IQWiG Reports – Commission No. H22-05

Transcervical radiofrequency ablation with intrauterine ultrasound guidance for uterine fibroids

2. Addendum to Commission H21-14[1]

Extract

[1] Translation of the executive summary of the addendum H22-05 *Transzervikale Radiofrequenzablation mit intrauteriner Ultraschallführung bei Uterusmyomen - 2. Addendum zum Auftrag H21-14* (Version 1.0; Status: 1 July 2022). 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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Executive summary

In a letter dated 25 May 2022, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission H21-14, to review the study protocol on an ongoing study.

Research question

The aim of the present investigation was to review the study protocol of the SUPERIOR RCT study with regard to new findings for the consultation procedure on transcervical radiofrequency ablation with intrauterine ultrasound guidance (TRFA) for uterine fibroids. The aim was to assess whether the study is in principle suitable for providing the necessary results to assess the benefit of the method in question.

Results

The SUPERIOR RCT study compares TRFA with laparoscopic myomectomy (possibly combined with hysteroscopic myomectomy) and thus addresses the primary relevant question for the intended use of TRFA. However, if the future use of TRFA is also seen as a possible alternative to (sole) hysteroscopic myomectomy, an additional study comparing TRFA with hysteroscopic myomectomy would still be necessary.

However, the SUPERIOR RCT examines the time to return to normal activities as the sole primary outcome, without additionally gearing the sample size calculation to an outcome on the effectiveness of treatment in an outcome category relevant to determine the benefit of the intervention (symptoms or health-related quality of life). In the context of a benefit assessment, however, it would be important that at least a comparable improvement in symptoms / quality of life (in the sense of non-inferiority) is also demonstrated. For the analysis of the outcome "symptom severity", the planned sample size of 132 patients (or only 60 patients after an interim analysis) would be expected to be too small to prove non-inferiority for this outcome within the scope of the study. As already outlined in H21-14, a sample size of approximately 250 patients is considered necessary for this purpose. Assuming that the data from the SUPERIOR RCT can be used for a later overall assessment in the terms of a meta-analysis, there is an option to conduct the planned study with a correspondingly smaller sample size.

Conclusion

The SUPERIOR RCT is probably not suitable to replace a testing study.

Therefore, it still seems necessary to compare TRFA and laparoscopic myomectomy in a testing study. However, the sample size for the testing study can be reduced compared to the initial calculation, since the results of the SUPERIOR RCT and the testing study can most likely be combined meta-analytically for a future assessment of benefit.

The full report (German version) is published under

https://www.iqwig.de/projekte/h22-05.html