Balloon Dilation of the Eustachian Tube Is Indeed a "Gizmo" Until Future Research Proves Safety and Efficacy

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What is This?
Balloon Dilation of the Eustachian Tube Is Indeed a “Gizmo” Until Future Research Proves Safety and Efficacy

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Abstract

In the April 2014 issue of this journal, Richard M. Rosenfeld, MD, MPH, wrote an editorial in which he recommends distinguishing “fanciful gizmos from truly useful technology,” provides 5 criteria to evaluate a gizmo, and includes as one of the current ones balloons to “open clogged ears.” The implication is that balloon dilation for suspected eustachian tube dysfunction–middle ear disease is an unproven procedure. Coincidentally, on April 1, the National Institutes of Health (NIH) awarded an Exploratory/Development grant to the University of Pittsburgh to evaluate this new treatment, which affirms that the NIH agrees that this procedure is of uncertain efficacy.

Keywords

commentary, balloon dilatation, eustachian tube

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The timing of Editor Richard M. Rosenfeld’s brilliant, whimsical, and extremely informative editorial on “Gizmos” in the April 2014 issue of this journal could not have come at a more opportune time. His editorial questions “what degree of due diligence should be brought to bear before embracing the latest therapeutic medical gizmos, including robots, lasers, and balloons.” In evaluating gizmos, one should ask the following questions: “Is it approved? Does it work? Is it safe? Are there conflicts of interest? Is it worth it?” Related to balloons, Dr Rosenfeld states that “experts use them to open clogged ears.” But, are they safe and effective?

Coincidentally, on April 1, 2014, the University of Pittsburgh was awarded a National Institutes of Health (NIH) Exploratory/Development grant to evaluate the efficacy of balloon dilation of the eustachian tube (ET) in adults. Cuneyt M. Alper, MD, is the principal investigator. Eustachian tube testing will be conducted at our Middle Ear Physiology Laboratory. This procedure has been advocated for patients, adults, and children who have suspected ET dysfunction (physician diagnosed) with and without middle ear disease. During the past 5 years, 15 articles have been published on feasibility, safety, and purported efficacy. In addition, there have been courses teaching physicians this procedure, as well as presentations at a national society of otolaryngologists in the United States, and the procedure has been used increasingly in Europe. Nevertheless, the few clinical studies published failed to evaluate the direct effect of the procedure on ET function, included small numbers of patients, had weak definitions of “cure,” and failed to study patients for the long term; most important, none were randomized controlled trials (RCTs). Thus, balloon dilation of the ET has not been proven to be effective and remains experimental. Indeed, this grant affirms that the NIH agrees that this procedure is of uncertain efficacy.

The new NIH-funded grant is not designed to test the safety and efficacy of balloon dilation of the ET in an RCT, but if this pilot study proves to be promising, then such a trial would be the next step. In addition, none of the published studies evaluated comorbid conditions that may adversely affect the ET, such as sinusitis, allergy, and gastroesophageal reflux, whereas this new study does include evaluating ET function before and after treatment of these relatively common maladies, since successful treatment would make the balloon procedure unnecessary.

For more details about this new grant, access the Society for Middle Ear Disease website (societyformiddleeardisease.org), Global Updates.

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Charles D. Bluestone, sole author.

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