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Original Research / Özgün Araştırma

Impact of urethrovesical anastomotic leakage after robotic radical prostatectomy on early postoperative continence

Robotik radikal prostatektomi sonrası üretrovezikal anastomoz kaçağının erken postoperatif kontinans üzerine etkisi

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Özet

Amaç: Bu çalışmada robot yardımlı radikal prostatektomi (RYRP) uygulanan hastalarda üretrovezikal anastomoz kaçağı (UAK) ve ilişkili faktörleri ve bunun erken kontinans üzerine etkisini değerlendirmeyi amaçladık.

Gereç ve Yöntemler: Bu retrospektif analizde Şubat 2017 ile Haziran 2022 tarihleri arasında RYRP uygulanan 81 hastanın verileri değerlendirildi. Ameliyat sonrası yedinci günde hastalarda UAK olup olmadığını belirlemek için sistografi çekildi. UAK'ye yol açabilecek faktörleri araştırmak için tek ve çok değişkenli analizler yapıldı. Ameliyattan 6-12 hafta sonra hastalarda kontinans oranları kaydedildi.

Bulgular: Toplamda 25 hastada (%31) UAK vardı; 12'si (%15) hafif, 8'i (%10) orta ve 5'i (%6) ileri derecedeydi. Dren/serum kreatinin oranının >1,5 olması ve prostat hacminin >53 cm^3 olması UAK'yi öngörmede hem tek değişkenli hem de çok değişkenli analizlerde anlamlı bulundu (sırasıyla p=0,017 ve p=0,046). Postoperatif ikinci veya üçüncü günde dren çıkışı 100 ml'den fazla olan 36 hastanın sekizinde (%22) yüksek dren/serum kreatinin oranı (>1,5) vardı ve bunların yedisinde (%88) UAK vardı. Erken dönem takip verilerine göre UAK'lı hastaların 9 (%36)'sında, UAK'sız hastaların ise 20 (%37)'sinde inkontinans saptandı (p=0,959).

Sonuç: Sistografi, RYRP sonrası anastomoz kaçağını tespit etmede etkili bir yöntemdir. Büyük prostat hacmi (>53 cm^3) ve yüksek postoperatif dren/serum kreatinin oranı (>1.5) UAK ile ilişkili bulunmuştur. UAK'ın erken kontinans üzerinde etkisi gözlenmemiştir.

Anahtar Kelimeler: anastomoz kaçağı, idrar kaçırma, robot yardımlı, prostatektomi, sistografi

Abstract

Objective: This study aimed to assess the urethrovesical anastomotic leakage (UAL) and associated factors in patients who underwent robot-assisted radical prostatectomy (RARP) and its effect on early continence.

Material and Methods: The data of 81 patients who underwent RARP between February 2017 and June 2022 were evaluated in this retrospective analysis. On the seventh postoperative day, we performed a cystography to determine whether the patients had UAL. Uni- and multivariate analyses were done to investigate the factors that could lead to UAL. Continence rates were recorded in patients at 6-12 weeks after surgery.

Results: Overall 25 patients (31%) had UAL; of them 12 (15%) were mild, eight (10%) were moderate, and five (6%) were extensive. A drain/serum creatinine ratio >1.5 and a prostate volume >53 cm^3 were determined to be significant in predicting UAL in both the uni- and multivariate analyses (p=0.017 and p=0.046, respectively). On the postoperative second or third day, of the 36 patients who had drain output greater than 100 ml, eight (22%) had a high drain/serum creatinine ratio (>1.5), seven (88%) of which had UAL. According to the early period follow-up data, incontinence was prevalent in 9 (36%) of the patients with UAL and 20 (%37) of the patients without UAL (p=0.959).

Conclusion: Cystography is an effective method for detecting leakage after RARP. A large prostate volume (>53 cm^3) and a high postoperative drain/serum creatinine ratio (>1.5) were found to be associated with UAL. UAL had no effect on early continence.

