2020 Health Technology Reassessment Report

Pulsed Dye Laser Surgery with Laryngoscope

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Summary

Background of Assessment

The National Evidence-based Healthcare Collaborating Agency is conducting a health technology reassessment project. Pulsed dye laser surgery with laryngoscope has been evaluated as a technology similar in safety and effectiveness to conventional laser surgery when used for benign laryngeal tumors in consideration of its technological strength at the 7th New Health Technology Assessment Committee (2008.08.22.) in 2008. Since then, it has been registered as a non-benefit service (November 11, 2008) and has been used until now. It was selected as a health technology re-assessment agenda to present the rationale for efficient use of health and medical resources at the 6th Health Technology Reassessment Committee (2020.06.12.~06.19., written) in 2020.

In this assessment, a subcommittee was formed to confirm the clinical safety and effectiveness of 'pulsed dye laser surgery with laryngoscope' to re-evaluate health technology.

Committee's Operation

It was selected as an agenda at the 6th reassessment committee in 2020. and it was deliberated that the subcommittee consists of a total of 4 members, one from the Department of Dermatology (laser major), two from the Department of Otolaryngology, and one from Evidence-based medicine. Then, from August 18, 2020, to October 20, 2020, a total of three subcommittees meetings were held for three months to evaluate the safety and effectiveness of this technology.

The final deliberation was conducted on the safety and effectiveness assessment results of pulsed dye laser surgery with laryngoscope at the 11th Health Technology Reassessment Committee (2020.11.13.) in 2020

Assessment Method

An updated systematic literature review was conducted to evaluate the safety and effectiveness of pulsed dye laser surgery with a laryngoscope. All assessment methods were finalized after deliberation by the pulsed dye laser surgery with laryngoscope reassessment subcommittee (hereinafter referred to as the subcommittee) in consideration of the research purpose.

The systematic literature review was conducted in 3 overseas and 5 domestic databases based on the above key questions and they were independently selected by two reviewers according to the literature inclusion and exclusion criteria. RoBANS 2.0 was used to evaluate the risk of bias, and GRADE was used to evaluate the level of evidence in the literature. In consideration of the subcommittee's review opinion, the reassessment committee presented the recommendation grade after final deliberation.

In this assessment, the target disease was divided into the benign vocal fold (laryngeal) disease and recurrent and intractable vocal fold (laryngeal) disease, and safety and effectiveness assessment criteria were applied differently depending on the study design. Both safety and effectiveness were evaluated in the literature with comparative procedures for benign vocal fold (laryngeal) diseases, and only safety was evaluated when there was no comparative procedure. When there is no effective treatment other than interventional procedures for recurrent and intractable vocal fold (laryngeal) diseases such as sulcus vocalis, both safety and effectiveness were evaluated according to the subcommittee's opinion that effectiveness review is necessary even in a before-and-after study without comparative procedure.

Assessment Results

As a result of searching domestic and foreign databases according to the protocol discussed in advance, in this assessment, nine pieces of literature were included in the assessment of the new health technology assessment system (2008) and five foreign documents selected through an updated systematic review were evaluated. The safety and effectiveness results on a total of fourteen selected studies are summarized as follows. The results below are presented separately for each target disease.

All twelve articles included in the previous new health technology assessment were case studies and were targeted for benign vocal fold diseases. A total of nine articles were included in the assessment excluding one article that set diseases not included in the study subject of this assessment as a patient group and two articles that did not report safety according to the criteria of this assessment, which was to evaluate only safety in case studies.

1. Safety Results

For the safety of pulsed dye laser surgery with a laryngoscope, adverse events during or after the procedure in patients with recurrent and intractable vocal fold (laryngeal) disease and neoplastic vocal fold (laryngeal) disease were evaluated as indicators.

The safety of this technology was evaluated in a total of 14 pieces of literature.

In one article (Hwang et al. (2013)) on sulcus vocalis, a recurrent and intractable vocal fold (laryngeal) disease, the time point was not reported, but no adverse events related to the procedure were reported.

In one of thirteen pieces of literature (Centric et al. (2014)) targeting neoplastic vocal fold (laryngeal) disease, adverse events were reported during the procedure. In three articles (Bower et al. (1998), Kim et al. (2017), Mouadeb et al. (2007)), adverse events were reported after the procedure.

