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Clinical Article Summary

High Intensity Focused Ultrasound
for the Treatment of Prostate Cancer

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Peer Reviewed Journal Articles

Key Poster Presentations

Focal Therapy for Localized Prostate Cancer: A Phase I/II Trial

H.U. Ahmed, A. Freeman, A. Kirkham, M. Sahu, R. Scott, C. Allen, J. Van der Meulen and M. Emberton.
Journal of Urology (2011)

KEY FINDINGS
- 20 patients
- Potency (defined as return of erections sufficient for penetrative sex): 95%
- Mean PSA decreased by 80%
- Trifecta status (defined as pad-free, leak-free continence, erections sufficient for intercourse and cancer control at 12 months): 89%

Purpose: Men with localized prostate cancer currently face a number of treatment options that treat the entire prostate. These can cause significant sexual and urinary side effects. Focal therapy offers a novel strategy that targets the cancer rather than the prostate in an attempt to preserve tissue and function.

Materials and Methods: A prospective, ethics committee approved trial was conducted to determine the side effects of focal therapy using high intensity focused ultrasound. Multiparametric magnetic resonance imaging (T2-weighted, dynamic contrast enhanced, diffusion-weighted) and template transperineal prostate mapping biopsies were used to identify unilateral disease. Genitourinary side effects and quality of life outcomes were assessed using validated questionnaires. Posttreatment biopsies were performed at 6 months and followup was completed to 12 months.

Results: A total of 20 men underwent high intensity focused ultrasound hemiablation. Mean age was 60.4 years (SD 5.4, range 50 to 70) with mean prostate specific antigen 7.3 ng/ml (SD 2.8, range 3.4 to 11.8). Of the men 25% had low risk and 75% had intermediate risk cancer. Return of erections sufficient for penetrative sex occurred in 95% of men (19 of 20). In addition, 90% of men (18 of 20) were pad-free, leak-free continent while 95% were pad-free. Mean prostate specific antigen decreased 80% to 1.5 ng/ml (SD 1.3) at 12 months. Of the men 89% (17 of 19, 1 refused biopsy) had no histological evidence of any cancer, and none had histological evidence of high volume or Gleason 7 or greater cancer in the treated lobe. In addition, 89% of men achieved the trifecta status of pad-free, leak-free continence, erections sufficient for intercourse and cancer control at 12 months.

Conclusions: Our results appear sufficiently promising to support the further evaluation of focal therapy as a strategy to decrease some of the harms and costs associated with standard whole gland treatments.

High-intensity Focused Ultrasound: Ready for Primetime

K. Rove, K. Sullivan and E. Crawford.
Urologic Clinics of North America (2010)

KEY FINDINGS
- HIFU technology is well understood in its effect on tissues, the resulting coagulative necrosis, and mechanical disruption of cell membranes.
- HIFU is generally well tolerated, and the most common side effect is acute urinary retention.
- HIFU therapy for low-risk clinically localized prostate cancer seems increasingly attractive for men who turn down the option of active surveillance but who are also poor surgical candidates.

SUMMARY
HIFU fills a niche role in the treatment of CaP for a select group of patients who are either unsuitable for more invasive interventions (prostatectomy, radiotherapy), or unwilling to enter into active surveillance. HIFU is also an alternative treatment for men who do not want to undergo radical prostatectomy or radiation therapy. In some patients with low-risk disease, HIFU is an option in the armamentarium of urologists in the treatment of prostate cancer. HIFU also may play a role as a salvage therapy in men who fail other localized primary treatments. As HIFU has not been approved by the FDA in the United States, clinical trials showing promising long-term clinical outcomes are currently underway.

Future: Imaging techniques continue to improve in the setting of HIFU treatment. Doppler or blood-flow ultrasound guidance and magnetic resonance guided HIFU are currently under investigation in the treatment of hepatic masses and uterine fibroids, and may improve precision of treatment. In addition to technical improvements, longer term clinical trials with standard measures of clinical efficacy are needed to bring HIFU into the fold of accepted treatments for men with localized prostate cancer.

