Original Article

Preliminary safety and efficacy results with robotic high-intensity focused ultrasound: A single center Indian experience

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ABSTRACT

Background: There are no Indian data of high-intensity focused ultrasound (HIFU). Being an alternative, still experimental modality, reporting short-term safety outcome is paramount.
Aims: This study was aimed at to assess the safety and short-term outcome in patients with prostate cancer treated by HIFU.
Settings and Design: A retrospective study of case records of 30 patients undergoing HIFU between January 2008 to September 2010 was designed and conducted.
Materials and Methods: The procedural safety was analyzed at 3 months. Follow-up consisted of 3 monthly prostate-specific antigen (PSA) levels and transrectal biopsy if indicated. All the patients had a minimum follow-up of 6 months.
Results: A mean prostate volume of 26.9 ± 8.5 cm^3 was treated in a mean time of 115 ± 37.4 min. There was no intraoperative complication. The postoperative pain visual analogue score at day 0 was 2.1 ± 1.9 and at day 1 was 0.4 ± 0.8 on a scale of 1-10. Mean duration of perurethral catheter removal was 3.9 days. The complications after treatment were: LUTS in seven patients, stress incontinence in two, stricture in two, and symptomatic urinary tract infection in five. Average follow-up duration was 10.4 months (range, 6-20 months). Mean time to obtain PSA nadir was 6 ± 3 months with a median PSA nadir value of 0.3 ng/ml. Two patients had positive prostatic biopsy in the localized (high risk) group.
Conclusions: HIFU was safe in carcinoma prostate patients. The short-term results were efficacious in localized disease. The low complication rates and favorable functional outcome support the planning of further larger studies.

Key words: Carcinoma prostate, high-intensity focused ultrasound, minimally invasive treatment, quality of life

INTRODUCTION

Radical surgery represents the treatment of choice for clinically localized prostate cancer patients with greater than 10 year life expectancy. Several minimally invasive treatments are now under evaluation that may prove to be of equivalent oncological value.[1] Transrectal high-intensity focused ultrasound (HIFU) is under evaluation as a treatment option for localized prostate cancer.[2-4] HIFU treatment of prostate cancer is currently an approved therapy in Europe, Canada, South Korea, Australia, and many places. HIFU treatment may be performed as a minimally invasive option, with low morbidity and simple post-treatment management. Its role in debulking the local tissue in advanced carcinoma prostate is under evaluation.

There are no Indian data of HIFU. This study is a single center Indian experience of this modality being used for carcinoma prostate. Being an alternative, still experimental modality, reporting short-term safety outcome is paramount. The primary objective of oncological control cannot be commented upon for the lack of adequate follow-up duration.

MATERIALS AND METHODS

HIFU was introduced in our urology department in January 2009. All patients were given counseling about the investigational nature of this treatment and the relative

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Access this article online

Quick Response Code:

Website: www.indianjurol.com

DOI: 10.4103/0970-1591.85431

lack of long-term oncological outcome data. HIFU was given with an intention to treat localized carcinoma prostate and local debulking in metastatic carcinoma prostate.

The inclusion criteria for patient selection in the intention to treat arm were localized prostate cancer, age over 70, poor surgical risk, multiple comorbidities and refusal for surgery. The localized group was further stratified according to the risk of progression in the low risk group (T1-T2a, Gs ²6, prostate-specific antigen (PSA) ²10 ng/mL), intermediate risk group (T2b, Gs = 7, PSA 11-20 ng/mL), and high risk group (T2c-T3 Gs ³8, PSA ³20 ng/mL). The exclusion criteria were anal stenosis, previous rectal surgery, and refusal to consent. For local debulking arm, the inclusion criteria were metastatic carcinoma prostate, more than 70 years and voiding lower urinary tract symptoms (LUTS). The exclusion criteria were life expectancy <6 months, HRPC status, no rectal wall involvement and no ureteric involvement, besides other exclusion criteria of the localized disease.

