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Foley catheter-assisted six-step thrombectomy technique in the surgical management of renal cell carcinoma with Mayo level II to IV tumor thrombus

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Abstract

Objective: To simplify Foley catheter-assisted thrombectomy to a six-step approach and determine the feasibility and results of this technique for renal cell carcinoma (RCC) with a Mayo level II to IV tumor thrombus (TT).

Methods: The surgical records of patients with RCC with a Mayo level II to IV TT treated in our hospital were retrospectively reviewed. Fifteen patients who underwent radical nephrectomy and thrombectomy with a Foley catheter-assisted procedure were included. Epidemiological and clinicopathological features, operation-related variables, and outcomes were evaluated.

Results: The TTs in all 15 patients were successfully retracted by the Foley catheter. The mean operation time was 420.1 ± 108.9 minutes. The mean intraoperative blood loss and perioperative red blood cell transfusion volumes were 1846.7 ± 1467.8 and 1288.7 ± 1060.6 mL, respectively. Five patients had perioperative complications. The median follow-up time was 9 (range, 0–34) months, and four patients died of the disease.

Conclusions: Simplification of Foley catheter-assisted thrombectomy to a six-step approach results in the probability of avoiding thoracotomy or cardiopulmonary bypass to a certain degree and is associated with fewer complications, less blood loss, and less perioperative red blood cell transfusion. However, experienced surgeons and multidisciplinary cooperation are still needed.

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Keywords
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Background

Renal cell carcinoma (RCC) represents 2% to 3% of all cancers, and its incidence has increased by about 2% during the past two decades in Western countries[1,2] as well as in China. Moreover, 4% to 10% of patients with RCC have venous invasion, which can extend into the inferior vena cava (IVC) and up to the right atrium.[3] For these patients, radical nephrectomy with thrombectomy appears to be the gold standard treatment, which offers the potential for cure with a 5-year cancer-specific survival rate of 40% to 65%.[4,5] However, this surgical procedure remains extremely challenging even for highly experienced surgeons.

In 2004, the Mayo clinic published a guideline regarding the tumor thrombus (TT) level according to the position of the TT in cases of venous invasion, revealing that different TT levels might require different surgical methods. Mayo level III and IV thrombi require thoracotomy and even cardiopulmonary bypass (CPB), which remains a surgical problem because it is a more difficult process with increased intraoperative bleeding.[6] Previous studies have shown a postoperative complication rate of 47% and mortality rate of up to 15%.[6–8]

The Foley catheter-assisted technique, which helps to avoid a complex operation, was first described by Musiani[9] in 1977. The author suggested that the risks of embolic dissemination and cardiocirculatory complications were decreased when using this technique. In 2015, Sobczyński et al.[8] also described four patients who underwent cavoatrial thrombectomy using the Foley catheter-assisted technique without CPB with few perioperative complications. To the best of our knowledge, however, only preliminary reports of this surgical technique involving few patients are available, and they lack further validation. Therefore, we herein present our clinical experience managing 15 patients with RCC and a Mayo level II to IV TT using the Foley catheter-assisted technique, which obviates the need for thoracotomy or CPB to a certain degree. We also analyzed the feasibility of this procedure and assessed the patients' outcomes.

Materials and methods

Patient selection

We retrospectively reviewed the surgical records of patients with RCC and a Mayo level II to IV TT treated in our hospital from April 2015 to January 2018. Patients who underwent radical nephrectomy and thrombectomy with the Foley catheter-assisted procedure were included, and patients with incomplete medical records were excluded.

Epidemiological and clinicopathological features

All patients' epidemiological data and clinical history were collected. All patients underwent preoperative routine blood examinations, chest radiography, electrocardiography, abdominal enhanced computed tomography (CT) or magnetic resonance imaging (MRI), and contrast-enhanced IVC ultrasonography. The venous TT was identified in the preoperative radiological examination and confirmed during the operation. The level of the IVC TT was classified by the Mayo clinic level[6] according to the extension of the thrombus. The preoperative distant metastasis status was routinely confirmed by chest X-ray or CT, abdominal ultrasound, and bone scans.

