Received: 20 July 2022 | Revised: 31 October 2022 | Accepted: 18 November 2022

DOI: 10.1111/andr.13346

ANDROLOGY

WILEY

ORIGINAL ARTICLE

The impact of robotic-assisted transperineal biopsy of the prostate on erectile function

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ABSTRACT

Background: Prostate biopsy represents one of the most frequently performed urologic procedures worldwide and therefore presupposes knowledge on potential effects like on the erectile function, especially in extensive or repeated biopsies. The robotic-assisted biopsy system (Mona Lisa) offers a minimal invasive approach via only two incision points ensuring maximal accuracy combined with protection of the neurovascular bundle of the prostate.

Objective: Our purpose was to analyse the impact of robotic-assisted transperineal biopsy of the prostate on the erectile function.

Methods: Our prospective study analyses the outcomes of 210 patients, who had undergone minimal-invasive, transperineal robotic-assisted biopsy of the prostate at the University Hospital Basel from January 2020 to March 2022 and provided sufficient data. Of these, 157 (74.8%) were included in final analysis.

Results: Mean (range) age, prostate volume, PSA and IIEF-5 score at baseline were 63.8 years (46.1–83.6), 46.4 ml (9–310), 13.2 ng/ml (0.2–561), and 18.8 points (6–25), respectively. EF before and 1 month after intervention was assessed with the IIEF-5 questionnaire for the whole cohort. No significant change of IIEF-5 was observed for the whole cohort with a mean (± SD) decrease of 0.4 (± 3.1) points. Except for patients > 69 years, subgroup analysis revealed no change of IIEF-5 in statistically significant manner for all subgroups. Number of biopsy cores (< 20 and ≥ 20), previous biopsies and active surveillance showed no significant influence.

Conclusion: Our results suggest that the minimally invasive and highly precise robotic technique can spare the erectile function without limiting the extent of biopsy and without compromising diagnostic accuracy.

KEYWORDS
erectile dysfunction, erectile function, minimal-invasive, prostate biopsy, robotic-assisted, transperineal

1 | INTRODUCTION

Worldwide prostate cancer (PCa) is the second most common malignant disease in men and its histological confirmation by biopsy remains essential for therapy decisions.[1] Different approaches and techniques have been described[2] and alone in Europe and the United States more than 2 million procedures are carried out every year. This high frequency presupposes a precise knowledge of possible complications to facilitate selection of an appropriate biopsy method.[3] Especially extensive or repeated biopsies may lead to a decrease of erectile function (EF) attributable to the acute healing phase after the procedure or anxiety related to a possible cancer diagnosis.[4,5] These impacts of either TRUS-guided transrectal (TRB_x) or perineal biopsies (TPB_x) have been assessed by some authors,[5–9] but the data are sparse and heterogenous and there is a lack of information for newly introduced minimal invasive approaches.[4,9]

Male erectile dysfunction (ED) is defined as a persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance.[10] For assessment of ED severity, the International Index of Erectile Function-5 (IIEF-5) questionnaire is in regular use.[5] Significant decrease of IIEF-5 1 month after biopsy was demonstrated for both, TRB_x and TPB_x,[9] however technique or number of biopsy cores showed no significant impact on EF up to 6 months after intervention.[11] The robotic-assisted biopsy system (Mona Lisa) applied, not only allows to perform multiple prostate biopsies with upmost precision in an automated fashion,[12] but offers a minimal invasive approach ensuring multiple needle entry through the same channel via only two incision points combined with the possibility of effective protection of the neurovascular bundles of the prostate under ultrasound guidance. This minimises local irritation and avoids multiple skin incisions that occur with conventional methods.[13,14] However, there are no reports on whether patients benefit from this minimally invasive approach in terms of preservation of EF: therefore, this work aims to evaluate the effect of minimally invasive, transperineal robotic-assisted MRI-US fusion-guided biopsies on EF.

