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24 female patients considered to have an elevated surgical risk and known to have a biopsy proven non-metastatic primary breast neoplasm were treated with MR-FUS thermoablation apparatus. After a 6 month followup, core biopsy was performed to evaluate if residual tumor was present. If tumor was still present, a second treatment was initiated with MR-FUS and biopsy repeated one month later. After this second treatment, the protocol was deemed terminated and results were tabulated. 19/24 (79.1%) patients were found to have no residual tumor after one or two MR-FUS treatment sessions. No patient has developed metastatic disease during the course of this 36 months study. MR-FUS offers a new, low morbidity, repeatable treatment method inducing thermal necrosis in pathological tissues.

Materials and Methods

Twenty-four female patients (average age 76.7 years; range 61-88 yrs) with a biopsy proven non-metastatic primary breast neoplasm were treated with MR-guided focused ultrasound (MR-FUS) thermoablative apparatus as opposed to classical surgical lumpectomy. All patients recieved hormonal therapy (tamoxiphen) for varying periods of time (average 11 months: range 3-31 months) before the thermoablative local therapy for their breast neoplasm.

Patients entered the treatment protocol with MR-FUS for one of two reasons: patients considered to be high surgical risk due to other systemic diseases (N=18) or patients who outright refused classical surgical lumpectomy (N=6). After obtaining informed consent and verifying that the breast neoplasm was visible and treatable with the MR-FUS apparatus all patients underwent an initial thermoablative tratment session.

Patients were then followed with standard MR imaging with and without contrast infusion at 1, 3, and 6 months post treatment as well as standard imaging to rule out metastatic disease. At six months post treatment all patients underwent multiple core biopsy (at least 4 and up to 8 core specimens obtained throughout the lesion) of the neoplastic lesion. If residual tumor was present, a second MR-FUS treatment session was performed and repeat biopsy performed one month later. At this point the protocol was deemed completed and results were tabulated.

Results

General

23/24 (95.8%) patients completed the protocol as described (one patient refused a second MR-FUS session and was considered as a treatment failure). Average total patient time in the MR-FUS apparatus was of the order of 133 minutes (range 106-180 min) but actual thermoablative treatment time was on average 78 minutes (range 34-118 min). Average lesion size treated was 16mm (range 6-25 mm). All patients remain free of metastatic disease as of completion of the treatment protocol. One minor second-degree skin burn at the entry point of the ultrasound beam remains the only immediate or long-term complication.

MR Imaging

All lesions were hypointense and easily identified due to contrast difference of surrounding fat in this elderly female population. Following MR-FUS treatment and completion of the protocol 19/24 (79%) lesions showed no appreciable enhancement following contrast injection while 5/24(21%) lesions enhanced to some extent (3 slight, 2 intense). All lesions were noted to have a surrounding hypointense rim of varying thickness (1-11 mm) which presumably represents necrosis of perilesional fat. MR imaging did not significantly change one-month initial MR-FUS treatment (22/24 patients). In 2/24 patients the lesion was no longer visible on MR imaging at 6 months (both lesions measured less than 10 mm pretreatment)

Biopsy Results

15/24 (62.5%) patients had no residual tumor after a single session of MR-FUS thermoablative treatment. Of the 9 remaining patients who underwent a second treatment phase, 4 others were found to be tumor free on the second biopsy (success rate total 19/24; 79%). The remaining 5 patients were noted to have residual tumor in varying degrees following two MR-FUS treatment sessions (5/24; 21% failure rate). All 5 patients with residual tumor demonstrated enhancement on post treatment MR imaging studies.

Conclusion

MR-FUS thermoablation of primary breast neoplasms is a low morbidity, repeatable and efficient method of tumor ablation. Persistent enhancement on followup MR stidies in treated neoplasms appears to be an indicator of residual tumor and suggests the need for retreatment.