Armamentarium

All HIFU treatments were performed by a second-generation Ablatherm® Robotic HIFU unit. A dual-head ultrasound probe positioned in the rectum incorporates a firing transducer (3 MHz) with a focal distance of 45 mm and an imaging transducer (7.5 MHz) surrounded by a coupling gel (Ablasonic gel) in a balloon. The patient lies in the right lateral position during treatment, which allows gas bubbles to remain out of the circulating Ablasonic fluid. In the ultrasound converging point (focal point), the ultrasound beam absorption generates an immediate growth of temperature (85-100°C), destroying prostate cells in the circumscribed area.[3-5] The Ablasonic fluid in a 5°C bath produces a peri-probe temperature of 16-18°C to cool the rectal wall as protection against inadvertent heating. The lesion size can be altered by the operator from 19 to 24 mm long with a constant diameter of 1.7 mm. Treatment is delivered in 4-6 blocks, depending on the size of the gland.

Procedure

After inducing the patient with spinal and epidural anesthesia, the patient was placed in the lithotomy position. Transurethral resection of the prostate (TURP) was done in all patients with transrectal ultrasound prostate AP dimension of more than 25 mm or calcification at the junction of the transitional and peripheral zone.[5] The patient was then transferred to the Ablatherm platform and secured in the right lateral position with appropriate protection of all pressure points [Figure 1]. After introducing the rectal probe, anatomic limits were echographically set. Then, the procedure was started with the probe (equipped with the transducer) giving out a beam of highly focused convergent ultrasounds. Adequately translating the focal point with a robotic and automatic device, the successive ultrasound emissions destroyed all prostate cells. A 20-Fr three-way Foley catheter was used for bladder drainage and irrigation. Irrigation was kept for 12 h. The patient was started on antibiotics and anti-inflammatory medicines. Foley catheter was removed 3-5 days postoperatively. If the patient voided well with insignificant residual urine, he was discharged or else, catheter replaced for a further period of 7 days and the patient discharged.

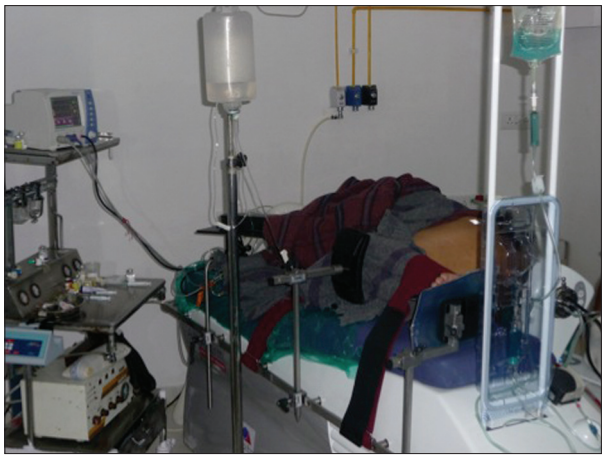

Figure 1: The patient lies in lateral decubitus with the transrectal ultrasound probe inserted for imaging as well as focussed ultrasound emission. The probe is surrounded by a coupling gel (Ablasonic gel) in a balloon. The Ablasonic fluid in a 5°C bath produces a peri-probe temperature of 16-18°C to cool the rectal wall. The patient is warmed by a warmer and covered with blankets to avoid inadvertant hypothermia

Follow-up

The patient was monitored for safety and efficacy outcome. A note for postprocedural complication with special emphasis on pain, urinary, and rectal morbidity was done. Quality of life scores, urinary symptoms, and sexual potency were evaluated before and at postoperative 3 months by Functional Assessment of Cancer Therapy-Prostate (FACT-P) scores, International Prostate Symptom Score (0-7, mildly symptomatic; 8-19, moderately symptomatic; and 20-35, severely symptomatic) and International Index of Erectile Function 5 (6-10, high erectile deficit; 11-16, moderate deficit; 17-25, low deficit; and 26-30, no deficit). For oncological outcome, the patient was followed up at hospital with PSA measurement at every 3 months. Oncological failure was defined by several criteria, including biochemical failure, starting salvage therapy (androgen deprivation therapy), or the presence of cancer on biopsy after treatment. Biochemical failure was assessed using Phoenix definition (PSA nadir + 2 ng/ml).[3] An increasing PSA level triggered targeted prostatic biopsies. Nadir PSA was defined as the lowest concentration measured after the last HIFU.

RESULTS

HIFU was given to 30 patients between February 2008 and September 2010 of which minimum oncological follow-up of 6 months was available for 24 patients. The demographic data of the study population are as in Table 1.

