Ultrasound-guided focal Laser Ablation in Patients with Localized Prostate Cancer- Oncological outcome after 6 months follow up in the Pro-FLA trial

Simon Blaschke[1], Alexander Fehr[1], Melis Gür[1], Christian Samtleben[1], Frank Fischbach[2], Martin Schostak[1;3]
[1] Dept. of Urology, University Magdeburg Germany. [2] Dept. of Radiology, University Magdeburg, Germany. [3] Arbeitskreis fokale und Mikrotherapie

CONTACT:
Dr. Simon Blaschke, simon.blaschke@med.ovgu.de
www.med.uni-magdeburg.de

Introduction

Focal laser ablation (FLA) is based on thermal destruction of tumor tissue. A new approach is navigating the laser fiber into the tumor lesion transperineally by MR/US fusion.
To determine the clinical safety and feasibility of transperineal ultrasound guided FLA of prostate cancer, we designed the Pro-FLA trial. Here, we present the results of the confirmatory biopsies after six months.

Objectives

Primary Objective:
Biopsy-proven cancer-free tissue in the treated areas after 6 months using MRI/TRUS-guided fusion biopsy.
Secondary Objectives:
Cancer-free tissue outside the treated areas. Functional outcomes: continence (ICS male score), urinary function (IPSS), erectile function (IIEF-5). Quality of life (EORTC QLQ-C30) and mental health (HADS). Safety: Monitoring adverse events per Clavien-Dindo and CTCAE 5.0.

Methods

Study Design:
This was a prospective, interventional, single-center, non-randomized, and non-controlled pilot study aimed at evaluating the safety and feasibility of transperineal, ultrasound-guided FLA in patients with localized prostate cancer.
Laser System:
The procedure utilized the CLS TRANBERG System, a CE-certified laser device emitting at a wavelength of 1064 nm with an 8W power output. The laser's penetration depth in tissue is approximately 7 mm, with tissue destruction depending on temperature and duration of exposure.
Imaging and Guidance:
FLA was performed using MRI/Ultrasound (US) fusion imaging. Multiparametric MRI (mpMRI) data was fused with real-time ultrasound images to accurately guide the laser probe into the tumor lesion transperineally (Fig. 1).

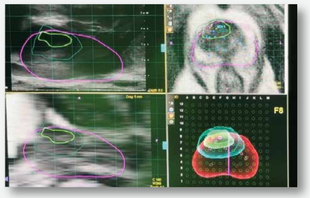
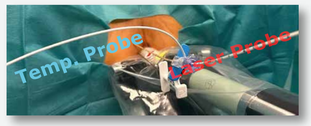


Fig. 1:
MRI-planned ablation zone, safety margin and ultrasound fusion



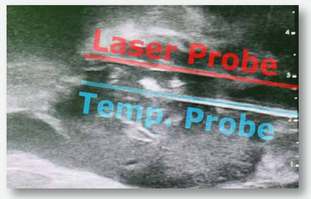
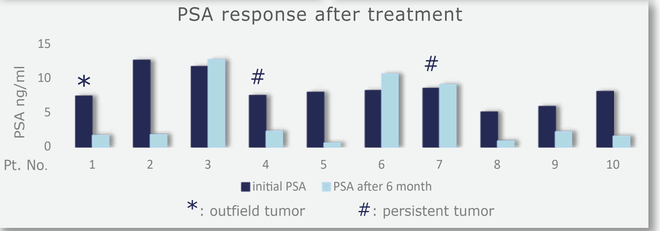


Fig. 2:
Ultrasound-guided placement of the laser and temperature probe

Temperature Monitoring:
The tissue temperature was continuously monitored during the procedure, with sensors placed 10 mm from the laser probe to ensure safety and precision (Fig. 2).
Inclusion Criteria:
-Patients with localized prostate cancer (Gleason score ≤ 7a)
-PSA level ≤ 15 ng/mL
-Lesion size ≤ 20 mm confirmed by mpMRI and biopsy
-Correspondence between MRI findings and positive biopsies
Procedure:
Laser ablation was carried out transperineally under real-time MRI/US fusion guidance, with the goal of achieving precise thermal destruction of the cancerous tissue while preserving surrounding healthy tissue.
Follow-up:
Patients were monitored post-procedure with regular PSA measurements, MRI imaging, and confirmatory biopsies after 6 months.

Results after 6 months	
Biopsy results	7 out of 10 patients NED 1 outfield tumor Gl. 6 2 infield persistence
PSA reduction	7 out of 10 patients (Average PSA reduction from 8,36 ng/ml to 3,88 ng/ml)



Adverse events	3 urinary retention 1 urinary tract infection

Results

Biopsy Results: 7 patients with NED. 1 patient experienced a recurrence outside the treated area (Gl 6). 2 patients showed persistent cancer in the treated area (regression grade II).
PSA Levels: 7 patients demonstrated a significant decrease in PSA levels.
Adverse Events: 3 patients developed urinary retention, requiring temporary catheterization. 1 patient had a urinary tract infection and was treated with antibiotics.
No significant impact on continence and erectile function, as reflected in stable ICS and IIEF-5 scores.

Conclusion

FLA for prostate cancer appears to be feasible and safe, providing promising oncological control in localized prostate cancer.
The procedure was well-tolerated and could be a valuable addition to focal therapy options for prostate cancer.