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Prognostic Factors for Anastomotic Urinary Leakage Following Retropubic Radical Prostatectomy and Correlation With Voiding Outcomes

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Abstract: This study aimed to determine the occurrence and grade of cystographically detected urinary leakage (UL) in a contemporary series of open retropubic radical prostatectomy (RP), whether patients' clinical variables predict occurrence of UL, and whether occurrence of UL correlates with patients' voiding outcomes in terms of urinary continence and anastomotic stricture (AS).

Enrolled patients underwent cystography 7 days after retropubic RP; in case of UL, the catheter was left in situ and cystography repeated at 7 days intervals until demonstrating absence of UL. Leakage was classified as grade I = extraperitoneal leak <6 cm, grade II = extraperitoneal leak >6 cm, grade III = leak freely extending in the small pelvis. Voiding was evaluated at 3, 6, and 12 months after RP using the 24-hour pad test and uroflowmetry; in cases of maximum flow rate <10 mL/s, urethrocystoscopy was carried out to determine presence and location of an AS.

The first postoperative cystogram showed UL in 52.6% of patients (grade I in 48.1%, grade II in 21.5%, and grade III in 30.4% of the cases). Multivariate analysis demonstrated that patients with UL had significantly greater prostate volume (64.5 vs 34.8 cc, $P < 0.001$), loss of serum hemoglobin (4.77 vs 4.19 g/dL, $P < 0.001$), lower postoperative serum total proteins (4.85 vs 5.4 g/dL, $P < 0.001$), and higher rate of AS (20.6% vs. 2.8%, $p < 0.001$) than those without UL. Continence rate at 3, 6, and 12 months postoperatively was 34.2%, 76%, and 90%, respectively, in patients with UL compared with 77.5%, 80.3%, and 93% in patients without UL; such difference was statistically significant ($P < 0.001$) only at 3 months follow-up. ROC curve analysis showed that prostate volume and postoperative serum total proteins had the best AUC (0.821 and 0.822, respectively) and when combined, their positive and negative predictive values for UL were 90% and 93%, respectively.

In conclusion, half of the patients undergoing open retropubic RP may present, 7 days postoperatively, some degree of cystographically detected UL; prostate volume, loss of serum hemoglobin, and postoperative serum total proteins could be used to predict it. UL delayed return to urinary continence without affecting long-term results, but led to a significantly higher rate of AS.

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Abbreviations: ΔHb = difference between pre- and postoperative hemoglobin, AS = anastomotic stricture, AUC = area under the curve, BMI = body mass index, DM = diabetes mellitus, LUTS = lower urinary tract symptoms, PVR = post-void residual urine, Qmax = maximum flow rate, ROC = receiver operator characteristic, RP = radical prostatectomy, TPS = total serum proteins on fifth postoperative day, UC = urethral catheterization, UL = urinary leakage, VUA = vesicourethral anastomosis.

INTRODUCTION

Radical prostatectomy (RP) is the only treatment for localized prostate cancer to show a benefit for overall survival and cancer-specific survival, compared with watchful waiting, as demonstrated in the Scandinavian Prostate Cancer Group Study Number 4 (SPCG-4).[1] The majority of patients who undergo surgery for prostate cancer experience treatment-related side effects, which can be short term or long term, and that can significantly impact their quality of life.[2]

Adequate urinary drainage after RP is fundamental to promote healing of the vesicourethral anastomosis (VUA) but the duration of urethral catheterization (UC) remains controversial. As the description of the current surgical technique of open retropubic RP by Walsh et al,[3] the recommended UC time has progressively decreased from 21 to 30 days[4] to 14 to 21 days,[5,6] and more recently to 7, or even 3 to 4 days.[7–9]

The most commonly used method to test the integrity of the VUA and, consequently, determine the UC time remains a postoperative cystogram. In case of a cystographically detected urinary leakage (UL), surgeons tend to prolong UC time to allow complete healing of the VUA.