2 | MATERIAL AND METHODS

This prospective study analyses the results of 210 patients, who had undergone minimal-invasive, transperineal robotic-assisted biopsy of the prostate at the University Hospital Basel from January 2020 to March 2022 due to elevated prostate-specific antigen (PSA) values, suspicious lesions in MRI or as part of active surveillance (AS). All patients provided written informed consent. The study was approved by the local ethical commission (ID 2020-01381) and performed in accordance with the Declaration of Helsinki. Demographic, clinical and histopathological data were collected and analysed.

ED severity before and 1 month after intervention was assessed with the IIEF-5 questionnaire. Five categories of ED have been defined according to Rosen et al.[15]: none (22–25), mild (17–21), mild to moderate (12–16), moderate (8–11), and severe (5–7), since patients with an IIEF-5 score of 5 points were excluded, moderate and severe group were merged (6–11). Subgroup analysis was performed for patients undergoing AS, first or repeat B_x, and for different age groups (<60, 60–69, >69), which were defined based on the study of Ferrini et al. according to the prevalence for ED in the respective age group (~50%, ~ 60%, >70%).[16]

Only patients with completed questionnaires before and after B_x were included in the analysis. Patients with an IIEF-5 of 5 points before

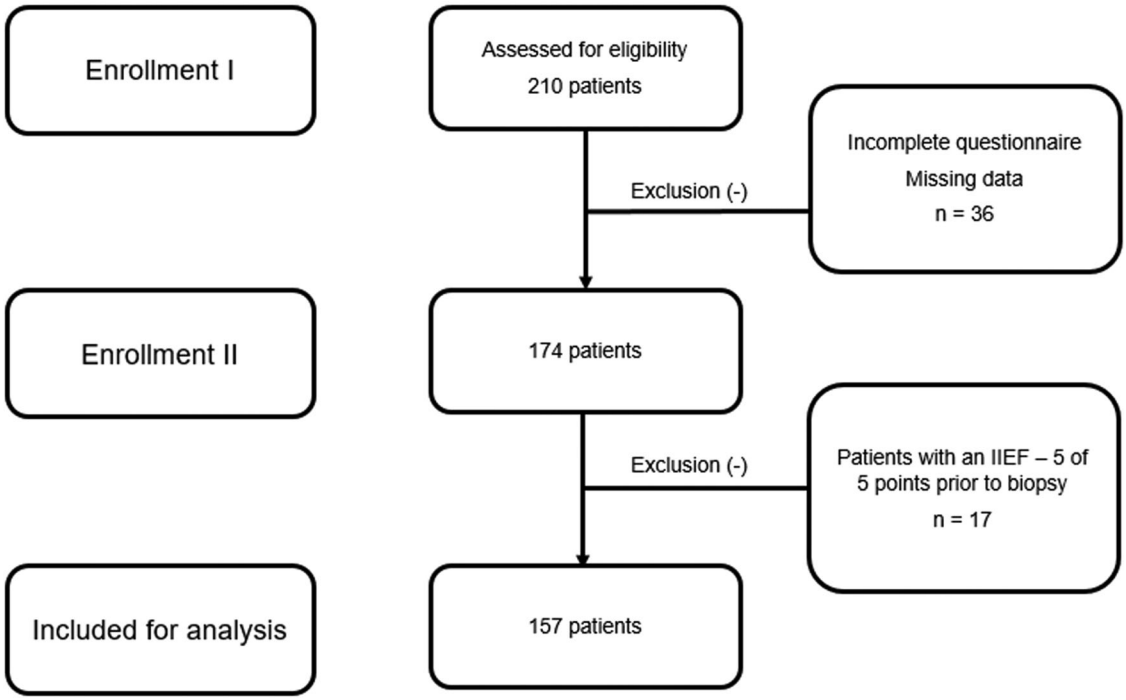

FIGURE 1 Flow chart of inclusion

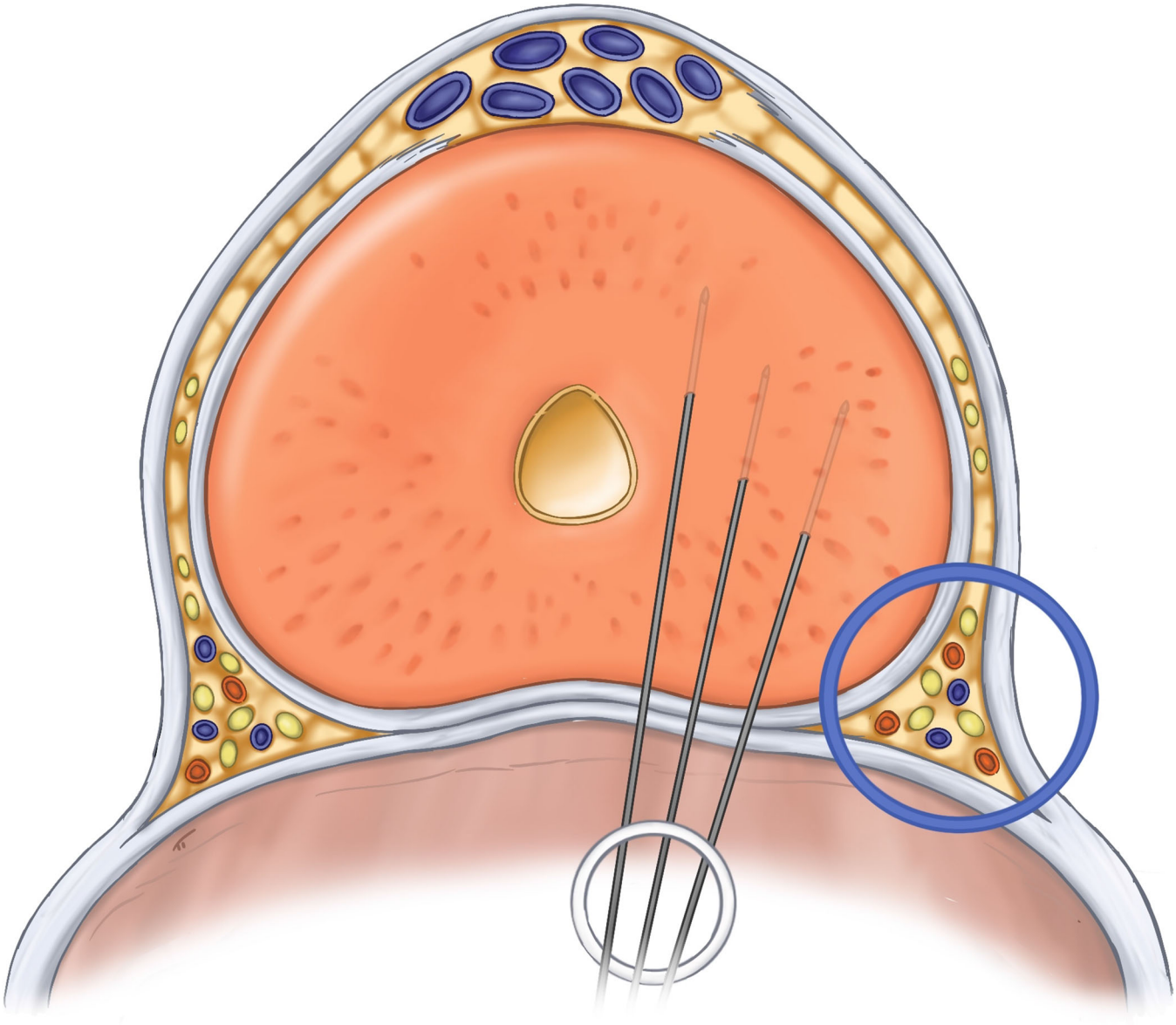

FIGURE 2 Transperineal needle trajectory and neurovascular bundles. Axial schematic view of the prostate (as seen in ultrasound during the biopsy procedure. Robotically assisted high-precision transperineal needle trajectory allows to safely spare the neurovascular bundle (blue circle). Two perineal entry points (grey circle) with a fan technique allow for complete coverage of the prostate. Needle trajectory shown for the left lobe only

B_x were excluded as no change of ED would be expected in these men and an inclusion would bias a statistical analysis in a positive way. A flowchart of the study course is presented in Figure 1.

