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ORIGINAL PAPER

Does routine intraoperative Double J stent insertion avoid urine leakage after open partial nephrectomy?

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Summary ***Objective: To evaluate the impact of Double J stent (DJS) insertion during open partial nephrectomy (OPN) on postoperative prolonged urinary leakage.***

Materials and methods: A retrospective study was made in consecutive cases of OPN performed between 2002 and 2020 for localized kidney tumors at our tertiary center. Urinary leakage was defined as drainage > 72 hours after surgery by biochemical analysis consistent with urine or radiographic evidence of urine leakage. The patients were divided into two groups according to intraoperative DJS placement, and compared regarding clinicopathologic characteristics, perioperative and postoperative outcomes. Univariate and multivariate logistic regression analyses were performed to determine the factors associated with urinary leakage after the operation.

Results: Review of records identified 182 patients who were included in the study. In 73 (40%) patients PN was performed without insertion of a DJS. Thus, 109 (60%) of patients had a DJS inserted. Apart from higher preoperative eGFR values among patients with DJS (96.6 vs. 94.3 mL/min/1.73 m²; p = 0.03), demographic characteristics were similar between groups. The two groups were not different regarding perioperative, postoperative and clinicopathologic outcomes. Patients with DJS had longer ischemia times (31 vs. 23 min; p = 0.02) and longer length of stay (6 vs. 5 days; p = 0.04). Urinary leakage was seen in 7.6% (n = 14) of all patients and it did not differ according to DJS placement (DJS+ 9.2 vs. DJS- 5.5%; p = 0.41). On multivariate analysis, the tumor nearness to the collecting system was the sole independently significant factor (p = 0.04) predicting postoperative urine leak.

Conclusions: Routine intraoperative DJS insertion during OPN does not appear to reduce the probability of postoperative urine leak.

KEY WORDS: *Kidney tumor; Double J stent; Urine leakage; Partial nephrectomy.*

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INTRODUCTION

Kidney tumors are the third most common type of cancer among the urological malignancies and constitute 2-3% of adult cancers (1). Following rapid developments in imaging techniques and their more widespread use, incidental detection of renal tumors has increased to 60% in some reports (2). Increased diagnosis of early-stage, incidental renal tumors in tandem with advances in surgical techniques preventing ischemic renal damage and current oncologic outcomes equivalent to the results of *radical nephrectomy* (RN) at medium-long term, have increased interest in *partial nephrectomy* (PN) worldwide. However, the risk of postoperative complications is higher in patients who have undergone PN compared to RN (3). Among these, postoperative urine leakage is a clinically important complication, adversely affecting patient recovery, and is reported to occur in 0.8% to 15.2% of the patients (4-7). Inadequate repair of a collection system during deep layer renorraphy is the main cause of urine leakage. Ureteral catheterization during PN has been applied to obviate this risk and to visualize an opened renal calyx for closure and impact on urinary leakage after PN has been fully established (7-9). For each patient *Double J stent* (DJS) ureteral catheterization in our clinic is at the surgeon's own discretion. In this study, the usefulness of DJS placement in detecting and preventing urinary leakage during *open PN* (OPN) was assessed retrospectively.

MATERIALS AND METHODS

Patients

After the ethical committee board approval, we designed a retrospective study for OPN patients performed between 2002 and 2020 for localized RCC at our center. Due to limited access to the previous hospital patient record system, patients who underwent OPN between 1996 and 2001 were excluded. The analysis was done with a total of 182 patients.

Pathological and clinical variables

Patient demographics included age, gender, comorbidities (presence of Diabetes Mellitus and hypertension), *estimated glomerular filtration rate* (eGFR), *American Society of Anesthesiology* (ASA) score, incidence of solitary kidney, and *Charlson Comorbidity Index* (CCI).