High-intensity-focused ultrasound in the treatment of primary prostate cancer: the first UK series

H.U. Ahmed, E. Zacharakis, T. Dudderidge, J.N. Armitage, R. Scott, J. Calleary, R. Illing, A. Kirkham, A. Freeman, C. Ogden, C. Allen and M. Emberton.
British Journal of Cancer (2009)

ABSTRACT

Background: The use of minimally invasive ablative therapies in localised prostate cancer offer potential for a middle ground between active surveillance and radical therapy.

Methods: An analysis of men with organ-confined prostate cancer treated with transrectal whole-gland HIFU (Sonablate 500) between 1 February 2005 and 15 May 2007 was carried out in two centres. Outcome data (side-effects using validated patient questionnaires, biochemical, histology) were evaluated.

Results: A total of 172 men were treated under general anaesthetic as day-case procedures with 78% discharged a mean 5 hours after treatment. Mean follow-up was 346 days (range 135–759 days). Urethral stricture was significantly lower in those with suprapubic catheter compared with urethral catheters (19.4 vs 40.4%, P=0.005). Antibiotics were given to 23.8% of patients for presumed urinary tract infection and the rate of epididymitis was 7.6%. Potency was maintained in 70% by 12 months, whereas mild stress urinary incontinence (no pads) was reported in 7.0% (12 out of 172) with a further 0.6% (1 out of 172) requiring pads.

There was no rectal toxicity and no recto-urethral fistulae. In all, 78.3% achieved a PSA nadir 0.5 μgml-1 at 12 months, with 57.8% achieving 0.2 μgml-1. Then, 8 out of 13 were retreated with HIFU, one had salvage external beam radiotherapy and four chose active surveillance for small-volume low-risk disease. Overall, there was no evidence of disease (PSA <0.5 μgml-1 or negative biopsy if nadir not achieved) after one HIFU session in 92.4% (159 out of 172) of patients.

Conclusion: HIFU is a minimally invasive, day-case ablative technique that can achieve good biochemical outcomes in the short term with minimal urinary incontinence and acceptable levels of erectile dysfunction. Long-term outcome needs further evaluation and the inception of an international registry for cases treated using HIFU will significantly aid this health technology assessment.

PATIENT INFORMATION & KEY FINDINGS
- 172 Patients
- Median Follow-up: 346 days
- Range: 135-759 days
- Biochemical disease free rate after one HIFU session: 92.4%
- Potency: 70%
- Incontinence rate (requiring pads): 0.6%
- No rectal toxicity and no recto-urethral fistulae

Transrectal high-intensity focused ultrasound for the treatment of localized prostate cancer: Eight-year experience

T. Uchida, S. Shoji, M. Nakano, S. Hongo, M. Nitta, A. Murota and Y. Nagata.
International Journal of Urology (2009)

ABSTRACT

Objective: To report on the long-term results of high-intensity focused ultrasound in the treatment of localized prostate cancer.

Methods: A total of 517 men with stage T1c–T3N0M0 prostate cancer treated with Sonablate devices (Focus Surgery, Indianapolis, IN, USA) between January 1999 and December 2007 were included in the study. Biochemical failure was defined according to the Phoenix definition (prostate-specific antigen nadir + 2 ng/mL).

PATIENT INFORMATION & KEY FINDINGS
- 517 patients
- Median Follow-up: 24 months
- Range: 2-88 months
- Biochemical disease-free rate in all patients at five years: 72%
- Biochemical disease-free rate in low risk patients: 84%
- Erectile Dysfunction: 28.9%

Results: The median follow-up period for all patients was 24.0 months (range, 2 to 88). The biochemical disease-free rate (BDFR) in all patients at 5 years was 72%. The BDFR in patients with stage T1c, T2a, T2b, T2c and T3 groups at 5 years were 74%, 79%, 72%, 24% and 33%, respectively ($P < 0.0001$). BDFR in patients in the low, intermediate and high-risk groups at 5 years were 84%, 64% and 45%, respectively ($P < 0.0001$). The BDFR in patients treated with or without neoadjuvant hormonal therapy at 7 years were 73% and 53% ($P < 0.0001$), respectively. In multivariate analysis, pretreatment prostate specific antigen levels (hazard ratio 1.060; $P < 0.0001$; 95% confidence interval 1.040–1.080), neoadjuvant hormonal therapy (hazard ratio 2.252; $P < 0.0001$; 95% confidence interval 1.530–3.315) and stage ($P = 0.0189$) were demonstrated to be statistically significant variables. Postoperative erectile dysfunction was noted in 33 out of 114 (28.9%) patients who were preoperatively potent.