To date, little effort has been made to obtain a standardized grading system for cystographically detected UL according to its extension, as well as to correlate patients' clinical outcomes with the occurrence and grade of UL. Moreover, no effort has, to our knowledge, been made to determine the impact of patients' clinical variables on the occurrence and extent of cystographically detected UL. The present study, therefore, aimed to determine the occurrence and grade of cystographically detected UL in a contemporary series of open retropubic RP; to determine whether patients' clinical variables correlate with the occurrence of UL, to predict it and consequently rationalize the use of postoperative cystograms; and to determine whether

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the occurrence and grade of UL correlates with patients' voiding outcomes, in terms of both urinary continence and development of anastomotic complications, particularly anastomotic stricture (AS).

Patients and Methods

Data of consecutive patients scheduled for open retropubic RP by 2 senior surgeons (GC and LC) between January 2011 and April 2013 were prospectively entered into an institutional review board-approved database. Patients having undergone previous prostate surgery were excluded, as were those who received adjuvant radiotherapy during the study period.

After a standard open retropubic RP, the VUA was created with 6 sutures of 2/0 copolymer lactid and ε-caprolactone (Caprolon, Resorba Medical, Nuremberg, Germany) placed at 1, 3, 5, 7, 9, and 11 o′clock over a 22Fr Foley catheter. Sizing bladder neck to the urethral stump was carried out only if needed. A para-anastomotic drain was left in the Retzius space and removed when it discharged <100 mL/day, usually by the third or fourth postoperative day. All patients had a cystogram on seventh postoperative day, instilling by gravity 150 mL of iodinated contrast medium through the catheter and taking anteroposterior (AP), lateral (L), and oblique (O) views. In case of a normal cystogram (absence of UL), the catheter was removed and a postvoid view taken; conversely, in case of UL, the catheter was left in situ and the cystogram repeated at 7 days intervals until demonstrating absence of urinary extravasation. All cystograms were independently evaluated by 1 radiologist (CS) and 1 urologist (GDF) and classified as negative or positive (for leak); the positive ones were classified, according to UL extension,[8,10] in grade I = extraperitoneal leak within 6 cm of the VUA (Figure 1), grade II = extraperitoneal leak to the side wall >6 cm from the VUA (Figure 2), grade III = leak freely extending in the small pelvis (Figure 3).

For the purpose of this study, patients were seen by an independent investigator (OS) at 3, 6, and 12 months after RP. Urinary continence status was evaluated by means of the patient-reported 24-hour pad test.[11] Patients reporting obstructive lower urinary tract symptoms were evaluated by uroflowmetry and ultrasonographic measurement of postvoid residual urine; in cases of maximum flow rate (Qmax) <10 mL/s, urethrocystoscopy was carried out to determine the presence and location of an AS.

The study protocol was approved by University of Foggia Ethics Committee and it conforms to the provisions of the Declaration of Helsinki. Written informed consent to take part was given by all participants.

Statistical Analysis

Continuous data were reported as mean ± standard deviation; those with normal distribution, according to Kolgomorov-Smirnov test, were compared by Student *t* test for paired or unpaired data, whereas those with a nonparametric distribution were compared by the Mann–Whitney *U* test for independent groups. Categorical data were assessed in contingency tables by Pearson chi-squared test and Fisher exact test.

The combined predictive effect of the covariates was tested by logistic regression analysis, performing a backward selection procedure with a removal criterion of $P > 0.10$ based on the likelihood ratio test. Model calibration was measured by the Hosmer-Lemeshow goodness of fit test, with $P < 0.05$ considered statistically significant. Finally, the receiver operator characteristic (ROC) curves analysis was used to test the diagnostic performance of the different clinical parameters. The suggested cutoff value was determined by the Youden index. Statistical analysis was performed with the Statistical Package for Social Sciences version 18.0 (SPSS, Inc., Chicago, IL) and the package GraphPad Prism 6.0 for Windows (GraphPadSoftwareInc., San Diego, CA). A two-sided value of $P < 0.05$ was considered statistically significant.

RESULTS

The first postoperative cystogram showed UL in 52.6% (79/150) of patients, which was classified as grade I in 48.1% (38/79), grade II in 21.5% (17/79), and grade III in 30.4% (24/79) of the cases. Inpatients with UL at the first postoperative cystogram, mean UC time was 21 (±2).

