



Efficacy and safety evaluation of complete intrafascial prostatectomy in suspected prostate cancer patients with dysuria: a retrospective cohort study

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Background: Suspected localized prostate cancer (PCa) patients with dysuria Complete intrafascial prostatectomy (CIP) can remove the whole prostate gland with the maximal retain of adjacent normal tissues around the prostate, and can be applied in some suspected localized prostate cancer (PCa) patients with dysuria. However, precious few studies have assessed the efficacy and safety of CIP in these patients without preoperative needle biopsies.

Methods: In this retrospective single-arm cohort study, all 22 suspected PCa patients with dysuria who underwent CIP at our hospital were enrolled. The clinical data including age, prostate-specific antigen (PSA), free-serum PSA, prostate volume, perioperative and postoperative complications were collected. The PSA level at 6 weeks after CIP and recoveries of urinary continence and erectile function were acquired in the follow-up procedures, and were used as the main measurements of efficacy and safety for CIP respectively.

Results: The patients had an average age of 71.91 ± 8.29 years and an average preoperative PSA level of 10.75 ± 4.25 ng/mL. The operations for all 22 patients were successfully completed. The average operation time was 135.20 ± 41.44 min (range, 40.0–215.0 min), and the average blood loss volume was 128.64 ± 145.09 mL. In total, 17 patients (77.27%) had PCa confirmed by postoperative pathology, and 5 patients (22.73%) had benign prostatic hyperplasia. The PSA level dropped to 0.010 ± 0.004 ng/mL at 6 weeks after surgery. According to the loose criteria to assess urinary incontinence, the patients achieved continence rates of 63.6% immediately after the operation, 95.5% at 1 month, and 100% at 3 months. According to the strict criteria, the continence rates immediately, and at 1, 3, 6, and 9 months after surgery were 27.3%, 63.6%, 90.9%, 95.5%, and 100%, respectively. None of the patients complained of urinary obstruction symptoms after surgery. Before CIP, all the patients had erectile dysfunction and an International Index of Erectile Function 5 (IIEF-5) score of 9.64 ± 5.91 . After surgery, the patients had IIEF-5 scores at 3, 6, and 12 months of 5.45 ± 4.43 , 6.95 ± 5.30 , and 7.57 ± 5.69 , respectively.

Conclusions: Although the study had some limitations, CIP may be a prudent option for patients with suspected localized PCa who also present with dysuria.

Keywords: Prostate cancer; non-puncture; prostatectomy; intrafascial; complication

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Introduction

A prostate needle biopsy is the gold standard for the diagnosis of prostate cancer (PCa) (1). However, due to the non-specificity of prostate-specific antigen (PSA), the biopsy-positive rate of localized PCa is only 22.8–42.0% (2,3). With the development of magnetic resonance imaging–ultrasound fusion prostate biopsy, the accuracy of prostate biopsy has increased to approximately 60%, but missed diagnoses still occur (4,5). Radical prostatectomy (RP) is recommended as a curative method for localized PCa confirmed by needle biopsy. However, suspected PCa patients with dysuria caused by enlarged prostate gland are usually suggested to undergo transurethral resection of the prostate (TURP) when the negative results of needle biopsy come out. TURP does not provide the final accurate pathological diagnosis, which may lead to the delays in treatment due to missed PCa diagnoses. Meanwhile, tissue adhesion around the prostate after TURP increases the operative difficulty of subsequent RP and even the incidence of urinary incontinence following RP. Based on the above reasons, some, though not many, patients with localized suspected PCa refuse to undergo repeated prostate needle biopsies, and thus require *en bloc* resection of the prostate gland to identify and treat the underlying PCa and relieve the symptoms of dysuria (6).