Table 1: Demographic data of the patients

Total number of patients	30
Patients analyzed (minimum 6 months follow-up)	24
Age (years, average) [range]	70 (58-87)
Risk stratification	
Localized	
Low risk	5 (21%)
Intermediate risk	4 (16%)
High risk	8 (33%)
Advanced CA prostate	7 (29%)
Gleason score	
<6	12.5%
7	33%
>7	54.5%
Co-morbidity	
Diabetes	13 (54.1%)
Hypertension	21 (87.5%)
IHD	12 (50%)
ASA score (average)	III (range II-IV)

Transurethral resection of the prostate was done in all patients before HIFU. One session of HIFU was given in all patients except one. A mean prostate volume of 26.9 ± 8.5 cm^3 was treated during one session of HIFU in a mean time of 115 ± 37.4 min. A total of 412 ± 162 lesions were treated per HIFU session (range, 58-706) while 440 ± 205 (range, 58-966) lesions targeted. Mean hospital stay was 6 days. Mean duration of perurethral catheter removal was 3.9 days.

Functional result

Treatment-related morbidity

The postoperative pain visual analogue score (VAS) at day 0 was 2.1 ± 1.9 and at day 1 was 0.4 ± 0.8 on a scale of 1-10. Three patients did not void after catheter removal on day 3, but voided successfully after one additional week of per urethral catheterization. Immediate grades 1 and 2 stress incontinence was observed in nine patients. At 3 months, only two patients persisted to have incontinence, the rest improved with pelvic floor exercises. Seven (29%) patients had obstructive LUTS following removal of foley catheter. Two passed slough (necrosed prostatic tissue) in urine following which their urine flow improved. Two patients developed urethral stricture at posterior urethra, which required balloon dilatation. Symptomatic urinary tract infection diagnosed in five (20.8%) patients, which was managed by appropriate antibiotics. One patient had secondary hemorrhage with foley catheter *in situ*. He required cystoscopy and clot evacuation.

Urinary symptoms

Mean baseline I-PSS was 12 (range, 0-28, median 14). After treatment mean I-PSS was 7.2 (range, 0-26, median 6) with a mean paired difference of 4.8. Three patients had score of more than 13.

Table 2: Quality of life scores; all patients

	Preoperative	3-month follow-up
FACT-P		
Physical well-being	4.52 ± 4.84	4.0 ± 5.27
Social well-being	21.6 ± 4.18	19.27 ± 6.7
Emotional well-being	8.26 ± 6.88	7.61 ± 5.64
Functional well-being	19.52 ± 6.72	21.17 ± 4.9
Additional concern	19.6 ± 6.72	19.2 ± 5.1

Quality of life

Preoperative scores of health-related quality of life related to physical well-being, social well-being, emotional well-being, functional well-being, and additional concern are as in Table 2. There was improvement in physical well-being, emotional well-being, functional well-being, and additional concern, but there was no improvement in social well-being most probably due to erectile dysfunction following HIFU. After treatment, of the 24 patients 4 patients related to the high-risk group were unsatisfied with quality of life.

Sexual function

Before treatment, 13 patients had normal sexual life with normal erection, 9 patients were impotent, and 2 were not involved in sexual activity. Following HIFU treatment, all 13 patients had erectile dysfunction (7 high and 6 moderate erectile deficit).

Oncological result

Average follow-up duration was 10.4 months (range, 6-20 months). Mean time to obtain PSA nadir was 6 ± 3 months with a median PSA nadir value of 0.3 ng/ml, mean PSA nadir of 0.53 ng/ml. Biochemical recurrence was not seen in both low and intermediate risk groups [Figure 2]. Of the eight patients in the high-risk group, two had biochemical recurrence at 7 and 9 months follow-up with positive prostatic biopsy [Figure 2]. Patients were planned for neoadjuvant hormonal treatment followed by Re-HIFU. In one patient after hormonal treatment, we could not find prostatic tissue amenable for HIFU. Hence, repeat HIFU was given in one patient only. This patient tolerated the procedure well. His 6-month follow-up so far has shown nadir PSA of 0.1 ng/ml. The other patient was continued on hormonal treatment with 6 monthly PSA levels being in the nadir levels. HIFU was also given in the post-laparoscopic radical prostatic recurrence and postradiotherapy recurrence. Both patients did well postoperatively. They were excluded from the analysis arm due to lack of 6 months follow-up.

