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Can androgen-deprivation therapy obviate the need of channel transurethral resection of the prostate in advanced prostate cancer with urinary retention? A prospective study

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KEYWORDS

ADT;
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ABBREVIATIONS

ADT, androgen-deprivation therapy;
AUR, acute urinary retention;
pTURP, palliative TURP;
TWOC, trial of voiding without catheter;

Abstract ***Objective:*** To evaluate the efficacy of androgen-deprivation therapy (ADT) in relieving urinary retention in patients with advanced prostate cancer presenting with urinary retention or a high post-void residual urine volume (PVR).

Patients and methods: Patients with advanced prostate cancer with an indwelling catheter for acute/chronic urinary retention, or with a high PVR (> 200 mL) who had not received any previous treatment were included in the study. Patients with localised prostate cancer eligible for receiving any therapy aimed at cure were excluded. All enrolled patients were managed by ADT (LHRH antagonist/agonist or orchidectomy) combined with α-adrenoceptor antagonist/combined therapy for at least 1 month to a maximum of 3 months; they were given their first trial of voiding without catheter after 1 month, and monthly thereafter.

Results: A total of 101 patients received ADT of which 97 were able to void successfully at the end of 3 months. In all, 27 patients could void in the first month, fol-

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USG KUB, ultrasonography of the kidney, ureter and bladder

lowed by 50 in the second month, and an additional 20 in the third month. There was a significant decrease in prostate volume, PVR, and International Prostate Symptom Score, and maximum urinary flow rates improved with normalisation of renal functions and resolution of upper tract changes noted on ultrasonography.

Conclusion: ADT can relieve retention and decrease PVR over a period of time obviating the need for channel transurethral resection of the prostate.

Introduction

Prostate cancer rarely causes symptoms at an early stage. The presence of symptoms usually suggests locally advanced or metastatic disease [1]. The estimated incidence of urinary retention in patients with advanced prostate cancer is nearly 13.0% [2]. Besides acute urinary retention (AUR), chronic urinary retention, bladder stones, and hydronephrosis are the most frequent complications of locally advanced prostate cancer [2]. Avoiding further complications, curing retention, and improving the health-related quality of life of these patients are often the main aims of treatment.

There are various treatment options for LUTS/urinary retention including: minimally invasive procedures (stents, laser, etc.), catheterisation, hormonal manipulation, and palliative TURP (pTURP) [3]. Although pTURP offers immediate relief from BOO, the potential negative oncological effect due to intravascular dissemination of prostate cancer cells and escalation of incontinence makes it less acceptable [4]. Hormonal manipulation can hence be offered as the first-line treatment for obstructive voiding symptoms in patients with locally advanced/metastatic prostate cancer who are not candidates for curative treatment [5]. Androgen suppression is known to result in a reduction in the size of malignant, as well as benign prostatic disease, and the re-establishment of spontaneous voiding. However, it may take ~2–3 months, as there is a delay between hormonal manipulation and tumour response [5].

Despite the availability of various treatment options, there is paucity of literature in standardising the protocol for management of patients with advanced prostate cancer presenting with AUR or chronic urinary retention. Therefore, the present study was undertaken to evaluate the efficacy of androgen-deprivation therapy (ADT) in relieving urinary retention in patients with advanced prostate cancer presenting with urinary retention or a high post-void residual urine volume (PVR).

Patients and methods

The present prospective observational study was carried out between September 2014 and April 2016, and the study protocol was approved by the Institutional Ethics Committee.

Patients presenting to our outpatient department with advanced prostate cancer (inclusive of both locally advanced and metastatic prostate cancer not amenable for definitive/curative management) with chronic urinary retention (> 200 mL) or with an indwelling catheter for AUR or chronic urinary retention (> 200 mL) who had not previously received any hormonal or surgical treatment were enrolled after taking informed consent. Patients with localised prostate cancer eligible for receiving any therapy aimed at cure (radiotherapy/radical prostatectomy) and patients with urethral stricture were excluded.

Initial evaluation included: a thorough clinical history and a detailed physical examination including IPSS (in those with high PVR) and DRE; complete blood panel including haemogram, blood urea, serum creatinine, liver function tests, serum PSA, serum calcium, serum testosterone; urine routine and microscopic examination, and urine culture and sensitivity. Ultrasonography of the kidney, ureter and bladder (USG KUB) was performed to assess the prostate size, upper tract changes, and PVR followed by uroflowmetry to assess the maximum urinary flow rate (Q_{max}) and PVR. A Foley catheter was inserted in patients with LUTS with a high PVR (> 200 mL). Imaging studies, e.g. bone scans, positron-emission tomography CT/MRI were performed to delineate the extent of the prostate cancer, to classify them as per our inclusion criteria, and to exclude those who were eligible for curative treatment.