Table 1 summarizes the main clinical variables of the overall patients' population and compares those of patients with (group 1) and without (group 2) UL at first postoperative cystogram. There was no significant difference in age, body mass index (BMI), diabetes mellitus (DM), preoperative serum prostate-specific antigen (PSA) level, Gleason score, and operative characteristics (nerve-sparing attempts and surgical time) between the 2 groups. Conversely, prostate volume was significantly greater in patients with UL. As for postoperative data, the difference between pre- and postoperative hemoglobin (ΔHb) was significantly higher and total serum proteins on fifth postoperative day (TSP-5) were significantly lower in patients with UL. In particular, the mean ΔHb was 4.77 g/dL in men who developed UL and 4.19 g/dL in men who did not ($P < 0.001$); TSP-5 level was 4.85 g/dL in men who developed UL and 5.40 g/dL in men who did not ($P < 0.001$).

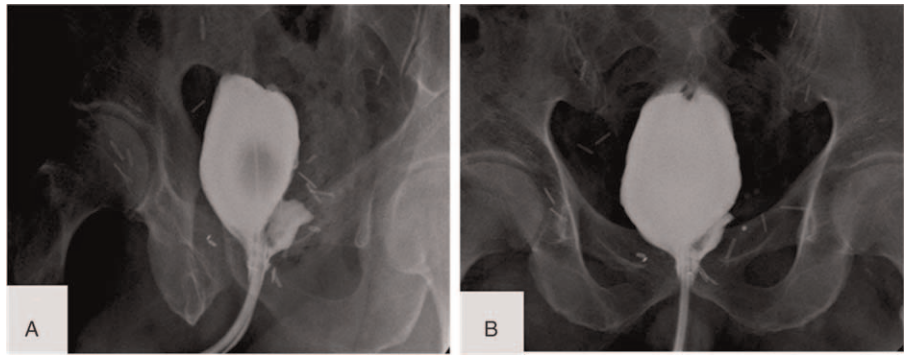

FIGURE 1. Minimal leak of contrast medium (grade I) in projection LAO (A) and AP (B). AP = anteroposterior; LAO = left anterior oblique.

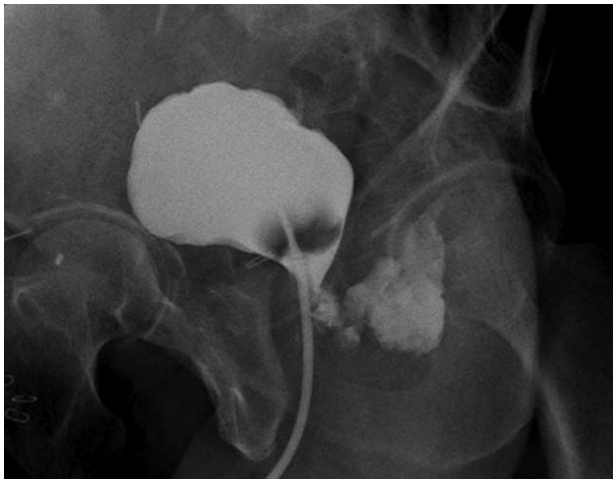

FIGURE 2. LAO view showing a moderate extravasation of contrast medium that exceeds the margin of the bladder wall (grade II). LAO = left anterior oblique.

Univariate analysis of factors negatively influencing the postoperatory course of RP revealed that higher prostate volume, postoperatory Hb and Δ-Hb, and lower postoperatory total proteins were associated with UL, whereas no association was found for age, preoperatory PSA, Gleason score, BMI, DM, surgical time, attempted nerve-sparing, and preoperatory Hb (Table 2). Multivariate logistic regression analysis (Table 2) showed that prostate volume was the best independent predictor (OR = 2.641 [1.137–3.081], $P = 0.018$) of UL, followed by TSP-5 level (OR = 1.521 [1.195–1.872], $P = 0.026$) (Table 2). The Hosmer-Lemeshow statistics confirmed adequate model calibration ($P = 0.4$).

