Recurrent Benign Urethral Strictures Treated with Covered Retrievable Self-Expandable Metallic Stents: Long-Term Outcomes over an 18-Year Period

Min Tae Kim, MS, Kun Yung Kim, MD, Ho-Young Song, MD, PhD, Jung-Hoon Park, PhD, Jiaywei Tsauo, MD, Zhe Wang, MD, and Pyeong Hwa Kim, MD

ABSTRACT

Purpose: To assess the long-term outcomes of covered retrievable self-expandable metallic stent (REMS) placement for recurrent benign urethral stricture and to compare the outcomes associated with 3 types of covered REMSs.

Materials and Methods: A retrospective study was performed in 54 male patients in whom 114 REMSs were placed between November 1998 and December 2016. These included 26 polyurethane-covered REMSs in 13 patients (group A), 47 internally polytetrafluoroethylene (PTFE)-covered REMSs in 21 patients (group B), and 41 externally PTFE-covered REMSs in 20 patients (group C). The outcomes were analyzed and compared between the groups.

Results: Overall clinical success was achieved in 14 of the 54 patients (24%) at 5-year follow-up (group A, 12%; group B, 19%; group C, 40%). The overall complication rate was 60.5%, and the complication rate was significantly higher in group B than in groups A or C (group A vs B, $P = .018$; group B vs C, $P = .002$). The median stent indwelling time and maintained patency period were 3.1 months and 108 months, respectively. In multivariate analysis, stent indwelling time was the only significant factor associated with maintained patency.

Conclusions: The long-term outcome of covered REMSs has not achieved the desired success rate for the standard treatment of recurrent urethral stricture. However, externally PTFE-covered REMSs showed a better long-term outcome than the other studied types.

ABBREVIATIONS

PTFE = polytetrafluoroethylene, PU = polyurethane, REMS = retrievable self-expandable metallic stent, RGU = retrograde urethrography

Despite recent developments in endoscopic and reconstructive urology, the management of urethral strictures remains a challenge to urologists (1–5). A direct visual internal urethrotomy or dilation remains the primary treatment, but 46%–76% of strictures recur within 2 years, and the treatment of recurrent strictures involves an even greater risk of further recurrences (2,5,6). Many patients eventually undergo open reconstruction surgery, such as excision and primary anastomosis, and skin graft urethroplasty, which provide better long-term outcomes (7).

Since Milroy et al (4) first reported the use of self-expandable metal stents in the treatment of benign urethral strictures in 1988, various reports have been published on the efficacy of urethral stents. However, despite great expectations of this minimally invasive technique, the outcomes of permanent urethral stent placement are unsatisfactory, mainly because of high recurrence and complication rates (2,4,6,8–19). Therefore, retrievable self-expandable metallic stents (REMSs), such as those with a spiral design or a thermo-expandable coil design and covered

From the Departments of Radiology and Research Institute of Radiology (M.T.K., K.Y.K., H.-Y.S., J.-H.P., J.T., Z.W., P.H.K.) and Biomedical Engineering Research Center (J.-H.P.), Asan Medical Center, University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 138-736, Republic of Korea; and Department of Radiology (Z.W.), Tianjin Medical University General Hospital, Tianjin, P.R. China. Received April 18, 2017; final revision received July 10, 2017; accepted July 14, 2017. **Address correspondence to** H.-Y.S.; E-mail: hysong@amc.seoul.kr

M.T.K. and K.Y.K. contributed equally to this work and are co-first authors.

None of the authors have identified a conflict of interest.

J Vasc Interv Radiol 2017; 28:1584–1591

http://dx.doi.org/10.1016/j.jvir.2017.07.017

metallic stents with a drawstring design, have been developed for temporary placement (1,3,20,21).

