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Comparison of MemoKath™ ureteral stent versus tumor ureteral stent: A single-center long-term analysis

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Introduction The MemoKath™-051 (MK) is a thermo-expandable spiral stent for the treatment of benign or malignant ureteral obstruction. Existing studies on outcome measurements, like complication rate or time to stent exchange for MK differ significantly. In this retrospective analysis, we investigated the supposed superiority of the MK over conventional tumor ureteral stent (TUS) insertion.

Material and methods In this monocentric retrospective analysis, 72 consecutive patients with benign or malignant extrinsic ureteral stenosis who either underwent insertion of a MK or TUS between 03/2008 and 12/2018 were analyzed. Indications for stent insertion were either chronic benign or malignant extrinsic obstruction in patients who were unsuitable for or refused definitive surgery. Patients who underwent urinary diversion were excluded. We compared the indwelling time, the complication rates and the time to occurrence of complications using Mann-Whitney-U-test and χ^2 test for categorical variables. Complication rates of both, the MK and the TUS were compared using Fisher´s test. Complications were classified according to Clavien-Dindo Classification (CDC).

Results The total number of ureteral units analyzed was 171, including 89 MK stents and 82 TUSs. No significant differences between both groups regarding age, stent indications, and stricture characteristics occurred. At a median follow-up of 32 and 27 months in the MK and TUS groups, postoperative complications occurred in 82 (92%) and 19 (23%) patients, respectively (p = 0.01). Almost all complications were major (CDC grade 3b) that required stent removal or replacement, with the exception of one patient in the MK group. Median time to complications was significantly longer for the MK group, 5.6 months, compared to 3.5 months in the TUS group (p = 0.01), and median time to stent replacement was 8 months for the MK group vs 5.2 months for the TUS group (p <0.001).

Conclusions Although the MemoKath™ is designed for a long indwelling time of up to years, it is associated with higher complication rates and premature replacement. However, compared to the TUS, the MK still has a significantly longer indwelling time. Further studies are needed to determine the predictors of failure and the best candidates for both stents.

Key Words: MemoKath™ stent ‹› tumour stent ‹› chronic ureteral obstruction

INTRODUCTION

Ureteral stents are often used as a palliative option for the treatment of patients with chronic ureteral obstruction due to either extrinsic (e.g., tumor compression, retroperitoneal fibrosis) or intrinsic causes (e.g., stricture, tumor) [1, 2]. The use of conventional polymeric double-J (DJ) stents for chronic obstruction is associated with high failure rates due to the lower resistance to compression, especially

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in malignant obstruction. Moreover, a regular exchange in short periods is needed [2]. Thus, different types of metallic stents have been introduced to treat the chronic ureteral obstruction effectively and to avoid the drawbacks of conventional stent [3–5]. The MemoKath™ (MK) stent (PNN Medical A/S, Denmark) is one of the most commonly used metal stents. MK is a thermolabile ureteral stent that is inserted into the area of the ureteral obstruction in a non-expanded state and then expanded by flushing with warm saline solution. In principle, the MK can be used for several years and only needs to be replaced in the event of complications. Theoretically, this leads to a lower number of necessary interventions per patient, thus increasing the quality of life and reducing the burden of operations and costs [6]. However, the recent literature on MK stents is inconsistent with regard to the complication rates, indwelling time, and mostly smaller patient groups with a limited follow-up period have been studied [7–13]. Another type of ureteral stent that can be used for the treatment of chronic ureteral obstruction is the so-called tumor stent (TUS), a polymeric stent with a reinforced middle section that can withstand external compression and remain in place for up to 1 year. Moreover, it could be inserted easily like the regular DJ stent. A recent large study involving 556 reinforced stents showed their efficacy in the treatment of malignant obstructions [14]. In the present study, we aimed to compare the results of the MK vs TUS regarding their complication rate and indwelling time.

MATERIAL AND METHODS

We retrospectively reviewed medical records for patients who received a ureteral stent either as a permanent MK or TUS between March 2008 and December 2018. The indication for stent insertion was either chronic benign or malignant obstruction in patients who were unsuitable for or refused definitive surgery. Patients who underwent urinary diversion were excluded.