The predictive value of these clinical variables was then tested by ROC curve analysis. The area under the curve (AUC) for prostate volume and TSP-5 level in predicting UL was 0.821 (CI, 0.753–0.888; $P < 0.001$) and 0.822 (CI, 0.753–0.891; $P < 0.001$), respectively (Figures 4 and 5), whereas the cutoff value was 40 cc (sensitivity, 78.2%; sensibility, 76.1%), and 5.40 g/dL (sensitivity, 76.1%; sensibility, 76.9%), respectively. Turning findings into clinical practice, of the 79 patients with prostate volume >40 cc, 62 (78.5%) had UL whereas 17 (21.5%) had not; of the 70 patients with TSP-5 <5.40 g/dL, 56 (80%) had UL whereas 14 (20%) had not. Of the 50 patients with both prostate volume >40 cc and TSP-5 <5.40 g/dL, 45 (90%) had UL whereas 5 (10%) had not.

FIGURE 3. AP cystogram showing a large spreading of the contrast medium in the small pelvis, away from the anastomosis (grade III). AP = anteroposterior.

Table 3 analyzes the impact of UL on postoperative urinary continence at 3, 6, and 12 months; continence was defined as a 24-hour pad test yielding up to 10 g. Continence rate at 3, 6, and 12 months postoperatively was 34.2%, 76%, and 90%, respectively, in patients with UL compared with 77.5%, 80.3%, and 93% in patients without UL; such difference was statistically significant ($P < 0.001$) only at 3 months follow-up.

A total of 18 patients (12%) suffered anastomotic stricture (AS). Significantly, almost all AS (16/18) occurred in patients with UL ($P < 0.001$); in particular, the AS rate was 2.8% (2/71) in patients without UL compared with 7.9% (3/38, $P = 0.34$), 23.5% (4/17; $P = 0.012$), and 37.5% (9/24; $P = 0.0001$) in patients with UL grade I, II, and III, respectively.

DISCUSSION

The present study showed that in a contemporary series of open retropubic RP, the occurrence of cystographically detected UL at 7 days postoperatively was 52.6%; the entity of UL was scored as minimal (grade I) in 25.3% of cases, moderate (grade II) in 11.3%, and severe (grade III) in 16%. The reported rate of cystographically detected UL following RP at 7 days postoperatively ranges from 4.6% to 33% [11–14]; however, reported series referred to grade II and III UL, whereas grade I was not included as patients had their urethral catheter removed. Considering UL grade II and III only, our overall UL rate in 7 days would have been 27.3%, in accordance with that reported in literature. Unfortunately, our study did not provide information on whether our policy of keeping the catheter in case of grade I UL is more appropriate than removing it. On the one hand, prolonged catheterization can be a source of infection, as well as patient's discomfort and anxiety[15]; on the other hand, available data suggest a close correlation between premature catheter removal and the risk of AS.[11,12] Independently, we found a greater though not significant rate of AS in patients with grade I UL compared with those without UL.

In agreement with another study in which the first cystography was performed on seventh postoperative day,[16] our study confirmed that intraoperative blood loss, as assessed by ΔHb, was an independent predictor of cystographically detected UL. The higher incidence of UL associated with high intraoperative blood loss might be explained by poor visualization of the urethra, compromising the quality of the anastomosis.

Novel findings of our study were that large (>40 cc) prostate volume and low levels (<5.40 g/dL) of TSP-5 were the most significant independent predictors of UL. As for prostate volume, it is likely that the higher occurrence of UL in case of large prostates might be related to difficulties in obtaining a long urethral stump. On the other hand, low levels of TSP-5 may be responsible for a slow/incomplete healing of the anastomosis. Independently on the mechanisms leading to UL, the present study showed that UL occurred in 78.5% of patients with prostate volume >40 cc, 80% of patients with TSP-5 <5.40 g/dL, and 90% of patients with both prostate volume >40 cc and TSP-5 <5.40 g/dL. These findings would suggest that in such patients cystography would better be postponed.