2.1 | Biopsy technique

After classification of suspicious lesions according to Prostate Imaging-Reporting and Data System (PI-RADS) v2.1 a 3D model of the prostate was generated by board-certified radiologists with more than 5 years of experience in prostate MRI (DJW, PB). The subsequent B_x were accomplished with an iSR'obot™ MonaLisa device (Biobot©) under general anaesthesia. Antibiotic prophylaxis with a single-shot of an anti-infective agent was applied in the first 60 patients, for further interventions antibiotic prophylaxis, in the absence of specific indication, was abstained. Histological samples were gained minimally invasive through two incision points and so, despite extensive B_x, an effective protection of neurovascular bundles of the prostate, which mediate EF, was provided by sonographic guidance. Schematic visualisation of the prostate and neurovascular bundles is presented in Figure 2. Insertion of an indwelling catheter was omitted. Histological evaluation was performed by specialised urological pathologist. The detailed technique has already been described previously.[17]

Database was created using Excel (Microsoft©), maintained prospectively and analysed retrospectively. All statistical analyses were performed with SPSS Statistics 24.0 (IBM©). We used a paired

TABLE 1 Baseline characteristics

Parameter	*n* (%)
Patients (total)	157 (100)
Suspicious DRE	25 (15.9)
First B_x	112 (71.3)
Previous B_x	45 (28.7)
Under AS	25 (15.9)
Positive B_x	93 (59.2)
Negative B_x	64 (40.7)
Positive MRI-findings	136 (86.6)
Negative MRI-findings	21 (14.4)
Medication for/causing ED	10 (6.37)
	Mean ± SD (range)
Age (years)	63.8 ± 7.8 (46.1–83.6)
Prostate volume (cm^3)	46.4 ± 31.5 (9–310)
Serum PSA (ng/ml)	13.2 ± 47 (0.2–561)
IIEF-5 prior to B_x	18.8 ± 4.9 (6–25)
Number of B_x cores	25.2 ± 8.1 (5–46)

Abbreviations: AS, active surveillance; B_x, biopsy; DRE, digital rectal exam; ED, erectile dysfunction; IIEF, international index of erectile function; MRI, magnet resonance imaging; PCa, prostate cancer; PSA, prostate-specific antigen; SD, standard deviation.

Student *t*-test for the analysis of our data and all calculations were performed at a significance level of $\alpha = 0.05$.

3 | RESULTS

Minimal-invasive, transperineal robotic-assisted biopsy of the prostate (mTP-RA-PB_x) was performed successfully in 210 patients. Of these, 157 (74.8%) were included into final analysis.

Mean (range) age, prostate volume (PV), PSA and IIEF-5 score at baseline were 63.8 years (46.1–83.6), 46.4 ml (9–310), 13.2 ng/ml (0.2–561) and 18.8 points (6–25), respectively. Twenty-five (15.9%) patients were under AS and 45 (28.7%) received at least one previous B_x of the prostate. PCa was detected for the first time in 73 (46.5%) cases. Detailed patient baseline characteristics are summarised in Table 1. Additional data are presented in Table S1.

For the whole cohort IIEF-5 scores 1 month after B_x did not differ significantly from baseline IIEF-5 scores prior to B_x. A mean (± SD) decrease of 0.4 (± 3.1) points of IIEF-5 score 1 month after biopsy was observed. Except for patients > 69 years, subgroup analysis revealed no change of IIEF-5 in statistically significant manner for all subgroups, especially patients with/without previous B_x, men under AS and patients with a newly diagnosed Pca. No significant change of IIEF-5 was shown for patients with < 20 and ≥ 20 cores taken ($p = 0.9$ and 0.09), comparison of these two groups did not reveal a significant decrease ($p = 0.5$). Compared to patients with a negative B_x, new cancer diagnosis had no significant effect on EF (odds ratio 1.1, 95% CI 0.6–2.3, *p*-value 0.72, patients on AS excluded). All categories of ED according to Rosen et al.[15] showed no significant change in IIEF-5. Detailed results are displayed in Table 2.

