

Title:

An Open-Label, Randomized, Controlled Study of the Effectiveness and Safety of a High Intensity Focused Ultrasound Device Compared with Observation in Patients With Non-Malignant Cold Thyroid Nodules

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Abstract: (Your abstract must use Normal style and must fit into the box. Do not enter author details)

AIM

To compare nodule volume change at 6 month follow-up in patients treated by US-HIFU (Ultrasound guided High Intensity Focused Ultrasound) with patients undergoing observation in a simple monocentric, open label, randomized-control study.

PATIENTS AND METHODS

The study was IRB approved and all patients signed an informed consent. 32 patients with 34 benign cold thyroid nodules indicated for surgery were recruited for the study: 21pts assigned to the HIFU arm and 11pts/13 nodules to the observation arm. Nodule volume was assessed by US and thyroid function determined by routine assays before and during follow-up. The presence and severity of pressure symptoms and cosmetic complaints were also evaluated. Safety was assessed in all patients during the study period.

Mean age was 49±12y. Median HIFU duration was 54 min [32 -114]. The overall median energy deposited was 25kJ [0.8 - 79].

RESULTS

At M6, the mean decrease in volume was 1.1ml [-5.5 - 1.7] and 0.3 ml [-1.1 - 3.7] in the HIFU group and the observed group respectively. ($P = 0.0223$). In the HIFU group 5 patients experienced a volume reduction of over 30% [40.4 – 82] compared with 0 patients in the observed group. At baseline, 66% of the treated patients and 45% of the observed patients had pressure symptoms. At 6M only 23.8% of the treated patients were still having pressure symptoms while no change was recorded in the observed patients. One transitory vocal cord palsy occurred just after HIFU ablation but disappeared within 14 days. After that incident, the device was equipped with a safety feature. Side effects were restricted to mild local pain after the HIFU session. Thyroid function remained unaltered.

CONCLUSION

HIFU is safe in benign cold thyroid nodule treatment. Its promising impact on nodule volume reduction and pressure symptoms needs to be evaluated on a larger scale.