Conclusions: High-intensity focused ultrasound therapy appears to be minimally invasive, efficacious and safe for patients with localized prostate cancer, particularly those with low- and intermediate-risk cancer.

Visually Directed Transrectal High Intensity Focused Ultrasound for the Treatment of Prostate Cancer: A Preliminary Report on the Italian Experience

L. Mearini, L. D'Urso, D. Collura, A. Zucchi, E. Constantini, A. Formiconi, V. Bini, G. Muto and M. Porena.
The Journal of Urology (2009)

ABSTRACT

Purpose: High intensity focused ultrasound is a minimally invasive treatment option for prostate cancer. Data from the literature show promising early oncological outcomes and a favorable side effect profile. This study is a preliminary report of the Italian experience (Perugia and Turin) of patients treated with the Sonablate® 500 high intensity focused ultrasound device.

PATIENT INFORMATION & KEY FINDINGS
- 163 patients
- Median Follow-up: 23.8 months
- Biochemical disease free rate: 71.9%
- Negative biopsy: 66.1%
- Mean nadir post-HIFU: 0.15ng/mL

Materials & Methods: Between 2004 and 2007, 163 consecutive men with T1–T3 N0M0 prostate cancer underwent high intensity focused ultrasound with the Sonablate 500. Follow-up included prostate specific antigen tests at 1 month and then every 3 months after treatment, and a random prostate biopsy at 6 months. Failure was defined according to prostate specific antigen nadir, positive findings on followup biopsy and biochemical failure according to Phoenix criteria.

Results: Median patient age was 72 years old, median baseline prostate specific antigen was 7.3 ng/mL, and disease stage was T1 in 44.1%, T2 in 42.5% and T3a in 13.4% of patients. Median follow-up was 23.8 months. After high intensity focused ultrasound treatment prostate specific antigen decreased to a median nadir of 0.15 ng/mL. Median prostate specific antigen at 3 and 6 months was 0.30 and 0.54 ng/mL, respectively. At 6 months the negative biopsy rate was 66.1%. There was no biochemical evidence of disease in 71.9% overall. On multivariate analysis prostate specific antigen nadir became the only independent predictor of no biochemical evidence of disease and positive biopsy at a cutoff of 0.40 ng/mL.

Conclusions: A favorable outcome of high intensity focused ultrasound is associated with lower baseline prostate specific antigen, lower prostate specific antigen nadir, lower Gleason score and lower tumor stage. As with any novel technology long-term data will be required before this technique gains widespread clinical acceptance.

Minimally-invasive technologies in uro-oncology: The role of cryotherapy, HIFU and photodynamic therapy in whole gland and focal therapy of localised prostate cancer

H.U. Ahmed, C. Moore and M. Emberton.
Surgical Oncology (2009)

ABSTRACT

The use of minimally-invasive ablative therapies in localised prostate cancer offer potential for a middle ground between active surveillance and radical therapy. This article reviews the evidence for cryotherapy, high intensity focused ultrasound (HIFU) and photodynamic therapy in the treatment of localised prostate cancer. These ablative technologies can deliver a minimally invasive, day case treatment with effective early cancer control and low genitourinary morbidity. In addition, all have the ability to deliver focal therapy of only the malignant lesions within the prostate.

Conclusion: The therapeutic dilemma between surveillance and radical therapy for men with localised prostate cancer and the significant morbidity associated with surgery or radiotherapy has led to development of minimally-invasive procedures that attempt to achieve effective cancer control whilst reducing the treatment burden for men. Photodynamic therapy is in its infancy and longer follow-up with prospectively designed trials is warranted. HIFU and cryosurgery have emerged as forerunners in this field. However, although single centre retrospective case series exist showing mature datasets and cancer control rates which are encouraging together with good side-effect profiles, the data is far from conclusive. Definitions of disease control are not uniform and there is vast inconsistency in reporting morbidity outcomes which make it difficult for these technologies to be accepted into the mainstream. The use of prospective data collection into national and international registries may aid this dearth of good data, but in order for the uro-oncological community to show optimism towards these there must be transparency and stringent controls to ensure that there is no selective case entry into such registries. Nonetheless, men with prostate cancer currently suffer many side effects from standard therapy, and minimally-invasive therapies used in a whole gland and focal therapy manner offer promise.