TABLE 2 Results for erectile function

Group	No. *N* (%)	IIEF–5 baseline Mean ± SD (range)	IIEF-5 1 month after B_x Mean ± SD (range)	*p*-Value *p*
All patients	157 (100)	18.8 ± 4.9 (6–25)	18.4 ± 5.4 (6–25)	0.12
First B_x	112 (71.3)	19.2 ± 4.8 (6–25)	18.9 ± 5.2 (5–25)	0.36
Previous B_x	45 (28.7)	17.7 ± 4.9 (7–25)	17 ± 5.6 (5–25)	0.15
Positive MRI-findings	136 (86.6)	19 ± 4.7 (6–25)	18.5 ± 5.3 (5–25)	0.15
Under AS	25 (15.9)	17.8 ± 5 (7–25)	17 ± 5.7 (5–25)	0.2
First PCa diagnosis	73 (46.5)	18.7 ± 4.8 (6–25)	18.1 ± 5.3 (6–25)	0.1
Negative B_x	64 (40.8)	19.3 ± 5.1 (7–25)	19.2 ± 5.5 (5–25)	0.9
Age < 60 years	52 (33.1)	20.2 ± 4.3 (10–25)	20.2 ± 5 (7–25)	1
Age 60–69 years	61 (38.9)	18.5 ± 4.8 (8–25)	18.3 ± 5 (7–25)	0.65
Age > 69 years	44 (28)	17.5 ± 5.2 (6–25)	16.4 ± 5.6 (5–25)	0.008
Number of cores < 20	35 (22.3)	19.7 ± 5.1 (9–25)	19.7 ± 5.9 (5–25)	0.9
Number of cores ≥ 20	122 (77.7)	18.5 ± 4.8 (6–25)	18 ± 5.2 (5–25)	0.09
IIEF-5 before B_x (22–25)*	55 (35)	23.8 ± 1.2 (22–25)	22.9 ± 3.5 (7–22)	0.06
IIEF-5 before B_x (17–21)*	51 (32.5)	19.4 ± 1.3 (17–21)	18.8 ± 3.1 (11–25)	0.19
IIEF-5 before B_x (12–16)*	35 (22.3)	14.3 ± 1.6 (12–16)	14.5 ± 2.7 (10–21)	0.8
IIEF-5 before B_x (<12)*	16 (10.2)	9.4 ± 1.4 (6–11)	9.9 ± 4.4 (5–21)	0.6

Abbreviations: AS, active surveillance; B_x, biopsy; IIEF, international index of erectile function; MRI, magnet resonance imaging; PCa, prostate cancer; SD, standard deviation.

*IIEF-5 (22–25): no erectile dysfunction (ED); IIEF-5 (17–21): mild ED; IIEF-5 (12–16): mild to moderate ED; IIEF-5 (<12): moderate to severe ED.

4 | DISCUSSION

A negative impact of ED on health-related quality of life is beyond question[6] and especially in a vulnerable situation of a possible cancer diagnosis this factor may be neglected.