Keywords: anastomotic leak, cystography, prostatectomy, robot-assisted, urinary incontinence

The study was approved by Koç University Ethical Committee, (Decision No: 2022.449.IRB1.175, Date: 2022/12/06).
All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

INTRODUCTION

Urethrovesical anastomotic leakage (UAL) is one of the possible early complications in patients undergoing radical prostatectomy (RP) for prostate cancer. Until recently, radical prostatectomy was performed using the open method, and most of the studies on UAL were conducted in the open RP era. In these studies, especially the anastomosis part of open surgery was seen as an important predictor among the factors that caused UAL (1, 2). Recently, robot-assisted radical prostatectomy (RARP) has become increasingly popular and the most widely used method. One of the points that robot assistance is most utilized is urethrovesical anastomosis. In addition to providing a better view, the comfort created by the robot arms in a narrow space such as the Retzius space can facilitate urethrovesical anastomosis (3).

The clinical significance of UAL in prolonged catheterization time, peritonitis, ileus, need for intra-abdominal drain placement, prolongation of time to continence, and urethral stricture has been demonstrated by many studies (4, 5).

While in some centers the Foley catheter is removed based on the creatinine level of the drain output, in other centers the catheter can be taken out on the specified day without any control. Cystography, on the other hand, is one of the most effective diagnostic methods for UAL (2). However, cystography to evaluate urethrovesical anastomosis is not a routine practice in many centers. While failing to perform cystography can lead to the underdiagnosis of anastomotic leakage, performing it on all patients, on the other hand, is not cost-effective and may cause overdiagnosis.

In this study, we aimed to reveal the incidence and severity of UAL, and its effect on early continence in patients who underwent RARP and indicate the associated risk factors.

MATERIAL AND METHODS

After the approval of the ethics committee (2022.449. IRB1.175), the data of 92 patients who underwent RARP followed by cystography between 2017 and 2022 were evaluated in this retrospective analysis. Patients with regular follow-up data were included in the study. Of them, 11 patients were excluded from the study since their cystographies were performed in another center that did not meet our standards for cystography. The remaining 81 patients were included in the study.

Variables including demographic and perioperative data were recorded. The cystography findings at the end of the first week and the continence statuses between the 6th and 12th weeks were noted.

All surgeries were performed by a single surgeon (MDB) who had fifteen years of experience in robotic surgery, using the transperitoneal approach, utilizing the da Vinci Surgical System (Intuitive Surgica, Sunnyvale, CA, USA). The posterior reconstruction of urethrovesical anastomoses was performed using the Rocco technique. Then, the anastomosis was completed using the 3.0 STRATAFIX™ Spiral PGA-PCL sutures over a 22 Fr Foley catheter using the Van Velthoven technique, starting at the six o'clock position. At the end of the operation, a drain was placed in the minor pelvis.

All patients were scheduled for cystography on the postoperative seventh day. The patients were given 150 ml of contrast material through the Foley catheter during cystography. Oblique and anteroposterior images were obtained under C-arm fluoroscopy. Anastomotic leakage was categorized according to Han's classification. Moderate and extensive leakage were both considered major leakage (6). The Foley catheters were removed from patients with mild leakage at the end of cystography. In case of moderate and extensive leakage, cystography was performed again on the 14th day, and if there were no or mild leakage, the urethral catheter was removed. The same technique was performed on day 21 and day 28 if the leakage persisted with the same severity. The continence statuses of the patients were evaluated between the 6th and 12th weeks. According to the recommendation of the International Continence Society (ICS), any level of involuntary urine leakage was considered urinary incontinence (UI) (7).

Statistical Method

Descriptive statistics (mean, standard deviation, median, minimum, and maximum) were used to describe the continuous variables. The conformity of the continuous variables to the normal distribution was examined using the Shapiro-Wilks test. Univariate

evaluation between leakage/non-leakage groups and minor/major leakage groups were analyzed with the Univariate Logistic Regression Analysis. The statistical evaluation was followed by using Multivariate Logistic Regression Analysis, by including the independent variables, which are found as statistically significant in univariate analysis.

The statistical significance level was determined as $p<0.05$. Analyses were performed using MedCalc® Statistical Software v.19.7.2 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2021) and IBM IBM SPSS Statistics for Windows, v.28.0. (IBM Corp., Armonk, NY, USA).