The entire resection of the prostate gland is effectively equivalent to a RP, and the main postoperative complications

are urinary incontinence and erectile dysfunction (7,8). Improvements in surgical techniques, such as the preservation of neurovascular bundles (NVBs), pelvic floor structures, bladder sphincter, and functional urethra, can reduce the complication rates of urinary incontinence and erectile dysfunction to a certain extent (8–10). Complete intrafascial prostatectomy (CIP) can maximize the preservation of adjacent normal tissues around the prostate, which is conducive to the returns of urinary continence and even erectile function. At present, CIP is often used as a radical surgical approach for localized PCa. However, precious few studies have explored the application of CIP in patients with suspected localized PCa who also presented with serious dysuria, and the cancer cure and complications of CIP are unclear (6). Thus, we performed a CIP in these specific patients to evaluate the efficacy and safety of this technique in this study. We present the following article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-26/rc>).

Methods

Clinical information

This study was a retrospective single-arm cohort study. The study was approved by the Hainan General Hospital Medical Ethics Committee (No. Med-Eth-Re[2022] 267), and conducted in accordance with the ethical standards of the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from all the individual participants in this study.

There were a total of 22 eligible PCa patients who had undergone CIP without needle biopsy at our department from September 2018 to January 2022, and the clinical data of all these patients were retrospectively collected in this study. The clinical data included age, PSA, free-serum PSA (fPSA), prostate volume, Eastern Cooperative Oncology Group (ECOG) performance status score, multiparametric magnetic resonance imaging (mpMRI), operation-related data, perioperative complications, and postoperative pathology. The perioperative complications were assessed using the Clavien-Dindo grading system (11).

To be eligible for inclusion in this study, the patients had to meet the following inclusion criteria: (I) have presented with dysuria requiring surgical intervention; (II) have a PSA level ≤ 20 ng/mL; (III) have a prostate imaging reporting and data system (PI-RADS) score for mpMRI score ≥ 3 , and tumor lesions that did not involve the prostate capsule; (IV) have no pathological diagnosis; (V) have a life expectancy of

Highlight box

Key findings

- Complete intrafascial prostatectomy (CIP) may be a prudent option for suspected localized prostate cancer (PCa) patients with dysuria if such patients are unwilling to undergo a biopsy and have no desire to engage in sexual activity.

What is known and what is new?

- Precious few studies have explored the application of CIP in patients with suspected localized PCa who also presented with serious dysuria.
- In the absence of a needle biopsy, if selected with caution, CIP may be a safe option to treat underlying PCa and relieve the symptoms of dysuria in suspected localized PCa patients.

What is the implication, and what should change now?

- CIP represents an alternative treatment for specific suspected localized PCa patients. Prostate-specific membrane antigen positron emission tomography can be performed if necessary to reduce the positivity of surgical margin and unwarranted surgical trauma in benign patients.

