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ORIGINAL PAPER

A single-operator experience using EchoLaser SoracteLite™ for focal laser ablation of prostate cancer: One more arrow in the quiver for the conservative management of the disease

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Summary

Background: *The aim of this study was to evaluate the outcomes of patients suffering prostate cancer (PCa) treated conservatively using 1064 nm laser energy for focal laser ablation (FLA). The patients included in the study were unsuitable for surgery or unwilling to receive external beam radiotherapy because they were afraid of the possible side effects of whole-gland therapies.*

Methods: *This study included patients with a diagnosis of non-metastatic PCa who underwent FLA using SoracteLite™ system. Tissue ablation was performed at a fixed power of 5 W by the diode multichannel laser system EchoLaser X4 that uses laser light transmitted through optical fibres causing the target tissue to undergo irreversible thermal damage. Functional outcomes were evaluated with the International Prostatic Symptoms Score (IPSS) and 5-item version of the International Index of Erectile Function (IIEF-5) before the treatment and one year later.*

Results: *Ten patients suffering non-metastatic PCa were included. Four decided upon a conservative treatment because of reduced performance status and for six patients the procedure was chosen electively. All patients underwent multiparametric magnetic resonance imaging at 3 and 12 months and eight out of ten patients underwent prostate biopsy at 6 months. Persistent disease was detected in 3 patients who underwent a second ablation. In these patients at the biopsy following the second ablation none harbored residual disease. At follow-up, no patient suffered urinary incontinence requiring the use of pads. No significant worsening in sexual potency measured with IIEF-5 ($p = 0.356$) or prostatic symptoms measured at IPSS ($p = 0.462$) were recorded comparing pre-treatment condition vs one-year follow-up. Compared with baseline, prostate-specific antigen was significantly reduced at one-year follow-up (3.7 ± 1.1 vs 7.9 ± 4.1 ng/mL; $p = 0.008$).*

Conclusions: *Although whole gland therapies remain the gold standard treatment for PCa, our results indicate that the SoracteLite™ system for focal laser ablation, as a very preliminary step, appears to offer a short-term oncologic control of PCa with negligible side effects.*

KEY WORDS: *Focal laser ablation; Focal therapy; Prostate cancer; Prostate magnetic resonance imaging; Transperineal treatment.*

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INTRODUCTION

Currently whole-gland therapy such as *radical prostatectomy* (RP) and *external beam radiotherapy* (EBRT) still represent the gold standard treatments for localized *prostate cancer* (PCa). Both treatments are effective but they can be burdened with procedure-related side effects such as urinary incontinence and erectile dysfunction (1, 2).

Nowadays there are well-established studies in support of prostate-sparing procedures in low-risk cancer, but the treatment indications have also expanded to small intermediate-risk and high-risk tumours, which are considered life-threatening (3-5).

Concerns have arisen about the focal treatment of a disease that has been found to be multifocal in 50-76% of patients (6). A high degree of genomic heterogeneity and a 13-26% Gleason Score heterogeneity have also been reported, even within the positive cores of prostate biopsy (7, 8).

In a therapeutic approach for PCa the concept of index lesion is therefore decisive. Despite the multifocality and heterogeneous disease pattern inside the same gland, the index lesion represents the largest prostatic tumour with the highest histologic grade within the prostate. This is likely to drive the biology of the patient's disease. In fact, the same genomic sequence has been found in metastatic lesions and in the index lesion within the prostate (9). Interestingly, despite being limited to one case, *Haffner et al.* used the whole-genome sequencing and molecular analyses to characterize the lethal clone in a patient who died of PCa. Surprisingly, the lethal clone arose from a small, relatively low-grade cancer focus in the primary tumour. These findings highlighted le potential importance of investigate molecular prognostic and/or predictive markers to optimize the pathological evaluation and delineate clonal heterogeneity (10).

Laser interstitial thermotherapy performed by the diode multichannel laser system *EchoLaser X4* is a transperineal percutaneous procedure named *SoracteLite™* that uses laser light transmitted through optical fibres to produce irreversible thermal damage of target tissue.

The *EchoLaser X4* system allows multifibre ablation management and provides planning software for optimization

No conflict of interest declared.

of the ablation strategy. It also supports the surgeon with planning for effective and safe needle positioning with respect to the tumour and critical structures to be spared. Here, we present the results obtained from our updated single-surgeon prospective cohort of 10 patients with at least one-year follow-up after the use of 1064 nm laser energy for *focal laser ablation* (FLA) of PCa. In this cohort we treated patients with only one lesion so as not to have to decide whether to treat the index lesion or also the other/s considered less aggressive/s.

