2020 Health Technology Reassessment Report

Nasal Valve Reconstruction

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Summary

Background

Nasal valve reconstruction is a procedure to widen the internal and external nasal valves by inserting, repositioning, folding, pulling, suturing, or extending cartilage when necessary in patients with nasal obstruction caused by internal or external nasal valve stenosis. This technology was reviewed as a health technology with a basis for safety and effectiveness at the 6th New Health Technology Assessment Committee (2014.07.25.) in 2014, and was subsequently registered as a non-benefit item (Ministry of Health and Welfare Notice No. 2016-61 2016.4.27.).

At the 5th HealthTechnology Reassessment Committee (May 11, 2020, - May 13, 2020, written review), to provide information based on the literature on decision-making for efficient use of health and medical resources, it is deliberated that the medical evidence for the clinical safety and effectiveness of nasal valve reconstruction was reevaluated through updated systematic literature review and the decision was made to determine the grade of recommendation for this case.

Methods

An updated systematic literature review was conducted to evaluate the safety and effectiveness of nasal valve reconstruction. All evaluation methods were finalized after deliberation by the nasal valve reconstruction reassessment subcommittee (hereinafter referred to as the subcommittee), which consisted of a total of 5 members including 3 from the Department of Otolaryngology, 1 from Department of Plastic & Reconstructive Surgery, and 1 from Department of Evidence-based Medicine, in consideration of the research purpose.

The nasal valve reconstruction reassessment subcommittee evaluated the technology based on the literature and submitted the review results through three subcommittees operating for about 3 months from July 2020 to October 2020.

The safety and effectiveness reevaluation results of nasal valve reconstruction were finally reviewed at the 11th Health Technology Reassessment Committee (2020.11.13.) in 2020.

A key question in the updated systematic literature review is 'Is nasal valve reconstruction safe and effective for patients with nasal obstruction due to internal/external nasal valve stenosis?'. Based on this key question, three overseas and five domestic databases were searched, and two reviewers

independently screened and selected them according to the literature inclusion and exclusion criteria. The evaluation of the risk of bias in the literature was conducted independently by two reviewers using RoBANS ver 2.0 and consensus was reached. Data extraction was performed independently by two reviewers using a pre-determined data extraction format, and in case of disagreement, it was agreed upon by discussion with a third party. Qualitative analysis was applied for data analysis. The Health Technology Reassessment Committee decided on the final grade of recommendation in consideration of the review opinions of the subcommittee.

Results

A total of 9 pieces of literature finally selected for the updated systematic literature review were all before and after studies (5 prospective, 4 retrospective studies) conducted abroad. A total of 20 articles were selected for this reevaluation, including 11 articles that satisfy the conditions for subjects for the treatment of obstruction and the single intervention of nasal valve reconstruction among 18 articles included in the previous new health technology assessment.

Safety

For the safety of nasal valve reconstruction, treatment-related side effects and adverse events were set as outcome indicators based on the discussion of the subcommittee, and evaluation was made based on 16 literature reports of side effects and adverse events. Among them, it was reported that no side effects or adverse events occurred (0%) during/after surgery in 6 articles (37.5%). In 10 articles that reported the occurrence, edema was 5.8-16.7%, infection 0.9-25.0%, and pain 7.7-12.5%. No other serious complications or side effects were reported, so the subcommittee concluded that the safety was acceptable.

Effectiveness

The effectiveness of nasal valve reconstruction was evaluated by objective measures of improvement in nasal obstruction, such as the minimal cross-sectional area, nasal airway resistance (NAR), and peak inspiratory flow rate (PIFR), and subjective measurement indicators, which are including nasal obstruction symptom evaluation (NOSE), visual analogue scale (VAS), rhinoplasty outcomes evaluation (ROE), linear symptom scale (LSS), recurrence of nasal obstruction and patient satisfaction, based on the discussion of the subcommittee.

The average minimum cross-sectional area before and after nasal valve reconstruction was reported in 4 before and after studies. In all three studies that presented the mean values before and after surgery, the average minimum cross-sectional area was improved after surgery compared to before surgery, and it was found to be statistically significant in two of them. NAR was reported in two before and after studies. In the study of Palesy et al. (2015), median NAR improved after surgery, but it was not statistically significant. In the study of Paniello et al. (1996), 83.3% (10/12 patients) showed significant improvement after surgery. PIFR was reported in 3 before and after studies. In all studies, the mean PIFR was statistically significantly improved after surgery compared to before surgery.

The NOSE score before and after nasal valve reconstruction was reported in 9 before and after studies, and in all studies, it was statistically significantly improved after surgery compared to before surgery. VAS score was reported in 8 before and after studies, and in all studies, it was statistically significantly improved after surgery compared to before surgery. The ROE score was reported in two before and after studies, and in all studies, it was statistically significantly improved after surgery compared to before surgery. The LSS score was reported in one before and after study, and it was statistically significantly improved after surgery compared to before surgery. Patient satisfaction was reported in 8 before and after studies, and all studies showed that the patient satisfaction level after surgery was excellent.

The subcommittee was of the opinion that the procedure was effective as it showed a significant improvement in objective indicators of nasal obstruction, such as minimum cross-sectional area, nasal flow, and in subjective indicators, including NOSE, VAS, ROE, LSS, and patient satisfaction.

Conclusion

The nasal valve reconstruction reassessment subcommittee made the following recommendations based on the current evaluation results.

Although nasal valve reconstruction is a health technology that has evidence for safety and effectiveness in treating nasal obstruction symptoms in patients with nasal obstruction caused by nasal valve stenosis, it was evaluated that there are limitations with the low level of evidence in the literature.

The Health Technology Reassessment Committee deliberated on “nasal valve reconstruction” as follows based on the results of the subcommittee’s review (November 13, 2020).

The Health Technology Reassessment Committee recommends nasal valve reconstruction for the treatment of nasal obstruction symptoms in patients with

nasal obstruction caused by internal/external nasal valve stenosis (grade of recommendation I-b). The reasons for the recommendation are as follows.

Although nasal valve reconstruction is a health technology that has evidence for safety and effectiveness in treating nasal obstruction symptoms in patients with nasal obstruction caused by nasal valve stenosis, it was evaluated that there are limitations with the low level of evidence in the literature.

Keywords

Nasal Valve Stenosis, Nasal Valve Insufficiency, Nasal Obstruction, Nasal Valve Reconstruction