To assess tumor complexity RENAL score was used, which considers the size, location, depth, and exophytic characteristics of the tumor. The RENAL score is catego-

No conflict of interest declared.

rized as low score (4-6), moderate score (7-9), and high score (10-12). Tumor characteristics considered included tumor size, pathological T stage, histology (including subtype), and Fuhrman-ISUP Grade. Nuclear tumor grading was performed using Fuhrman-ISUP nuclear grading system and grades were classified as low grade (1-2) and high grade (3-4). All histological specimens were analyzed by our institution's dedicated urological pathologists.
Main intraoperative parameters such as insertion of DJS, operation time, cold and *warm ischemia time* (CIT, WIT), *estimated blood loss* (EBL), intraoperative blood transfusion and complication rates were recorded.
Postoperative variables included were 30-day postoperative complication rate, length of hospital stay, and 30-day readmission rate. Clavien-Dindo classification system (10) was used for grading complications that were characterized as minor complications (Clavien 1-2) and major complications (Clavien 3-5).
Preoperative and postoperative functional results were assessed by using serum creatinine, and MDRD formula to calculate eGFR (11). eGFR preservation was defined as follow-up postoperative eGFR divided by preoperative eGFR x 100. *Chronic kidney disease* (CKD) was defined as GFR < 60 mL/min/1.73m^2.

Surgical technique

In most patients, DJS was inserted immediately after induction in the lithotomy position. Under the cystoscopy guidance 4.8 French DJS placement through guidewire was performed under fluoroscopic guidance. In a small proportion of these patients DJS insertion was performed immediately after PN at the surgeon's discretion. In the remaining patients PN was performed without insertion of DJS. We used extraperitoneal flank approach. Ice slush was used for parenchymal cooling in almost all cases. In a small proportion of the cases non-ischemic PN was performed without clamping the renal artery. During PN, all renal tumors were excised with sufficient resection margin. The defect was closed with two layers of suture method, one to close the bleeding vessels and collecting system, the other to approximate the parenchyma over reconstructed fat pad (12). A single surgical drain (Jackson-Pratt drain) was inserted at the operative site. In patients who had intraoperative DJ stent placement, urethral catheter was removed at postoperative (PO) 5th day. In these patients, the Jackson-Pratt was removed next day if the drain output was not increased after a day period of ureteral urine reflux within the DJ stent during active voiding.
This was a kind of DJ stent reflux test developed by one of us (OD) to make sure that the collecting system was completely closed. In other cases, the Jackson-Pratt was removed on the 3rd PO day, provided that the output was less than 50 cc per 24 hours.

Outcomes

Urinary leakage was defined as a biochemical analysis consistent with urine persisting for more than 72 hours and/or a radiology finding suggestive of urine leakage.
As a routine procedure, in patients with no complications, DJSs were removed from the patients on the third week after surgery under local anesthesia. For the purposes of this study, according to intraoperative DJS placement, the patients were divided into two groups. Perioperative postoperative outcomes, and clinicopathologic characteristics were compared between the two groups (DJS+ *vs.* DJS-). Furthermore, to determine the variables associated with urinary leakage after OPN, univariate and multivariate logistic regression analyses were performed.

Statistical analysis

For variables with normal distribution, the data are expressed as mean ± SD. Chi-squared test was used to compare categorical variables. For non-normal distributed variables, we presented the data as median [*interquartile range* (IQR)] and compared the respective groups with Mann-Whitney U-test. All analyzes were made within 95% confidence interval and the $p < 0.05$ value was accepted as significant. For the analysis SPSS v23 (*IBM SPSS Statistics, Armonk, NY, USA*) was used.

Results

In the analysis, a total of 182 patients were included. OPN was technically successful in all cases using a retroperi-

Table 1.
Patient's demographics, tumor characteristics, and surgical outcomes.

Variables	Total open partial nephrectomy (n = 182)
Age years; mean (± SD)	54.4 (± 10.8)
Male; n (%)	79 (43.4)
White race; n (%)	182 (100)
BMI; mean (± SD)	28.3 (± 5.3)
CCI; med (IQR)	1 (0-1)
ASA; med (IQR)	2 (2-2)
Diabetes; n (%)	51 (28)
Hypertension; n (%)	90 (49.5)
Prior abdominal surgery; n (%)	48 (26.4)
Solitary kidney; n (%)	6 (3.3)
Pre-op eGFR; med (IQR)	96 (82.4-105.9)
R.E.N.A.L score; med (IQR)	6 (5-8)
Tumor size, cm; mean (±SD)	3.1 (± 1.2)
Surgical approach; n (%)	
Retroperitoneal	180 (98.9)
Operation time, min; med (IQR)	240 (180-240)
Double-J stent; n (%)	109 (60)
Routinely (Pre-PN)	95 (52.3)
As required (Post-PN)	14 (7.7)
None	73 (40)
EBL, ml.; med (IQR)	400 (300-600)
Technique of ischemia; n (%)	
Warm	15 (8.2)
Cold	161 (88.5)
Zero	6 (3.3)
Ischemia time, minutes; mean (±SD)	26.1 (± 7.7)
Intraoperative complication; n (%)	10 (5.5)
Intraoperative transfusion; n (%)	52 (28.6)
Urine leak; n (%)	14 (7.6)
Length of stay, days; med (IQR)	5 (4-7)
Follow up times, months.; med (IQR)	42 (21.3-84.6)