Materials and methods

Population characteristics

Between October 2019 and October 2020, 10 patients candidate to organ-sparing treatment for PCa were selected to undergo FLA using the *SoracteLite™* procedure.
SoracteLite™ for FLA treatment was offered to patients with no metastatic PCa, Gleason score ≤ 8, TNM stage T1c-T2cN0M0, p*rostate-specific antigen* (PSA) ≤ 20 ng/mL, a single lesion with a concordant *multiparametric magnetic resonance imaging* (mpMRI), a tumour volume ≤ 20 mL and a good life expectancy. All patients included in this study had a prostate volume smaller than 65 mL.
The patients included in the study were unsuitable for surgery or unwilling to receive EBRT.
It was fully explained to the patients that different focal therapies validated were available, but the patients, due to the trust acquired with our working group, choose the aforementioned approach that was presented as experimental. Each case had been previously discussed in a multidisciplinary meeting and extensively with the patient, who received written information on the benefits and risks of the procedure.
Prior to the start of patient recruitment, the surgeon (NP) followed a training program, visiting centres with expertise in FLA with *SoracteLite™* technology to achieve proficiency in the main aspects of FLA (fibre positioning, energy dose, ablation strategy and ablation margin). Finally, a representative from the manufacturer of the device trained the surgeon and operating theatre staff on the use of *SoracteLite™*, and assisted the operator for the first 3 cases.

Protocol and assessment of data

The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The confidentiality of patient data was guaranteed as the patients were entered into a database in the form of a number. Following *Institutional Review Board Commitee* approval and registration of the protocol (0014161/2019), patients with localized PCa were prospectively recruited. The informed consent was obtained from all patients for the use of their data.

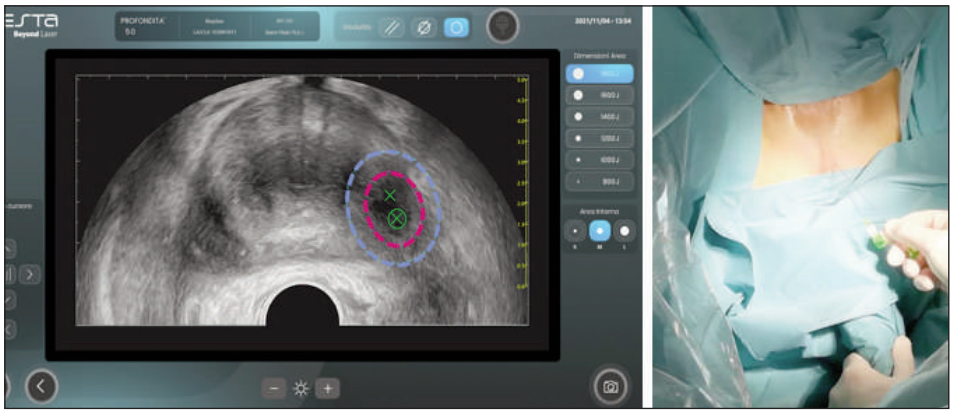
Pre-operative assessment

All the patients we followed had undergone mpMRI and transperineal prostate biopsy with systematic sampling of the prostate with 12 samples per side for a total minimum of 24 samples. Six out of 10 patients underwent biopsy before the mpMRI, in the other 4 mpMRI was done before the biopsy. In those patients in whom a mpMRI was performed before the biopsy, two more samples were taken, targeted, as cognitive biopsy, in the area identified on mpMRI. The inclusion of random samples was fundamental for us to exclude the presence of disease in areas not frankly suspicious on mpMRI. We classified these patients as carriers of single lesion disease inasmuch the positive biopsy samples were found only in the area highlighted as suspicious on mpMRI. All patients had undergone systematic PSA testing prior to diagnostic biopsy.
In addition, a questionnaire for the evaluation of urinary symptoms and sexual function were administered to the patients before undertaking the therapeutic treatment.

