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PURPOSE

PURPOSE: In the United States alone, new prostate cancer cases for 2017 were estimated at 161,360 and deaths at 26,730 according to the AACR. Focal therapies for low risk and intermediate risk localized prostate cancer are increasingly being explored.

MATERIALS AND METHODS

METHODS AND MATERIALS: All MRI-guided therapy was delivered using a 1.5 Tesla Philips Achieva XR system (Philips Healthcare, Best, The Netherlands) for both image acquisition and real-time thermometry. DynaCAD and DynaLOC (Invivo, Orlando, FL, USA) software were used for image analysis and interventional planning using the DynaTRIM positioning hardware (Fig. a) (Invivo, Orlando, FL, USA). Laser therapy was delivered using a Visualase (Medtronic, Minneapolis, MN, USA) 15W, 980 nm diode laser (Fig. b) with cooled (Medtronic, Minneapolis, MN, USA) or non-cooled (Clinical Laserthermia Systems, Lund, Sweden) laser fiber introduced transrectally.

Methodology

- IRB approved, 510k cleared technology
- NCT# 02243033
- Outpatient trans-rectal laser therapy (15W, 980 nm diode laser) guided with 1.5T MRI system (image acquisition & real-time thermometry)
- True focal therapy
- Goal to eliminate MRI abnormality + 1cm
- 175 cancer foci treated in 119 patients from 2010 – 2018
- 6-Month biopsies performed with MRI active surveillance follow-up
- Evaluation of PSA, PSAD, mpMRI, recurrence rates (marginal, incidence), IPSS, SHIM, PHQ-9

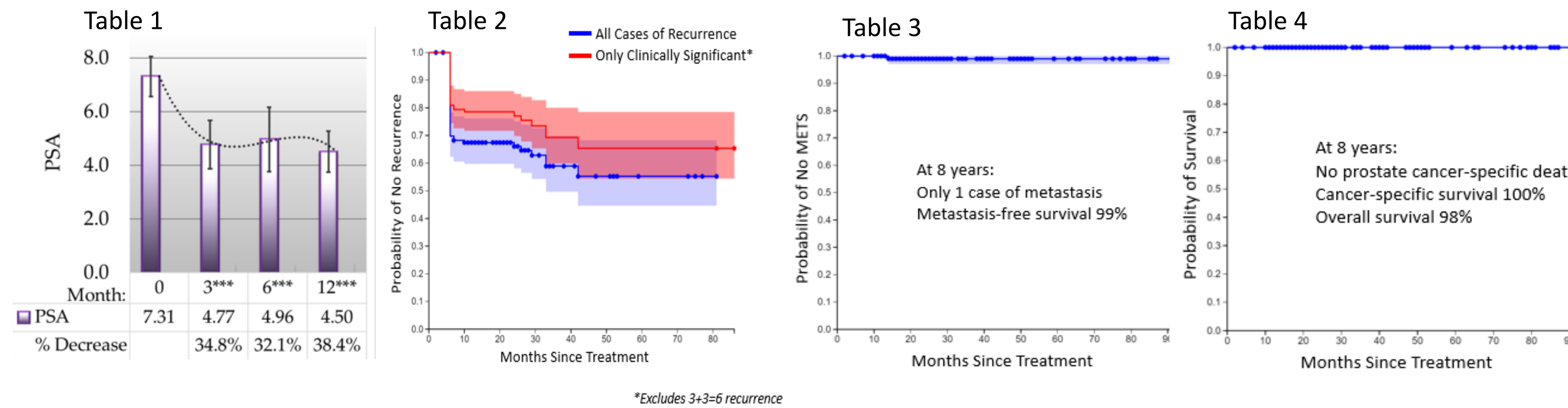
Patient Population At A Glance:

Statistic	Data
# of Patients	119
# of Treatment Naive Patients	100 / 119 (84%)
# of Salvage Patients	19 / 119 (16%)
# of Total Lesions	175
# of Treatment Naive Lesions	150 / 175 (86%)
# of Salvage Lesions	25 / 175 (14%)
Mean Initial PSA	7.31
Mean Nadir PSA	3.19 (56% drop)
Min Age	48
Max Age	87
Median Age	67