MK was used routinely in our center until December 2018. From 2018, we changed our policy and started to routinely use only the TUS (7F, Coloplast, Denmark). According to the manufacturer, the recommended indwelling time can be up to 1 year for the TUS. We used to replace the TUS every 9 months or if the patient developed complications. MK stents are permanent ureteral stents, which were only removed if complications such as obstructions by incrustations or stent dislocations occurred. After stent fixation, the patients underwent regular follow-up examinations using abdominal and renal sonography, urinalysis and renal function at the outpatient clinic. In the event of complications such as progressive hydronephrosis, deterioration in renal function or recurrent urinary tract infections (UTIs), patients were readmitted for removal or replacement of the stent. All procedures were performed inpatient under general anesthesia. Only patients with available complete follow-up data were included in the analysis.

A linear regression analysis was performed to examine the relationship between patient characteristics and stent type with time to stent removal.

Data collection

We retrospectively recorded preoperative patient data regarding age, gender, side of obstruction, and indication for surgery. The intraoperative findings regarding the length of the obstruction and the localisation of the stricture within the ureter (upper, middle, lower third of the ureter) were also recorded. Postoperative complications were recorded and categorized according to the Clavien-Dindo Classification (CDC) system [15]. The time until the occurrence of complications and removal of the stent was analyzed. The time to stent removal in TUS was calculated from insertion to replacement of the stent, either regularly or due to the development of complications.

Statistical analysis

Demographic and clinical data of all patients were analyzed descriptively using Student's t-test, Mann-Whitney U-test, and χ^2 test for categorical variables. Complication rates of both, the MK and the TUS were compared using Fisher´s tests and confidence intervals. A p-value of ≤ 0.05 indicated significance. All statistical analyses were performed using SPSS software version 26 (Chicago, IL, USA).

Bioethical standards

This retrospective study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and after written informed consent of the patients. The study was approved by Institutional Ethics Board of the University Duisburg-Essen (approval number 21-9863-BO).

RESULTS

Between March 2008 and December 2018, either MK or TUS was inserted in a total of 72 patients (34 men and 38 women) and 171 ureteral units

(UUs) at our hospital. MK and TUS were used in 89 (52%) and 82 (48%) UUs, respectively. The median age in the MK group was 70 years, significantly higher than in the TUS group at 60 years (p = 0.001). Most patients in the MK group were female (63%), while men were predominant in the TUS group (66%) (p = 0.013). Ureteral stents were inserted in 60% of patients on the right and 40% on the left. The stent was mostly used for benign indications (66%), including intrinsic strictures of different etiologies, after radiotherapy, endometriosis, and retroperitoneal fibrosis, while the remaining patients received ureteral stents for malignant obstruction. The length of the obstruction was <5 cm and ≥5 cm in 55% and 45%, respectively. The localisation of the obstruction was mostly the mid-third of the ureter (45%), followed by the distal and upper ureter (39% and 16%, respectively). There were no significant differences between the two groups in terms of side, cause, length, and location of ureteral obstruction (Table 1). Surgical outcomes was shown in Table 2.

In the MK subgroup, the median time to stent removal was 8.3 months compared to 7.5 months for benign and malignant indications, respectively (p = 0.8). Similarly, no significant difference was found in the TUS subgroup: The median time to stent removal was 5.7 months compared to 4.5 for benign and malignant cases, respectively (p = 0.55). In univariable analysis, MK was only seen to be associated with longer indwelling time (Table 3).

At a median follow-up of 32 and 27 months in the MK and TUS groups, postoperative complications occurred in 82 (92%) and 19 (23%) patients, respectively (p = 0.01). Median time to complications was significantly longer for MK group 5.6 months compared to 3.5 months in TUS group (p = 0.01). The most common major complication in both groups was stent occlusion, which occurred in 47 (53%) patients in the MK group and in 13 (16%) in the TUS group. Other complications such as stent dislocation (29.2%), stone formation (2.2%) and UTI (6.7%) were also reported in the MK group, whereas only UTI (7.3%) was reported in the TUS group. All complications in both groups were Clavien grade IIIb that included stent removal or replacement, with the exception of one complication in the MK group, which was UTI managed with antibiotic treatment only (Clavien grade II). Finally, in the TUS subgroup, 63 (77%) stents were exchanged in the regular time span (6–9 months) without harboring any complications. Nineteen (21%) ureteral units were still being treated with the initial MK at the time of the data analysis, and a total of 35 units (39%) received the MK for ≥12 months. The median time to stent removal or replacement was 8 months for the MK group vs 5.2 months for the TUS group (p <0.001). Supplementary Figure 1 shows the flow chart of the treated partners. By analyzing complication rates within the first nine months, as this is the maximum indwelling time of the tumor stent, a significantly higher complication rate was reported in the MK group, 53 (60%), compared to 19 UUs (23 %) in the TUS

