

IQWiG Reports – Commission No. E14-04

Magnetic resonance imaging-guided high-intensity focused ultrasound therapy for uterine fibroids¹

Executive Summary

¹ Translation of the executive summary of the assessment of potential *Magnetresonanztomografie-gesteuerte hochfokussierte Ultraschalltherapie zur Behandlung des Uterusmyoms* (Version 1.0; Status: 28 May 2014). 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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Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Im Mediapark 8
50670 Köln
Germany

Phone: +49 221 35685-0

Fax: +49 221 35685-1

E-mail: berichte@iqwig.de

Internet: www.iqwig.de

IQWiG employees involved in the assessment of potential:²

- Sebastian Grümer
- Thorsten Busan
- Charlotte Guddat
- Elke Hausner
- Julia Kreis
- Ulrike Lampert
- Stefan Sauerland
- Fülöp Scheibler
- Christoph Schürmann

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

Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the potential of the method of magnetic resonance imaging guided high-intensity focused ultrasound (MRIg-HIFU) therapy for uterine fibroids (also called leiomyomas or myomas) according to §137e Social Code Book (SGB) V. The application was transferred to IQWiG on 16 April 2014.

According to the applicant, MRIg-HIFU aims to alleviate symptoms and improve quality of life and thus to replace more elaborate and invasive treatment methods in patients with symptomatic uterine fibroids. The applicant listed 50 publications and registry entries which, however, did not in all cases refer to patient populations that were independent of each other. One of these publications referred to a prospective comparative study, which, however, investigated an inappropriate comparator (hysterectomy), 3 referred to 2 retrospective comparative studies investigating an appropriate comparator (uterine artery embolization, UAE), and 26 referred to single-arm observational studies. In addition, the applicant pointed out further completed (11), ongoing (6), planned (1) as well as discontinued (2) studies. However, no full-text publications were available to the applicant for these studies, so that they could not be used for the assessment of potential. The potential of the method was assessed on the basis of the 2 retrospective comparative studies and the supplementary examination of single-arm observational studies.

Due to a lack of comparative data, the application documents submitted did not indicate that MRIg-HIFU, with its possibly less invasive character than comparator methods, has patient-relevant advantages in terms of a potential. This especially referred to the outcomes of length of hospital stay, time to return to normal activities, post-interventional pain, and adverse events. For the comparison of MRIg-HIFU and UAE, neither the comparative studies nor the single-arm observational studies provided report-relevant data on this group of outcomes. No data were submitted for the comparison with myomectomy.

Instead, the documents submitted indicate that, in comparison with UAE, MRIg-HIFU possibly has lesser effects with regard to symptom severity, health-related quality of life, and necessity of re-intervention. No data were submitted for the comparison with myomectomy. On the basis of the before-after differences reported in the comparative studies and the single-arm observational studies it remained unclear whether MRIg-HIFU is effective in comparison with the natural course or treatment with placebo. Furthermore, it remained unclear whether MRIg-HIFU can achieve sufficiently relevant symptom alleviation in at least some of the patients.

Hence, on the basis of the documents submitted, no potential for MRIg-HIFU can be inferred. For this reason, no key points for a testing study are specified for the method applied.

The full report (German version) is published under <https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/e14-04-magnetic-resonance-imaging-guided-high-intensity-focused-ultrasound-therapy-for-uterine-fibroids.7793.html>.