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Original Article

The Efficacy of Mirabegron for the Relief of Ureteral Stent-Related Symptoms

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To investigate the efficacy of mirabegron for lower urinary tract symptoms in patients with an indwelling ureteral stent after ureterorenoscopic lithotripsy. This was a prospective follow-up study of 76 patients with stent-related symptoms (SRSs). Patients with upper urinary calculi who were pre-stented for >2 weeks before lithotripsy were examined for the presence of SRSs by tests including the International Prostate Symptom Score (IPSS), OAB Symptom Score (OABSS), and urinary bother and pain measured by a Visual Analogue Scale (VAS) before lithotripsy. Mirabegron (50 mg/day) was prescribed post-lithotripsy for 2 weeks. SRSs were assessed at the time of stent removal. The IPSS scores improved significantly from 16.2 to 14.3 ($p<0.001$) and the IPSS-QoL scores decreased significantly from 5.0 to 4.6 ($p=0.012$). The OABSS scores improved significantly from 7.7 to 6.8 ($p=0.006$), and the urinary urgency scores (OABSS-Q3) decreased significantly from 3.24 to 2.68 ($p<0.001$). The number of nocturia episodes decreased significantly from 2.5 to 2.2 ($p=0.045$). Urinary bother and pain assessed by the VAS declined from 4.2 and 3.1 to 3.8 ($p=0.15$) and 2.5 ($p=0.075$), respectively. Mirabegron significantly improved SRSs and the number of nocturia episodes due to a ureteral stent.

Key words: stent-related symptoms, overactive bladder, mirabegron, ureterorenoscopic lithotripsy, ureteral stent

Ureteral stents are widely used for the management of upper urinary tract obstruction for various etiologies, and approx. 80% of patients with an indwelling ureteral stent suffer from stent-related symptoms (SRSs), including lower urinary tract symptoms (LUTS), hematuria, body pain, and poor quality of life (QoL) [1,2]. The most effective approach to manage SRSs is to prevent the need for a stent initially; however, after a ureterorenoscopic lithotripsy (URSL) for upper urinary calculi, a majority of the patients require ureteral stent placement for the alleviation of an obstruction by a stent's maintenance of the ureteral lumen's patency.

LUTS, bladder discomfort, and hematuria are presumed to arise from a mechanical irritation of the bladder neck and/or trigone induced by an indwelling stent, whereas flank pain is associated with vesicoureteral reflux [3]. To address these problems, several studies aimed at improving stent designs and compositions have been conducted [4-6]. Although many studies have indicated that alpha-1 blockers, antimuscarinics, and other agents can relieve the discomfort and problems related to an indwelling stent and ultimately improve the patients' QoL [7-24], conflicting results have been obtained by studies that compared the effi-

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cacy of monotherapy with that of combination therapy using both alpha-1 blockers and antimuscarinic agents [17, 18].

To date, only one study has concentrated on the β3-adrenoceptor agonist mirabegron as part of efforts to address SRSs, and in that study a significant improvement of urinary symptoms was not achieved with mirabegron treatment [25]. Mirabegron has demonstrated efficacy and tolerability for patients with overactive bladder (OAB) symptoms [26-28]. We conducted the present study to investigate the efficacy of mirabegron in patients with an indwelling ureteral stent after URSL.

Patients and Methods

Patients. This was a single-center, prospective follow-up study that targeted patients with SRSs. We studied patients who underwent a URSL with an indwelling ureteral stent at Abiko Toho Hospital (Chiba, Japan) between November 2016 and March 2018. The study was approved by the Institutional Review Board of our hospital (Approval no. 201601). Written informed consent was obtained from all of the study participants.

The inclusion criteria were as follows: (1) patients with upper urinary calculi who received a 6-Fr ureteral stent > 2 weeks before their URSL, (2) those with OAB symptoms due to an indwelling ureteral stent, (3) those with a stone-free status attained after URSL, (4) those who provided consent for 2-week mirabegron administration, and (5) those who were evaluated for SRSs before the removal of their stent.

After the URSL of each patient, a stent of the same size as that inserted at pre-stenting was inserted. After both insertions, kidney-ureter-bladder (KUB) X-ray plain film images were taken to ensure that the stent was at an appropriate position, because an over-midline positioning of the distal end of the stent might worsen LUTS [29, 30]. The details of our URSL procedures have been described [31, 32].

The exclusion criteria were as follows: patients with (1) lower ureteral calculi; (2) pre-existing OAB, interstitial cystitis, chronic prostatitis, chronic pelvic pain syndrome, or active urinary tract infection (UTI); (3) those with stent dislodgement; (4) those with a concomitant use of an adrenergic alpha-1 receptor antagonists, antimuscarinic agent, or analgesic; and those (5) with a history of urinary tract surgery, (6) drug allergy, or (7) a history of neurogenic bladder, neurologic and psychiatric disease(s), or dementia.

