2019 Health Technology Reassessment Report

Safety and Effectiveness Reassessment of Ultrasound guided-High Intensity Focused Ultrasound, USg-HIFU

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Abstract (English)

□ Assessment background

Ultrasound guided-high intensity focused ultrasound (USg-HIFU) is a minimally (non) invasive treatment method that uses B-mode ultrasound guided extracorporeal ultrasound to induce coagulation necrosis of solid tumors. This technique was recognized as a new health technology for liver cancer only in 2010 and has been registered as a non-coverage item.

□ Committee operation

A subcommittee consisting of six members held a total of four subcommittee sessions over a 5-month period between April and August 2019 to submit the results of assessment and review of this procedure based on literary evidence.

□ Assessment objectives and methods

A systematic literature review was performed to assess the evidence for the safety and effectiveness of USg-HIFU for liver cancer. Detailed study methods were as follows and all assessment methods were established through review and approval by the “Subcommittee for the Assessment of USg-HIFU Safety and Effectiveness for Liver Cancer” (*hereinafter* the Subcommittee) with consideration for the study objectives.

For systematic literature review, five Korean and three foreign databases were searched based on the key question above. Two reviewers independently screened and selected the articles according to the selection and exclusion criteria. Risk of bias assessment was performed independently by two reviewers using RoBANS

to reach an agreement. Data were extracted independently by two reviewers using pre-determined format. If there was a disagreement between the reviewers, such cases were discussed with a third party to reach an agreement. For data analysis, since quantitative analysis was possible, qualitative review was applied.

Table. Details of PICO-TS

Item	Details
Patients	Primary liver cancer Metastatic liver cancer
Intervention	Ultrasound guided-high intensity focused ultrasound (USg-HIFU)
Comparators	Surgery Non-invasive procedure
Outcomes	- Safety · Fever, (secondary) infection, abscess, skin burn, subcutaneous fat edema, abdominal pain, ascites, diarrhea, gastrointestinal perforation, pancreatic duct stenosis, peripheral organ damage, tissue and vascular coagulation necrosis, tumor bleed, large vessel rupture, postoperative embolism, tissue destruction by cavitation, adverse events, etc. - Effectiveness · AFP level · Complete necrosis rate concept indicators including complete response (CR) · Partial response (PR) · Stable disease (SD) · Progressive disease (PD) · Survival rate: overall

Item	Details
Follow-up period (Time)	No limit
Study type	Randomized controlled trials (RCTs), non-randomized studies (cohort, cross-sectional, and pre-post comparison studies), case studies, and case reports
Years	2007 ~ Search date (May 3, 2019)

□ Assessment results

A total of 24 articles were used in the assessment, which included 18 articles selected from searching domestic/foreign databases according to predetermined protocol and six articles used to at the time of new health technology assessment. Safety and effectiveness assessment results were as follows:

□ Conclusions

Based on articles reporting that there are serious postoperative complications or adverse events after USg-HIFU for liver cancer, the Subcommittee determined that it is necessary to consider the condition of the patient during the procedure. Moreover, because some articles reported third degree burn and rib fracture and the area where high intensity ultrasound is focused and the experience of the operator are associated with occurrence of complications, it was determined that preventing occurrence of complication through enough experience and training is important from a safety aspect.

From an effectiveness aspect, most articles reported that complete/partial response rate and overall survival rate were higher and stable/progressive disease rate was lower in the USg-HIFU group than the comparator group. Accordingly, it was determined that USg-HIFU has a therapeutic effect as curative and

palliative treatment modality, and thus, the need for this was agreed in subcommitte. However, there was only one RCT in the past 10 years and most relevant studies were case studies or case reports, while comparison studies reported that USg-HIFU is valuable when combined with other procedures. Therefore, it was determined that additional studies are needed to confirm the effects of USg-HIFU as a standalone therapy.

The Health Technology Reassessment Committee reviewed and determined that the findings of the Subcommittee on “USg-HIFU for liver cancer” are valid (October 11, 2019).