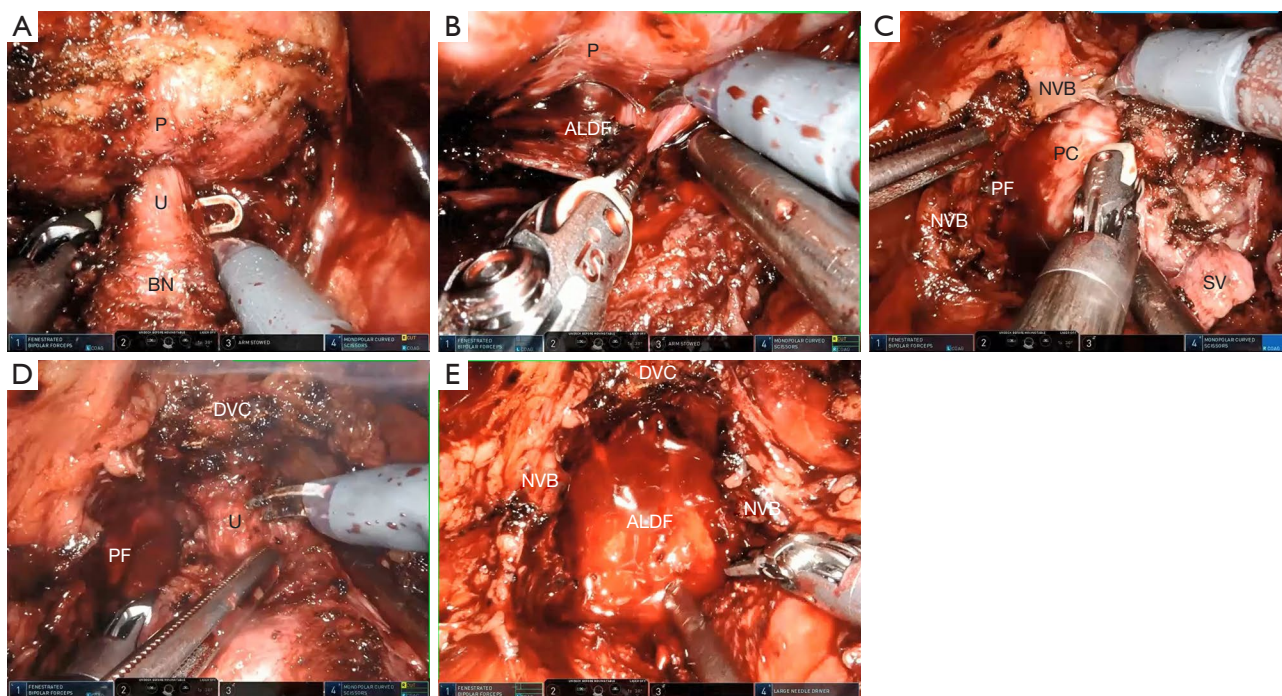


Figure 1 Schematic of the operation. (A) preservation of bladder neck; (B) preservation of the anterior layer space of Denonvilliers' fascia; (C) intrafascial preservation of NVBs; (D) exposure of the urethra at the apex of the prostate; (E) the fossa after prostatectomy. P, prostate; U, urethra; BN, bladder neck; ALDF, anterior layer of Denonvilliers' fascia; NVB, neurovascular bundle; PC, prostate capsule; PF, prostate fascia; SV, seminal vesicle; DVC, dorsal vascular complex.

≥5 years; (VI) have a ECOG performance status score of 0; and (VII) have refused to undergo a prostate biopsy.

Patients were excluded from the study if they met any of the following exclusion criteria: (I) had a clinical stage ≥ T3; (II) had lymph node, bone, or visceral metastasis; (III) had a desire to engage in sexual activity; (IV) had an American Society of Anesthesiologists score >2; and/or (V) had a history of TURP.

Surgical approach

All the operations were performed using the laparoscopic/robot extraperitoneal approach. The pelvic fascia was not incised, the puboprostatic ligament was not severed, and the deep dorsal vein complex (DVC) was not ligated. The junction between the bladder neck and prostate was separated using a combination of blunt and sharp methods, and the posterior urethra at the base of the prostate was exposed and then severed, leaving the bladder neck intact. After the bilateral vas deferens were severed, the space between the anterior layer of Denonvilliers' fascia and the posterior capsule of the prostate was bluntly dissociated

to the apex and lateral wall of the prostate. The prostatic lateral ligament was separated along the posterior capsule of the prostate, and the prostatic lateral capsule was then exposed. The lateral capsule was freed anteriorly to the apex of the prostate and up to the anterior fibromuscular stroma of the prostate. The DVC was divided, and the membranous urethra was exposed and then cut off close to the apex of the prostate (*Figure 1*). The specimen was removed, the urethra and bladder neck were anastomosed, and the puboprostatic ligament was sutured continuously to the anterior layer of the bladder detrusor.