Results in the advanced group

HIFU was given to these categories of patients with the aim to control local symptoms. Overall, the patients in the advanced group did not benefit with HIFU. There were seven patients in this group. One patient lost to follow-up. Two patients died of progression of the disease of which

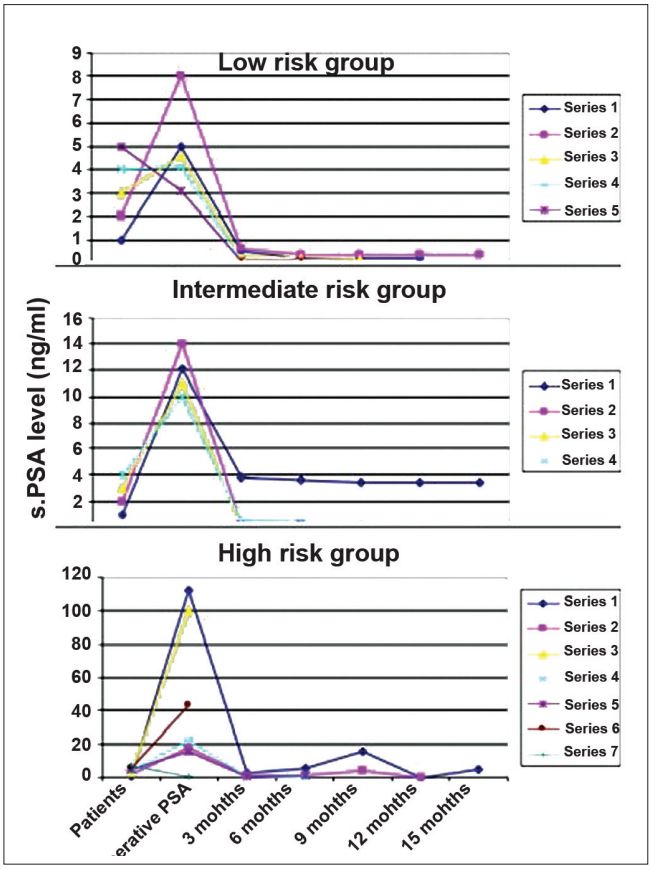

Figure 2: Oncological efficacy: The X-axis show time duration while Y-axis show PSA levels. The top, middle, and bottom graph depicts the efficacy in low, intermediate, and high grade localized carcinoma prostate, respectively

one patient continued to have local morbidity. One patient developed recto urethral fistula. Initially perurethral and suprapubic foley catheter was placed and later on transverse colostomy was done. Two patients did well after HIFU. Of these two patients, one patient at 12 months follow-up had terminal hematuria. On evaluation, he had regrowth of prostate tissue. He subsequently underwent re-resection.

DISCUSSION

In 1995, Madersbacher *et al.*[6] reported the first successful series of prostate cancer patients using HIFU technology. From these first cases to recent published series, the rates of local control have significantly increased [Table 3], approaching 85-90%. Biochemical outcomes were also encouraging and led to a low PSA nadir [Table 3].

In most cases, the PSA nadir was reached 3-4 months after the HIFU treatment. Many studies have demonstrated that the PSA nadir was a significant predictor of HIFU failure. In the entire localized carcinoma prostate group, we observed the patients without doing prostatic biopsies unless the PSA levels were showing a rising trend. One patient in the intermediate risk group had a high nadir PSA level of 3.5 ng/ml. However, the values when observed till the 9-month period at intervals of 3 months showed a stable value. Hence, the prostatic biopsy was deferred. This methodology of not doing biopsy in that patient was based on the ASTRO definition of biochemical relapse. Even Stuttgart definition recommends the PSA to raise 1.2 ng/ml above the nadir value.[12] Lee *et al.* has proposed a careful monitoring of patients in whom the PSA nadir has not dropped below 0.5 ng/mL.[9] Poissonnier *et al.*[7] reported that the 5-year disease-free survival rate, combining pathological and biochemical outcomes, was 66%, with a significant inverse relationship with the pre-HIFU PSA level. Our study is limited by the unavailability of the long-term follow-up. As a result, for patients who would like to have this treatment, as well as for those who are offered the treatment, it seems reasonable to inform them that only short-term follow-up is currently available.