Transrectal High-intensity Focused Ultrasound of the Prostate-State-of-the-art Treatment with the Sonablate® 500

M. Sahu, R. Illing, S. Govindaraju, H.U. Ahmed and M. Emberton.
Touch Briefings (2008)

KEY FINDINGS
- HIFU has the potential to meet many of the necessary attributes for a minimally invasive treatment with potentially equal oncological outcome to conventional therapies
- UPDATE: Tissue change monitoring (TCM) is available as of 2010.

Discussion: Despite the incidence of prostate cancer rising with the advent of PSA screening, the current mainstay of radical treatment is still between open or laparoscopic surgery and radiation therapy. The improvement of disease-specific survival with radical surgery is not extensive, with a reported 5% increase over a 10-year period compared with watchful waiting. When a comparison is made between side effects reported with radical treatments, i.e. deterioration in urinary, sexual and bowel function, the morbidity profile conferred is often unattractive to many patients. This applies especially to those who have a long life expectancy and who have been diagnosed with much lower-risk disease than that evaluated in the randomised controlled trial in Scandinavia, in which the 5% absolute risk reduction was demonstrated. Current radical treatments do not include conformal therapy that is required to selectively treat prostatic tissue, therefore limiting damage to important structures close to the prostate, the external sphincter, neurovascular bundles and rectal mucosa. On the other hand, HIFU has the potential to meet many of the necessary attributes for a minimally invasive treatment with potentially equal oncological outcome to conventional therapies.

There is a trend towards less invasive treatments in all surgical fields and, therefore, it is no surprise that HIFU is gaining popularity in a disease that is increasing in incidence worldwide. Thus far the oncological data looks promising, with five-year data emerging that appear comparable to all of the current conventional modalities for the treatment of organ-confined prostate cancer. Reported complication rates are continuously improving due to improvements in technology and refinements in operative technique. From the aforementioned studies it is apparent that the Sonablate 500 HIFU device in the primary setting is becoming more established and feasible in the salvage setting. In the focal setting, it is an exciting development that requires further study.

Future Developments: The online Sonablate International HIFU Registry (SIHR) has been established to offer a single, secure, standardised repository of treatment information from all Sonablate users. Anonymous data entered from worldwide centres is stored with an independent IT company and overseen by a clinical steering committee. This will be a powerful tool for continuing medical education by allowing the identification and dissemination of best practice, and will also provide a comprehensive international data set with which to assess the determinants of outcome. New treatment monitoring methods are being explored. Although 'visually directed HIFU' is currently the best mechanism for tailoring HIFU therapy to the individual gland, it is acknowledged that this may be overtreatment as cell death may occur before brightness (B)-mode ultrasound changes are apparent. As a result, realtime 'tissue change monitoring' (TCM) is in development, the goal of which is to quantify tissue changes based on radiofrequency data during the HIFU treatment. By analysing the returned echo signals from the tissue during treatment, attenuation changes can be calculated that may accurately reflect in situ ablation. Ex vivo experimentation has been positive and implementation of TCM in the clinical Sonablate system is under clinical evaluation.

Conclusion: Sonablate HIFU has many of the desirable attributes of a new tissue ablation technology. It is considerably less expensive than the alternatives, can be performed as an outpatient procedure, is repeatable, exhibits short-to-medium-term effective oncological control and has an acceptable side-effect profile. Since its development it has undergone a number of technological refinements that make it an attractive option in the primary setting and give it great potential in both salvage and focal therapy. The SIHR should allow for mass, high-quality data collection, and tissue-change monitoring may provide even greater refinement of the treatment process.