Table 1. *Patient demographics*

Parameter	MK (n = 89)	TUS (n = 82)	p
Age (years), median (IQR)	59.5 (48–71.7)	69.5 (59–75)	0.001
Sex, n (%)			0.013
Male	33 (37)	54 (66)	
Female	56 (63)	28 (34)	
Side of obstruction, n (%)			0.62
Right	53 (60)	49 (60)	
Left	36 (40.4)	33 (40)	
Causes of ureteral obstruction, n (%)			0.36
Malignant	29 (32.5)	29 (35.3)	
Post radiotherapy	20 (22.4)	10 (12.2)	
Benign	40 (45)	43 (52.5)	
Stricture length, no. (%)			0.76
<5 cm	39 (43.8)	38 (46.3)	
≥5 cm	50 (56.2)	44 (53.7)	
Stricture site, n (%)			0.1
Upper ureter	20 (22.5)	9 (11)	
Middle ureter	35 (39.3)	41 (50)	
Distal ureter	34 (38.2)	32 (39)	

Table 2. *Surgical outcome*

Parameter	MK (n = 89)	TUS (n = 82)	p
Median follow-up, months (IQR)	31.8 (13–71.2)	27 (19.2–23.5)	0.02
Total complications, n (%)	82 (92)	19 (23)	0.01
Stent occlusion	48 (53.9)	13 (15.9)	
Stent dislocation	26 (29.2)	0	
Stone formation, patients	2 (2.2)	0	
UTI, patients	6 (6.7)	6 (7.3)	
Complications within first 9 months, n (%)	53 (59.6)	19 (23)	<0.001
Stent occlusion	31 (34.8)	13 (15.9)	
Stent dislocation	17 (19.1)	0	
Stone formation, patients	1 (1.1)	0	
UTI, patients	4 (4.4)	6 (7.3)	
Median time to complications (months)	5.6	3.5	<0.001
Median (IQR) time to stent removal, months	8 (2.3–20.7)	5.2 (3–7.1)	<0.001

UTI – urinary tract infection

(p = 0.01). In the TUS group, all patients underwent stent replacement due to complications, while in the MK group, 11 patients received a temporary nephrostomy tube, one patient underwent nephrectomy due to loss of kidney function, and one patient in the MK subgroup underwent ureteral reimplantation with psoas-hitch.

DISCUSSION

The MK ureteral stent was introduced in the treatment of ureteral strictures as a palliative treatment for non-operable patients in order to avoid high failure rates associated with regular DJ ureteral stents and, consequently, aimed to reduce the frequency of stent replacements [8, 9]. The studies available to date have shown variable results in terms of complication rates and indwelling time; moreover, there have been no studies comparing the results of the MK stent with another commonly used stent for the treatment of chronic obstructions, the TUS.

A recent review linked certain materials to stent-related symptoms, offering contradictory conclusions, and the majority of research does not specify the precise properties of the materials utilized [16]. Most patients in the MK group (92%) in our study experienced complications at a median follow-up of 5.6 months. In addition, complications in the MK group always required removal or replacement of the stent, and sometimes a temporary nephrostomy tube is required. By analyzing the complication rates within the first nine months, as this was the maximum time for the routine TUS replacement in our cohort, 60% developed complications compared to 23% in the TUS (p = 0.01). However, despite the higher complication rate in the MK group, MK was still associated with longer indwelling time than TUS. The median time to stent removal was 8 months for MK vs 5.2 months for TUS (p <0.001), and 39% received MK for ≥12 months.

However, the complication rate in our cohort is higher. In particular, the median indwelling time of the MK group in our study is significantly lower than expected in some previous reports, reporting complication rates between 25 and 70% and a median time to removal between 5 months and 4 years [7, 8, 10, 13, 17]. This large difference in complications and indwelling time between studies may be related to the retrospective nature of the studies and the differences between the centers in the included patients, follow-up protocols, and frequency of postoperative physical and radiographic examinations. Thus, comparing results between different studies is difficult, and the evidence regarding MK stents is still lacking. Klarskov et al. [8] published the results of MK in 33 patients with 37 stents in 2005. They reported stent malfunction requiring replacement in 22/37 (60%) stents after a median time of only 5 months, comparable to our study's early stent replacement. In addition, the median follow-up time for 15 stents that remained in place and did not require replacement was relatively short at 14 months (range 3–30 months) [8]. Papatsoris et al. [13] published a large cohort of 102 MK stents. After a median follow-up of 17 months, the authors reported complications in 26 (25%) patients, including stent manipulation due to dislocation in 15 patients and stent removal due to blockage in 5 patients. The cost of using MK stents was associated with annual savings of $7,539 from the second year after fixation compared with the cost of regular DJ replacement. However, the median follow-up time in this study is short, and 14% of patients experienced spontaneous resolution of the stricture, so the stents were removed after a median follow-up time of 9 months; this subset of patients was considered a success [13]. Recently, Forster et al. [7] published the largest series of MK stents with 100 patients who received 162 stents, while two researchers independent of the surgeons examined the long-term results. They reported a comparable high complication rate as in our study: at a mean follow-up of 5 years, a complication rate of 72% was found. The median time to first complication was

