

**METHODS:** This study includes 156 patients with clinical T1/T2 prostate cancer treated with transperineal interstitial brachytherapy with I-125 as monotherapy, who had not been treated with an alpha-blocker for LUTS before brachytherapy. The incidence of alpha-blocker dependency for more than one month for LUTS following brachytherapy was evaluated, and multiple clinical parameters including international prostate symptom score (IPSS) and urodynamic findings were evaluated to identify the factors associated with alpha-blocker dependency on univariate and multivariate analyses.

**RESULTS:** All the patients received prophylactic alpha-blockers on urinary morbidity for 2 weeks after brachytherapy. Afterwards, 91 (58%) of 156 patients needed a therapeutic alpha-blocker because of LUTS for more than one month (alpha-blocker dependency). The incidences of alpha-blocker dependency in patients with age  $\geq 63$  years (63% vs 36%), with IPSS  $\geq 9$  (70% vs 50%), with QOL index  $\geq 3$  (68% vs 47%), with maximum flow rate (MFR)  $< 15$  ml/s (66% vs 49%) and with residual urine (RU)  $\geq 20$  ml (65% vs 24%) were significantly higher than those of their respective counterparts. On the other hand, preimplant prostate volume, serum PSA and Gleason score were not significantly associated with the alpha-blocker dependency. Multivariate logistic regression analysis demonstrated that IPSS  $\geq 9$ , RU  $\geq 20$  ml and MFR  $< 15$  ml/s were independent predictors for the alpha-blocker dependency. A nomogram predicting the incidence of alpha-blocker dependency were constructed using these three parameters. The probability estimated by the nomogram was significantly correlated ( $R=0.90$ ,  $p<0.05$ ) with the real incidence. For example, the estimated probability and real incidence of alpha-blocker dependency were 23.5% and 27.3% when these three parameters are all favorable and 81.1% and 80.6% when all these parameters were unfavorable.

**CONCLUSIONS:** These results indicate that 58% of prostate cancer patients treated with brachytherapy needed an alpha-blocker for more than one month following brachytherapy and that IPSS, RU and MFR were independent parameters for the prediction of the alpha-blocker dependency. The nomogram constructed by these three factors may provide useful information before brachytherapy.

**Source of Funding:** None

## 462

### CORRELATION OF DIFFERENT PSA-NADIR CUT OFFS AND BIOCHEMICAL FAILURE AFTER HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU) OF PROSTATE CANCER BASED ON THE STUTTGART FAILURE CRITERIA – ANALYSIS FROM THE @-REGISTRY

*Roman Ganzer\*, Regensburg, Germany; Stephen C.W. Brown, Stockport, United Kingdom; Giaro N. Conti, Como, Italy; Francois J. Murat, Lyon, France; Gilles Pasticier, Bordeaux, France; Albert Gelet, Lyon, France; Cary N. Robertson, Durham, NC; Stefan Thueroff, Munich, Germany; John F. Ward, Houston, TX; Andreas Blana, Fuerth, Germany*

**INTRODUCTION AND OBJECTIVES:** The PSA-nadir has been shown to correlate with oncological outcome and treatment failure after HIFU therapy for localized prostate cancer (PC) in single centre studies. However, since recently there had been no HIFU-specific failure criteria. In this multicentre study we present an analysis from the @-registry database after application of the recently published HIFU-specific failure criteria ("Stuttgart criteria": PSA-nadir + 1.2 ng/ml).

**METHODS:** The study is based on a retrospective analysis of 803 patients after HIFU treatment (Ablatherm, EDAP TMS, France) for PC meeting the following inclusion criteria: cT1/T2, PSA  $\leq 20$  ng/ml, Gleasonscore  $\leq 7$ , no previous hormonal therapy, regular follow-up visits every 3 months. Biochemical failure was defined according to the Stuttgart criteria (PSA nadir + 1.2 ng/ml). Four PSA-nadir groups were defined: group 1:  $\leq 0.2$  ng/ml, group 2: 0.21–0.5 ng/ml, group 3: 0.51–1 ng/ml, group 4:  $> 1$  ng/ml. DFSR were calculated using life table methods. The log rank test was used to compare the curves based on Kaplan–Meier models.