All patients were counselled about the various treatment options available. As all patients preferred ADT over other forms of treatment, patients were offered to choose between a LHRH antagonist/agonist or orchidectomy as their choice of ADT. Additionally, α-adrenoceptor antagonist/combined therapy, and calcium and iron supplements were given for at least 1 month after which they had their first trial of voiding without catheter (TWOC). If the first TWOC failed, two additional TWOCs were given each 1 month apart. Channel pTURP was considered if the patient failed a third TWOC or had persistent PVR of > 200 mL even

after successful TWOC. Irrespective of whether TWOC was successful at the first, second or third attempt, all TWOC-successful patients were investigated after treatment with a renal function test, and measurement of serum calcium, testosterone, and PSA at 3 months. USG KUB and uroflowmetry was also advised at the end of 3 months to assess the improvement of the upper tract, reduction in the size of prostate, and also to assess post-treatment PVR.

Statistical analysis

The data were analysed using Statistical Package for the Social Sciences (SPSS®, version 21.0; SPSS Inc., IBM Corp., Armonk, NY, USA). Categorical variables are presented as numbers and percentages, and continuous variables are presented as the mean ± SD and median. The normality of the data was tested by the Kolmogorov–Smirnov test. If the normality was rejected then a non-parametric test was used. Quantitative variables were compared using the unpaired *t*-test/Mann–Whitney test (when the data sets were not normally distributed) between the two groups, ANOVA/Kruskal–Wallis test between three groups, and paired *t*-test/Wilcoxon ranked-sum test (for non-parametric data) between pre- and post-treatment variables. Qualitative variables were correlated using the chi-squared test/Fisher's exact test. A $P < .05$ was considered statistically significant.

Results

A total of 101 eligible patients were recruited and analysed. All patients were offered either surgical or medical castration and were treated as per their choice. The baseline characteristics are summarised in Table 1. Those who opted for surgical management were designated Group 1 and those on medical management were designated Group 2, in order to elucidate any further implications of these two modes of treatment beside the primary aim of relief of AUR and LUTS with high PVR.

Table 2 summarises the clinical variables, stage and Gleason grade of the study population across both the treatment groups.

Table 1 Demographics of the study population.

Variable	Value, mean (SD, range)
Age, years	74.53 (6.99, 55–90)
Serum PSA level, ng/mL	90.78 (228.16, 2.33–1600)
Serum calcium level, mg/dL	8.66 (228.16, 7.11–10.56)
Serum testosterone level, ng/dL	456.35 (188.50, 186–980.12)
Serum creatinine level, mg/dL	1.22 (0.83, 0.60–8.00)
Prostate volume, mL	55.37 (18.72, 28–115)

At the end of the first month, 27 patients were able to void successfully at TWOC. Likewise, 50 voided successfully at the second TWOC. In the third month, an additional 20 patients were able to void successfully. Four patients were unable to void after the third and last TWOC and thus underwent channel pTURP (Fig. 1; Table 3). There was no correlation between grade of prostate cancer, Gleason score and stage of the disease and successful TWOC (Table 4). At the 3-month follow-up all patients achieved castrate levels of testosterone (21.46 ng/dL) and a significant drop in PSA level (mean = 2.17 ng/mL). The mean (SD) post-treatment serum creatinine level was 1.06 (0.45) mg/dL and the serum calcium level was 8.29 (0.7) mg/dL. At 3 months after treatment, the prostate volume was also considerably reduced (30.6%). The mean (SD) pretreatment prostatic volume was 55.37 (18.72) mL and after treatment it was 38.27 (13.78) mL, this decrease in prostatic size was statistically significant ($P < 0.001$). On assessing the treatment outcomes in terms of improvement in Q_{max} and reduction in PVR in those with LUTS, we found a significant increase in Q_{max} with a median rise of ~8.4 mL/s and a reduction in PVR from 550 to 80 mL (Fig. 2).