Table 3. *Univariable analysis of factors influencing stent indwelling time*

Variable	Coefficient (95% CI)	p
Age	–0.64 (from –0.21 to 0.08)	0.47
Gender		
Female	Ref.	0.95
Male	0.15 (from –4.5 to 4.5)	
Side		
Right	Ref.	0.46
Left	1.7 (from –2.8 to 6.2)	
Causes of ureteral obstruction		
Benign	Ref.	0.38
Malignant	–2.1 (from –6.9 to 2.68)	
Stricture length		
<5 cm	Ref.	0.18
≥5 cm	3 (from –1.4 to 7.5)	
Stricture site		
Upper ureter	Ref.	
Middle ureter	0.99 (from –3.54 to 5.53)	0.66
Distal ureter	0.07 (from –4.5 to 4.7)	0.97
Stent type		
TUS	Ref.	<0.001
MK	9.4 (5.1–13.6)	

MK – MemoKath™; TUS – tumor ureteral stent I am running a few minutes late; my previous meeting is running over.

12.5 months, and according to the Kaplan-Meier curve, the median stent life was 14.5 months.

Taken together, stent removal time in our cohort was shorter as in the studies of Forster et al. [18] and Moskovitz et al. [19] (using Allium stents), however comparable to Papatsoris et al. [13] (median 9 months).

Complications after MK stent insertion are usually major and require either removal, adjustment or replacement, which is considered to be the major disadvantage of MK stenting. In the present study, stent occlusion (54%) and dislodgement (30%) were the most commonly reported complications in the MK group, while stone formation (2.2%) and UTI (6.7%) occurred to a lesser extent. However, it is important to acknowledge that complications in the MK subgroup are more severe as compared to regular stenting, as 11 patients received a temporary nephrostomy tube before new stent insertion and one patient underwent nephrectomy due to loss of kidney function. Papatsoris et al. [13] reported 26 complications, including 57% stent dislocations, 20% stent occlusions and 23% UTIs. Similarly, Forster et al. [7] reported 46% stent migration, 34% obstruction, followed by lower rates of renal function loss, urosepsis and other complications including 1 postoperative mortality.

The factors influencing the outcome of MK have not yet been well studied in the literature. Agrawal et al. [12] tried to identify predictors of stent migration by comparing 13 patients who experienced stent migration to a control group including 61 patients without stent migration, no relationship was observed between stent migration and stricture related characteristic. Bier et al. [11] found that the median time to stent removal was longer in patients with adequate renal function than in patients with renal insufficiency (386 vs 317 days; $p = 0.007$) and in patients with active malignancy compared to benign disease (455 vs 190 days; $p = 0.006$). Otherwise, no further correlations were found between stent failure and patient and stricture characteristics. In contrary, Forster et al. [7] reported lower complication rate (62.7% vs 85.4%, $p = 0.04$) and longer mean indwelling time (14.5 months vs 13.4 months, $p = 0.02$) for malignant compared to benign obstruction. Further prospective studies on factors affecting outcome of MK are still needed. Taking into account the lower survival rates in patients with malignant obstruction and the longer indwelling time of MK compared to TUS, MK may be more suitable for such patients with malignant obstruction.

The outcome of TUS in our study is comparable with the largest series of tumour stent in the literature: Vogt and Blanchet [14] reported 23% failure rate at a mean of 4.4 months in a study including 556 tumour stents. One of the main disadvantages of the TUS, which we have not analyzed, is stent-associated urinary symptoms. Maan et al. reported severe urinary symptoms in 32% of DJ-stent patients compared to only 5.6% of MK patients. In the TUS group, 67% of patients reported stent-associated bother, like urinary symptoms, compared to 35% of MK patients. In addition, physical pain and impairment of daily activities were significantly higher in the TUS group. Finally, the patients were in favor of the MK stent for future stent insertion. However, it is worth noting that a subset of 10 patients who underwent MK stenting after TUS reported no improvement in pain or urinary symptoms [14]. Aziz et al. [20] reported a significant improvement in urinary symptoms after MK fixation in a small series of 16 patients who underwent MK stenting after DJ stenting for chronic ureteral strictures. The available findings indicate a better quality of life in favor of the MK stent, which is a significant advantage compared to TUS [20].