Adverse effects

Side effects following HIFU have been extensively described in many articles [Table 4]. A common adverse event was urinary retention, reported in 0.3-8.6% of cases. A swollen gland can cause this or the passage of necrotic debris (sloughing) induced by coagulated adenoma. With the Ablatherm device, the combination of a TURP performed just before the HIFU seems to reduce this side effect.[5] In our experience of TURP before the HIFU procedure, still seven patients had obstructive LUTS. In two patients, there was slough in the bladder responsible for the symptoms. These patients spontaneously passed slough and the LUTS improved. Other obstructive LUTS was mainly due to edema that subsided at 1 month. Our results match Vallancien *et al.*,[8] who reported no significant change in IPSS in a series of 30 patients who were treated using Ablatherm. Reported rates of impotence ranged from 20% to 49.8%. Our experience suggests a 100% incidence of erectile dysfunction after the procedure. However, comparisons between series are difficult due to the absence of validated questionnaire use for potency assessment. Potency preservation is related to the positioning of elementary lesions on the lateral edges of the prostate, where the neurovascular bundles are located. A conservative approach sparing the neurovascular bundle by preserving an untreated area on the edge of the prostate opposite to the suspected cancer location for selected patients has to be balanced with a higher re-treatment rate.[12,13]

The rate of incontinence, reported between 0.6% and 15.4%, has decreased with time. Improvements in technology have led to this decrease mostly because of a better definition of the safety margin from the apex.

HIFU re-treatment

For some patients, HIFU needs to be repeated due to incomplete treatment or treatment failure. Blana *et al.*[14] recently reported on the morbidity related to repeated HIFU treatment. While urinary infection, infravesical obstruction, and chronic pelvic pain did not significantly differ after one or several sessions, they found a significant increase

Table 3: Selected reports of the efficacy of HIFU for the treatment of localized prostate cancer

Author	No. of patients	Clinical stage	Mean or median follow-up (months)	Negative biopsies (%)	Disease-free survival rate (criteria)
Poissonnier *et al*.[7]	227	T1-2 Nx	27	86	66% at 5 years
Vallancien *et al*.[8]	30	T1-2 Nx	20	83	-
Lee *et al*.[9]	58	T1-2 Nx	14	-	69% at 14 months
Blana *et al*.[10]	146	T1-2 N0	22.5	93.4	84% at 22 months
Chaussy and Thuroff *et al*.[5]	271	T1-2 Nx	14.8	84.6	82.1%
Thuroff *et al*.[11]	402	T1-2 Nx	13.1	87.2	-

Table 4: Side effects associated with HIFU treatment

Author	Urinary retention (%)	Stress incontinence (%)	Bladder outlet obstruction (%)	Urinary tract infection (%)	Impotence (%)	Fistulas (%)	Sloughing (%)	Perineal pain (%)
Poissonnier *et al*.[7]	-	13	12	2	-	0	9	3
Vallancien *et al*.[8]	6	3	0	10	32	0	-	0
Lee *et al*.[9]	0.3	16 (16/0/0)	0	-	-	0	14	-
Blana *et al*.[10]	-	-	19.7	0.4	49.8	0.5	-	0.9
Chaussy and Thuroff[5]	-	15.6	-	47.9 vs. 11.4	35.9	0	-	-
Thuroff *et al*.[11]	8.6	13.1 (10.6/2.5/0)	3.6	13.8	-	1.2	-	-
This study	10	6.6		20.8	100	3.3	6.6	16

of urinary incontinence and impotence rates. We had to perform re-treatment in one patient of the high-risk group. Following repeat treatment, he developed rectourethral fistula. We assume that this may have been due to additional damage following repeat treatment. Henceforth, we are careful in doing repeat treatment and are sparing more areas adjacent to the rectum.