On further comparison, of the two modes of management (medical vs surgical castration) the prostate volume reduction was comparable across both the treatment groups, at 30.71% in Group 2 (medical management) and 30.43% in Group 1 (surgical management). Both groups achieved castrate levels of testosterone with a significant drop in PSA level after treatment. The post-treatment fall in serum creatinine levels was also comparable, at 94.23% in Group 2 and 94.66% in Group 1, due to resolution of hydronephrosis. In all, 40 of 42 patients could successfully void in Group 1 and 57 of 59 patients could void successfully in Group 2. The mean time to successful voiding was 1.88 and 2 months in Group 2 and Group 1, respectively, which was not statistically significantly different. The mean increase in Q_{max} was 8.1 mL/s and 8.29 mL/s in Group 2 and Group 1, respectively. The mean IPSS was 5.91 and 6.75 and the mean decrease in PVR was 476.6 mL and 444.72 mL in Group 2 and Group 1, respectively. In those with LUTS and a high PVR the increase in Q_{max} and decrease in PVR were also comparable, at a median of 8.9 mL/s and 8.62 mL/s and 455 and 510 mL in Group 2 and Group 1, respectively (Fig. 3).

Discussion

Prostate cancer is a relatively common cancer of older men [6], and they may develop AUR as the disease progresses. Generally, localised prostate cancer causes LUTS because most of the tumours arise in the periphery of the gland and progress toward the capsule more often than toward the urethral lumen [7]. LUTS can

Table 2 Descriptive statistics among the study groups (n = 101).

Variable	Castration, n (%)		Total, n (%)	P
	Group 1 Surgical (n = 42)	Group 2 Medical (n = 59)		
Presenting condition:				0.907
AUR	23 (54.76)	33 (55.93)	56 (55.45)	
LUTS with high PVR	19 (45.24)	26 (44.07)	45 (44.55)	
Co-morbidities:				0.601
Absent	20 (47.62)	25 (42.37)	45 (44.55)	
Present	22 (52.38)	34 (57.63)	56 (55.45)	
DRE grade:				0.206
1	13 (30.95)	10 (16.95)	23 (22.77)	
2	18 (42.86)	34 (57.63)	52 (51.49)	
3	11 (26.19)	15 (25.42)	26 (25.74)	
Prostate consistency on DRE:				0.525
Normal	21 (50.00)	23 (38.98)	44 (43.56)	
Firm	4 (9.52)	8 (13.56)	12 (11.88)	
Hard	17 (40.48)	28 (47.46)	45 (44.55)	
Upper tract changes:				0.512
Hydronephrosis	22(52.38)	27(45.76)	49 (48.51)	
Normal	20(47.62)	32(54.24)	52 (51.49)	
Urine culture and sensitivity:				0.337
Positive	18 (42.86)	31 (52.54)	49 (48.51)	
Negative	24 (57.14)	28 (47.46)	52 (51.49)	
Stage:				0.772
Locally advanced	18 (42.86)	27 (45.76)	45 (44.55)	
Metastatic	24 (57.14)	32 (54.24)	56 (55.45)	
Gleason score:				0.051
<7	11 (26.19)	5 (8.47)	16 (15.84)	
7	14 (33.33)	27 (45.76)	41 (40.59)	
>7	17 (40.48)	27 (45.76)	44 (43.56)	

arise in locally advanced prostate cancer when the tumour invades the prostatic urethra, the bladder, or the neurovascular bundles. Another, more common, reason for the rise of LUTS in patients with prostate cancer is the parallel growth of the prostate due to BPH, which shows increasing prevalence with age [7].

About 80% of prostate cancers are sensitive to hormonal manipulation and hormonal cytoreduction, both LHRH analogues and orchidectomy have been shown to equally significantly reduce prostatic volume [5], with the maximum effect seen after 3 months. In patients with locally advanced prostate cancer, the effect could be related to tumour volume reduction rather than prostate volume reduction. Most patients with prostate cancer with AUR regain their voiding ability within 3 months after medical castration. Although favourable results are achieved with ADT [8], there is still limited information from randomised clinical trials on the impact of ADT on LUTS. Channel TURP still remains the most commonly used treatment for patients with prostate cancer bothered by LUTS or experiencing urinary retention [8]. However, the procedure is not devoid of various complications including bleeding, TUR syndrome and incontinence [8]. Hence, our present study was conducted to assess the effectiveness of ADT in obviating the need for channel pTURP in patients with prostate cancer presenting with urinary retention or high PVR (>200 mL), so that ADT could be used as the primary mode of therapy. A significant number of patients with metastatic or advanced prostate cancer present with high PVRs and LUTS, albeit the more common presentation of AUR [9]. This was reflected in our present study, where in 55.4% presented with refractory AUR, which was closely followed by LUTS with high PVR (44.6%).

