of combination therapy with ADT and/or EBRT significantly increases erectile dysfunction following BT. Increased BED does not negatively impact potency.

Source of Funding: None

1205

AGE STRATIFIED OUTCOMES AFTER PRIMARY HIFU FOR ORGAN LOCALIZED PROSTATE CANCER IN THE SERIE OF 5206 PATIENTS

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INTRODUCTION AND OBJECTIVES: High intensity focused ultrasound (HIFU) performed by Ablatherm® has been used as primary treatment of localized prostate cancer since 1993. In the last years, HIFU has been recognized as a therapeutic option in patients over 70 years old with 10 years life expectancy. The objective of this study is to report the biochemical and biopsy outcomes, stratified by age, in patients who have undergone HIFU.

METHODS: 5206 consecutive patients with cT1-T3 prostate cancer treated by HIFU Ablatherm® (EDAP-TMS, Lyon, France), 16 European HIFU centers were included. Treatment results, and post treatment morbidity as the bladder outlet obstruction (BOO) or urethra stenosis have been registered in the online Ablatherm® HIFU database, @-Registry. This is a secured on-line database collecting relevant de-identified clinical and technical information for patients treated by HIFU. Patients were stratified by age into two groups: below 70 years (n=2291) and above 70 years (n=2915) and according to D'Amico's 2003 risk group classification. Kaplan-Meier analyses were performed to determine biochemical survival with failure defined according to the 2006 Phoenix definition (nadir+2). Univariable and multivariable Cox analyses were performed to adjust for possible confounding variables (clinical stage, Gleason score, PSA, prostate volume).

RESULTS: Follow-up time was 3.4 $\pm$ 2.9 years. The median PSA nadir: 0.15 ng/ml was reached 14.0 $\pm$ 11.5 weeks after HIFU. The negative biopsy rates (<70 yrs / >70yrs) were 70% / 73%, actuarial biochemical disease free survival (BDFS) at 5 years: 84% / 73% low risk, 74% / 65% intermediate risk, 69% / 63% high risk patients. Urinary incontinence rates (GII and GIII) were 4% / 7%. BOO or urethra stenosis rates were 18% / 19 %.

CONCLUSIONS: HIFU presents positive oncological and functional outcome in patients both below and above 70 years. HIFU treatment appears therefore as a valuable therapeutic option for prostate cancer control independent of age.

Source of Funding: None

1206

BIOCHEMICAL SURVIVAL AND MORBIDITY OF HIGH INTENSITY FOCUSED ULTRASOUND (HIFU) AS A PRIMARY MONOTHERAPY FOR LOW-RISK LOCALIZED PROSTATE CANCER: OUTCOMES FROM THE @–REGISTRY FOLLOWING THE ENLIGHT TRIAL INCLUSION CRITERIA

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INTRODUCTION AND OBJECTIVES: Ablatherm® HIFU is used as primary treatment for prostate cancer in Europe since 1993 and is currently under investigation in the U.S. under an FDA granted Investigational Device Exemption. The objective of this study is to report the biochemical and biopsy outcomes along with the morbidity evaluation of a population of low risk localized prostate cancer patients who meet the the FDA trial inclusion criteria.

METHODS: The @-Registry is a secured on-line database which collects de-identified clinical and technical information for patients undergoing HIFU treatment. The patient's selection criteria for this study were: low risk prostate cancer patients (cT1 to T2a, PSA<10ng/ml, Gleason≤6), with a prostate A-P diameter and volume of ≤ 25mm and ≤ 40cc, and no pre treatment hormone therapy. Kaplan-Meier analysis was performed to determine biochemical survival with failure defined according to the Phoenix definition (PSA nadir+2). Need for salvage treatment and biopsy data were also analyzed. The morbidity data were evaluated.

RESULTS: A total of 358 consecutive patients from 12 European HIFU centers met the inclusion criteria. The average age was 69.7 $\pm$ 6.4 years. Pre treatment PSA was 5.8 $\pm$ 2.4 ng/ml, the median Gleason sum was 6, 65.9% and 34.1% of patients were cT1and cT2a, respectively. Patients were followed for 6.6 $\pm$ 3.1 years (range: 0.6 to 18 years). Median PSA nadir was 0.09 ng/mL which was reached 13.9 $\pm$ 10.7 weeks after HIFU. The salvage treatment rate was 8.7%, and the negative biopsy rate was 90.2%. Actuarial BDFS at 5 and 10 years was 87% and 73% respectively. The morbidity data were evaluated for all the 358 patients. Grade I, II and III stress incontinence was observed in 12.3%, 4.5% and 1.7% of the population, respectively. The bladder outlet obstruction rate was 20.7% (considering retention, stenosis and necrosis). No urethro-rectal fistula was observed.

CONCLUSIONS: HIFU provides good disease control with only 8.7% of patients receiving salvage treatment after HIFU through a follow-up period extending 18-years. HIFU therapy achieves good biochemical control at 10 years of follow-up for low risk cancer patients and negative biopsy rates are high. HIFU has low morbidity, especially with the lack of any serious morbidity (specifically fistulas). Bladder outlet obstruction has been the most bothersome adverse event. Ablatherm® HIFU treatment appears as a valuable and safe therapy for long term low risk prostate cancer treatment.

Source of Funding: EDAP, inc. provides an unrestricted grant to support the maintenance of the Ablatherm Registry. EDAP remains independent of the data analysis, data repository or the conclusions drawn from the data.

1207

COMBINATION OF EXTENDED BIOPSY AND MRI IDENTIFIES CANDIDATES FOR QUADRANT-ABLATION FOCAL THERAPY OF PROSTATE CANCER

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INTRODUCTION AND OBJECTIVES: We provide hemiablative focal therapy (FT) of prostate cancer (PC) for selected patients based on our finding that significant cancer (SC) is absent in 95% of lobes in which both 14-core biopsy (Bx) and MRI are negative (Eur Urol *in press*). In cases with anterior unilateral SC, however, the preservation of bilateral posterior areas and neurovascular bundles (NVB) might be an option. Our aim is to evaluate the applicability of Bx combined with MRI to patient selection for quadrant-ablation FT.

METHODS: Between 2007 and 2012, 228 lobes in 114 men with clinically localized PC were enrolled who underwent multiparametric MRI and 14-core Bx prior to radical prostatectomy (RP). MRI and RP findings were analyzed in each quadrant: anterior or posterior halves of a lobe. In Bx, anterior and posterior quadrants were assessed through the anterior/lateral 3-core sampling and the posterior/lateral 5-core sampling, respectively. SC was defined as a lesion with extraprostatic extension and/or ≥0.50 cm^3 and/or Gleason score ≥4+3. When SC extended to the adjacent quadrant, the both were assigned to quad-