ASA: American Society of Anesthesiologists; BMI: Body mass index; CCI: Charlson comorbidity index; eGFR: Estimated glomerular filtration rate; EBL: Estimated blood loss; IQR: Interquartile range; OPN: Open partial nephrectomy; SD: Standard deviation.

Table 2.
Comparison of patients and tumor characteristics between pre-PN Double-J insertion and no insertion populations.

	DJS+ (n = 109)	DJS- (n = 73)	P value
Age, years; mean (± SD)	53.8 (±10.9)	55.3 (±10.8)	0.38
Male; n (%)	59 (54.1)	44 (60.3)	0.44
BMI; mean (±SD)	28.1 (±5.8)	28.7 (4.5)	0.54
CCI; med (IQR)	1 (0-1)	1 (0-2)	0.09
ASA; med (IQR)	2 (2-2)	2 (2-2)	0.8
Diabetes; n (%)	33 (30.3)	18 (24.7)	0.5
Hypertension; n (%)	55 (50.4)	35 (47.9)	0.8
Prior abdominal surgery; n (%)	27 (24.8)	21 (28.8)	0.6
Solitary kidney; n (%)	3 (2.8)	3 (4.1)	0.6
Pre-op eGFR; med (IQR)	96.6 (87.2-107.3)	94.3 (78.8-101)	0.03
Tumor size, cm; mean (± SD)	3.2 (±1.1)	3 (±1.3)	0.26
Side, right; n (%)	67 (60.5)	43 (58.9)	0.7
Cystic lesion; n (%)	30 (33)	16 (33.3)	1
Hilar location; n (%)	2 (2.3)	2 (4.5)	0.6
R.E.N.A.L score; med (IQR)	6 (5-8)	5 (5-7)	0.26
R.E.N.A.L complexity; n (%)			
Simple (4-6)	53 (60.2)	28 (65.1)	
Intermediate (7-9)	33 (37.5)	15 (34.9)	0.5
Complex (10-12)	2 (2.3)	0	
(R)adius, max diameter in cm; n (%)			
≤ 4	87 (80.6)	59 (83.1)	
> 4 but < 7	20 (18.5)	20 (15.5)	0.8
≥ 7	1 (0.9)	1 (0.6)	
(E)xophytic/Endophytic; n (%)			
≥ 50%	42 (47.7)	25 (58.1)	
< 50%	41 (46.6)	16 (37.2)	0.5
Entirely endophytic	5 (5.7)	2 (1.5)	
(N)earness of the tumor to pelvicalyceal system or renal sinus; mm			
≥ 7	41 (46.6)	18 (41.9)	
> 4 but < 7	26 (29.5)	15 (34.9)	0.8
≤ 4	21 (23.9)	10 (23.3)	
(L)ocation relative to the polar lines, points; n (%)			
1	45 (51.1)	26 (60.5)	
2	21 (23.9)	14 (32.6)	0.04
3	22 (25)	3 (2.3)	

ASA: American Society of Anesthesiologists; BMI: Body mass index; CCI: Charlson comorbidity index; eGFR: Estimated glomerular filtration rate; IQR: Interquartile range; OPN: Open partial nephrectomy; SD: Standard deviation.

toneal approach. Of these, 95 (52.3%) had DJS insertion immediately after induction of general anesthesia, 14 (7.7%) had DJS inserted immediately after performance of the OPN while in the other 73 (40%) patients PN was performed without insertion of a DJS. Thus, 109 (60%) of patients had a DJS inserted.

Table 1 summarizes the main demographical and clinical outcomes for the entire series.