Reduction in prostate volume

At the baseline visit, patients were primarily treated with either a LHRH agonist/antagonist or bilateral orchidectomy, together with a concomitant α-adrenoceptor antagonist and 5α-reductase inhibitor in all patients. Anti-androgens predominantly non-steroidal were given as and when deemed necessary. Castration is known to reduce prostate volume with continued reduction on long-term therapy [10]. Original work by Huggins et al. [11] showed a maximal decrease in prostate volume after orchidectomy at 3 months. Our present study had

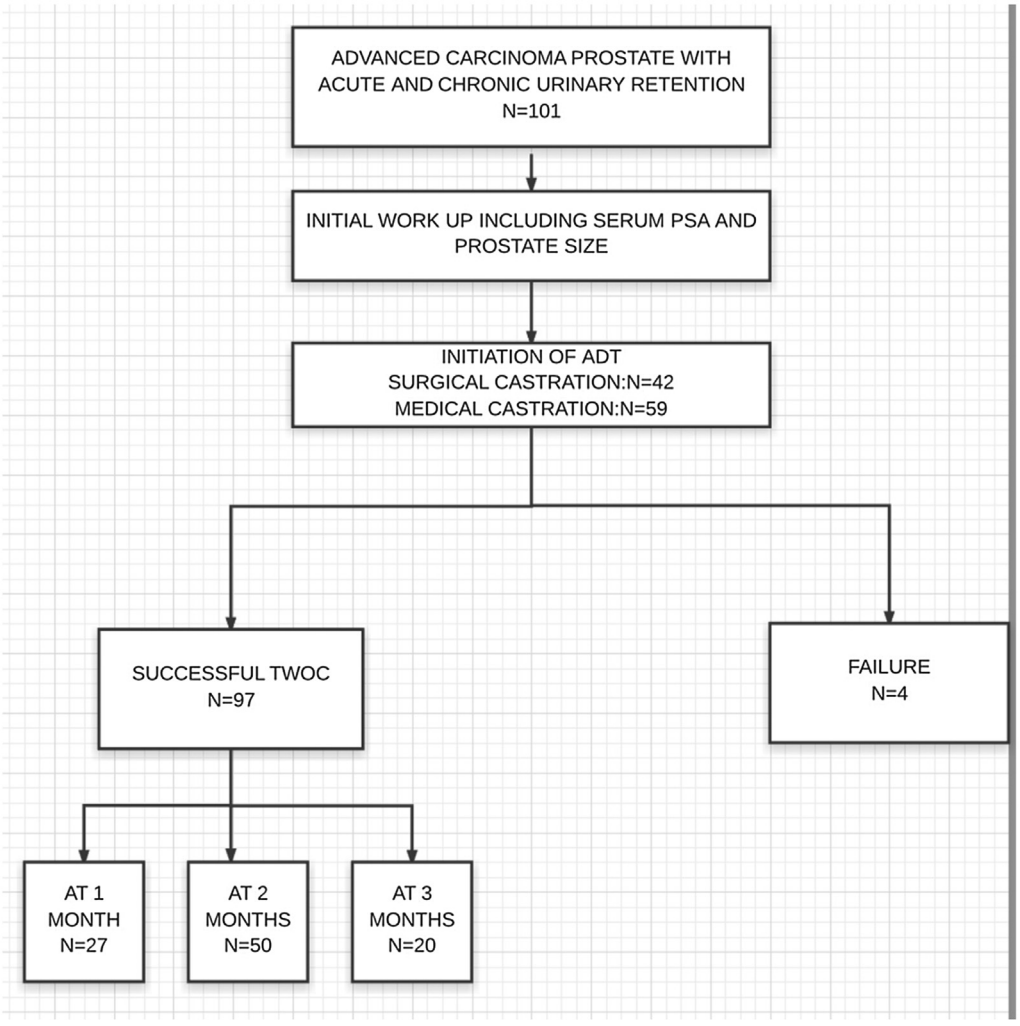

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Table 3 Comparison of TWOC success between medical and surgical castration.

