

NECA-Health Technology Reassessment Project
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Health Technology Reassessment Report 2020

Hyoidthyroidpexia

Summary

Background

In the 1st Health Technology Reassessment Committee (2020.1.10.) in 2020, 'hyoidthyroidpexia' is expected to increase in demand for the technology as the number of target patients (patients with obstructive sleep apnea syndrome) increases. Therefore, to support the provision of evidence for efficient use of health and medical resources, it was determined that an evaluation based on the latest evidence for the technology was necessary and this was selected as a health reassessment subject.

Therefore, this assessment aims to evaluate the clinical safety and efficacy of 'hyoidthyroidpexia'.

In this assessment, service was defined in accordance with the 'hyoidthyroidpexia' notification item (Article-374) specified by the Health Insurance Review and Assessment Service, and the scope of the assessment was determined based on this.

Method

This assessment evaluated whether hyoidthyroidpexia is a safe and effective surgery in patients with obstructive sleep apnea syndrome through an updated systematic review of the literature. All evaluation methods were finalized after deliberation by the 'hyoidthyroidpexia reassessment subcommittee (hereinafter referred to as the 'subcommittee'), which consists of 6 experts: 2 from the department of otolaryngology, 1 from the division of pulmonology, 1 from the department of oral and maxillofacial surgery, 1 from the department of neurology, and 1 from the department of evidence-based medicine.

This updated systematic literature review was searched from 3 overseas and 5 domestic databases based on key questions. Article selection process was carried out by two reviewers independently, based on the inclusion and exclusion criteria. In case of disagreement between two reviewers, final decision was conducted by discussion with confirmation of subcommittee members.

The risk of bias regarding selected articles was assessed using RoBANS ver 2.0 by two reviewers independently. Data analysis was performed qualitatively because the quantitative analysis was impossible. Based on the results of this updated systematic literature review conducted in this assessment, the Health Technology Reassessment Committee decided the grade of recommendation.

Results

The safety and effectiveness of hyoidthyroidpexia were evaluated based on the 17 articles. The types of study design are 16 before-and-after studies, 1 case series study, and 16 combined surgery studies, and 1 single-surgery study.

The safety of this technology was evaluated in terms of surgery-related side effects and complications. The evaluation was based on 15 articles report surgical-related side effects and complications.

1. Safety results

Surgery-related side effects and complications reported in 15 articles reporting safety-related results were, in order of severity, 1 case of tracheotomy due to airway damage after operative bleeding (Herder et al. 2005), 2 articles reporting minor hematomas (Tschopp 2007; Bowden et al. 2005), 3 articles reporting neck seroma one week after surgery (Gillespie et al. 2011; Benazzo et al. 2008; Riley et al. 1994). The incidence of self-regulation or disappearance of aspiration within 3 weeks after surgery was 9.3% to 10% (Neruntarat et al. 2003; Karatayli et al. 2012), and 3 articles report dysphagia (Benazzo et al. 2008; Bowden et al. al. 2005; Neruntarat et al. 2003).

In addition, there was one article reporting the occurrence of wound infection (2/15 patients) (Stuck et al. 2005), one article reporting mild pain in all patients (20 patients) within 1 to 5 days after surgery. (Karatayli et al. 2012), and one article reporting the occurrence of mild-to-moderate pain (VAS \leq 7) (30/32 patients) for 5-7 days after surgery (Neruntarat et al. 2003).

6 of 15 articles reported that no early or late complications were observed after surgery, and only 1 article (Ong et al. (2017)) reported a complication rate as 0%.

There is 1 case where tracheostomy was performed for airway damage due to bleeding after hyoidthyroidpexia in a patient with obstructive sleep apnea. However, it was difficult to decide that the cause of the side effects was due to this technology, because this is a case of hyoidthyroidpexia performing a combined surgery rather than a single surgery. In addition, it was judged that no serious side effects or complications were reported by this technology. Thus, this technology was considered as a safe operation.

2. Effectiveness results

The effectiveness of this technology was evaluated by the degree of improvement

in sleep disturbance indicators, including the Apnea Hypopnea Index (AHI), Epworth Sleepiness Scale (ESS), the lowest O₂ saturation level, the success rate of surgical treatment, quality of life, and patient satisfaction. Effectiveness-related results were reported in 15 selected articles.

13 articles reporting the apnea hypopnea index results before and after hyoidthyroidpexia surgery reported a marked decrease after surgery compared to before surgery. Of these, 10 articles showed statistical significance.

14 articles reporting the results of the Epworth Sleepiness Scale before and after surgery reported a marked decrease after surgery compared to before surgery, and 12 articles showed statistical significance.

A total of 11 articles reported the lowest oxygen saturation, and 6 articles did not present the lowest oxygen saturation result (Canzi et al. 2013; Karatali et al. 2012; Benazzo et al. 2008; Tschopp 2007; Herder et al. al. 2005; Stuck et al. 2005). All of the 11 articles reporting the oxygen saturation results before and after surgery reported a marked increase after surgery compared to before surgery, and 8 articles showed statistical significance.

A total of 11 articles (6 articles included in the new health technology assessment in 2009) reported the success rate of surgical treatment for hyoidthyroidpexia. The success rate of hyoidthyroidpexia was 17.2 - 90%, and the response or improvement was 7.1- 61.5%. On the other hand, the results reported as non-response were 14.6 -50%.

Hyoidthyroidpexia reassessment subcommittee expressed the opinion that the hyoidthyroidpexia was effective as it showed a significant pattern after hyoidthyroidpexia in the AHI, ESS, and lowest O₂ saturation level, which are indicators of improvement of sleep disorders in obstructive sleep apnea syndrome.

Conclusion and Suggestions

Hyoidthyroidpexia reassessment subcommittee made the following recommendations based on the currently reviewed literature evidence.

Although there are some studies that have been conducted since the 2009 New Health Technology Assessment, it was confirmed that the level of evidence is low because most articles are before-and-after studies without a comparison group, and most of the studies performed combined surgery rather than hyoidthyroidpexia surgery alone.

However, it is judged that there are no reported cases of serious side effects or complications due to hyoidthyroidpexia, so the safety is at an acceptable level. It was judged as having surgery. In the sleep disorder improvement index and the

lowest O₂ saturation level, there was a significant pattern after surgery, so it was judged to be an effective operation.

Hyoidthyroidpexia subcommittee evaluated hyoidthyroidpexia as a safe and effective health technology for improving the symptoms of sleep disorders in patients with obstructive sleep apnea syndrome based on the evidence of literature review.

The Health Technology Reassessment Committee judged that this technology is a safe surgery since there were no reported cases of complications due to the serious side effects of hyoidthyroidpexia and that it is an effective technique since there was significant evidence after surgery in the sleep disorder improvement index and minimum oxygen saturation results. Therefore, the Health Technology Reassessment Committee judged that 'hyoidthyroidpexia' is a safe and effective health technology for improving symptoms of sleep disorders for patients with obstructive sleep apnea syndrome, and deliberated it as 'recommended' (recommended grade I-b) (November 13, 2020).

Keywords

Hyoidthyroidpexia, Hyoid myotomy and suspension, Obstructive sleep apnea syndrome,