Focal Therapy with High-intensity-focused Ultrasound in the Treatment of Localized Prostate Cancer

S. Muto, T. Yoshii, K. Saito, Y. Kamiyama, H. Ira and S. Horie.
Japan Journal of Clinical Oncology (2008)

PATIENT INFORMATION & KEY FINDINGS
- Patients: 70
- Median Follow-up: 34 months
- Range: 8-45 months

Whole Gland Therapy
- Biochemical disease-free rate at 2 years: 90.9% (low risk), 49.9% (intermediate risk)
- Negative biopsy at 1 year: 76.5%

Focal Therapy
- Biochemical disease-free rate at 2 years: 83.3% (low risk), 53.6% (intermediate risk)
- Negative biopsy at 1 year: 76.5%

ABSTRACT

Background: We evaluated the efficacy and feasibility of high-intensity-focused ultrasound (HIFU) for localized prostate cancer.

Methods: Seventy patients received HIFU using Sonablate®500 (Focus Surgery, IN, USA). In patients whose cancer was confined to only one lobe by multi-regional biopsies, total peripheral zone and a half portion of transitional zone were ablated (focal therapy). Otherwise, patients received whole organ ablation (whole therapy). Scheduled biopsies were performed at 6 and 12 months after treatment. Pre- and post-HIFU serum testosterone levels were measured. Result The 2-year biochemical disease-free survival (DFS) rates in patients at low, intermediate and high risk were 85.9, 50.9 and 0%, respectively, (P = 0.0028). After 12 months, 81.6% (40/49) of patients were biopsy negative; 84.4% in patients who received whole therapy, whereas 76.5% in those with focal therapy. The 2-year biochemical DFS rates for the patients at low and intermediate risk was 90.9 and 49.9%, respectively, in patients with whole therapy, whereas 83.3 and 53.6% in patients with focal therapy. In patients without neoadjuvant androgen deprivation, serum testosterone levels continuously decreased after whole therapy, whereas no changes were seen in those with focal therapy. The patients whose follow-up biopsies were positive tended to have significantly higher changes in prostate-specific antigen levels than biopsy negative patients.

Conclusions: In patients with low-risk prostate cancer, HIFU monotherapy resulted in comparable immediate cancer control with other modalities. Particularly, focal therapy might offer a feasible minimally invasive therapeutic option, which maintained serum testosterone level. To our knowledge, this is the first report that whole, but not focal, therapy affects the serum testosterone level.

The feasibility and safety of high-intensity focused ultrasound as salvage therapy for recurrent prostate cancer following external beam radiotherapy

E. Zacharakis, H.U. Ahmed, A. Ishaq, R. Scott, R. Illing, A. Freeman, C. Allen and M. Emberton.
British Journal of Urology International (2008)

PATIENT INFORMATION & KEY FINDINGS
- Patients: 31
- Median Follow-up: 7.4 months
- Range: 3-24 months
- Biochemical disease free rate: 71%
- Incontinence Rate: 7%
- Recto-Urethral fistula: 3%
- Nadir PSA: 50%

ABSTRACT

Objectives: To investigate the use of minimally invasive high-intensity focused ultrasound (HIFU) as a salvage therapy in men with localized prostate cancer recurrence following external beam radiotherapy (EBRT).

Patients and Methods: A review of 31 cases treated using the Sonablate 500 HIFU device, between 1 February 2005 and 15 May 2007, was carried out. All men had presumed organ-confined, histologically confirmed recurrent prostate adenocarcinoma following EBRT.

Results: The mean (range) age was 65 (57-80) years with a mean preoperative PSA level of 7.73 (0.20-20) ng/mL. The patients were followed for a mean (range) of 7.4 (3-24) months. Side-effects included stricture or intervention for necrotic tissue in 11 of the 31 patients (36%), urinary tract infection or dysuria syndrome in eight (26%), and urinary incontinence in two (7%). Recto-urethral fistula occurred in two men, although one was due to patient movement due to inadequate anaesthesia, so the 'true' rate is 3%. Half of the patients had PSA levels of <0.2 ng/mL at the last follow-up. Three patients had metastatic disease whilst another two had only local, histologically confirmed, failure. A further four patients had evidence of biochemical failure only. Overall, 71% had no evidence of disease following salvage HIFU.