Perioperative management and follow-up

Postoperatively, a retropubic drainage tube was indwelled and removed when the drainage fluid volume was ≤10 mL. The urinary catheter was routinely indwelled for 2 weeks. The follow-up times were 2 weeks, 6 weeks, and then every 3 months for the 1st year after the operation at the outpatient department. Outpatient or telephone follow-ups were irregularly performed for 1 year after the operation according to each patient's condition. The follow-up procedures

Table 1 General clinical data of PCa and BPH patients

Group	Age (year)	PSA (ng/mL)	f/tPSA	Prostate volume (mL)	PSA density (ng/mL ³)	PI-PADS score		
						3	4	5
PCa (n=17)	73.1±8.16	10.73±4.13	0.16±0.086	44.47±25.91	0.30±0.155	2	11	4
BPH (n=5)	67.8±8.23	10.82±5.15	0.27±0.108	86.42±54.94	0.15±0.070	3	1	1
P value	0.2467	1	0.039	0.039	0.048	0.060		
Statistics	<i>t</i> =-1.2727	<i>W</i> =43	<i>W</i> =69	<i>W</i> =69	<i>W</i> =17	-		

Data are reported as mean value with standard deviation. PCa, prostate cancer; BPH, benign prostatic hyperplasia; PSA, prostate-specific antigen; f/tPSA, free-serum/total-serum prostate-specific antigen; PI-PADS, prostate imaging reporting and data system.

included postoperative PSA, and the recoveries of urinary continence and erectile function. The undetectable PSA level (<0.1 ng/mL) at 6 weeks after CIP was defined as the main criterion to evaluate the efficacy of CIP. On the basis of the International Consultation on Incontinence Questionnaire Short Form, the loose criterion for urinary incontinence was defined as the use of diapers during daily activities, and the strict criterion was defined as urine leakage during coughing. Erectile function was assessed by the International Index of Erectile Function 5 (IIEF-5) (12). All the questionnaires were completed at the outpatient department to avoid response bias.

Statistical analysis

The statistical analysis of this study was performed using R4.1.0 software. The continuous variables are expressed as the mean ± standard deviation. According to Shapiro-Wilk test, all of the continuous variables were judged to be non-normally distributed continuous variables except the age. The *t* test was used to compare the differences between normally distributed continuous variables, the Wilcoxon rank sum test between non-normally distributed continuous variables, and the Fisher's exact test between PI-PADS scores. A 2-tailed *P* value <0.05 was considered statistically significant.

Results

General clinical data

The patients had an average age of 71.91±8.29 years, an average preoperative PSA level of 10.75±4.25 ng/mL, an average fPSA of 2.08±1.59 ng/mL, and an average free-serum/total-serum PSA (f/tPSA) of 0.18±0.10. In relation to the PI-PADS scores for mpMRI, 22.73% (5/22) of the

patients had a score of 3, 54.55% (12/22) had a score of 4, and 22.73% (5/22) had a score of 5.

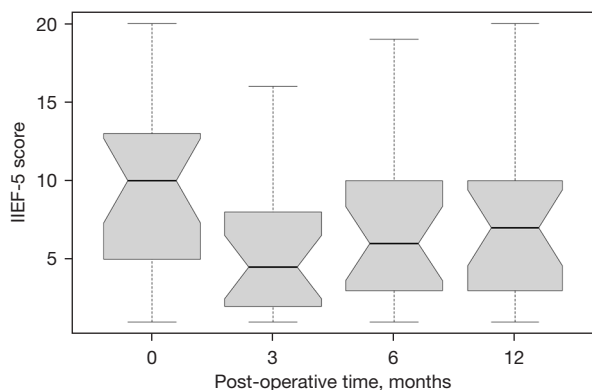
All 22 patients completed the operation as expected without conversion to open surgery. The patients had an average operation time of 135.20±41.44 min (range, 40.0–215.0 min), an average hospital stay of 7.00±3.06 days (range, 4–19 days), and an average intraoperative blood loss volume of 128.64±145.09 mL. According to the Clavien-Dindo complication grading system, the perioperative complications of grade I were 45.5% (10/22), and grade II were 4.5% (1/22). The patient with grade II complication required an intraoperative blood transfusion. In total, 77.27% (17/22) of the patients had PCa confirmed by postoperative pathology, and 22.73% (5/22) had benign prostatic hyperplasia (BPH). There were statistically significant differences in the f/tPSA, prostate volume, and PSA density between the PCa group and the BPH group (Table 1). Among the 17 patients with PCa, the positivity of surgical margin was 11.76% (2/17). According to the International Society of Urological Pathology guidelines, 23.5% (4/17) of the patients had grade 1 PCa, 11.8% (2/17) had grade 2, 47.1% (8/17) had grade 3, and 17.6% (3/17) had grade 4.

