Balloon Dilation of the Eustachian Tube

Effective: July 1, 2017

DESCRIPTION

A eustachian tube balloon dilation system is a device that includes an inflatable balloon and flexible catheter that dilates the cartilaginous portion of the eustachian tube for treating persistent eustachian tube dysfunction.

MEDICAL POLICY CRITERIA

Balloon dilation of the eustachian tube is considered investigational for the treatment of any condition, including but not limited to eustachian tube dysfunction.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

BACKGROUND

The eustachian tube equalizes pressure across the tympanic membrane, protects the middle ear, and clears middle ear secretions. Eustachian tube dysfunction can interfere with any of
these functions. There is limited clinical trial data to determine a preferred treatment choice. Causes of eustachian tube dysfunction, include but are not limited to sinusitis, rhinitis, laryngopharyngeal reflux, and mass lesions. Conventional pharmacological treatments for eustachian tube dysfunction include decongestants, systemic glucocorticoids, topical nasal steroids, and direct steroid application. Medical and surgical management may include, but are not limited to tympanostomy, eustachian tuboplasty, or balloon dilation/tuboplasty.[1]

REGULATORY STATUS

The Aera Eustachian Tube Balloon Dilation System manufactured by Acclarent received FDA approval in 2015.[2] The device is classified as class II and is indicated for treatment of eustachian tube dysfunction in adults 22 and older. The device is restricted to prescription use in accordance with 21 CFR 801.109.

EVIDENCE SUMMARY

SCIENTIFIC EVIDENCE

Evaluating the safety and effectiveness of balloon dilation of the eustachian tube requires randomized comparisons with standard treatments. These comparisons are necessary to determine whether the benefits of balloon dilation of the eustachian tube outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing long-term morbidity and mortality, or secondary outcomes such as improved eustachian tube function. The evidence summary below is focused on systematic reviews and randomized controlled trials.

Systematic Reviews

Hwang (2016) published a systematic review (SR) that included nine studies with a total of 713 balloon dilations in 474 patients and follow-up times of 1.5 – 18 months.[3] The authors concluded that “Prospective case series can confirm the safety of eustachian tube balloon dilation. As a potential solution for chronic eustachian tube dysfunction, further investigations are warranted to establish a higher level of evidence of efficacy.”

Jufas and Patel (2016) published a SR that evaluated balloon dilation, with a transtympanic approach for eustachian tube dysfunction (ETD).[4] Three limited case series were included. The authors concluded there was a high risk of bias and safety and efficacy outcomes were conflicting.

Randrup and Ovesen (2015) published a SR evaluating balloon eustachian tuboplasty for ETD.[5] The authors evaluated nine case series and health outcomes for 443 patients. All case series were poor quality and had a high risk of bias.

Randomized Controlled Trials

No randomized control trials since the above 2016 SRs were identified.

PRACTICE GUIDELINE SUMMARY

No practice guidelines were identified that address balloon dilation of eustachian tubes.
SUMMARY

There is not enough research to show that balloon dilation improves health outcomes for people with eustachian tube dysfunction. No clinical guidelines based on research recommend balloon dilation for eustachian tube dysfunction. Therefore, balloon dilation of the eustachian tube is considered investigational for the treatment of any condition, including but not limited to eustachian tube dysfunction.

REFERENCES

1. UpToDate. Eustachian tube dysfunction. 9/21/16 (Ed). UpToDate, 2016.
2. FDA. ACCLARENT AERA™ Eustachian Tube Balloon Dilation System. FDA.GOV; 2015.

CODES

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