TABLE 1. Baseline Characteristics of Patients Undergoing Radical Prostectomy According to the Presence or the Absence of UL. The Significance of Differences Was Assessed by Student *t* test (Age, Prostate-Specific Antigen, Gleason Score, Body Mass Index, Prostate Volume, Surgical time, Pre- or Postoperatory Hemoglobin, Delta-Hb, Postoperatory Total Proteins), or by Pearson Chi-Squared Test and Fisher Exact Test (Other Variables)

Parameter	All Patients (n = 150)	With UL (n = 79)	Without UL (n = 71)	*P*
Age, y	65.11 ± 6.37	65.85 ± 5.6	64.28 ± 7.06	0.06
Prostate-specific antigen, ng/mL	8.43 ± 5.12	8.7 ± 5.04	8.13 ± 5.23	0.70
Gleason score	6.96 ± 1.01	6.87 ± 0.99	7.07 ± 1.03	0.79
Body mass index, kg/m^2	26.89 ± 3.18	27.22 ± 3.11	26.52 ± 3.25	0.70
Diabetes mellitus (n/%)	17 (11.3%)	13 (16.4%)	4 (5.6%)	0.06
Prostate volume, cc	50.47 ± 32.06	64.51 ± 36.43	34.84 ± 15.47	< 0.001
Surgical time, min	133.43 ± 28.05	136.0 ± 28.0	129.82 ± 27.86	0.90
Attempted nerve-sparing (n/%)	72 (48.0%)	43 (54.4 %)	29 (40.8 %)	0.13
Preoperatory Hb, g/dL	14.99 ± 1.22	14.97 ± 1.19	15.03 ± 1.26	0.90
Postoperatory Hb, g/dL	10.48 ± 1.58	10.05 ± 1.53	10.95 ± 1.51	< 0.001
ΔHb, g/dL	4.49 ± 1.54	4.77 ± 1.62	4.19 ± 1.40	< 0.001
TSP-5, g/dL	5.11 ± 0.47	4.85 ± 0.48	5.40 ± 0.22	< 0.001
Anastomotic stricture (n/%)	18 (12.0%)	16 (20.6%)	2 (2.8%)	< 0.001

ΔHb = difference between pre- and postoperative hemoglobin; TSP = total serum proteins on fifth postoperative day; UL = urinary leakage.

The present study also provided information regarding the poorly explored issue of the impact of cystographically detected UL on patients' urinary continence. Varkarakis et al[11] previously pointed out that UL had no effect on urinary continence after RRP, both at 3-, 6-, and 12-month follow-up. Patel et al[8]reported a progressive increase in urinary continence rate of patients with UL from 70% to 85% to 94% at 3, 6, and 12 months, respectively, but did not compare such rates with those obtained in patients who did not leak. Our study conversely pointed out that urinary continence rate differed between patients with and without UL only at 3 months postoperatively, with no difference at 6- and 12-month follow-up. In other words, it seems that UL impairs short-term but not long-term urinary continence.

Another relevant information coming from our study was the impact of occurrence and grade of UL on the development of an AS. Our AS rate was 2.8% in patients without UL and raised to 7.9%, 23.5%, and 37.5% in patients with UL grade I, II, and III, respectively, thus pointing out a direct correlation between occurrence and grade of UL and development of AS. Similar findings were obtained by Altinova et al[17]who, like us, kept the urethral catheter until cystography demonstrated absence of UL. In their series, the AS rate was 4%, 12,5%, and 40% in patients who had the catheter for 1, 2, or 3 weeks, respectively. Webb et al[18]showed the ''racquet handle'' bladder neck repair to be the major risk factor for AS; minor UL seemed unlikely to be a significant etiological factor whereas major UL was associated with AS. Huang et al,[19] who left the urethral catheter until extravasation resolved, found that AS development correlated with the amount of bleeding and the caliber of the reconstructed bladder neck rather than occurrence and even degree of UL on cystography. Finally, Borboroglu et al[20] found comorbidities associated with microvascular disease, in particular, cigarette smoking, to be more relevant risk factors for development of AS than UL. Taking all these findings together, there are grounds to assume the etiology of AS after RRP to be multifactorial. Factors such as blood loss and consequent decrease in total serum proteins, ischemia of the bladder neck due to patient's

TABLE 2. Univariate and Multivariate Logistic Regression Analysis for Factors Associated With Urinary Leakage

