IQWiG Reports – Commission No. E15-02

Magnetic resonance imaging-guided high-intensity focused ultrasound therapy for uterine fibroids (2nd addendum to commissions E14-04 and E14-05)[1]

Executive Summary

[1] Translation of the executive summary of the addendum to the assessment of potential *Magnetresonanztomografie-gesteuerte hochfokussierte Ultraschalltherapie zur Behandlung des Uterusmyoms (2. Addendum zu den Aufträgen E14-04 und E14-05)* (Version 2.0; Status: 10 March 2017). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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[2] Due to legal data protection regulations, employees have the right not to be named.

Executive summary

With its letter of 8 June 2015, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) with a supplementary assessment of commissions E14-04, E14-05, and E14-14 in order to evaluate the conclusions on the potential (in terms of §137e Social Code Book V) of the method of magnetic resonance imaging guided high-intensity focused ultrasound (MRIg-HIFU) therapy for uterine fibroids (also called leiomyomas or myomas). The assessment (version 1.0) was completed on 11 August 2015 and transferred to the G-BA. As this version contained information that is protected by the administrational procedure, the present version 2.0 was prepared for publication, which does not contain this information. These changes in the presentation do not affect the result of the assessment.

Research question

The aim of this examination was to determine for MRIg-HIFU whether, besides the documents already used in the assessments of potential E14-04 and E14-05 as well as in addendum E14-14, further relevant studies or publications on relevant studies exist,. If this was the case, it was to be evaluated whether, under their consideration, the present examination or treatment method still offers potential. Furthermore, it was to be evaluated whether, besides the studies already considered in the assessments of potential E14-04 and E14-05 as well as in addendum E14-14, further studies are being conducted that in principle are suited to demonstrate a benefit in the near future.

Methods

A 2-step hierarchical procedure was used in this assessment. In a first step (search step 1) relevant randomized controlled trials (RCTs) and prospective comparative studies on MRIg-HIFU were searched for (evidence levels I and II).

The derivation of the potential was conducted on the basis of indirect comparisons of MRIg-HIFU with studies on the natural course or comparator interventions. If no relevant studies could be identified on evidence levels I and II, in a second step (search step 2) those studies or publications on MRIg-HIFU and on the natural course were thus included that corresponded at least to the evidence level IV of the G-BA (single-arm observational studies and other non-comparative studies). In this context, only studies or publications were included that had not already been used within the framework of the previous reports. Furthermore, in order to obtain data on the comparator interventions myomectomy and uterine artery embolization, a systematic review on each of these topics was searched for in search step 2.

For both research steps, bibliographic databases were searched. These included MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the Health Technology Assessment Database. In expectation of the commission, the last search was

conducted on 22 May 2015. In addition, systematic reviews and publicly available study registries were searched.

The selection of relevant studies or publications from the results of the searches of bibliographic databases, publicly accessible study registries, and potentially relevant studies from systematic reviews, was conducted by 2 reviewers independently of each other.

The assessment, synthesis and analysis of information followed the principles described in the Institute's methods paper.

Results

The systematic search for studies of evidence levels I and II in search step 1 did not yield any relevant studies. In search step 2, 1 additional relevant completed study of evidence level III was identified. Three additional publications were identified in addition to the studies of evidence level IV on the test intervention that had already been used in the reports on the assessment of potential (E14-04/05 and E14-14). Furthermore, 2 additional relevant completed studies of evidence level IV on the test intervention and 1 additional relevant completed study on the natural course were identified. One systematic review was used for each comparator intervention. The results of the publications or studies additionally identified did not change the evaluation with regard to the potential.

No additional ongoing RCTs on MRIg-HIFU were identified in the systematic literature search.

Conclusion

After a systematic evaluation and under consideration of the further completed studies identified, the method of MRIg-HIFU for the treatment of uterine fibroids still possesses a potential. Beyond those studies already considered in the reports on the assessment of potential (E14-04/05 and E14-14), no further completed or ongoing studies were found that in principle would be suited to demonstrate a benefit in the near future.

The full report (German version) is published under https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/e15-02-magnetic-resonance-imaging-guided-high-intensity-focused-ultrasound-therapy-for-uterine-fibroids-2-addendum-to-commissions-e14-04-and-e14-05.7818.html.