

PD19-07**REAL-WORLD OUTCOMES AFTER MRI-GUIDED TRANSURETHRAL ULTRASOUND ABLATION OF THE PROSTATE IN A MULTICENTER POST-MARKET REGISTRY**

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INTRODUCTION AND OBJECTIVE: Regulatory studies of MRI-guided transurethral ultrasound ablation of the prostate (TULSA) demonstrated safety and efficacy of whole-gland ablation in men with favorable-risk, localized prostate cancer (PCa) using first-generation technology. Here, we report 1-year outcomes from a broader spectrum of primary PCa patients after focal to whole-gland TULSA in the multi-center Customized TULSA-PRO Ablation Registry ("CARE", NCT05001477).

METHODS: Five U.S. centers enrolled 208 patients (Jul 2020-Oct 2024). All consented to prospective data collection and received the local standard of care. Primary endpoints were the rate of complications attributable to TULSA (safety), and the rate of freedom from additional PCa treatment (efficacy). Follow-up took place at 0, 3, 6, 12 months and annually thereafter, including complications (Clavien-Dindo), PSA, MRI, biopsy and salvage treatment. Quality of life questionnaires administered at each visit include select questions from the International Index of Erectile Function (IIEF) and Expanded Prostate Cancer Index Composite (EPIC).

RESULTS: A subgroup of 201 patients enrolled in CARE had treatment-naïve PCa; the other 7 had prior radiation (6) or HIFU (1). Median (IQR) age, prostate volume, and PSA pre-treatment were 68 (64-73) y, 40 (31-53) cc, and 6.4 (4.8-9.5) ng/mL. The range of histological Grade Group (GG) at baseline was: 14% GG1, 57% GG2, 18% GG3, 5% GG4, and 6% unknown. Treatment plans included lesion-targeted (18%), hemi-gland (7%), subtotal (29%), and whole-gland (37%). 125 patients reached 1-year follow-up, with follow-up MRI and biopsy in 108 and 49. On MRI, 16 (13%) had evidence of focal abnormality; on biopsy, 7 (6%) had evidence of $\geq$ GG2 disease. Median (IQR) PSA nadir was 0.65 (0.20-1.67) ng/mL, decrease of 89 (69-96)%. 8 patients received salvage treatment: 4 external beam radiation+ADT, 4 repeat TULSA between 10-24 months without unexpected complications. Among patients with $\geq$ 12 months follow-up, potency (IIEFQ2 $\geq$ 2), pad-free continence (EPIC Q5=100), and leak-free continence (EPIC Q1 $\geq$ 50) were preserved by 76%, 92% and 97%. Median (IQR) IPSS was stable from 7 (4-13) at baseline to 7 (3-11) at 1 year. Grade III complications were incurred by 6 patients (3%): correction of urinary incontinence (1) or erectile dysfunction (1), and endoscopic treatment of retention/stenosis (3) or bladder calculus (1).

CONCLUSIONS: The CARE registry has captured excellent early radiologic and histologic control in a diverse cohort of patients with GG1-GG4 PCa treated with focal to whole-gland ablation. A head-to-head comparison between TULSA and radical prostatectomy (NCT05027477) is currently accruing.

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PD19-09**PROSTATE CANCER FOCAL THERAPY AND MALPRACTICE: A 25-YEAR ANALYSIS OF LEGAL CLAIMS**

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INTRODUCTION AND OBJECTIVE: Focal therapy is a targeted, image-guided treatment for localized prostate cancer, which offers a reduced side effect profile compared to traditional treatments like surgery and radiation. However, focal therapy may carry

procedural risks, including rectal injury, and is still regarded by many as an investigational approach. Its medical-legal dimensions remain under-explored. We aim to review and analyze the malpractice lawsuits related to prostate cancer focal therapy.