Before surgery, a multidisciplinary team including specialists from the urology, general surgery, cardiac surgery, anesthesiology, and radiology departments performed a comprehensive assessment of the patient. The American Society of Anesthesiologists classification was used to classify the patients' physical condition and surgical risk.[10] The following clinical features and operation-related variables were collected: age, sex, body mass index, Mayo TT level, tumor location, tumor size, operation time, blood loss, perioperative red blood cell transfusion, histology, tumor grade, hospital stay, and complications. The modified Clavien grading system[11] was used to evaluate the postoperative complications. Grade >III complications were considered serious.[12] The postoperative specimens were evaluated by two experienced pathologists in our institution. Pathological features including histology and tumor grade were also reviewed according to the 2016 World Health Organization (WHO) classification.[13]

Surgical strategy

The patients were placed in the supine position after induction of general anesthesia. For patients with right RCC, a Chevron incision was made from the xiphoid process to the midaxillary line 2 cm below the right subcostal region and then extended to 5 cm below the left subcostal region. For patients with left RCC, an incision symmetric to the above-described incision was made. The surgical technique of radical nephrectomy was performed using routine procedures; i.e., exposing the blood vessels of the renal portal system, ligating the renal artery and ureter, freeing the kidney along the perirenal fascia, and exploring the adrenal gland. Foley catheter-assisted thrombectomy consists of the six steps described below.

Step 1: Preparation of vascular block

The distal IVC and the uninjured side of the renal vein are freed and exposed for blocking. Exposure of the retrohepatic segment of the IVC should be differentiated according to the Mayo TT levels. For a Mayo level II TT, several short hepatic veins must be cut off, and the long IVC must be dissociated for blocking. For a Mayo level III TT, more tissues should be cut, including the round ligament, triangular ligament, falciform ligament, and coronary ligament of the liver. The liver is then mobilized to completely show the retrohepatic segment of the IVC. The vessels of the porta hepatis should first be dissociated to prepare for blocking in the next step. For a Mayo level IV TT without entrance to the atrium, the central tendon of the diaphragm should be freed or cut off to expose the proximal part of the IVC for blocking; thoracotomy is not included in this technique. However, if the TT enters the atrium, a thoracoabdominal midline incision is necessary, and the "milking" technique is carried out to squeeze the intra-atrial TT back into the IVC.

Step 2: Vascular block

A rubber band is used to successively block the distal IVC and left renal vein. For patients with a Mayo level III or IV TT, the vessel of the first porta hepatis should be blocked, but not the proximal end of the IVC.

Step 3: IVC incision and Foley catheter-assisted thrombectomy

The IVC wall is cut using scissors along the long axis of the IVC on the dorsal part of the junction of the affected renal vein and IVC. A Foley catheter is then inserted and palpated until it exceeds the proximal end of the TT; normal saline is injected into the air balloon. Transesophageal echocardiography (TEE) guidance is needed to ensure that the catheter balloon transcends the proximal end of the TT. The TT is retracted from the IVC with the inflated balloon of the Foley catheter by softly pulling the catheter downward. The IVC wall should be removed if the TT has invaded it. Moreover, segmental resection of the IVC should be performed when invasion of the IVC wall is wide.

Step 4: Blocking of proximal part of the IVC

When the proximal end of the IVC is retracted by the Foley catheter below the block band of the IVC, bleeding is reduced and the TT is prevented from falling off because the proximal end of the IVC is blocked. For a Mayo level III or IV TT, the block band of the first hepatic portal vein can be removed at this time instead of after suturing the IVC wall.

Step 5: IVC suture

After removing the TT, the IVC should be rinsed with heparin saline and sutured using polypropylene vascular suture in a continuous pattern. Before suturing of the IVC wall is complete, the IVC lumen should be rinsed again with heparin saline to ensure the thrombus has been completely removed.