Covered metallic stents with a drawstring design have been used for almost 20 years. Polyurethane (PU)-covered REMSs were used initially, but tissue ingrowth as a result of PU membrane degradation occurred in 18% patients (22). This led to the development of stents covered internally with polytetrafluoroethylene (PTFE). Although membrane degradation was not observed, tissue ingrowth as a result of PTFE membrane separation from the wire mesh was reported in 9% of patients (23,24). The most recent design involves an external covering with the PTFE membrane to prevent membrane separation. Na et al (23) reported promising initial results without membrane separation in 33 patients with recurrent urethral strictures. However, no follow-up study was conducted. Therefore, the present study was performed to assess the long-term outcomes of covered REMS placement for recurrent benign urethral strictures and compare the outcomes of 3 types of covered REMSs through the review of a 18-year single-center experience. We also attempted to identify prognostic factors associated with long-term outcomes.

MATERIALS AND METHODS

Patient Population

This retrospective study was approved by the institutional review board, and the requirement to obtain written informed consent was waived. From November 1998 to December 2016, 114 REMSs were placed in 54 consecutive patients (mean, 2.1 per patient; range, 1–6) with traumatic (n = 32), indwelling recurrent urethral (n = 11), or postoperative strictures (n = 11). Patients' ages ranged from 16 years to 77 years (mean, 51 y). The diagnosis of strictures was based on history, clinical signs and symptoms, radiographic and urethroscopic examinations, and, when necessary, biopsy. Patients with a documented malignancy at the time of diagnosis of urethral stricture were excluded. The study population was divided into 3 groups based on stent type: PU-covered REMS (group A), internally PTFE-covered REMS (group B), and externally PTFE-covered REMS (group C). The characteristics of the patient population are summarized in Table 1.

Table 1. Characteristics of Patient Populations before REMS Placement

Characteristic	Value %
No. of patients	54
No. of REMSs	114
Age (y)	50.9 ± 14.2
Stricture length (mm)	31.8 ± 17.6
Stricture location	
Membranous	12 (22.2)
Bulbous	38 (70.4)
Prostatic	4 (7.4)
Cause of stricture	
Traffic accident	14 (26)
Fall	6 (11)
Straddle injury	12 (22)
Indwelling Foley catheter	11 (20)
Previous surgery	11 (20)
Stent characteristic	
Polyurethane covering	
No. of patients	13 (24)
No. of stents	26
Internal PTFE covering	
No. of patients	21 (39)
No. of stents	47
External PTFE covering	
No. of patients	20 (37)
No. of stents	41

Note–Values in parentheses are percentages. Values presented as mean ± standard deviation where applicable. PTFE = polytetrafluoroethylene; REMS = retrievable self-expandable metallic stent.

Stents and Retrieval Set

Stents and retrieval sets have been described in detail elsewhere (2,22,23). Briefly, the REMS was woven from 0.1-mm-thick nitinol wires into a tubular configuration and was 10 mm in diameter and 30–100 mm in length when fully expanded. To make the stent retrievable, 2-mm-diameter nylon loops were hooked inside each bend in the distal end of the stent and at another site, with a nylon thread passing through each nylon loop to form larger loops (ie, drawstrings), filling the circumference of the inside of the distal REMS. All REMSs were constructed as described by the manufacturer (Niti-S Urethral Stent; Taewoong, Seoul, Korea).

The REMS retrieval set consists of a 9-F braided sheath, a dilator (Cook, Bloomington, Indiana), and a hook wire (Taewoong). The end of the hook wire was constructed in a question-mark configuration to hook the drawstring of the REMS. The distal 20-mm section of the question-mark portion was positioned at an angle of approximately 30° to the axis. An additional bend was made in this section with the use of pliers so that the hook would not catch the end of the sheath while being withdrawn (Fig 1).

Stent Placement and Removal

In brief, after disinfection of the external urethral orifice with 0.05% chlorhexidine, the urethra was routinely anesthetized topically with 10 mL of lubricating jelly containing 2% lidocaine. Before stent placement, retrograde urethrography (RGU) was performed to evaluate the site, severity, and length of the stricture, and the stricture site was marked on the skin of the patient. Under fluoroscopic guidance, a 180-cm, 0.035-inch exchange guide wire (Radifocus M; Terumo, Tokyo, Japan) was inserted through the urethra across the stent into the bladder. A sizing catheter (Song-Lim Biliary Catheter; S&G Biotech, Seongnam, Korea) was introduced over the guide wire into the proximal part of the