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Health Technology Assessment (HTA) feasibility study: the XprESS device for the treatment of patients with Eustachian tube dysfunction

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INTRODUCTION

The XprESS device is a minimally invasive technique for Eustachian tube dysfunction (ETD), relieving symptoms like hearing difficulties and plugged ears. It improves tube function, increasing middle ear ventilation and drainage, making it a valuable tool for ETD management.

The project aims to examine the existing evidence in the literature to establish a subsequent multidimensional assessment of the patient treated with XprESS.

METHODS

A scientific literature review of the main indications of the XprESS device was conducted as part of the project. The results were subsequently further enriched by grey literature sources and scientific evidence identified through a hand search. To conduct the most detailed analysis of the XprESS device, based on the different indications for which it has been approved, three separate literature reviews were developed:

- First search strategy: treatment of frontal and sphenoid sinuses in adolescents and adults;
- Second search strategy: treatment of maxillary sinuses in children and adults;
- Third search strategy: treatment of adult patients with Eustachian tube dysfunction.

The research question was formulated using the PICO model, which includes the study population (P), the evaluated intervention (I), the comparator (C), and the outcome of interest (O). Research strategies formulated based on these information were launched on the PubMed and Scopus databases.

RESULTS

The PRISMA models below illustrate the path conducted by each literature review (Figure 1, 2, 3). The first search strategy at the end of the review included a total of 6 articles, the second a total of 5 articles, and finally the third search strategy included a total of 17 articles.

Figure 1 – PRISMA model. Diagram showing the literature review process (first search strategy)

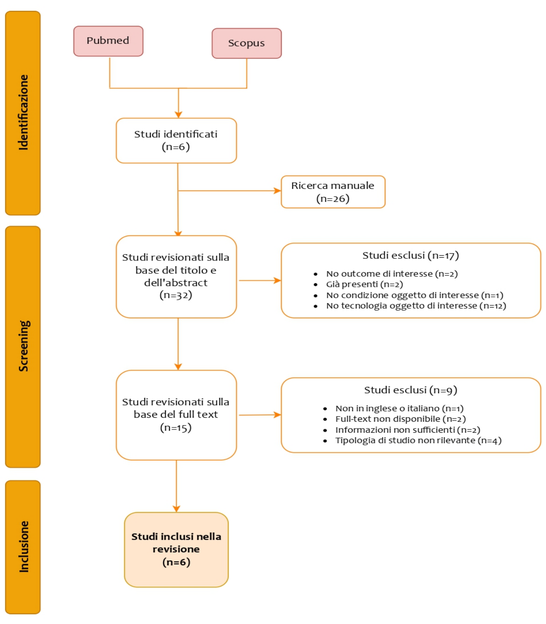


Figure 2 – PRISMA model. Diagram showing the literature review process (second search strategy)

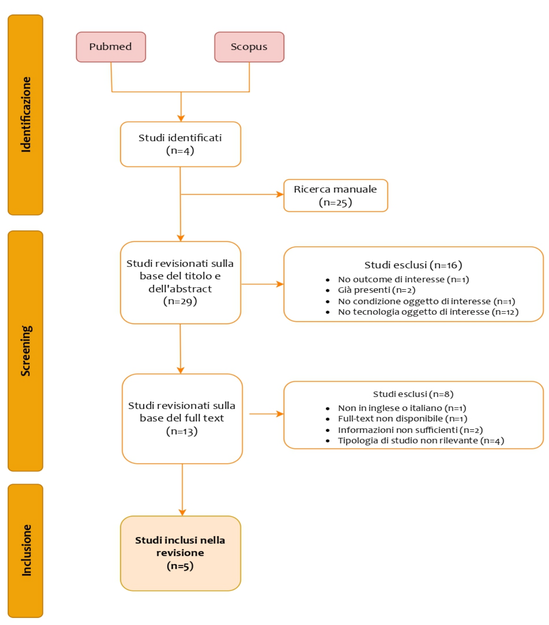
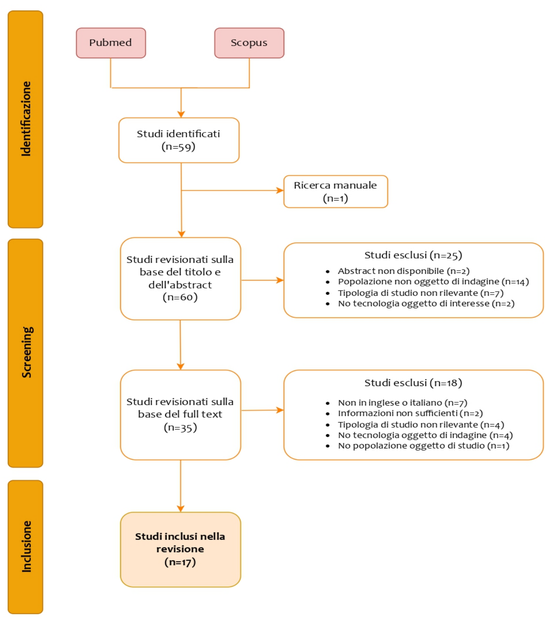


Figure 3 – PRISMA model. Diagram showing the literature review process (third search strategy)



The scientific evidence currently resulting from the literature review about the first and the second research strategies appears insufficient for the production of a Health Technology Assesstment (HTA) report, although their analysis presents promising results for the XprESS device. In fact, the final evaluation of the evidence from these research strategies showed that the maxillary, frontal and sphenoidal sinus dilation procedure with balloon presents high efficacy on symptom control, in terms of reduction of the score detected with the most common and validated symptom questionnaires. This efficacy also appears to be long-lasting, with significant results up to 24 months after the procedure. In addition to this aspect, patients presented in the investigated studies a shorter duration of hospitalization; a lower incidence of post-discharge epistaxis; a lower use of pain medications. The evaluation of the safety profile of the XprESS device, including for children with CRS aged 2 years and older, shows that it is a safe device that does not expose the patient to greater risks than those associated with current surgical techniques. In terms of quality of life, it also showed that there are significant improvements following the use of the device, up to 24 months after the procedure.

The final evaluation of the evidence that emerged from the third research strategy showed that there is currently sufficient evidence in the literature with respect to this topic, reporting a relevant interest from the scientific community for the procedure, given also the high prevalence of the pathology in question. However, the methods of studying the pathology under investigation are still a matter of controversy, given the poor repeatability and high interindividual variability. Currently, otoscopy, tympanometry and the Valsalva maneuver represent the most popular tests for assessing the patient's condition. Analysis of the results of the studies showed that the application of the device provides promising improvement in long-term outcomes, particularly in terms of improvement in the results obtained at the Valsalva maneuver, overall subjective symptoms, and otoscopic results; in contrast, tympanometry and tubomanometry manifested less overall improvement.

CONCLUSION

In conclusion, from the scientific evidence obtained by the the first and the second research strategies, the device under study has been shown to be effective and safe in the treatment of the patient with recurrent or chronic acute sinusitis; future studies should evaluate long-term results (beyond 24 months) and further define the role of the procedure within the treatment algorithm for both pediatric and adult CRS.

From the scientific evidence obtained by the the third research strategies, in conclusion, the application of the XprESS device in chronic tubal dysfunction has already been demonstrated as effective and safe. However, further prospective studies with longer-term follow-up (>12 months) and more uniform efficacy measures would be needed for a more comprehensive view with respect to the effectiveness of the device.