Conclusions: Salvage HIFU is a minimally invasive day case procedure that can achieve low PSA nadirs and good cancer control in the short term, with comparable morbidity to other forms of salvage treatment. The issue of accurate staging at the time of recurrence is still problematic, as a proportion of these men will harbour microscopic metastases undetected by conventional staging investigations.

Visually directed high-intensity focused ultrasound for organ-confined prostate cancer: a proposed standard for the conduct of therapy

R. Illing, T. Leslie, J. Kennedy, J. Calleary, C. Ogden and M. Emberton.
British Journal of Urology International (2006)

Objective: To propose a standard for the conduct of visually directed transrectal high-intensity focused ultrasound (HIFU) and to offer a formal description of the changes observed on B-mode ultrasonography (US) during this procedure. We describe our early experience of using two different treatment methods; algorithm-based HIFU and visually directed HIFU for the treatment of organ-confined prostate cancer.

PATIENT INFORMATION & KEY FINDINGS
- Patients: 34

Visually directed therapy
- PSA nadir: 85%
- Visually directed HIFU significantly lower PSA nadirs than algorithm-based HIFU

Patients and Methods: Between November 2004 and October 2005, 34 men were treated using the Sonablate®-500 (Focus Surgery, Indianapolis, IN, USA) as primary therapy for T1 or T2 prostate cancer. None had had previous hormone therapy and all had 3-month PSA nadirs recorded at the follow-up. Nine men were treated using an algorithm-based protocol (group 1) and 25 using visually directed therapy (group 2). The conduct of visually directed treatment was described and changes seen using B-mode US were categorized using three 'Uchida' grades.

Results: The mean PSA nadir achieved in group 2 was 0.15 ng/mL, vs 1.51 ng/mL in group 1 ($P < 0.005$). In group 2, 21 of 25 men achieved PSA nadirs of 0.2 ng/mL 3 months after treatment. Seven men achieved undetectable PSA values. The occurrence rate of treatment related toxicity was similar in both groups.

Conclusion: Visually directed, transrectal HIFU enables clinically important and statistically significantly lower PSA nadirs to be achieved than algorithm-based HIFU. This is the first reported experience of visually directed HIFU for the treatment of organ-confined prostate cancer. We think that this is the first attempt to standardize the conduct of therapy; such standardization facilitates teaching it, and makes it possible to derive quality standards. The standardization of the conduct of therapy is a key step in the process of health technology assessment.

Trifecta outcomes after whole-gland high intensity focused ultrasound for the treatment of localised prostate cancer: A registry-based analysis

L. Dickinson, H.U. Ahmed, P. Cathcart, N. Mccartan, C.M. Moore, A. Kirkham, A. Freeman, C. Allen and M. Emberton.
EAU Annual Congress (2011)

Introduction & Objectives: The trifecta metric is a summary statistic that has been proposed as a useful measure of therapeutic success following radical surgery for men with early prostate cancer. It incorporates the three domains that matter to patients – freedom from prostate cancer, erectile function and continence status. Radical prostatectomy trifecta outcomes are reported between 20% and 76% at 12 to 48 months. We report trifecta outcomes in men following whole-gland HIFU.

Material & Methods: We performed a registry-based analysis of whole-gland therapy of localised low, intermediate and high risk prostate cancer using transrectal whole-gland HIFU (Sonablate 500, Focus Surgery Inc). Functional outcome was assessed using IPSS, continence status and erectile function. Trifecta outcomes were derived using biochemical disease free rates according to the Stuttgart definition (PSA nadir+1.2ng/mL), urinary continence (leak-free pad-free), and erectile function sufficient for penetration.

Results: 253 consecutive men received whole-gland HIFU (2004-2009). 74% had radiological T2 disease and 26% T3 disease (88% T3a, 12% T3b). The median Gleason grade was 7 (6–9). The median number of positive cores per patient was 4 (1–36) with a median number of cores taken of 10 (4–111). Neo-adjuvant hormones were used in 13%. Mean number of treatments 1.3. Median follow-up was 2.5 years. Median PSA fell from 7 ng/mL at baseline to 0.3ng/mL and 0.24ng/mL at 1 and 2 years. Trifecta outcomes measured 61% at 1 year in those 51 men with good baseline genitourinary function.