METHODS: This retrospective study utilized the LexisNexis Database to analyze focal therapy malpractice lawsuits between 1999 and 2024. We used keywords "focal therapy, high-intensity focused ultrasound (HIFU), cryotherapy, laser, irreversible electroporation (IRE)" to search for relevant cases. We excluded cases that did not involve focal therapy treatment of prostate cancer. We then reviewed cases for treatment method, allegation, claimed liabilities, verdict, and plaintiff award.

RESULTS: A total of 180 unique lawsuits were found using the keywords provided, and 5 cases met inclusion criteria. All five of the lawsuits involved cryotherapy for prostate cancer. 2 (40%) lawsuits precipitated from rectourethral fistula, while the rest were isolated injuries (hematuria and dysuria, delayed treatment of prostate cancer, death). Allegations included negligence (2, 25%), deviation from the standard of care (2, 25%), deliberate indifference (2, 25%) and failure to consent (2, 25%). Verdicts were predominately favorable to defendants (4, 80%), and only one case (20%) resulted in settlement of unknown amount.

CONCLUSIONS: This study is the first existing effort to analyze the medical legal side of focal therapy for prostate cancer. Over its two-decade existence, focal therapy had a limited number of lawsuits, with outcomes generally favorable to surgeons and minimal financial payouts. While some cases involved substantial injuries to the patients, they are mostly known complications of focal therapies. This study shows that as focal therapy continues to gain popularity, urologists must continue to advance surgical techniques to decrease occurrences of severe complications, conduct more thorough informed consent, and exercise excellent patient-provider communication to provide high quality care and reduce the number of malpractice lawsuits.

Case	Year	State	Precipitating Issue	Allegation	Treatment Method	Case Summary	Verdict	Award	References
Richards v. Pickett	2023	CA	Delayed diagnosis and treatment of prostate cancer	Deliberate indifference	Cryotherapy for prostate cancer	Plaintiff claims that his treatment resistant metastatic prostate cancer is a result of the defendant's alleged deliberate indifference to plaintiff's recurring prostate cancer and failure to diagnose and treat with cryotherapy timely.	Defendant	0	Richards v. Pickett, 2023 U.S. Dist. LEXIS 247119
Moore v. Hedge	2024	CO	Hematuria and dysuria	Deliberate indifference	Cryotherapy for prostate cancer	Plaintiff claims that the defendants showed deliberate indifference in not treating plaintiff's dysuria and hematuria after cryotherapy.	Defendant	0	Moore v. Hedge, 2024 U.S. App. LEXIS 1775
Ladner v. Northside Hosp.	2012	GA	Death	Negligence and deviation from the standard of care	Cryotherapy for prostate cancer	Plaintiff claimed patient's wife, sued surgeon for alleged negligent execution of cryotherapy which caused his death.	Defendant	0	Northside Ladner v. Northside Hosp., 314 Ga. App. 138
Davis v. Simon	2010	OH	Rectourethral fistula	Failure to consent	Cryotherapy for prostate cancer	Plaintiff sued defendant for alleged failure to consent which resulted in a rectourethral fistula.	Settlement	Unknown	Davis v. Simon, 2010 Ohio Misc. LEXIS 17055
Roberts v. Rickard	2001	TN	Rectourethral fistula	Negligence, failure to consent, and deviation from the standard of care	Cryotherapy for prostate cancer	Plaintiff sued defendant for alleged failure to consent, negligence, and deviation from standard of care which resulted in a rectourethral fistula.	Defendant	0	Roberts v. Rickard, 73 S.W.3d 106

Table 1. Characterization of Lawsuits against Urologists Regarding Focal Therapies.

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PD19-10**OUTCOMES OF FOCAL HIFU FOR LOCALISED PROSTATE CANCER DETERMINED BY MODERN RISK STRATIFICATION STRATEGIES**

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INTRODUCTION AND OBJECTIVE: Consensus statements determine focal HIFU could be used for patients with intermediate and carefully selected high risk localised prostate cancer, however, have yet