TWOC	Castration, *n* (%)		Total, *n* (%)	*P*
	Group 1 Surgical	Group 2 Medical		
Successful at:				0.143
1 month	7 (16.67)	20 (33.90)	27 (26.73)	
2 months	26 (61.90)	24 (40.68)	50 (49.50)	
3 months	7 (16.67)	13 (22.03)	20 (19.80)	
Failure	2 (4.76)	2 (3.39)	4 (3.96)	
Total	42 (100)	59 (100)	101 (100)	

a follow-up duration of 3 months, during which the prostate volume decreased by ~31%, which correlates well with most previous studies [12].

Successful TWOC

In a retrospective study conducted by Varenhorst and Alund [13], of 122 patients with prostate cancer with urinary retention, a total of 80 (65.6%) responded to endocrine therapy with mitigation of the urethral obstruction, and the indwelling catheter could be removed. In 35 patients (28.7%), the obstruction was relieved within 2 months, in 58 (47.5%) within 3 months, and in 70 (57.4%) within 4 months. In the remaining 10, the catheter was removed at 4–6 months after initiating treatment. Unlike that study, where surgical castration in form of

Table 4 Correlation of grade of prostate on DRE, Gleason score and stage of disease with successful TWOC.

Variable	Successful TWOC, *n* (%)			Failure, *n* (%)	*P*
	1 month	2 months	3 months		
DRE grade:					0.826
1	5 (21.74)	13 (56.52)	5 (21.74)	0	
2	14 (26.92)	25 (48.08)	11 (21.15)	2 (3.85)	
3	8 (30.77)	12 (46.15)	4 (15.38)	2 (7.69)	
Gleason score:					0.631
<7	4 (25.00)	10 (62.50)	2 (12.50)	0	
7	13 (31.71)	20 (48.78)	6 (14.63)	2 (4.88)	
>7	10 (22.73)	20 (45.45)	12 (27.27)	2 (4.55)	
Stage:					0.893
Locally advanced	11 (24.44)	24 (53.33)	8 (17.78)	2 (4.44)	
Metastatic	16 (28.57)	26 (46.43)	12 (21.43)	2 (3.57)	

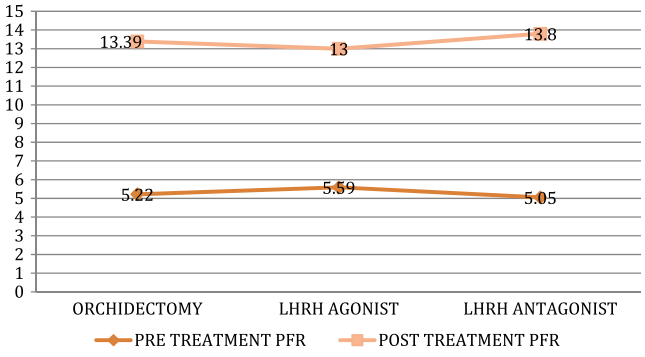

Fig. 2 Pretreatment and post-treatment Q_{max} (peak flow rate, PFR, mL/s) in the study population.

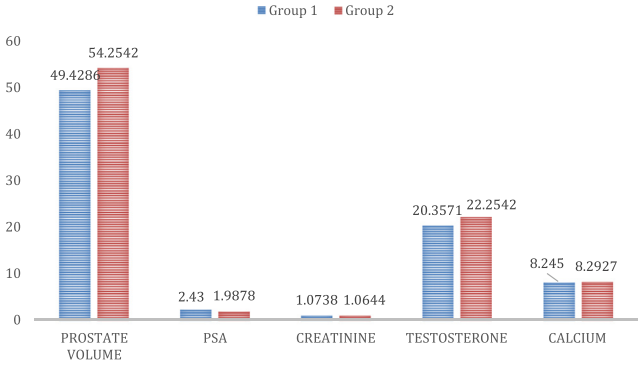

Fig. 3 Comparison of post-treatment variables across the two groups.

orchidectomy was the mode of management, we used both medical as well as surgical castration as per patient preference. Our present follow-up period was also different, ending at 3 months, whereas those who were catheter-free up to 6 months were recorded as responders in their study. Despite a shorter follow-up, the success rate in our present study was considerably higher. The use of a concomitant α-adrenoceptor antagonist and 5α-reductase inhibitors along with castration could have resulted in the higher success rate. However, this requires further validation and a longer duration of follow-up to substantiate their role as concomitant therapy.

