

High-intensity focused ultrasound (HIFU) as focal therapy of posterior deep invasive endometriosis: a feasibility clinical trial.

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OBJECTIVE:

Posterior deep infiltrating endometriosis (DIE) is one of the most frequent and symptomatic location of endometriosis. The bowel is involved between 8 and 12% of symptomatic patients and surgery is often required. There are two surgical approaches: colorectal resection or rectal shaving. In this study, we suggest an alternative to digestive surgery for patients with rectal or sigmoid endometriotic nodules using HIFU. The aim of this preliminary study is to evaluate the feasibility, the safety and the efficacy of trans-rectal HIFU for the treatment of patients with symptomatic posterior DIE. This study was confirmed by the ANSM (the French Drug and Safety Administration) and by the ethic committee.

METHODS:

In this feasibility prospective uncontrolled clinical trial, we will include 10 women suffering from symptomatic posterior DIE as an alternative to surgery. Using the Focal one® HIFU device we are targeting the lesions using an intensity of ultrasound limited to 50W. The regression of the size of the nodule is assessed by imaging using ultrasound and MRI. The clinical symptoms and quality of life (SF-36 score) are also evaluated for each patient pre- and post-operatively. The incidence of complication is also monitored in particular rectovaginal fistula.

RESULTS:

In the first 4 patients, the procedure was performed optimally in 3 cases. For one patient, the length of the Ablatherm device was too short to reach the lesion, which was localized beyond the first loop of the sigmoid colon. Two months after the procedure, all the 3 patients were clinically improved by the treatment, despite a stability of the nodule size on imaging. No complication was reported during or after the procedure. Inclusion is still going on.

CONCLUSION:

To our knowledge this is the first study using trans-rectal HIFU in the treatment of posterior DIE including bowel location. Although the study is still undergoing, this procedure seems already feasible when the nodule is located at the rectosigmoid junction or lower and effective at least on patient symptoms.

Mots clefs : High-intensity focused ultrasound; Deep Invasive Endometriosis; Digestive endometriosis, Focal one®.

Auteurs :

Références : , , ,

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