA clinical trial that led to its approval in USA. For full disclosure, I am a consultant for Acclarent so that they may reimburse my time and expenses, but I receive no royalties from their products and I have no financial interest in the company. There have been many developments since NICE last looked into the Balloon Dilation of the Eustachian Tube (BDET) in 2011. There have been two Randomised Clinical Trials (RCT) for FDA clearance and two follow up studies, one with one year and the second with a mean of 29 months follow up, both showing significant durability of the results. It should be noted that the FDA trial for the Acclarent AERA device required normalisation of tympanograms and patient reported	Thank you for your comments. The evidence considered by the committee included the 2 randomised controlled trials. The systematic review by Huisman J et al. is included in table 2 of the overview (study 4). Ashry Y et al. (2017) is included in the appendix of the overview. Luukkainen V et al. (2018) is included in table 2 of the overview (study 8). Section 1.1 of the draft guidance states ‘Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that

			outcomes as an unusually rigorous standard to achieve as the study was required to pursue a de novo approval process. There have been a number of smaller, retrospective studies and some systematic reviews of those studies, the best of which is Huisman et al (2017). In that review, outcomes were consistently significantly improved in all major categories (otoscopic exams, tympanograms, ability to perform a Valsalva manoeuvre, and Eustachian tube function scores), despite heterogeneity in inclusion criteria, outcomes measures, and risk of bias. Longer term follow up in some of those studies has been reported and with consistent duration of benefit from the procedure. • Huisman et al 2017 – Systematic review & meta-analysis of 15 case series, 1155 patients (1881 ETs) o Mean f/u 6.9 mo. (range 0 – 50 mo) o Significant improvement : Valsalva, Otoscopy, Tympanometry, ET scores (including tubomanometry) • Ashry et al 2017 – 48 patients (67 ETs), mean f/u 1.3 yrs (range 0.4 – 3.4), with adjunctive procedures o Success rate 79% (tympanogram, otoscopy, Valsalva) • Luukkainen et al 2018 – 46 patients (52 ETs) o Mean f/u 3.1 years (range 1.8 – 4.6) 77 % improved ETDQ-7 symptom scores These data were sufficient for the American Academy of Otolaryngology Head-Neck Surgery to publish a Clinical Consensus Statement (CCS) on BDET recently in which a definition of Eustachian tube dysfunction, acceptable means for diagnosis, indications for the procedure, recommendations for the procedure regarding safety, and recommendations for outcomes measures were specified. These guidelines were made taking into consideration the recently published diagnostic algorithm proposed by Smith et al from	standard arrangements are in place for clinical governance, consent and audit.'

			Cambridge, so that these statements reflect consideration of the very latest evidence in this field. I noted that one of your consultants expressed concern about uncertainty of results and durability of benefit. These concerns have arisen out of inappropriate use of balloon dilation. Prior to establishing a uniform definition for obstructive Eustachian tube dysfunction, many patients with other differential diagnoses that cause aural fullness have been subjected to dilation, without benefit in their aural fullness symptoms. Using appropriate indications, as specified in the CCS, clinical benefit has been consistent and durable, assuming that patients keep their underlying medical conditions that cause nasal & nasopharyngeal inflammation under appropriate control. Thank you very much for kindly allowing me to offer some late comments. Very best regards, [redacted]	
6	Consultee 5 Professor of Otolaryngology, US	General	Thank you for kindly accepting these comments. In my haste to get out those comments after the deadline, I neglected to mention that the randomised-controlled trials did not allow for the use of adjunctive procedures, such as concurrent tympanostomy tubes to drain an effusion or adenoidectomy, even though the surgeons believed that they might have been indicated. Adjunctive procedures are commonly indicated as inflammation of the Eustachian tube is often accompanied by inflammation elsewhere in the adenoid, nasal cavity or sinuses. Therefore, the outcomes from these rigorous RCTs should be regarded in light of the restrictions of such a study. Increased benefits would be expected when doing the procedure in association with adjunctive procedures when indicated in ordinary clinical use.	Thank you for your comment.

understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."