Technique

SoracteLite™ for FLA consists of ultrasound-guided positioning of up to 4 applicators (depending on the tumour volume and shape) consisting of a 21-gauge Chiba needle (*INTRODUCER, Elesta SpA, Calenzano, Italy*) in whose lumen is inserted a 272-µm quartz optic fibre (*Fiber Optic for PLA, Elesta SpA, Calenzano, Italy*). The fibre tip protrudes 10 mm from the introducer tip. The optic fibres are connected to a multisource laser system operating at 1064 nm (*EchoLaser X4, ELESTA SpA, Calenzano, Italy*). Each treatment is performed at a fixed power of 5 W, with the single illumination dose determined on a case-by-case basis according to the tumour size. Additional laser fibres can be placed within the tumour volume at a mutual distance ranging from 5 to 10 mm in order to amplify the volume of necrosis obtained by simultaneous tissue irradiation and summative volumetric necrosis.
Depending on the tumour size in the longitudinal direction, one or more consecutive illuminations are performed with a '*pull-back*' technique (retraction of the needle-fibre kit by 5-10 mm) during the same treatment session. For the same duration of illumination and dose of energy administered, the thermoablated area is always reproducible regardless of tissue properties and vascularity. The anatomopathological study of a thermoablated tissue area showed that the necrotic area assumes an ellipsoid shape.
The treatment ends when the total planned dose is delivered. A single illumination dose ranges from 1200 J to 1800 J, which corresponds to an illumination time of 4 to 6 minutes. In cases where a '*pull-back*' maneuver is used, the illumination time doubles.
A touch panel device (*ESI, EchoLaser Smart Interface, Elesta SpA, Calenzano, Italy*) can be connected to the auxiliary video output of a general ultrasound scanner and used for treatment planning. ESI has a dedicated planning software that allows the visualization of needles insertion trajectories of the needle guide mounted on the US biplanar probe of the connected ultrasound. This facilitates the insertion of regularly spaced multiple parallel needles simultaneously. The treatment planning is crucial for the outcome of the treatment. The ESI superimposes on the ultrasound image a graphical representation, consisting of guidelines for the needle trajectories and the depiction of two concentric closed perimeters, an external one for the size of safety distances and an internal one for the size of the ablation area. The size and position of both of these perimeters depend on the treatment parameters (dose, number of fibres, '*pull-back*') and the surgeon can simulate the best treatment strategy before needle insertion. The planning ends when the

Figure 1.



On the left: EchoLaser Smart Interface settings during the planning phase. The ablation area (dotted magenta line) is simulated in order to define the best approach in terms of number of fibres, mutual tip position, 'pull-back' and energy dose. The external circle (dotted cyan line) represents the safety distance to be assured with respect to critical structures (nerves, rectum). On the right: two introducer needles are positioned in a parallel orientation according to the planning.

tumour is visualized within the internal closed perimeter and all critical structures (urethra, vascular bundle, sphincters, bladder wall and rectum) are located outside the external perimeter. If required, it is possible to increase the distance from the rectum by injecting a 33% (w/v) glucose solution between the prostate and the rectum. The goal of the planning phase of the procedure is to identify the point where the tip of the needle will be located, with respect to the area that will be ablated. The ultrasound software associated with a directional template for guidance allows the placement of the laser fiber(s) in the index lesion with millimeter precision (Figure 1).
After an observation period of about one hour, a transrectal contrast enhanced ultrasonography to evaluate the extent of the coagulation zone is performed. Patients are discharged the day of the procedure without a catheter.

Follow-up, functional and oncological outcomes

All patients were advised to undergo a 6-monthly biopsy sampling, and mpMRI at 3 and 12 months.
Complete response was defined on the basis of negative imaging study results and negative prostate biopsy at 6 months. Persistent disease was defined as the presence of suspected or positive imaging study results and/or positive prostate biopsy performed at 6 months. In case of persistent disease, a second ablation was planned.
The *International Prostatic Symptoms Score* (IPSS) and 5-item version of the *International Index of Erectile Function* (IIEF-5) were completed by each patient prior to the procedure and at 1-year follow-up without changing the intake of any type of drug. PSA was also confronted before treatment and at one-year follow-up.
Intraoperative and postoperative complications were recorded according to *Satava* (11) and *Clavien-Dindo* (12), respectively.

Statistical analysis

Categorical data were described by frequency; continuous data were expressed as mean and standard deviation.
To compare data (IPSS, IIEF-5 and PSA) measured at baseline and after 12 months of follow-up, t-tests for paired data were applied. Statistical significance was set at $p < 0.05$ and all analyses were carried out with SPSS Statistics version 27.0 (*IBM Corp., Armonk, NY*).