HIFU for high risk carcinoma prostate

The strongest evidence for patients with high-risk prostate cancer is in favor of hormonal therapy plus EBRT, using the data from a few randomized controlled trials.[15] The use of HIFU associated with concomitant hormonal therapy with adjuvant LHRH analogues is an investigational treatment in patients with high-risk prostate cancer (clinical stage ≥T3a or Gleason score 8-10, or total PSA level >20 ng/mL).[16] Ficarra *et al*. studied short-term outcome after HIFU in the treatment of patients with high-risk prostate cancer.[17] Of the 30 patients followed up to 12 months, only three patients had a PSA level of >0.3 ng/mL with a 23% positive prostate biopsy rate. The poor results obtained in the high-risk group were explained by the existence of undiagnosed silent metastasis by the time of the HIFU treatment. They identified only fibrosis in 77% of the treated patients, while there were small areas of vital cancer within one biopsy core in 13% of patients, suggesting good efficacy for HIFU in destroying prostate cancer cells. This study suggests the possible application of HIFU in patients with locally advanced or high-risk prostate cancer. The present oncological data are promising, although they must be regarded as preliminary and needing reassessment over a longer follow-up. The comparison of such biopsy data to those deriving from series of EBRT plus hormonal therapy is difficult, because prostate biopsies after radiotherapy are usually indicated at ≥18 months after treatment, in selected cases with local cancer recurrence when salvage radical prostatectomy is considered.[18] Indeed, data from patients undergoing brachytherapy showed that the percentage of positive biopsies at 2 years after implantation was 70-90%.[19,20]

A further potential advantage of HIFU treatment in high-risk patients might be the possibility of a second treatment if there is clinical local recurrence, with morbidity rates lower than those of other salvage therapies. As in patients with localized prostate cancer, HIFU was a safe treatment, with low complication rates even in those with locally advanced or high-risk prostate cancer. Specifically, there were no adverse events associated with the bladder or rectum.

We also included metastatic patients for HIFU with the purpose to control the local prostatic growth and reduce the morbidity of local extension. All the patients had local prostatic growth resulting in LUTS. After the procedure, HIFU was not able to control the local disease. On the contrary, the quality of life scores deteriorated and thus, it was decided to stop this treatment after 3-month safety analysis of seven patients.

For patients with a locally proven recurrence and no metastasis, there appears to be a role for salvage HIFU curative therapy. Results with the Ablatherm system involving 118 patients with local recurrence after radiation have been reported.[21] The complication rates of salvage

HIFU are higher than those for HIFU as a primary procedure. Nevertheless, the risk-benefit ratio is better for HIFU than for the other salvage options, with less morbidity and an efficacy similar to those reported for other local salvage therapies. HIFU appears to be a valid indication for patients with local recurrence after radiation failure, but a strict selection of patients who would benefit from this treatment is mandatory. We gave HIFU to two patients, one each with postradiotherapy and postradical prostatectomy local recurrence. They were excluded from the result analysis because they are still to complete at least 6 months follow-up. However, they safety profile in this scenario was quite favorable with no postoperative complications.

CONCLUSIONS

HIFU was given to a select group of 24 patients of carcinoma prostate belonging to the entire spectrum. The short-term efficacy results are promising in the localized carcinoma group. The results of HIFU were not satisfactory in patients of metastatic carcinoma prostate. HIFU was not able to control the local morbidity in these patients. All the patients are continued to be followed upon for assessing the long-term efficacy of the procedure. HIFU has got favorable quality of life parameter outcome at 3 months of follow-up. Similar to other mini-invasive treatment, HIFU needs a careful selection of patients and it could be reserved for patients with low-to-intermediate risk disease as defined by D'Amico risk stratification. However, only a more extensive follow-up study, and randomized control trial comparing HIFU with other form of treatment will definitely place HIFU in the armamentarium of prostate cancer control.

ACKNOWLEDGMENTS

We acknowledge Dr. Stefan Thuroff, MD, consultant urologist, at the Department of Urology, Academic Teaching, Mûnchen-Harlaching, as a tutor and mentor. He visited our hospital and personally guided all the tricks for planning the appropriate treatment strategies with our five initial cases. His able mentorship enabled us to quickly learn the technique.

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How to cite this article: Mishra S, Sharma R, Garg CP, Muthu V, Ganpule A, Sabnis RB, *et al*. Preliminary safety and efficacy results with robotic high-intensity focused ultrasound : A single center Indian experience. Indian J Urol 2011;27:331-6.

Source of Support: Nil, **Conflict of Interest:** None declared.