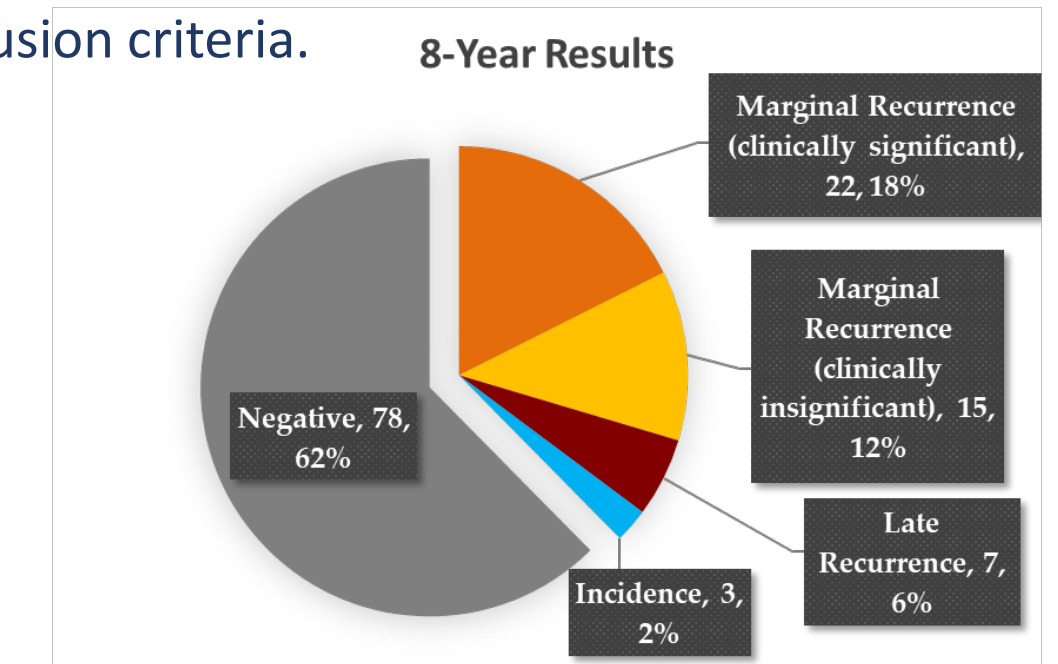
RESULTS

RESULTS: Mean PSA dropped 38%, 12 mos. post-treatment. 95% CI shown as error bars (Table 1). We observed more pronounced PSA decline (~50%) in the salvage cohort and attributed this to their comparatively high PSAs relative to the treatment naïve cohort. Compared to the initial PSA (Month 0), paired Student’s t-test used to evaluate mean PSA, p<.001***. No patient experienced permanent erectile dysfunction or incontinence as a result of treatment. While no prostate cancer-specific deaths have occurred, a Kaplan-Meier Curve of recurrent cancer is shown with 95% confidence interval bands (Table 2). The drop at the 6-month mark is due to the research protocol which requires that an MRI-guided biopsy be acquired from the treatment site (even in the absence of 6-month following treatment to detect marginal recurrence). Kaplan-meier curves in Tables 3 and 4 illustrate the low rate of metastasis and death in both the treatment naïve and salvage cohorts; however, two patients expired from metastatic melanoma.