Apart from higher preoperative eGFR values among patients with DJS+ compared to the DJS- (96.6 *vs* 94.3 mL/min; p = 0.03), demographic variables were similar (Table 2). No statistically significant differences were seen in RENAL nephrometry score (p = 0.26) and tumor size (p = 0.26). Tumors in the DJS+ group presented with a high L score (p = 0.04).

Between the two groups estimated blood loss (p = 0.12), intraoperative complication (p = 0.71), and transfusion rates (p = 0.4) were not significantly different (Table 3). Patients in the DJS+ group had significantly longer ischemia times (31 *vs.* 23 min; p = 0.02). In addition, DJS+ group patients had a longer length of stay due to reflux test (6 *vs.* 5 days; p = 0.04). Postoperative (p = 0.74) complication rates were similar between groups (p = 0.74) (Table 3). Urinary leakage was seen in 7.6% (n = 14) of all patients, and it did not differ according to DJS placement (DJS+ 9.2 *vs.* DJS- 5.5%; p = 0.41).

On univariate analysis, neither DJS stenting rates nor urine leakage rates were associated with distribution of cases by years (Supplementary Table 1).

On univariate analysis, RENAL nephrometry score (OR= 1.39; p = 0.04) and tumor nearness (proximity) to the collecting system (p = 0.04) had a significantly higher probability of experiencing urine leak (Table 4) whereas it was observed that intraoperative DJS placement did not have significant effect on urine leak (OR = 1.74; p = 0.36). On multivariate analysis, the tumor nearness to the collecting system was the sole independently significant factor (p = 0.04) predicting postoperative urine leak.

Table 3.
Comparison of pre-PN Double-J insertion and no insertion populations.

	DJS+ (n = 109)	DJS- (n = 73)	P value
Intraoperative variables			
Operation time, min; med (IQR)	240 (180-240)	220 (180-220)	0.3
EBL, ml.; med (IQR)	400 (300-525)	500 (262-900)	0.12
Ischemia time, min; mean (± SD)	31 (± 5.9)	23 (± 7.4)	0.02
Use of hemostatic agents; n (%)	11 (10.1)	6 (8.2)	0.79
Intraoperative complication; n (%)	7 (3.8)	3 (4.1)	0.71
Intraoperative transfusion; n (%)	29 (26.6)	23 (31.5)	0.4
Postoperative variables			
Length of stay, days; med (IQR)	6 (5-7)	5 (4-6)	0.04
Postoperative transfusion; n (%)	7 (6.4)	7 (9.6)	0.57
ES Units; med (IQR)	2 (1-3)	2 (1-2)	
Need for post-op angioembolisation, n (%)	1 (0.9)	1 (1.4)	0.64
Overall post-op complications; n (%)	31 (28.4)	23 (31.5)	0.74
Major (Clavien-Dindo 3-5)	6 (5.4)	7 (9.4)	
Minor (Clavien-Dindo 1-2)	25 (23)	16 (22.1)	
Acute kidney injury; n (%)	13 (12)	14 (19.7)	0.16
Readmission for urologic reasons; n (%)	7 (6.4)	4 (5.4)	0.81
< 30 days	4 (3.6)	3 (4.1)	
≥ 30 days	3 (2.2)	1 (1.3)	
Urine leak; n (%)	10 (9.2)	4 (5.5)	0.41
Malignant disease; n (%)	89 (81.7)	56 (80)	0.84
Pathological tumor stage; n (%)			0.1
T1a	91 (85)	56 (82.4)	
T1b	16 (15)	8 (11.8)	
T2a	0	1 (1.5)	
T3a	0	3 (4.4)	
Positive surgical margin; n (%)	4 (3.7)	1 (1.4)	0.1
Fuhrman/ISUP grade; n (%)			0.36
Low FG (1-2)	68 (80)	47 (87)	
High FG (3-4)	17 (20)	7 (13)	
Follow up times, months; med (IQR)	27.7 (12.6-53.4)	51 (9.1-113)	0.02
Latest eGFR; med (IQR)	89 (70.4-102.9)	83.7 (70.7-96)	0.16
Latest follow up eGFR preservation; % med (IQR)	93.1 (82.2-99.3)	92.3 (80-99.6)	0.94

EBL: Estimated blood loss; ES: Erythrocyte suspension; FG: Fuhrman grade; ISUP: International Society of Urological Pathology; eGFR: Estimated glomerular filtration rate; IQR: Interquartile range; SD: Standard deviation..