Step 6: Vascular decompression

The blocked uninjured side of the renal vein and the distal and proximal ends of the IVC can be removed successively. After meticulous hemostasis, surgical drains are left in place and the incision is closed in layers routinely.

Follow-up

In the present study, follow-up laboratory, chest radiography, urinary ultrasonography, and enhanced CT/MRI examinations were performed every 3 months for the first 2 years, every 6 months until year 5, and annually thereafter. The co-primary endpoints of the study were local recurrence, distant metastasis, cancer-specific death, and all-cause mortality. Appropriate treatments, such as targeted therapy, were provided in cases of local recurrence or distant metastasis.

Statistical analysis

All statistical analyses were performed using the IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA), and the results are expressed using descriptive statistics (mean $\pm$ standard deviation, median, and range).

Ethics

This study was approved by the institutional ethics committee of our hospital. Informed consent was obtained from all individual participants included in the study. The patients' information was anonymized prior to analysis. Informed consent was obtained from all individual participants included in the study, and all patients provided consent for publication.

Results

The patients' clinicopathological and operative characteristics are presented in Table 1, and the detailed information is shown in Table 2. Fifteen patients with RCC with a TT were included in the

Table 1. Patients' clinicopathological and operative characteristics.

Variables	Value
Number of patients	15
Age, years	52.2 ± 22.4 (median, 59.0)
Sex	
Male	10 (66.7)
Female	5 (33.3)
Body mass index, kg/m^2	21.9 ± 3.1
Mayo clinic TT level	
II	3 (20.0)
III	7 (46.7)
IV	5 (33.3)
Preoperative serum Cr, μmol/L	93.7 ± 29.3
Postoperative serum Cr, μmol/L	132.0 ± 178.8
Location	
Left	5 (33.3)
Right	10 (66.7)
Tumor size, cm	8.7 ± 2.5
ASA score, n(%)	
I	1 (6.7)
II	8 (53.3)
III	5 (33.3)
IV	1 (6.7)
Operation time, minutes	420.1 ± 108.9
Intraoperative blood loss, mL	1846.7 ± 1467.8
Perioperative red blood cell transfusion, mL	1288.7 ± 1060.6
Lymphadenectomy	
No	7 (46.7)
Yes	8 (53.3)
Adrenalectomy	
No	5 (33.3)
Yes	10 (66.7)
Histology	
Clear cell RCC	9 (60.0)
Papillary RCC	3 (20.0)
Nephroblastoma	2 (13.3)
Xp11.2 translocation/TFE3 gene fusion RCC	1 (6.7)
WHO/ISUP grading system	
2	2 (13.3)
3	8 (53.3)
4	3 (20.0)
n/a	2 (13.3)
Clavien classification	
<III	13 (86.7)
≥III	2 (13.3)
Length of hospital stay, days	13.1 ± 4.4 (median, 13)
Follow-up time, months	9 (0–34)
Local recurrence	
No	14 (93.3)
Yes	1 (6.7)
Distant metastasis	
No	12 (80.0)
Yes	3 (20.0)
Adjuvant therapy	
No	7 (46.7)
Yes	8 (53.3)

Data are presented as n (%), mean ± standard deviation, or median (range).
TT, tumor thrombus; Cr, creatinine; ASA, American Society of Anesthesiologists; RCC, renal cell carcinoma; WHO, World Health Organization; ISUP, International Society of Urological Pathology.

study (mean age, 52.2 ± 22.4 years). The preoperative and postoperative serum creatinine values were 93.7 ± 29.3 and 132.0 ± 178.8 μmol/L, respectively, and there was no significant difference between these two groups. All 15 patients underwent radical nephrectomy with thrombectomy, and the TT was successfully retracted by the Foley catheter. With respect to the operation-related data, the mean operation time was 420.1 ± 108.9 minutes, and the mean intraoperative blood loss and perioperative red blood cell transfusion volumes were 1846.7 ± 1467.8 and 1288.7 ± 1060.6 mL, respectively. Five patients had perioperative complications: one patient died, one patient developed venous thrombosis of the lower extremities, one patient developed a pulmonary infection, one patient developed anemia, and one patient developed anemia and renal failure. According to the Clavien classification, three patients had grade <III complications, and the other two had grade IVa and V complications, respectively. The mean hospital stay was 13.1 ± 4.4 days.