Results

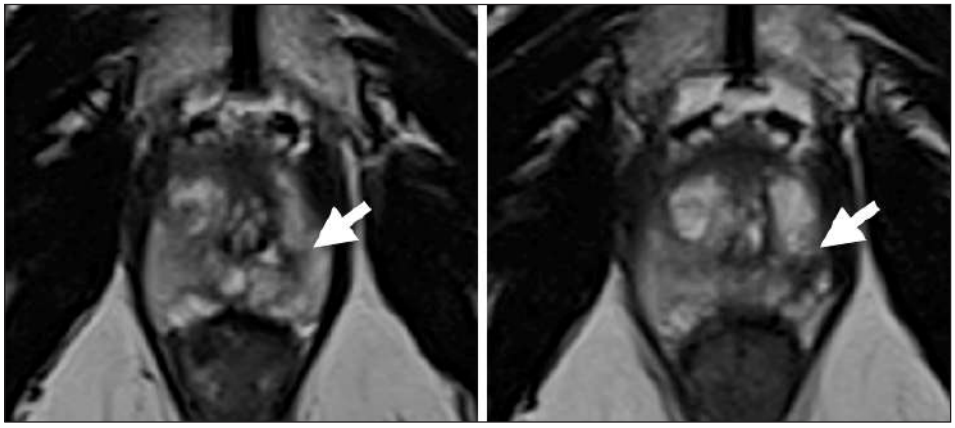
Patient characteristics are summarised in Table 1. A total of 10 patients suffering non-metastatic PCa were included in the present study. FLA for PCa was selected as the initial treatment for the following reasons: reduced performance status (4 patients) and patient's own choice (6 patients). At the diagnostic biopsy four patients suffered PCa Gleason 6 (3+3), two patients had Gleason 7 (3+4)

Table 1.
Patient characteristics.

Patient number	Age (years)	Indication for FLA	DRE	PSA (ng/mL)	GS	Laterality	Diameter of tumour at mpMRI (mm)	PSA (ng/mL) (12 mo)
1	65	Elective	+	7.3	6	Right	5	3.2
2	73	Elective	-	5.1	6	Left	14	3.1
3	60	Elective	-	5.1	6	Left	7	3.9
4	67	Unfit for surgery	+	11	7 (4+3)	Right	20	1.5
5	75	Elective	-	5.2	8 (4+4)	Left	9	3.6
6	69	Elective	+	5.7	7 (3+4)	Left	10	3.2
7	74	Unfit for surgery	+	17.8	7 (4+3)	Right	15	5
8	78	Elective	+	10.1	7 (3+4)	Right	15	5.2
9	73	Unfit for surgery	-	6.8	7 (4+3)	Left	11	4.1
10	70	Unfit for surgery	+	4.9	6	Left	7	3.9

+: Suspicious. -: Non-suspicious. DRE: Digital rectal examination. FLA: Focal laser ablation. GS: Gleason Score. mpMRI: Multiparametric magnetic resonance imaging. PSA: Prostate-specific antigen.

Figure 2.



On the left: mpMRI T2-weighted sequences on the axial view showing a 7 mm carcinoma located in the left apical portion (arrowhead) in a 53-year-old patient before treatment.
On the right: the same patient at 3-month follow-up after transperineal FLA.
A hypointense area compatible with necrotic-coagulative necrosis (arrowhead) matching the previous tumoural area is visible on the mpMRI T2-weighted image.