**RESULTS:** The median follow-up was 5.9 (3 – 15) years. Mean time to PSA-nadir was  $14.9 \pm 12.1$  weeks. A PSA-nadir of  $\leq 0.2$  ng/ml, 0.21–0.5 ng/ml, 0.51–1 ng/ml and  $> 1$  ng/ml was reached by 53.3%, 16.1%, 11.2% and 19.4% of patients, respectively. Biochemical-free survival during follow-up was 84.6%, 66.7%, 52.4% and 42.6%, respectively for the 4 groups ( $p<0.001$ ). The actuarial biochemical disease free survival rates (DFSR) at 5 years were 84%, 64%, 40% and 30% for the 4 groups, respectively ( $p<0.001$ ).

**CONCLUSIONS:** The present multicentre analysis confirms that PSA-nadir after HIFU correlates highly significantly with treatment failure and DFSR. Excellent oncological outcome is obtained for  $> 80\%$  of men if a PSA-nadir of  $\leq 0.2$  ng/ml is reached and for a majority of patients if a nadir  $\leq 0.5$  ng/ml is reached. This relatively immediate feedback of prognosis may be an advantage compared with external beam radiation for prostate cancer treatment where many patients do not reach the PSA-nadir for many years.

**Source of Funding:** None

## 463

### HIFU FOLLOWING FAILED RADIATION THERAPY: BIOCHEMICAL SURVIVAL OF ABLATHERM REGISTRY

*John F. Ward\*, Houston, TX; Roman Ganzer, Regensburg, Germany; Stephen C.W. Brown, Stockport, United Kingdom; Giaro N. Conti, Como, Italy; Francois J. Murat, Lyon, France; Gilles Pasticier, Bordeaux, France; Albert Gelet, Lyon, France; Stefan Thueroff, Munich, Germany; John Rewcastle, Calgary, Canada; Cary N. Robertson, Durham, NC; Andreas Blana, Klinikum Fürth, Germany*

**INTRODUCTION AND OBJECTIVES:** Patients with recurrent prostate cancer following radiation therapy represent a difficult population to manage as the disease is locally aggressive and often metastasizes. Local salvage therapy may offer cure however current methods (salvage prostatectomy, salvage cryotherapy) are often associated with unacceptable morbidity. The objective of this study is report the cancer specific outcomes following total gland salvage HIFU in patients with radiorecurrent, localized prostate cancer treated at centers participating in the Ablather-Registry (@-Registry; EDAP TMS Inc.).

**METHODS:** The @-Registry is a secure on-line database consisting of case report forms which collect relevant de-identified pre and post treatment information for patients undergoing prostate HIFU. Data from 3218 consecutively treated patients who underwent HIFU were reviewed to identify patients treated for locally recurrent prostate cancer (T1-2) following external beam radiation therapy. All patients had AP prostate diameter  $< 25$  mm and underwent whole gland HIFU salvage therapy. Survival analysis using the method of Kaplan and Meier was performed to determine biochemical survival according to the Phoenix definition (nadir+2). Post HIFU biopsy data was also analyzed.

**RESULTS:** A total of 434 patients met the inclusion criteria. The average age was  $68.6 \pm 5.8$  years. Mean Pre HIFU PSA was 6.9 ng/ml, the median Gleason sum was 7. Patients were followed for a mean of 2 years (+/- 2.1years). The median PSA nadir was 0.19 which was reached  $10.1 \pm 10.7$  weeks after salvage HIFU. Actuarial survival at 4 years was 54%. Of the 434 patients, 255 underwent biopsy and sixty-seven (26.2%) were positive.

**CONCLUSIONS:** The management of patients following radiation therapy is difficult. Four years after salvage HIFU 55% of patients remained biochemically disease free and 73.8% showed no evidence of local recurrence on follow-up biopsy. These results are encouraging and show the ability to return patients to disease free status following failed radiation therapy.

**Source of Funding:** EDAP, Inc.