The strength of the study is the long follow-up period after application of the MK vs TUS system, and the significantly higher number of ureteral units compared to other studies. Another strength of this study is the utilization of the MK stent in a real-world scenario and comparing the MK and the more common tumour ureteral stent. Our study has limitations. First, its retrospective nature and small sample size limit further subanalyses on subgroup differences. This retrospective analysis was not powered to identify statistically significant differences between the two subgroups. Another limitation is that in our analysis, we compared the MK stent to the more common TUS and no other long-lasting stents, as Allium or Resonance stents [21]. In addition, we did not examine other important factors, specifically changes in renal function that were measured by renal scintigraphy, stent-related symptoms, and costs. Further larger and/or prospective studies on this topic are still needed.

CONCLUSIONS

The MK was superior to TUS in terms of median time until stent replacement. However, there is a significantly increased risk of complications and time to MK exchange or removal is significantly shorter than reported in previous studies. These findings limit the anticipated advantages of the MK and should be taken into consideration. At least, patients should be informed that regular follow-up after MK insertion is mandatory.

CONFLICTS OF INTEREST

Boris Hadaschik: advisory boards for Janssen, Bayer, ABX, Lightpoint, Amgen, MSD, Pfizer, Novartis. Invited speaker for Accord, Astellas, Janssen R&D. Honoraria from Uromed. Research funding from AAA/Novartis, Bristol Myers Squibb, and German Research Foundation. Leadership roles for DKG AUO and DGU.
Jan Philipp Radtke: consulting – Saegeling Medizintechnik, Novartis, AAA, Dr. Wolf, Beckelmann und Partner: financial and non-financial donation – Astellas, Bayer, Janssen Pharmaceuticals, MedCom, Saegeling Medizintechnik, Philips Invivo, Bender Gruppe, Apogepha, AMGEN, Ipsen, Astra Zeneca; Clinical Studies – Janssen Pharmaceuticals, Bayer, Novartis AAA, SPL-01.
Christopher Darr: personal fees from Janssen-Cilag, IPSEN and travel fees from Janssen-Cilag, IPSEN and Bayer.
Ulrich Krafft: Grants to the author or organization: BMS, Novartis, Advanced Accelerator Applications. Personal fees: Janssen, Flatiron, MSD.
The other authors declare no conflict of interest.

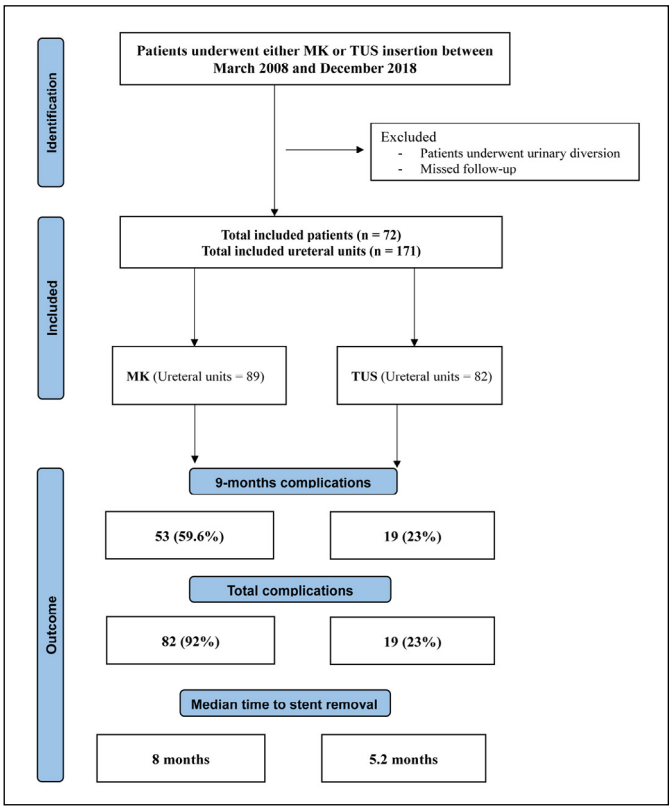
FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The study was approved by Institutional Ethics Board of the University Duisburg-Essen (approval number 21-9863-BO).

SUPPLEMENTARY MATERIAL



Suppl. Figure 1. *Flow chart of treated patients.*

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