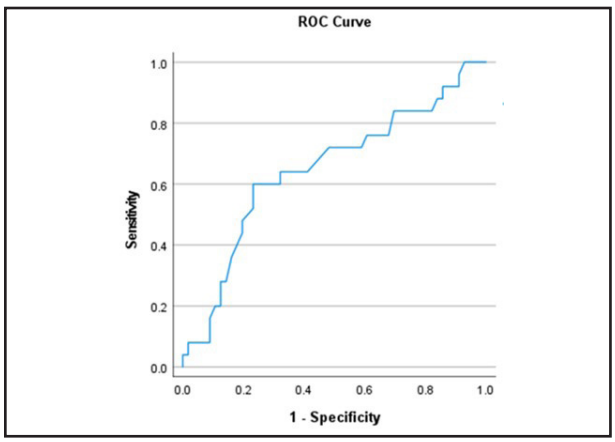

Figure 1. Area under the ROC curve for prostate volume in predicting urinary leakage

RESULTS

Demographic data and perioperative findings of the patients are summarized in Table 1. UAL was observed in 25 (31%) of the patients that underwent cystography at the end of the first week. Of them, 12 (15%) had mild, 8 (10%) moderate, and 5 (6%) extensive leakage.

The area under the curve (AUC) for prostate volume in predicting UAL was 0.649, with a cut-off value of 53 cm^3 (p=0.002) (Figure 1). Table 2 shows the univariate analysis results of the patients with and without UAL. UAL was observed more frequently in patients with a prostate volume greater than 53 cm^3 and patients with a drain/serum creatinine ratio above 1.5. In multivariate analysis, a prostate volume >53 cm^3 and a drain/serum creatinine ratio >1.5 were found to be significant predictors of UAL (p=0.046 and p=0.018, respectively).

On the second and third postoperative days, creatinine was measured in the drain fluid of seven patients with a mean drain output between 100-200 ml and 29 patients with a mean drain output above 200 ml. The mean drain fluid output was 339±206 ml. The drain/serum creatinine ratio was >1.5 in eight (22%) of the patients whose drain creatinine levels were measured. Seven (88%) patients with drain creatinine measurement had UAL.

Table 1. Demographic characteristics and perioperative data of the patients

Age, years	63(57.5-69.5)
BMI, kg/m²	28.1±3.6
Number of patients with diabetes	18 (22.2%)
Number of patients with previous prostate surgery	6 (7.4%)
PSA level (range), ng/mL	6.4 (4.8-9.5)
Prostate volume, cm^3	49.4±20.2
Duration of operation, minutes	200(180-235)
Number of patients with nerve sparing	76 (93.8%)
Number of patients with lymph node dissection	56 (69.1%)
Blood loss, mL	100(50-200)
Length of hospital stay, days	3(3-4)
Leakage	
None	56 (69.1%)
Mild	12 (14.8%)
Moderate	8 (9.9%)
Extensive	5 (6.2%)

Data are given as mean±SD for normal distributed data, med(IQR) for non-normally distributed data.

Table 2. Univariate analysis results of the demographic data in the diagnosis of urethrovesical anastomosis leakage

	Leakage - (n=56)	Leakage + (n=25)	p	OR	95% CI
Age, years	62(57-68)	66(58-70)	0.376	1.03	0.97-1.09
BMI, kg/m²	27.7(24.8-29.7)	29(26.2-30.6)	0.615	1.03	0.91-1.12
Number of patients with diabetes	14 (25%)	4 (16%)	0.372	0.57	0.17-1.95
Number of patients with previous prostate surgery	5 (8.9%)	2 (8%)	0.873	0.87	0.16-4.82
PSA level, ng/mL	6.2(4.7-9.5)	7(5.3-10.8)	0.821	1.01	0.96-1.06
Number of patients with a prostate volume >53 cm³	10 (17.8%)	12 (48%)	**0.002**	**4.96**	**1.80-13.67**
Duration of operation, minutes	195(180-227.5)	210(167.5-265)	0.073	1.01	0.99-1.01
Number of patients with nerve sparing	52 (92.8%)	24 (96%)	0.592	1.85	0.20-17.41
Number of patients with lymph node dissection	41 (73.2%)	15 (60%)	0.093	0.43	0.16-1.15
Number of lymph nodes	28(21.5-40.5)	21(16-31)	0.133	0.96	0.90-1.01
Blood loss, mL	100(77.5-200)	100(50-175)	0.554	0.99	0.99-1.01
Drain output, ml	120(52.5-281.5)	90(50-290)	0.456	1.00	0.99-1.01
Number of patients with a drain/ serum creatinine ratio >1.5†	1 (4.2%)	7 (58.3%)	**0.003**	**32.2**	**3.2-323.7**
Length of hospital stay, days	3.5(3-4)	3(3-4)	0.754	1.05	0.76-1.46

BMI: body mass index, PSA: prostate-specific antigen.
**Data are given as mean±SD for normal distributed data, med(IQR) for non-normally distributed data.*
†The drain/serum creatinine ratio was evaluated on a total of 36 patients.
Significant p values are written in bold.