Although success rates have been reported to be higher with ADT, patients have to endure the discomfort of prolonged catheterisation [13]. This was reflected in our present study, where only 27 of 101 patients (26.73%) could void at the end of 1 month. In the 97 patients who responded, the mean time until relief of obstruction was 1.9 months as compared to 2.7 months (after orchidectomy) and 3.4 months (after oestrogen therapy) in the Varenhorst and Alund study [13].

Other parameters measured at the 3-month follow-up were serum testosterone, serum PSA, serum calcium, and serum creatinine. Castrate levels of serum testosterone were achieved in all patients, with a mean testosterone level of 21.46 ng/dL. As expected the serum PSA level also significantly dropped to a mean of 2.17 ng/mL. The fall in creatinine was also significant, which probably correlated with the resolution of upper tract changes upon administering ADT. No data regarding this correlation could be obtained from previous studies. ADT leads to a substantial decrease in serum calcium [14], which is a known side-effect. However, in our present study there was a marginal decrease in serum calcium levels owing to supplementation of calcium and vitamin D.

Mommsen et al. [5] reported that 62% (43/69) of patients with prostate cancer with AUR regained their voiding ability within 3 months after orchidectomy. In patients who were treated with LHRH analogues in a study by Hampson et al. [15], 21 of 31 patients (68%) voided without the need for surgical intervention after 3 months. Treatment with triptorelin was effective in reducing LUTS severity and improving quality of life in patients with prostate cancer; the mean (SD) total IPSS improved from 14 (5) to 10 (5) at week 24 for patients with moderate-to-severe LUTS in a study by Alexandre Peltier et al. [16]. Klarskov et al. [17] documented statistically significant changes from baseline in numerous objective measures of voiding when 77

patients with prostate cancer were treated with different forms of hormone therapy for 12 months. After 12 months, the median Q_{max} increased by 38% (from 8 to 11 mL/s), median PVR decreased by 26% (from 86 to 63.5 mL), median voiding volume went up by 17%, and the median prostate volume was reduced by 37%. The major part of the changes took place within the first month and improvement was maintained through most of the follow-up. Our present study demonstrated equally good results, with an overall mean (SD) Q_{max} of 13.61 (2.26) mL/s, mean IPSS of 5.91, and median percentage decrease in PVR of 85.45% after treatment.

In our present study, four of the 101 patients (3.96%) underwent channel pTURP at the end of 3 months. Fleischmann and Catalona [18] noticed that neither tumour stage nor grade correlated significantly with the effect of orchidectomy on urination. No correlation could be found between DRE grade, Gleason score and the stage of the disease with successful voiding or failure leading to pTURP in the present study (Table 4). However, further studies are required to validate the risk factors for pTURP.

On further comparison, of the two modes of management (medical vs surgical castration) the results were comparable across both groups. However, there is no study, to the best of our knowledge, comparing medical and surgical castration in patients with prostate cancer presenting with urinary retention. An interesting finding noted on further sub-analysis was that better results and a faster mean time to successful voiding obtained in those patients treated with a LHRH antagonist (24 patients; Table 5). A randomised controlled trial comparing degarelix vs goserelin plus bicalutamide for volume reduction, LUT relief and quality-of-life improvement in patients with prostate cancer, showed that at 12 weeks, changes in prostate volume with goserelin and degarelix were similar [19]. However, the mean time to successful voiding was 1.58 months, which was significantly earlier compared to the other two treatment groups. In the present study, we also found a more rapid and pronounced relief of LUTS in the LHRH antagonist group.

The limitations of our present study include that serial assessment of post-treatment parameters was not performed and the duration of follow up was limited to 3 months. A longer follow-up would be required to assess the true outcomes of treatment.

Table 5 Comparison of mean time to TWOC success between the LHRH agonist and antagonist groups.

Successful TWOC	LHRH agonist	LHRH antagonist	*P*
Sample size, *n*	33	24	
Mean (SD), months	2.09 (0.72)	1.58 (0.72)	0.011
Median, months	2	1	

Conclusion

In patients with locally advanced and metastatic prostate cancer with AUR and chronic retention, ADT can relieve retention and decrease PVR over 3 months obviating the need for channel pTURP. The routine use of concomitant α-adrenoceptor antagonist and 5α-reductase inhibitors may have some additional role in management.

Conflict of interest

None.

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