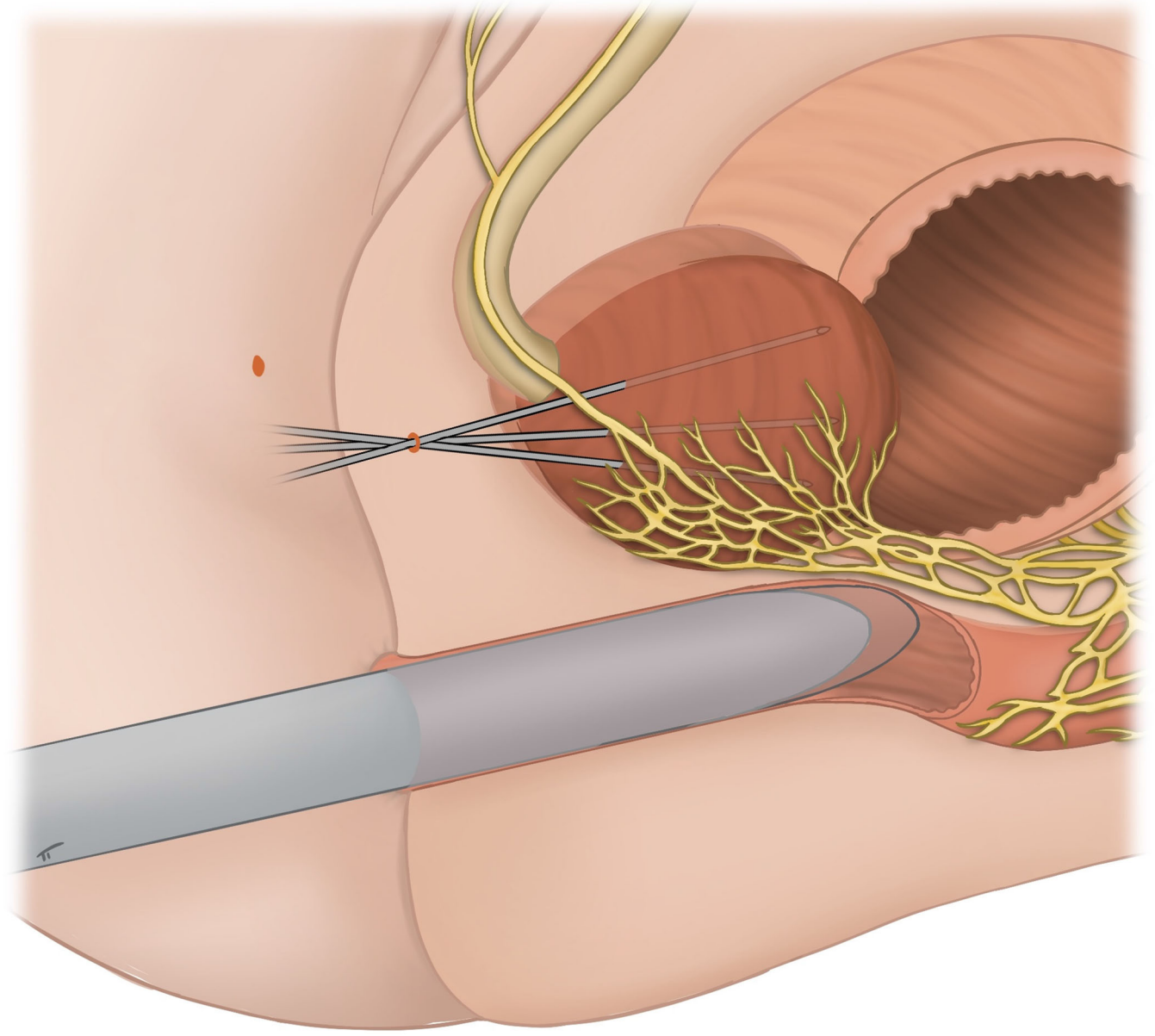

FIGURE 3 Minimally invasive biopsy and prostate anatomy. Anatomical presentation of the nerval input of prostate and penis. Minimally invasive transperineal biopsy trajectory allows to dimish local trauma affecting cavernous nerves

Alone in Europe and the United States more than 2 million prostate biopsies in search for PCa are carried out every year, so that a precise knowledge of possible complications is implied.[3]