Supplementary Table 1.
Distribution of urine leakage and DJ stenting by years.

Variables	Urine leakage (+) 14 (7.6%)	Urine leakage (-) 168 (92.4%)	P value	DJS (-) 73 (40.1%)	DJS (+) 109 (59.9%)	P value
Total cases			0.8			0.1
2002 (n = 1)	0	1 (100)		1 (100)	0	
2004 (n = 2)	0	2 (100)		2 (100)	0	
2006 (n = 4)	0	4 (100)		4 (100)	0	
2007 (n = 3)	0	3 (100)		3 (100)	0	
2008 (n = 9)	1 (11.1)	8 (88.9)		3 (33.3)	6 (66.6)	
2009 (n = 7)	0	7 (100)		3 (42.8)	4 (57.2)	
2010 (n = 6)	0	6 (100)		3 (50)	3 (50)	
2011 (n = 9)	1 (11.1)	8 (88.9)		3 (33.3)	6 (66.6)	
2012 (n = 13)	1 (7.7)	12 (92.3)		6 (46.2)	7 (53.8)	
2013 (n = 8)	2 (25)	6 (75)		3 (37.5)	5 (62.5)	
2014 (n = 11)	2 (18.2)	9 (81.8)		4 (36.3)	7 (63.7)	
2015 (n = 15)	2 (13.3)	13 (86.7)		5 (33.3)	10 (66.6)	
2016 (n = 14)	0	14 (100)		5 (35.8)	9 (64.2)	
2017 (n = 18)	1 (5.6)	17 (94.4)		6 (33.3)	12 (66.6)	
2018 (n = 28)	2 (7.1)	26 (92.9)		8 (29.6)	20 (71.4)	
2019 (n = 30)	2 (6.7)	28 (93.3)		12 (40)	18(60)	
2020 (n = 4)	0	4 (100)		2 (50)	2 (50)	

Table 4.
Logistic regression analysis for predicting urine leakage after partial nephrectomy.

	Univariate			Multivariate		
	OR	95 % CI	P value	OR	95 % CI	P value
Age	1.05	0.97-1.08	0.15	1.02	0.97-1.08	0.34
Female	Ref					
Male	1.02	0.34-3.08	0.96			
BMI (continuous variable)	0.93	0.82-1.07	0.35			
Tumor size (per cm)	1.18	0.80-1.74	0.39			
Baseline eGFR (per mL/min/1.73m^2)	0.99	0.97-1.02	0.9			
Ischemia time (per min)	1.07	0.82-1.39	0.6			
Pre-op hypertension	1.04	0.38-1.14	0.97			
Pre-op diabetes mellitus	1.03	0.3-3.4	0.96			
CCI = 0	Ref					
CCI > 0	1	0.33-3	1			
R.E.N.A.L score (continuous variable)	1.39	1.00-1.93	0.04			
Exophytic/endophytic			0.88			
≥ 50%	Ref					
< 50%	1.19	0.36-3.9				
Entirely endophytic	1.69	0.17-16.5				
Nearness			0.04			0.04
≥ 7	Ref			Ref		
> 4 but < 7	9.9	1.14-86.5	0.03	9.8	1.14-85.9	0.03
≤ 4	13.9	1.5-121.7	0.01	15.7	1.76-140.7	0.01
Location, relative to polar lines						
1	Ref					
2	1.39	0.36-5.3				
3	1.47	0.34-6.4				
Double J stent + (vs. -)	1.74	0.52-5.7	0.36			
Estimated blood loss (continuous variable)	1	0.99-1	0.8			
Ischemia time, (continuous variable)	1.07	0.82-1.39	0.6			
Intraoperative transfusion+	1.98	0.65-6.04	0.2			

BMI: Body mass index; CCI: Charlson comorbidity index; eGFR: Estimated glomerular filtration rate.

Discussion

The RCC incidence has increased in the last four decades; beginning from the mid 90's there has been a more rapid increase in diagnosis (13). PN is the preferred method in the treatment of small renal tumors (1) and the clinical target is to leave as much functional renal parenchyma as possible, without obviating the oncological principles. With increasing surgical experience, larger and deeper infiltrating lesions were also approached, requiring surgical access to the pelvicalyceal system to ensure adequate margins of tumor resection.