and three Gleason 7 (4+3). Only one patient presented a Gleason 8 (4+4) disease.
All patients underwent mpMRI at 3 and 12 months (Figure 2). Eight out of ten patients underwent prostate biopsy at 6 months. Six patients in which the mpMRI did not highlight suspected lesions (PI-RADS category < 3) had negative biopsy results according to the scheme (12 samples per side with the addition of sampling in the area previously subjected to FLA). These patients were considered to have a complete response to treatment. Three patients had a persistent disease according to positive (PI-RADS category ≥ 3) mpRMI at 3 months. Two of them underwent a prostate biopsy according to the scheme with additional samplings in the suspected area.
The pathology report revealed that those two patients still harbored PCa. One of them refused to undergo prostate biopsy and agreed to directly receive a second treatment in the area of persistence of disease identified on mpMRI (PI-RADS category 5).
The diagram in Figure 3 summarizes the diagnostic-therapeutic process of the entire cohort of patients in our study.
The three aforementioned patients with persistent disease underwent a second ablation and at 12 months, mpMRI revealed no lesions with PI-RADS category > 3. All three patients underwent a transperineal prostate biopsy at 12 months that was negative for PCa.
All the patients who required a second ablation had a disease > 10 mm at the first mpMRI.
Two patients were unwilling to repeat the biopsy at 6 months. One of them was the aforementioned patient who received directly a second treatment, the other one underwent a mpMRI at 6 and 12 months. In the latter patient, a PI-RADS category 2 was found in the ablated area at mpMRI, compatible with a necrotic area.
No complications related to diagnostic prostate biopsies were reported. No patient developed extracapsular invasion (> cT3) or appearance of bone lesions or lymph node swellings (> 1 cm) in the fields of inclusion on any mpMRI pelvic scan performed for primary diagnosis or follow-up at 6 months or 1 year. No intraoperative complications were recorded according to the *Satava* classification system (11). Postoperatively four patients required analgesic drugs (*Clavien-Dindo* grade I).
At 1-year follow-up, no patient suffered urinary incontinence that required the use of pads. Compared with baseline, no significant worsening in functional outcomes at 1 year was observed as measured with the IIEF-5 (p = 0.356) and IPSS (p = 0.462) (Table 2).

Figure 3.
Diagnostic-therapeutic process of the entire cohort of the 10 patients included in our study at follow-up.

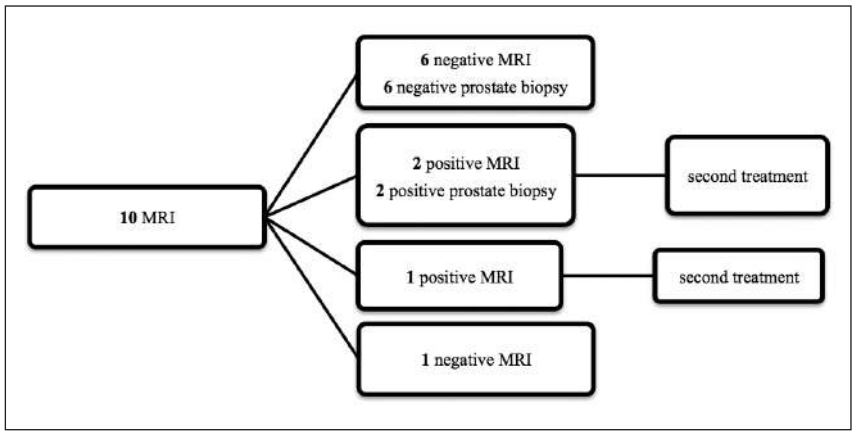
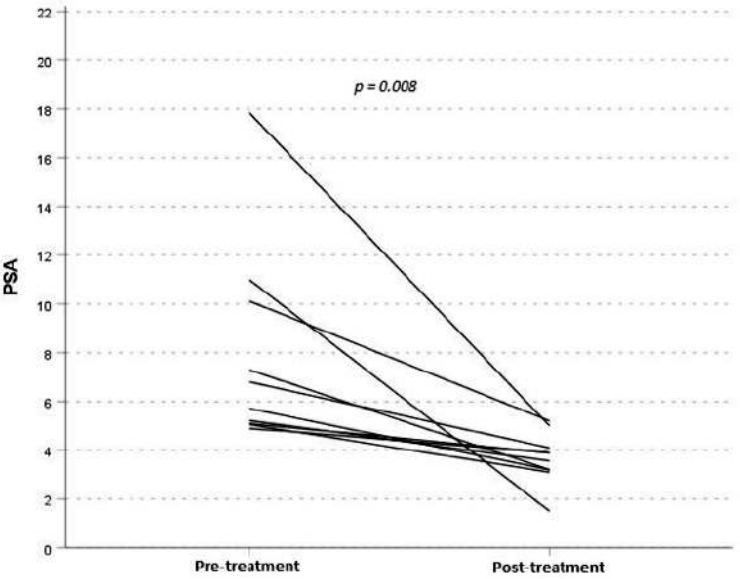


Table 2.
PSA (ng/ml), IPSS and IIEF-5 levels at baseline and after 12 months.