Table 3. Univariate analysis results of the demographic data in the diagnosis of major urethrovesical anastomosis leakage

	No or minor leakage (n=68)	Major leakage (n=13)	p	OR	95% CI
Age, years	63(57.3-69)	63(57.5-70.5)	0.962	0.99	0.93-1.07
BMI, kg/m²	27.7(25-29.7)	29(27.2-32.1)	0.124	0.13	0.97-1.34
Number of patients with diabetes	17 (25%)	2 (15%)	0.198	0.25	0.03-2.07
Number of patients with previous prostate surgery	5 (7.4%)	1 (7.7%)	0.883	0.85	0.093-7.69
PSA level, ng/mL	6.1(4.7-9.4)	7.2(6.2-11.4)	0.625	1.01	0.95-1.07
Number of patients with a prostate volume >53 cm³	18 (26.5%)	8 (61.5%)	**0.002**	**9.26**	**2.29-37.5**
Duration of operation, minutes	200(180-233.8)	210(152.5-255)	0.993	1.00	0.99-1.01
Number of patients with nerve sparing	64 (94.1%)	12 (92.3%)	0.804	0.75	0.08-7.31

Number of patients with lymph node dissection	49 (72.1%)	7 (53.8%)	0.119	0.38	0.12-1.28
Number of lymph nodes	27(19.5-37)	21(16-39)	0.823	0.99	0.93-1.06
Blood loss, mL	100(55-200)	100(50-225)	0.523	0.99	0.99-1.00
Drain output, ml	107.5(50-273.8)	250(50-385)	0.094	1.00	1.0-1.01
Number of patients with a drain/serum creatinine ratio >1.5†	4 (14%)	4 (50%)	**0.044**	**6.00**	**1.05-34.32**
Length of hospital stay, days	3(3-4)	3(3-7)	0.298	1.22	0.84-1.77

BMI: body mass index, PSA: prostate-specific antigen.
**Data are given as mean±SD for normal distributed data, med(IQR) for non-normally distributed data.*
†The drain/serum creatinine ratio was evaluated on a total of 36 patients.
Significant p values are written in bold.

Table 4. Multivariate analysis results of the variables for leakage and major leakage

	Multivariate analysis					
	No leakage vs leakage			No/minor leakage vs major leakage		
	p	OR	95% CI	p	OR	95% CI
Prostate volume >53 cm³	**0.046**	6.468	1.033-40.494	0.149	5.214	0.647-41.988
Drain/serum creatinine ratio >1.5	**0.017**	20.456	1.725-242.55	0.061	6.259	0.891-1568

CI: confidence interval, OR: odds ratio.
Significant p values are written in bold.

In the comparison of patients with major leakage and those with no/minor leakage, having a prostate volume >53 cm^3 and a drain/serum creatinine ratio >1.5 were significant in univariate analysis but not in multivariate analysis (Table 3 and Table 4).

The urinary catheters of three patients with moderate UAL among 13 patients with a major UAL were removed on the seventh day. In the remaining 10 patients, cystography was repeated at the end of the second week. While leakage with the same severity was observed in one patient, no/mild leakage was observed in the rest. The catheters of the patients who were not observed to have major leakages at the second week follow-up were removed, while the catheter of the only remaining patient was removed after the leakage regressed at the third week follow-up.

While full continence was prevalent in 16 (64%) of the patients with UAL at the 6th and 12th week follow-ups, the rate of patients using one pad a day was 5 (20%) and the rate of patients who did not prefer to use pads was also 4 (16%). Full continence was prevalent in 35 (63%) of the patients without UAL. In this group, the rate of patients using one pad a day was 13 (23%), while the rate of patients who did not use pads was 8 (14%) (p=0.959).