Table 2. Patients' clinicopathological and operative characteristics in detail.

Number	Sex	Age (years)	BMI (kg/m^2)	Mayo TT classification	Preoperative serum Cr (μmol/L)	Side	Tumor size (cm)	ASA score	Duration of surgery (minute)	Intraoperative blood loss (mL)	Perioperative red blood cell transfusion (mL)	Adrenalectomy
1	Male	62	23.3	IV (enter the atrium)	126	Left	5.8	3	589	2800	3200	Yes
2	Female	63	22.4	II	153	Right	6.2	2	258	300	400	No
3	Female	52	19.9	III	82	Right	8.3	2	272	1550	1200	Yes
4	Male	57	21.0	IV	92	Left	6.9	2	558	2000	1200	Yes
5	Male	50	24.8	III	85	Right	5.8	3	374	300	0	Yes
6	Male	71	28.0	III	133	Right	7.2	3	372	3000	1600	Yes
7	Male	2.5	17.3	II	43	Right	8.4	2	248	50	130	No
8	Male	59	23.4	III	108	Right	10.0	3	445	1500	1200	Yes
9	Male	69	22.0	II	122	Right	10.0	3	435	4000	2400	Yes
10	Female	55	24.8	III	79	Left	8.3	2	541	3000	1600	Yes
11	Male	68	21.7	III	84	Right	7.6	2	376	2000	2000	Yes
12	Female	69	25.1	IV (enter the atrium)	67	Left	10.9	2	515	5000	3200	Yes
13	Female	15	17.3	III	67	Right	13.0	1	372	600	0	No
14	Male	74	19.1	IV	75	Left	7.5	2	443	800	400	No
15	Male	17	18.9	IV	89	Right	14.0	4	504	800	800	No

TT, tumor thrombus; Cr, creatinine; ASA, American Society of Anesthesiologists; WHO, World Health Organization; ISUP, International Society of Urological Pathology.

Table 2. Continued

Number	Histology	2016WHO/ ISUP grading system	Hospital stay (days)	Postoperative serum Cr at 1 week (μmol/L)	Complication	Clavien classification	Survival status	Local recurrence	Distant metastasis	Adjuvant therapy
1	Clear cell RCC	3	14	86	Dead	V	Dead	No	No	No
2	Clear cell RCC	2	9	125	–	–	Alive	No	No	Targeted therapy
3	Clear cell RCC	3	14	94	–	–	Dead	Yes	Lung	No
4	Papillary RCC	3	9	111	–	–	Alive	No	Lung	Targeted therapy
5	Clear cell RCC	3	13	116	Venous thrombosis of lower extremities	II	Alive	No	No	Targeted therapy
6	Clear cell RCC	3	12	112	–	–	Loss	No	No	No
7	NB	n/a	15	32	Pulmonary infection	II	Alive	No	No	Targeted therapy
8	Papillary RCC	2	10	87	–	–	Dead	No	No	Targeted therapy
9	Clear cell RCC	4	9	772	Anemia and renal failure	IVa	Dead	No	No	No
10	Clear cell RCC	4	17	79	–	–	Loss	No	No	No
11	Papillary RCC	3	15	75	Anemia	II	Alive	No	No	Targeted therapy
12	Clear cell RCC	3	25	85	–	–	Alive	No	Lung	No
13	Xp11.2 translocation/ TFE3 gene fusion RCC	4	14	48	–	–	Alive	No	No	Targeted therapy
14	Clear cell RCC	3	7	93	–	–	Alive	No	No	Targeted therapy
15	NB	n/a	13	65	–	–	Alive	No	No	No

TT, tumor thrombus; Cr, creatinine; ASA, American Society of Anesthesiologists; WHO, World Health Organization; ISUP, International Society of Urological Pathology; NB, nephroblastoma.