Factor	Mean (SD)	p-value
PSA pre-treatment	7.9 (4.1)	0.008
PSA at 1 year follow-up	3.7 (1.1)	
IPSS pre-treatment	6.9 (3.1)	0.462
IPSS at 1 year follow-up	7.3 (4.1)	
IIEF-5 pre-treatment	11.1 (5.1)	0.356
IIEF-5 at 1 year follow-up	10.2 (6.7)	

IIEF: International Index of Erectile Function.
IPSS: International Prostate Symptoms Score.
PSA: Prostate-specific antigen.

Figure 4.
Ladder plot illustrating individual changes in PSA from pre-treatment (at baseline) to post-treatment (12 months).



PSA: Prostate-specific antigen.

At 1 year follow-up, mean ± SD PSA was significantly reduced relative to baseline (3.7 ± 1.1 *vs* 7.9 ± 4.1 ng/mL; p = 0.008) (Table 1, Table 2 and Figure 4).

Discussion

Conservative treatments aim to control the disease while minimizing the risk of developing side effects, primarily sexual impotence, urinary incontinence and bowel toxicity. In fact, the possibility to treat only a targeted part of the gland reduces the risk of damage to the neurovascular bundles, external urethral sphincter, bladder neck or rectum.

Our results regarding *lower urinary tract symptoms* (LUTS) and sexual function measured with IPSS and IIEF-5 did not demonstrate a statistically significant change one year after the treatment (p = 0.462 and p = 0.356 *vs* baseline, respectively). Our results are in agreement with *Eggener et al.*, who found no worsening of IPSS symptoms in FLA-treated patients. Interestingly, however, these investigators found a worsening of sexual function at 1 month (p = 0.03) and 3 months (p = 0.05), although the difference vs baseline was not significant at 12 months (p = 0.38) (13). Also *van Riel et al.* found a worsening of sexual function at 1 week after the procedure, although the difference *vs* baseline was not significant at 1 month (14). Moreover, *Chao et al.* in their experience using FLA for localized PCa found no adverse impact on LUTS or sexual function at 1 year (15).

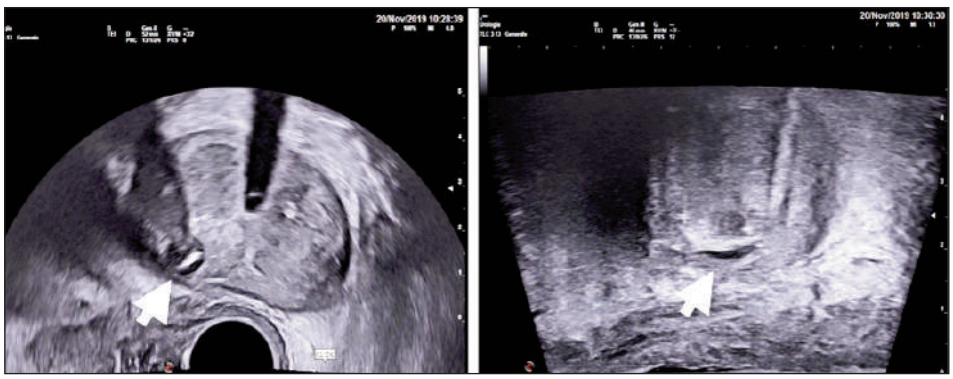
The presence of an expert technician for the device alongside the surgeon during the first cases is essential to reduce the initial learning curve and thus to improve safety of the procedure (16). Regarding the learning curve in using *SoracteLite*^{TM}, we believe that it is comparable to the training required for transperineal prostate biopsy, so that in the hands of an expert urologist, the use of the *SoracteLite*^{TM} procedure is quite simple.

Another strength of our study is the fact that all the procedures were performed by a single operator with extensive experience of the transperineal approach, and without the potential confounder of inter-operator differences.

The urologist (NP) who performed all the procedures in our study had extensive experience in performing transperineal prostate biopsies. To date, it is far more common to perform prostate biopsies via the transrectal access (17), so for the urologist who approaches the use of *SoracteLite*^{TM} for FLA it would be advisable to first acquire some biopsy experience with a transperineal access before engaging in ablative treatment. We believe that for the urologist experienced in transperineal access, three procedures are sufficient to complete the learning process and carry out adequate treatments.

Although our results and the overall literature are too preliminary to determine with adequate accuracy any possible advantage or disadvantage regarding the use of *SoracteLite*^{TM} for the treatment of PCa, we believe that an extraordinary advantage of the method is the ability to evaluate one hour later the effect on the tissue and to be able, in the same session, to expand the ablation in the desired area if this is not satisfactory (Figure 5).