	Univariate Analysis			Multivariate Analysis		
	Odds Ratio	Confidence Interval (95%)	*P*	Odds Ratio	Confidence Interval (95%)	*P*
Age	1.019	0.933–1.111	0.160			
Surgical time	1.012	0.991–1.033	0.207			
Preoperatory PSA	1.014	0.899–1.144	0.838			
Prostate volume	2.695	1.710–3.105	<0.001	2.641	1.137–3.081	0.018
Gleason score	0.890	0.500–1.584	0.151			
Postoperatory total proteins	1.922	1.302–3.083	<0.001	1.521	1.195–1.872	0.026
Preoperatory Hb	1.322	0.815–2.142	0.985			
Postoperatory Hb	1.787	1.106–2.422	0.001	0.959	0.508–1.810	0.244
ΔHb	1.891	1.086–2.393	0.001	1.262	0.796–2.000	0.191

ΔHb = difference between pre- and postoperative hemoglobin; PSA = prostate-specific antigen.

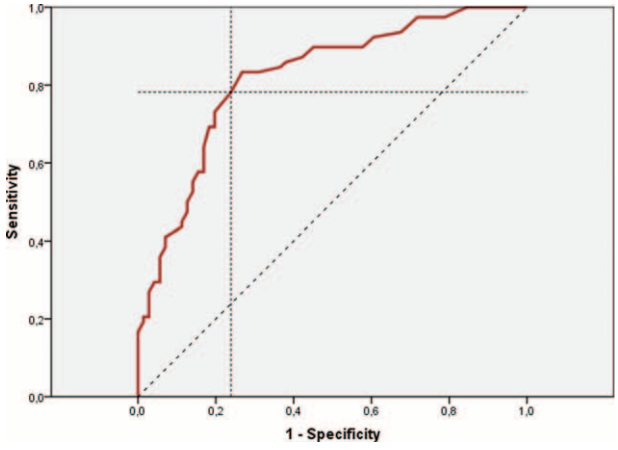

FIGURE 4. Area under the receiver operating characteristic curve for prostate volume in predicting urinary leakage.

comorbidities and/or excessive reconstructive sutures, and UL/catheterization time may play a role in the development of AS.

Strengths of our study include its prospective nature and outcomes having been evaluated by third parties. Potential limitations include not having evaluated the role of sizing bladder neck to the urethral stump, as well as not having planned a group of patients removing the urethral catheter on the seventh postoperative day in case of grade I UL.

CONCLUSIONS

Half of the patients undergoing open retropubic RP may present, 7 days postoperatively, some degree of cystographically detected UL that can be predicted by prostate volume, ΔHb, and TSP-5 values. UL seems to affect short- but not long-term urinary continence; occurrence and degree of UL seem to correlate with the development of AS. Predicting UL may reduce the number of unnecessary cystograms but whether extravasation of contrast medium contributes to development of AS and whether the rate of such complication could be reduced by postponing cystography in patients with factors predicting UL deserve further investigations.

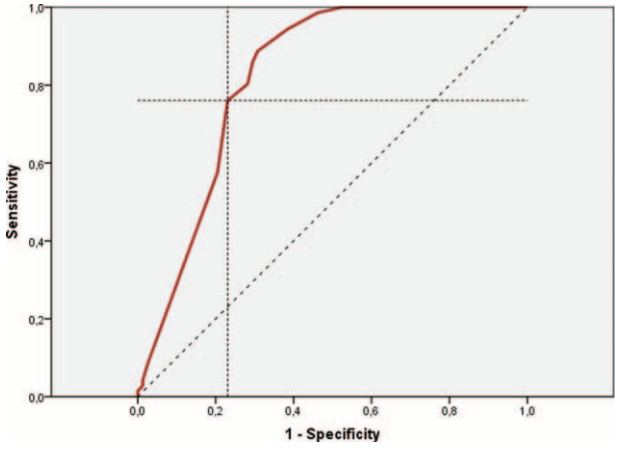

FIGURE 5. Area under the receiver operating characteristic curve for postoperative serum total proteins in predicting urinary leakage.

TABLE 3. Urinary Continence Rate at 3, 6, and 12 Months Postoperatively in Patients With and Without UL

Continence Rate	Without UL	With UL	*P*
3 mo	55/71 (77.5 %)	27/79 (34.2 %)	<0.001
6 mo	57/71 (80.3 %)	60/79 (76%)	0.52
12 mo	66/71 (93%)	71/79 (90%)	0.50

UL = urinary leakage.

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