Different approaches and their possible influence on EF have been described, but the data are sparse and heterogeneous and there is a lack of information for minimal invasive approaches.[4,9] A multifactorial cause for ED after B_x seems to be obvious. Overall, prostate B_x may cause a time-dependent, mild decrease of IIEF-5 with statistically significant results 1 month after B_x and spontaneous recovery at 3 months. Recently a comparison of transperineal versus transrectal B_x suggested no significant impact of biopsy technique on EF.[11] In contrast our cohort showed no significant change of IIEF-5 1 month after B_x, furthermore the mean score-decrease of 0.4 points was lower than the minimal difference of 4 points for clinical impact. However, due to a range of 2–7 points depending on the severity of patient's baseline EF, a possible clinical bother could appear at a 2-point change, especially for a mild ED before B_x .[9] Our 51 (32.5%) patients with mild ED showed no clinically relevant change with a mean decrease of 0.5 points.

Secondary trauma involving nerve compression from oedema or haematoma was suggested as a trigger for transient decrease of EF,[18] in addition this factor was accentuated by sonographic evidence of inflammation of bilateral neurovascular bundles and prostate parenchyma in 4/10 patients after B_x.[14] A limitation of this local process may be possible by our minimal invasive approach with only two incision points and effective protection of neurovascular bundles of the prostate by sonographic guidance, despite extensive B_x (Figures 2 and 3).

Anxiety regarding possibility of cancer represents a possible influencing factor as well[3], whereas in our cohort, newly diagnosed PCa was not a significant risk factor for deterioration of IIEF-5. Both our patients with a pathological MRI and those with no previous biopsy showed no significant change in IIEF-5. Like reported by other authors,[11,19] no significant impact on EF due to number of biopsy cores was detected in our cohort.

Affection of EF due to serial transrectal B_x remains disputed, with some authors reporting significant impairment of EF, especially after three B_x. However, they supposed multiple variables influencing EF, like age-related ED and duration of AS, rather than an isolated effect through B_x.[20–22] Impact of serial, transperineal B_x on patients under AS was assessed by Chong et al. and showed a significant short-term deterioration in EF after first/second B_x with a possible risk increase of long-term ED after serial B_x.[22] In contrast, no significant short-time deterioration of EF was detected in our subgroups under AS or with a previous B_x, whereby other B_x techniques were used before.

Our study has its limitations due to the single-centre data, a missing comparison group and using only the IIEF-5 questionnaire, which does not cover libido or sexual desire, as well as the relatively high number of excluded patients. Nevertheless, it is an established and validated assessment tool for patient-reported EF. Long-term results for ED several months after B_x and correlation with voiding function or concomitant diseases are not presented and may indicate further research. To the best of our knowledge, this is the first work to assess the impact of mTP-RA-PB$_x$ on EF. Our results suggest that this technique offers an EF sparing approach with no limitation of B_x extent and without compromising diagnostic accuracy. We assume that the minimally invasive approach with only two incision points and possibility for effective protection of neurovascular bundles contribute to reducing local trauma and thus minimising negative effects on EF. MTP-RA-PB$_x$ can be offered to all men seeking diagnostic accuracy without compromising EF.

5 | CONCLUSION

This work evaluates the impact of transperineal robotic-assisted biopsy of the prostate on EF. The combination of diagnostic accuracy with a minimally invasive approach not compromising EF makes this technique very appealing for urologist and patients alike.

CONFLICT OF INTEREST

Christian Wetterauer received research grants from Siemens Healthineers and Uromed. The rest of the authors declare that they have no conflict of interest.

AUTHORS CONTRIBUTION

All authors have conjointly designed the study, and Christian Wetterauer and Pawel Trotsenko interpreted the data and drafted the paper. Anja Meyer and Manuel Walter supported data collection and patient care. All authors designed and critically revised the paper for important intellectual content. Pawel Trotsenko and Christian Wetterauer were involved in the statistical analysis. All authors read, gave comments, and approved the final version of the paper.

DATA AVAILABILITY STATEMENT

Data will be provided by the corresponding author upon a reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Trotsenko P, Walter M, Engesser CH, et al. The impact of robotic-assisted transperineal biopsy of the prostate on erectile function. *Andrology*. 2023;11:1009–1015. https://doi.org/10.1111/andr.13346