Among all patients, histological examination showed that nine patients had clear cell RCC, three had papillary RCC, two had nephroblastoma, and one had Xp11.2 translocation/TFE3 gene fusion. According to the WHO/International Society of Urological Pathology grading system, two cases were graded as 2, eight as 3, and four as 4.

The median follow-up time was 9 (range, 0–34) months. During the follow-up period, two patients were lost to follow-up and four patients died of their disease. One patient developed local recurrence and three patients developed distant metastasis, all of which were lung metastases.

Discussion

Radical nephrectomy with tumor thrombectomy is a clinically important and widely available therapeutic measure in patients with RCC thrombus propagation into the IVC.[14,15] During the past few years, several surgical approaches have been developed to resect TT with less surgical difficulty and fewer perioperative complications. However, there is still no standard surgical procedure, and surgeons may therefore follow a different surgical process. In a review of the published literature, various techniques of performing suprahepatic IVC thrombectomy were identified, including the "milking" technique to retract the TT,[16] Foley catheter placement[8,9] under constant TEE guidance, and Fogarty catheter placement[17] with or without CPB. For Mayo level III and IV TT, hepatic mobilization and CPB with or without deep hypothermic circulatory arrest are needed.[6,18] However, in this procedure, the mortality rate may reach 33% with a 40% risk of postoperative complications, including platelet dysfunction,[19] neurological dysfunction,[20] renal failure, sepsis, cerebrovascular accidents, and pulmonary embolus.[21–23] Thus, a readily available and standard surgical procedure should be performed to markedly reduce the risk of complications and adverse effects of TT resection.

In previous studies, Kundavaram et al.[24] and Chopra et al.[25] reported an intracaval Fogarty balloon-assisted technique and described the surgical procedure in patients with Mayo level II and III TT. The Foley catheter and Fogarty balloon are similar, but different. The Foley catheter is less expensive and easier to obtain in the clinical setting. Sobczyński et al.[8] published a preliminary report of four patients with RCC patients with a TT who underwent Foley catheter-assisted thrombectomy. In their cases, the mean operative blood loss and intraoperative red blood cell transfusion volumes were comparable with or better than those reported in other studies for a Mayo level III or IV TT. As in our study, their patients required constant TEE guidance. However, the aim of using TEE guidance in our study was to ensure that the position of the balloon catheter was above the proximal end of the TT, not to monitor the entire process, suggesting that this method is also safe. Certainly, constant TEE guidance appears to have more security without considering the operation time and cost. Compared with that previous study, this surgical technique was performed in more patients in the present study, and we observed less intraoperative blood loss and perioperative red blood cell transfusion. The mean length of hospital stay in our study was also low, suggesting better postoperative recovery. In contrast, compared with previous studies of Mayo level III or IV TT treated with general surgical procedures,[26–28] we also found that the Foley catheter-assisted technique showed advantages in terms of the estimated blood loss, transfused blood volume, length of hospital stay, and lack of CPB, implying that fewer perioperative complications will develop.

In our study, we simplified Foley catheter-assisted thrombectomy to a six-step approach, suggesting that it is suitable for patients with Mayo level II, III, and IV TT. Additionally, the Foley catheter with the inflated balloon is located immediately above the proximal part of the TT by TEE guidance. The TT can thus be completely retracted with the inflated balloon, which is similar to the method of removing a deep vein thrombus in the lower extremity using a thrombectomy catheter during vascular surgery. These procedures can reduce the surgical burden on patients by avoiding a large incision in the IVC, thoracotomy, or CPB. Moreover, during TT removal, the IVC was completely closed by the inflated balloon. Even if the TT breaks or falls off, the tissue of the TT cannot enter the blood circulation, thus avoiding the risk of embolism and metastasis. Of course, the insertion length of the Foley catheter was determined by the length of the TT on preoperative images. Generally, the tip of the catheter should extend 5 cm beyond the proximal end of the TT; this can also be confirmed by intraoperative exploration using TEE guidance. Moreover, in our opinion, the Foley catheter should not be completely inserted all at once to prevent the inflated balloon from entering the right atrium.