Follow-up data

The follow-up duration ranged from 10–50 months (median: 23 months), and no patient was lost to follow-up within 1 year of the operation. The postoperative PSA level decreased to an undetectable level below 0.1 ng/mL at 6 weeks (average: 0.010±0.004 ng/mL; range, 0.008–0.021 ng/mL). According to the loose criterion for assessing urinary incontinence, the patients achieved continence rates of 63.6% immediately after the operation, 95.5% at 1 month, and 100% at 3 months. According to

Table 2 Postoperative urinary continence recovery

Group	Immediate	1 month	3 months	6 months	9 months	12 months
Loose criteria (n)	14	7	1	0	0	0
Strict criteria (n)	6	8	6	1	1	0

**Figure 2** Changes in postoperative IIEF-5 scores. IIEF-5, International Index of Erectile Function 5.

the strict criterion for assessing urinary incontinence, the continence rates immediately after surgery, and at 1, 3, 6, and 9 months after surgery were 27.3%, 63.6%, 90.9%, 95.5%, and 100%, respectively (Table 2). None of the patients complained of urinary obstruction symptoms after surgery.

Before CIP, all the patients had erectile dysfunction and an average IIEF-5 score of 9.64 ± 5.91 . After surgery, the patients had IIEF-5 scores at 3, 6, and 12 months of 5.45 ± 4.43 , 6.95 ± 5.30 , and 7.57 ± 5.69 , respectively. Erectile function was significantly worse at 3 months after surgery ($P=0.019$) but then recovered at 6 and 12 months ($P>0.05$). However, there was a certain decrease in the IIEF-5 score, even at 12 months, compared to that before the operation (Figure 2).

Discussion

PSA is usually used for the primary screening of PCa, but a variety of factors, such as inflammation and ejaculation, can cause abnormal PSA results, which is why PSA has a high sensitivity for diagnosing PCa but a relatively low specificity (13). The results of this study showed that there was no significant difference in PSA between the early PCa and BPH patients; however, if considering prostate volume,

the PSA density of the PCa patients was significantly lower than that of the BPH patients. Similar to other findings, we found that f/tPSA and PSA density could be used to improve the diagnostic specificity of identifying early PCa, but its accuracy remained unsatisfactory (14,15).

To improve the diagnostic accuracy of PCa, routine mpMRI is needed. According to a recent meta-analysis, the sensitivity, specificity, and accuracy of mpMRI for PCa were 0.84, 0.87, and 0.91, respectively (16). In this study, the specificity of mpMRI was 0.77, which was lower than the above-mentioned results; however, this might be related to the small number of patients included in this study and the inclusion of patients with early-stage tumors. Prostate-specific membrane antigen positron emission tomography has also begun to be used in clinical practice, but it is more suitable for the diagnosis of lymph nodes and distant metastases of PCa, and its diagnostic performance is not better than that of mpMRI for primary tumors (17).

RP is an important approach for curing localized PCa. However, unlike radical nephrectomy, which only requires imaging diagnosis, a Pca diagnosis needs to be supported by pathological evidence before RP is performed due to the postoperative complications that might affect the quality of life of the patients. For early PCa, there is still a certain missed diagnosis rate even with magnetic resonance imaging-ultrasound fusion prostate biopsy (4,5). Pathak *et al.* performed robotic total prostatectomy in patients with lower urinary tract symptoms who were still highly suspected to have PCa after the first negative biopsy, and the postoperative pathology diagnosed 90.91% (10/11) of the patients with PCa (6). In clinical practice, some patients will always be too concerned about tumor progression caused by missed diagnoses and the pain and complications caused by repeated needle biopsies to agree to undergo biopsies. If these patients have dysuria requiring surgical intervention, the performance of TURP after a missed diagnosis might seriously affect the efficacy of subsequent RP and increase the incidence of postoperative urinary incontinence. For these reasons, such patients require non-puncture prostatectomy to clarify the prostate pathology and relieve dysuria, which was also the original intention of

this study.