Conclusions: Whole-gland HIFU is a therapeutic option for prostate cancer with the benefits that it is repeatable and delivered within a day case setting. Trifecta outcomes are comparable to radical surgical outcomes.

Real Time Monitoring of Tissue Changes During the Treatment of Prostate Cancer with High Intensity Focused Ultrasound (HIFU)

G. Schatzl, N. Sanghvi, W. Chen, A. Lowe, M. Marberger.
World Congress Endourolgy, Chicago (2010)

Purpose: Validation of Tissue Change Monitoring (TCM) HIFU system with real-time thermometry

Materials And Methods: 5 patients with histologically confirmed, organ confined prostate cancer were enrolled for this study. Four patients with focal cancer had hemiablation only and one had a whole gland ablation. The Sonablate 500 HIFU device with Tissue Change Monitoring (TCM) was used for the ablative treatment. TCM generates energy reading based on spectral analysis on the RF backscattered ultrasound signals acquired during the HIFU procedure. TCM results are used as an estimator of tissue temperature. Needles containing three thermocouples separated by 1 cm distance were placed transperineally under TRUS guidance in the prostate that monitored temperatures from focal zone, posterior to the focal zone and on the lateral gland where no HIFU was applied. The HIFU treatments used 37, 35 and 19.7 average Watts for the treatment for anterior, middle and posterior zones.

Results: The measured temperatures (average, max, and min) in the HIFU treatment zones were 84, 114 and 70°C. TCM energy readings were 1.05, 2.6 and .4 resulting in 83% temperature from 75-100°C and 17% from 60-75°C with an estimated average temperature of 91°C. Outside the focal zone, average recorded temperature was 50°C. The temperature in the lateral lobe where no HIFU was applied was 40.7°C.

Conclusions: The backscattered RF data analysis is capable of estimating tissue changes reliably during the HIFU procedures and can be used as an aid in the HIFU operating procedure.

Ten-year Biochemical Disease-free Survival After High-intensity Focused Ultrasound (HIFU) for Localized Prostate Cancer: Comparison with Four Different Generation Devices

T. Uchida. M. Nakano, S. Shoji, T. Omata, Y. Harano, Y. Nagata, Y. Usui and T. Terachi.
9th International Symposium on Therapeutic Ultrasound-ISTU (2009)

ABSTRACT

HIFU has been recognized as a minimally invasive treatment option for localized prostate cancer. The purpose of the study was to assess with a long-term outcome of HIFU for prostate cancer. From January 1999, a total of 657 patients who had HIFU with at least 2 year follow-up were treated with four different types of Sonablate® (Focus Surgery, Indianapolis, USA) devices. Thirty-three patients were treated with Sonablate® 200 (S200) from 1999 to 2001, 406 patients with Sonablate® 500 (S500) from 2001 to 2005, 200 patients with Sonablate® 500 version 4 (V4) from 2005-2008 and 19 patients with Sonablate® 500 TCM (TCM) from 2007. Biochemical disease-free survival rate (bDFS) in all patients was 59% in 8 years. bDFS in 8 years in patients with S200 and S500 groups were 55% and 56%, and bDFS in 4 and 2 years in patients with V4 and TCM group were 72% and 84 %, respectively. bDFS in low, intermediate, and high risk groups were 75%, 54%, and 43% in S200/S500 and 93%, 72%, and 58% in V4/TCM group. Negative prostate biopsy rate after HIFU was 97% in S200, 79% in S500, 94% in V4 and 100% in TCM group. HIFU as primary therapy for prostate cancer is indicated in patients with low- and intermediate-risk (T1-T2b N0M0 disease, a Gleason score of 7, a PSA level of < 20 ng/mL) and a prostate volume of less than 40 mL. The rate of clinical outcome has significantly improved over the years due to technical improvements in the device.

PATIENT INFORMATION & KEY FINDINGS

- 657 Patients
- Minimum Follow-up: 2 years

Negative prostate biopsy rate

- S200: 97%
- S500: 79%
- V4: 94%
- TCM: 100%