Also, in one document (Koufman et al. (2007)), the time point was not reported, but adverse events related to the procedure were reported. The remaining eight articles reported that there were no adverse events related to interventional procedures. Document (Centric et al. (2014)), which reported adverse events during the procedure, reported that one out of thirty-three patients had anxiety symptoms and the procedure was stopped, but there were no related adverse reactions. Three documents were reporting adverse reactions after the procedure. Bower et al. (1998) reported that one out of nine patients with severe laryngeal papilloma developed early wheeze after surgery, and Kim et al. (2017) reported that eleven cases of submucosal vocal cysts occurred as adverse events among 186 patients who underwent interventional procedures. Mouadeb et al. (2007) reported that one out of forty-seven patients was hospitalized with wheezing after surgery for Reinke's edema. Also, although the time point was not reported in the literature, Koufman et al. (2007) performed 406 interventional procedures and reported adverse events in 4 of them, which were 1 case of vasovagal syncope, 2 cases of minor vocal cord bleeding, and 1 case of the broken laser tip.

2. Effectiveness Results

For the effectiveness of pulsed dye laser surgery with a laryngoscope, the importance of key indicators was evaluated differently depending on the disease. One document on sulcus vocalis, a recurrent and intractable disease, evaluated the degree of voice recovery as a major indicator. In the two documents on neoplastic vocal fold(laryngeal) diseases (leukoplakia, papilloma, etc.), the recurrence rate, lesion removal, voice recovery, and soft tissue complications were evaluated as major indicators.

There is only one document (Hwang et al. (2013)) on recurrent and intractable vocal fold (laryngeal) diseases, and the effectiveness of the intervention was evaluated to the degree of voice recovery. In the document by Hwang et al. (2013), values before and after intervention about perceptual assessment of voice quality, aerodynamic index, voice and electroglottograph (EGG) analysis, and voice handicap index (VHI) and statistical significance were presented to evaluate the degree of voice recovery. Statistical significance was shown in the perceptual

assessment of voice quality and VHI ($p<0.05$), but the remaining indicators did not show statistical significance.

The effectiveness of the intervention for neoplastic vocal fold (laryngeal) disease was reported in two articles (Bower et al. (1998), McMillan et al. (1998)), and the recurrence rate, degree of lesion removal, and soft tissue complications were evaluated as indicators. McMillan et al. (1998), who reported the recurrence rate, reported that 2 out of 3 patients had a relapse (66.7%). In Bower et al. (1998), who reported the degree of lesion removal, it was reported that patients (62.5%) with more than 90% removal of lesions in the intervention group were 5 out of 8 patients, patients with more than 50% removal (100%) were all 8 patients, and the control group had the level similar to that of the intervention procedure. McMillan et al. (1998) also reported that 2 out of 3 patients had complete lesion removal. Regarding the presence of soft tissue complications, Bower et al. (1998) evaluated the scar formation as an indicator and reported that no scar formation was observed.

Conclusion and Suggestions

With regard to the safety of pulsed dye laser surgery with a laryngoscope, some reports of adverse events during and after surgery were reported, but these were at an acceptable level, and the subcommittee evaluated it as a safe technology.

Regarding the effectiveness of pulsed dye laser surgery with a laryngoscope, the statistical significance of the detailed indicators that reported the degree of voice recovery, which is a critical outcome indicator for patients with sulcus vocalis, a recurrent and intractable disease, was not consistently reported. Also, an insufficient number of documents and subjects with only one before-and-after study, and the level of evidence in the literature was also 'Very Low', so it was difficult to prove its effectiveness. In addition, in neoplastic vocal fold (laryngeal) diseases such as leukoplakia and papillomas, it cannot fully explain the effectiveness of the technology because it did not consistently report the results of lesion removal and recurrence rate, which are critical outcome indicators related to effectiveness, and it did not report statistical significance. The opinion was that it was difficult to prove the effectiveness because the number of documents and subjects was very small as there are only two cohort studies, and the level of evidence in the literature was 'very low'.

Accordingly, the Health Technology Reassessment Committee deliberated pulsed dye laser surgery with laryngoscope for the treatment of patients with recurrent and intractable benign vocal fold (laryngeal) disease based on the review results of the subcommittee as follows (2020.11.13.).

In this assessment, the Health Technology Reassessment Committee cannot

confirm additional clinical effectiveness due to the small number of documents to judge additional clinical effectiveness compared to the previous assessment and the low level of evidence. However, the safety and effectiveness of the technology proven by case studies at the time of the existing new health technology assessment were judged to be acceptable.

Therefore, the Health Technology Reassessment Committee deliberated pulsed dye laser surgery with laryngoscope for the treatment of patients with recurrent and intractable, benign vocal fold (laryngeal) disease as ‘recommended’ (recommendation grade I-b). Regarding the reason for the review, endoscopic pulse dye laser laryngeal surgery was safe, but the literature reporting effectiveness was low in the level of evidence to change the effectiveness evaluated at the time of introduction of the existing new health technology, so it was judged as a health technology with low strength of recommendation.

Keywords

Pulse dye laser, Laryngeal Diseases, Vocal cords, Laser therapy