The most common complications after RP were erectile dysfunction and urinary incontinence. Previous studies have confirmed that NVB preservation reduces the incidence of postoperative erectile dysfunction and urinary incontinence (9,18). However, even with preservation of the NVBs, accessory pudendal artery or other structures, and the postoperative use of drugs, such as statins, erectile dysfunction appeared to be uncontrollable (7,18,19). Thus, all the patients enrolled in this study had erectile dysfunction and a lack of desire to engage in sexual activity. In addition, all the patients had symptoms of dysuria. The mean age of the patients in this study was nearly 72 years old, which is older than that reported in other related studies (3,4,15). We found that the IIEF-5 scores were the worst at 3 months postoperatively, and while they recovered at 6 and 12 months postoperatively, the scores were still slightly worse than those before surgery. Seetharam *et al.* considered that normal preoperative sexual function, an age <55 years, and NVB retention were the most influential factors affecting potency recovery following RP (20). In this study, the NVBs were preserved; however, potency recovery after the operation was not ideal, which was a result of the patients being older and having a certain degree of erectile dysfunction before CIP.

Previous studies have shown that the complete preservation of the pelvic floor structure (including the intact Denonvilliers' fascia), bladder sphincter, and functional urethra to preserve NVBs could further improve postoperative urinary continence (8-10). Retaining the Retzius space can significantly improve short-term urinary continence, but it is difficult to retain the Retzius space using conventional laparoscopy because the technical requirements are relatively high, and its application has been limited (21,22). In this study, CIP was performed using the conventional approach, with no incision of the pelvic fascia, no suture of DVC, the preservation of the Denonvilliers' fascia, and the retention of the bladder neck, which facilitated postoperative urinary continence recovery. Regardless of whether the loose or strict criteria were applied, none of the patients experienced urinary incontinence at 9 months after CIP, and the urinary continence rate was no less than that achieved by patients undergoing Retzius space-preserving surgery (22).

In this study, all the patients underwent successful operations, and except in 1 patient who required an intraoperative blood transfusion, all the perioperative complications were Clavien-Dindo grade I. In total,

22.7% of the patients had BPH, which was related to the diagnostic accuracy of preoperative mpMRI. All the patients had undetectable PSA levels at 6 weeks postoperatively (PSA <0.1 ng/mL), but 11.7% (2/17) of the patients had positive surgical margins, which is similar to the results of another study on NVB preservation (23). A previous study showed that the *en bloc* resection of the prostate gland did not increase the positivity of surgical margin without preoperative biopsy pathology (6).

This study had some limitations. This study was a retrospective single-arm cohort study, but the enrolled patients were strictly screened, which might have created a selectivity bias. Additionally, CIP requires a certain degree of surgical technical experience and cannot always be performed without issue. However, our study sought to use *en bloc* prostate gland resection to treat suspected PCa patients without preoperative pathology.

Conclusions

CIP may be a prudent option for patients with suspected localized PCa with dysuria who are unwilling to undergo a biopsy and have no desire to engage in sexual activity. This procedure has good safety and efficacy, but it is still insufficient at preserving potency.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://tau.amegroups.com/article/view/10.21037/tau-23-26/rc>

Data Sharing Statement: Available at <https://tau.amegroups.com/article/view/10.21037/tau-23-26/dss>

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Conflicts of Interest: All authors have completed the ICMJE

uniform disclosure form (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-26/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was approved by the Hainan General Hospital Medical Ethics Committee (No. Med-Eth-Re[2022] 267), and conducted in accordance with the ethical standards of the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from all the individual participants in this study.

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