DISCUSSION

The current study, in which we investigated UAL in patients undergoing RARP, revealed several noteworthy findings. First, we could demonstrate that prostate volume is a determinant in urinary incontinence. In addition, we found urinary anastomosis leakage to be higher in patients with a prostate volume >53 cm^3. Cormio et al. also found that prostate volume is the most effective factor in predicting UAL. In their study, the cut-off value for prostate volume was reported as 40 cc (8). In patients with a large prostate volume, the distance between the remaining urethra and bladder is

expected to be large, which in turn may lead to difficulty in bringing the urethra closer to the bladder. Techniques for both supporting anastomosis and preventing postoperative incontinence have been described in previous studies. Some of the common techniques include Rocco stitches, advanced reconstruction of vesicourethral support (ARVUS), and total anatomical reconstruction described by Porpglia et al. (9-11). We apply the Rocco method as a standard in all our cases. With this method, a tension-free posterior support and a tension-free vesicourethral anastomosis are provided. Previous studies have shown that posterior support facilitates vesicourethral anastomosis and reduces UAL rates (12, 13).

Second, we showed an association between the drain creatinine value and UAL. In our study, drain creatinine was measured in 36 patients (44%) whose drain fluid was observed to work excessively on the second or third postoperative day (>100 ml). Lymph node dissection was performed in two-thirds of the operated patients in our series, while the mean number of lymph nodes removed was 29. As a result, drain creatinine was measured to differentiate between lymphatic drainage and anastomotic leakage. Our study has shown that a drain fluid/serum creatinine ratio above 1.5 is a predictor of UAL. In a limited number of previous studies, various cut-off values between 1.2 and 2 have been proposed to predict UAL (14-16).

In previous studies, the effects of factors such as age, body mass index, diabetes, the duration of operation, the amount of intraoperative bleeding, and the number of dissected lymph nodes on UAL have been shown (4, 17). However, we could not establish a significant relationship between these factors and UAL.

Third, in our study, the incidence of UAL was 31%. The prevalence of UAL has been reported to vary between 4% and 33% in previous studies, which shows that our result is within the limits reported in the literature (2, 18-20). Although the surgical technique and patient characteristics are important, the method used for evaluating anastomotic leakage may also have an impact on the potential causes that affect UAL rates. During the imaging performed with a C-arm X-ray, the contrast medium can be given through the Foley catheter as a drop infusion with gravity or directly by a catheter tip syringe. Using a catheter tip syringe may result in a faster and more pressurized delivery than the other, which may affect leak detection rates (4). The difference between drip infusion cystography and fast-filling cystography may be the subject of other research.

Besides the studies showing the relationship of UAL with postoperative urinary incontinence, the literature holds other studies showing that even major UAL does not affect continence (4, 21, 22). Varkarakis et al. showed that there was no difference in the continence rates at the third, sixth, and 12th month controls between patients with and without UAL (20). In Tohi et al.'s study, the effect of UAL on urinary incontinence was determined only in the early period (3rd month) (23). In our study, we evaluated the continence status in the early period (6 to 12 weeks) and found that only 36% of the patients with UAL and 37% without UAL had incontinence. These rates are consistent with those from the previous studies (4, 20-22).

Our study had some limitations. First, it had a retrospective design. Second, the results of the study include the results of a single surgeon's operation. For this reason, the surgeon's ability, which is one of the factors that may affect UAL, could not be the subject of this study. Third, the fact that the number of patients with UAL was not high may have affected the results statistically. Fourth, the drain creatinine level was measured only in patients with a high drain output; we could not assess the remaining patients' drain/serum creatinine rates.

CONCLUSION

Cystography is an effective method to detect anastomotic leakage after RARP. Despite the routine Rocco sutures, UAL was more common in patients with large prostate volumes (>53 cm^3). We also found that a high postoperative drain/serum creatinine ratio (>1.5) was associated with UAL. Our study confirms that UAL had no effect on early urinary continence.

Conflict of Interest

The authors declare to have no conflicts of interest.

Financial Disclosure

The authors declared that this study has received no financial support.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Ethical Approval

The study was approved by Koç University Ethical Committee (Decision No: 2022.449.IRB1.175, Date:2022/12/06) and written informed consent was received from all participants. The study protocol conformed to the ethical guidelines of the Helsinki Declaration.

Author Contributions

Conception and design; Kılıç M, Balbay MD, Data acquisition; Kılıç M, Madendere S, Tekkalan FB, Köseoğlu E, Data analysis and interpretation; Kılıç M, Eden BA, Balbay MD, Drafting the manuscript; Kılıç M, Madendere S, Balbay MD, Critical revision of the manuscript for scientific and factual content; Kılıç M, Madendere S, Balbay MD, Statistical analysis; Eden BA, Supervision; Balbay MD.

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