Figure 5.



On the left: transverse ultrasound image during ablation.
On the right: longitudinal ultrasound image of the same tumour during ablation phase. Coagulated tissue appears as a hypoechoic area overlapped by gas artefacts (arrowhead).

Similar to other authors who have approached PCa with focal therapy for PCa, no patient in our cohort needed pads or complained of urinary incontinence after the treatment (18). This represents an outstanding success, as incontinence is statistically the most bothersome side effect of RP with an incidence that in some series reaches 65% (19). Even approaches such as EBRT or brachytherapy, which are considered less invasive, are burdened with considerable rates of worsening of urinary obstruction, irritation and worsened bowel symptoms (2).

One year after the procedure, a statistically significant reduction in PSA was observed compared with baseline ($p = 0.008$). Although three of the patients who had residual disease at 6 months prostate biopsy underwent a second ablation before 12 months, a reduction in PSA was evident for each patient in our cohort (Figure 4). In contrast to our results, *Chao et al.*, reporting oncological and functional outcomes for 34 men who had undergone FLA for PCa, found that PSA was a poor discriminator of disease recurrence in the ablated zone at two-year follow-up (15).

None of our patients had a PSA > 20 ng/mL at diagnosis, which, as a single factor for *D'Amico*'s criteria, would place the case into a high-risk category. While there is no clear indication on the use of both PSA and PSA-density as eligibility criteria for FLA (20), it is often suggested to consider PSA ≤ 15 ng/mL as a limit for a patient's suitability for focal therapy (21). The only patient who presented with Gleason Score 8 disease was a patient who wished to undergo some kind of treatment but was considered unsuitable for other therapeutic treatments because of age and comorbidities.

In three patients, disease was persistent after the first FLA procedure and in all three cases the disease was present in the same area at follow-up. This is likely related to inaccuracy in pinpointing the entire lesion during the first procedure. Our results suggest that the treatment of lesions > 10 mm could be less accurate and require a second-look. The disadvantage of not achieving complete disease ablation at the first attempt, especially in more aggressive diseases, could potentially give the disease the chance to progress.

In a study of ultrasound-guided laser ablation in the thyroid gland of a porcine model, *Ridouani et al.* concluded that 3 W/1800 J was the optimal setting to obtain a coagulated necrotic zone of 10 mm with 2 mm margin when utilizing a single needle (22). In our cohort of patients, the energies used were greater and for a single treatment were not lower than 5 W/3600 J.

Other clinicians who used the *SoracteLite™* system for benign prostatic hyperplasia used a power of 3W for tissue ablation (23). We chose to use greater ablation power for tumour tissue with the aim of greater certainty in disease ablation. In fact, higher powers reduce the duration of the initial phase of heating which can be affected by local tissue properties, and therefore trigger the ablation phase very quickly. This leads to lower interpatient variability of treatment outcomes. In the case of larger lesions, depending on the tumour shape with respect to the needle insertion direction, a '*pull-back*' maneuver was carried out (needle retraction and second energy dose delivery) or a second fibre was placed in a parallel way with respect to the first one and simultaneous energy delivery was performed.

There are some limitations to our study. Firstly, the small number of patients limits the robustness of our results, especially those concerning cancer control. Secondly, follow-up in this study was limited to one year. Therefore, while our data on functional outcome are interesting, the oncological results still need to be validated with a longer follow-up.

Finally, our data are not sufficient by themselves to formulate an indication for *SoracteLite* FLA in PCa, especially since this is a non-randomized series without a strict exclusion criterion for class of risk.

Our study highlights important opportunities for future work. It would be interesting to carry out a comparative study for functional and oncological results, standardizing it with patients in the same class of risk, comparing different conservative approaches for the treatment of PCa. Furthermore, to evaluate the possibility of adopting this technique on a large scale it would be useful to involve both experienced and novice operators to evaluate the feasibility of this technique in therapeutic practice.

Conclusions

Our results confirm that *SoracteLite™* for FLA treatment is an interesting emerging technology for the treatment of PCa. As is the case for other conservative approaches, it must find its place in the landscape of treated patients. Safety profiles and functional and oncological results are promising; however, long-term follow-up results are not yet available. Additional prospective, multicenter studies are awaited to confirm our results.

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