CONCLUSIONS

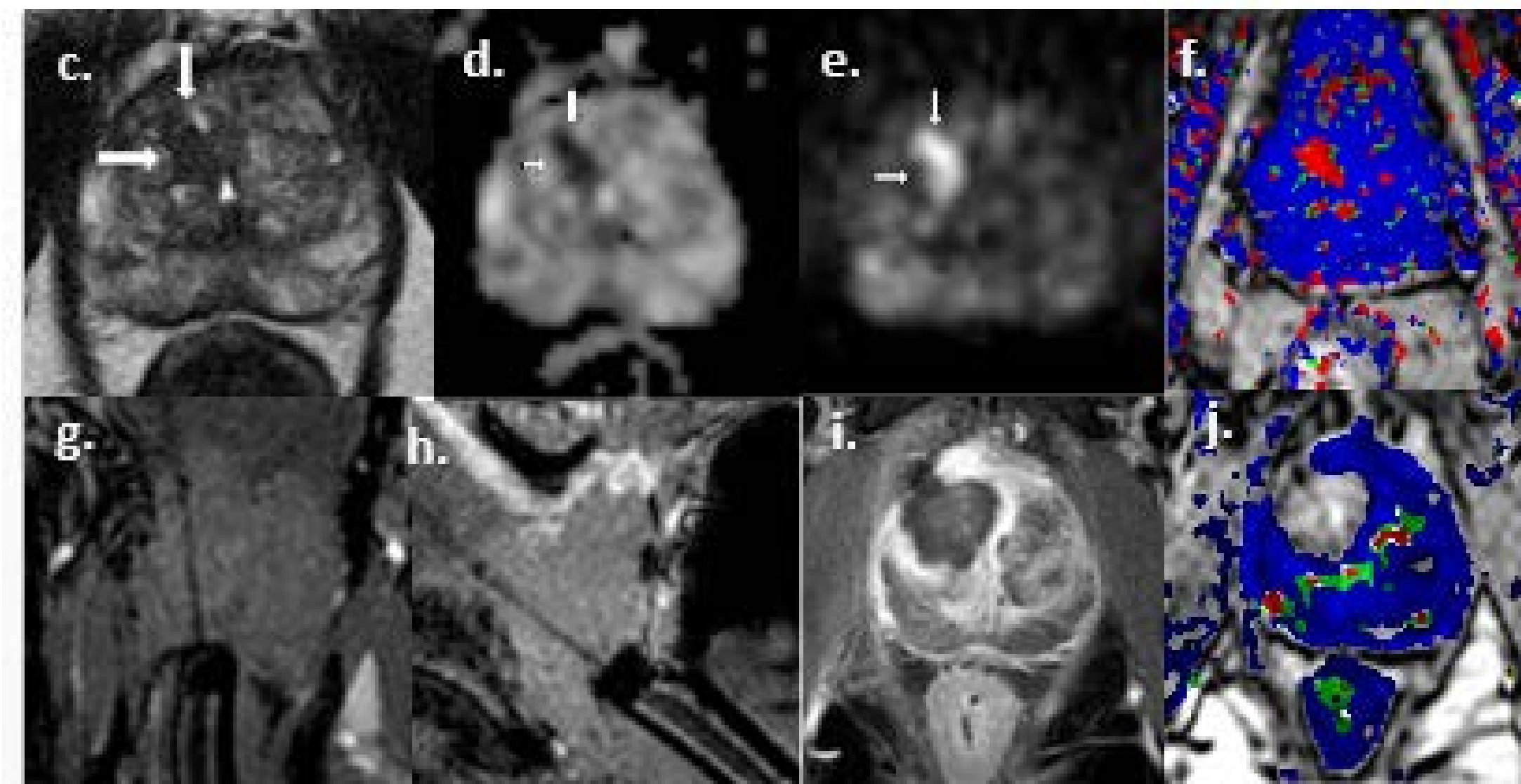
CONCLUSIONS: Eight year interim results in over 100 patients indicates that outpatient, MRI-guided, transrectal laser focal therapy is both safe and feasible. No statistically significant erectile dysfunction or incontinence occurred. Short-term and intermediate-term oncologic control is achievable in 75% of patients that include both treatment naïve and salvage inclusion criteria.



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CLINICAL CASE



Multiparametric prostate MRI (T2-weighted images [Fig.c], apparent diffusion coefficient maps [Fig. d], high b-value diffusion-weighted imaging [Fig. e], and dynamic, contrast enhanced images [Fig. f]) depict biopsy- proven adenocarcinoma Gleason score 3+4=7.

The laser fiber is placed precisely in the location of the tumor. Figs. g and h show axial and sagittal views respectively. Post-ablation, dynamic, contrast enhanced imaging demonstrated the area of coagulation necrosis (Figs. i and j).