Incomplete repair of the collecting system during renorraphy causes urine leak which most probably results in considerable morbidity (14-17).

In this study, we evaluated the impact of intraoperative routine DJS placement on urinary leakage after OPN.

The incidence rate of urine leakage reported after PN varies between institutions. In the current study, urinary leakage occurred in 7.6% of the patients. In early OPN series the rate of urine leakage was reported to average 6.5%, ranging from 2.1-17% (18, 19). In the new PN series, the rate of urine leakage is around 1-5% (15, 20, 21). The clinical management of urine leakage after PN varies from patient to patient (22). Follow-up with serial imaging options is the most preferred approach. Another option, ureteral stent insertion, creates a low-pressure system facilitating urine drainage from the collection system and that promotes healing. Patients may need percutaneous drainage or repeat surgical intervention when they have complex urine leaks (23). In addition, minimally invasive techniques are a safe option to resolve urinary leakage after PN. Application of gelatin sponge (*Spongostan®*) and N-butyl2 cyanoacrylate improves results without increasing the risk of urinary obstruction, especially in the cases of persistent urine leakage (24).

In the present study, preoperative DJS placement did not significantly reduce the incidence of urinary leakage after PN.

For each patient DJS ureteral catheterization in our clinic is at the surgeon's own discretion. As described above, preoperative DJS placement was a part of DJS reflux test to make sure that the collecting system was completely closed. In patients who had positive DJS reflux test (increased drain urine output following Foley removal), a new Foley catheter was placed again to wait for sufficient time for the self-sealing of the collecting system, during which a number of intervals retrograde testing pyelography were performed. It was observed that use of a DJS, which was usually placed as a treatment when a urinary leak developed, did not prevent urinary leakage when applied before surgery. At the same

time, although not statistically significant, DJS inserted patients tended to have more urinary leakage compared to the group that was not inserted although the difference was not significant. It could be suggested that making a preoperative clinical decision to place a DJS, based on surgeon preference and tumor complexity, may create a bias in the analysis. However, we believe that there is no such bias because of both groups are comparable in terms of patient and tumor characteristics.

During PN routine ureteral catheterization has been used to reduce the risk of urine leakage in open, laparoscopic, and robotic cases (7, 9, 25-27). In these studies, it was reported that ureteral catheterization did not reduce the risk of urinary leakage after PN. Common feature for these studies, and the difference between these and our study, was that if there was no evidence of urinary leakage, the ureteral catheter was generally removed within two days postoperatively. As far as we know, we report the first study to evaluate the impact of intraoperatively inserted long term DJS on urinary leakage after PN. Our results showed that OPN patients who had a DJS inserted can safely be discharged because the rate of urine leakage is similar in these patients compared to patients who did not have.

We found that urine leakage following OPN was associated with tumor characteristics, rather than DJS insertion, consistent with previous reports (5, 28). In our multivariate analysis, nearness of the tumor to the collecting system was the sole independently significant factor predicting urine leakage. This is intuitively reasonable and is thus not an unexpected result. In a considerable proportion of the operations it is not possible to completely remove these tumors without entering the collecting system; inherently, likelihood of later urine leakage increases in such cases. This relationship has been reported previously (15, 29).

Our study does have some limitations, including its retrospective, non-randomized, single institution design. In addition, as there was a small number of events, multivariable analysis was limited. Therefore, our results need to be verified in a large, prospective, multi-institutional studies. In addition, our findings may have limited applicability to other settings because OPN was performed using a single technique. In this context, the effect of surgical technique should also be evaluated in any future study. Despite these limitations, and although generally not used routinely and mostly used only for therapeutic purposes in the presence of urinary leak, we think our results answer the question of the association between routine DJS application in OPN and the risk of urinary leakage.

Conclusions

Routine intraoperative DJS insertion during PN does not appear to reduce the probability of postoperative urine leak.

It causes additional costs and does not eliminate the risk of urine leakage but may provide a reasonable means to test urine leakage (DJS reflux test) which allows for safety Foley catheter reinsertion before the patient had been discharged.

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