Although this six-step surgical approach is effective and feasible, it has some limitations and contraindications. First, it is difficult to perform Foley catheter-assisted thrombectomy in patients with a thrombus that reaches the right atrium. Moreover, the IVC TTs were divided into infiltrating and floating IVC TTs based on the preoperative images. This method is applicable for floating and localized infiltrating IVC TT, the location of which is limited to the IVC wall surrounding the renal vein; however, it is not suitable for the removal of a TT that has extensively invaded the IVC wall. Thus, MR angiography or contrast-enhanced ultrasonography of the IVC should be performed preoperatively to identify the location of the proximal end of the TT and determine whether the TT has invaded the IVC wall. Intraoperative exploration is also important, and the surgeons can perform different operative procedures according to different conditions of the patient. We attempted the Foley catheter-assisted technique first, but this failed for some solid and invasive TTs. We then performed IVC resection or some other procedures for these patients. Thus, if the tumor has completely obstructed the IVC or is adhered to the IVC, we do not suggest this Foley catheter-assisted thrombectomy technique; instead, partial or segmental removal of the IVC wall is recommended. Finally, any surgical technique has a chance of failure, including the risk of pulmonary embolism caused by TT fragments and incomplete extraction of the TT.[8] To prevent these complications, surgeons should avoid squeezing the renal vein or IVC. Moreover, before the blood flow is opened, the IVC should be washed with heparin saline so that the residual TT fragments and blood clot are washed out. TEE was also performed intraoperatively to verify any tumor embolization of the TT into the pulmonary arteries. Briefly, if Foley catheter-assisted thrombectomy is not feasible because of the above intraoperative factors, it should only be considered as an alternative therapy.

The use of low-molecular-weight heparin (LMWH) can increase the risk of major bleeding episodes, especially during operations with a high risk of bleeding. Moreover, neither the European Association of Urology nor American Urological Association guidelines currently recommended the use of LMWH to prevent thrombosis. Therefore, we do not routinely use subcutaneous injection of LMWH, but only use heparin saline to rinse the IVC lumen as soon as the incision has been made in the IVC and before suturing of the IVC has been completed. However, for patients with a TT and thromboembolism, anticoagulant therapy with subcutaneous injection of LMWH is recommended to decrease the risk of venous thromboembolic events perioperatively.[29,30]

To date, no studies have been performed to investigate the indications for Foley catheter-assisted thrombectomy. According to our study, this technique should only be performed if the TT has not invaded or adhered to the IVC wall. Otherwise, the IVC partial resection technique should be performed. Enhanced MRI of the IVC is usually performed to determine whether the TT has invaded the IVC wall, and the imaging features are as follows[31]: (1) The wall of the IVC is rough, not smooth, and has a "burr sign"; (2) the IVC wall is thickened and the diameter is >1.5 times that of the normal one; (3) an edematous zone surrounds the IVC wall; and (4) the TT is irregular in shape. Indeed, this is only a preliminary study; subsequent randomized controlled clinical trials should be performed in the future.

Conclusion

Radical nephrectomy with Foley catheter-assisted six-step thrombectomy can avoid thoracotomy or CPB to a certain degree and results in fewer complications and less blood loss and perioperative red blood cell transfusion. We have simplified this technique into a six-step approach and have proven that it is feasible and effective; however, experienced surgeons and multidisciplinary cooperation are still needed for a successful operation.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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