Assessment of the patients' symptoms and outcomes. Based on the patient's OAB Symptom Score (OABSS) [33], the diagnosis of OAB was defined as a Urinary Urgency Score (OABSS-Q3) ≥ 2 plus an OABSS total score ≥ 3. All patients were investigated for the absence of OAB before the first ureteral stent placement (pre-stenting). Pre-stenting was performed > 2 weeks before the URSL. The patients completed a form that included the International Prostate Symptom Score (IPSS), the IPSS-QoL score, the OABSS, and a visual analog scale (VAS) that was used to assess the patient's sense of urinary bother and pain before URSL.

For the patients with OAB due to a ureteral stent, mirabegron (50 mg/day) was prescribed the day after the URSL and continued until the stent removal. Patients were discharged on day 2 or 3 after their URSL surgery. Approximately 2 weeks after the URSL surgery, each patient returned to our hospital and was interviewed by a physician for the identification of any side effects; the patient underwent a urinalysis to check for a UTI; and he or she was checked for stent dislodgement and the presence/absence of visible fragments on KUB X-ray films, any symptoms after mirabegron administration. The stent's removal was then conducted. The flowchart of this study is given as Fig. 1. We analyzed the collected data of the patients by using a paired *t*-test. Probability values < 0.05 were accepted as

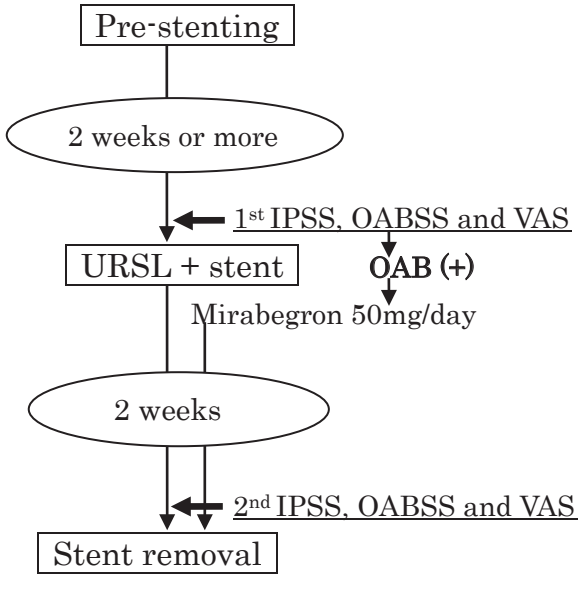

Fig. 1 Study flowchart.

significant.

Results

Of the 98 eligible patients, 22 patients without SRSs were not prescribed mirabegron after their URSL, and the final sample size was thus 76. Table 1 summarizes the patients' demographics. None of the patients had a history of urinary tract surgery or concomitant use of other similar drugs or any other comorbidity that could have affected the assessment of SRSs. No stents were dislodged.

The changes in the patients' urinary symptom scores are summarized in Table 2. The total IPSS score was 16.3 without mirabegron, and this score was significantly reduced to 14.3 after mirabegron treatment (50 mg/day) ($p<0.001$). The patients' IPSS voiding score and storage symptom score fell from 7.2 and 9.1 to 6.5 ($p=0.074$) and 7.7 ($p<0.001$), respectively. The IPSS-QoL values decreased from 5.0 to 4.6 ($p=0.012$). The total OABSS value fell from 7.7 before surgery to 6.8 after the mirabegron treatment ($p=0.006$). The urinary urgency score (OABSS-Q3) decreased significantly from 3.24 to 2.68 ($p<0.001$), but the patients' urgency incontinence score (OABSS-Q4) did not change significantly (from 1.08 to 0.95, $p=0.4$). The change in the patients' urinary bother score as revealed by the VAS decreased from 4.2 to 3.8, which was not significant ($p=0.15$). The pain score evaluated by the VAS dropped from 3.1 before the mirabegron treatment to 2.5 at the time point of stent removal; however, this change was not significant ($p=0.075$).

The number of nocturia episodes per night fell by one episode in 37% of the patients, whereas it did not change in another 36% of the patients. The number of nocturia episodes fell significantly from 2.5 to 2.2 after mirabegron treatment ($p=0.045$). None of the patients discontinued their mirabegron treatment due to side effects.

Table 1 Demographics of the patients

		Overall (n = 76)		
Factors		Mean ± SD	Rate	Range
Gender	Male	48	63%	
	Female	28	37%	
Age (years)		59.9 ± 11.7		31–82
BMI		24.0 ± 4.3		13.4–43.3
ASA score	class 1	43	57%	
	class 2	30	39%	
	class 3	3	4%	
Comorbidity	Diabetes mellitus	15	20%	
	Hypertension	25	33%	
	Hyperlipidemia	12	16%	
	Hyperuricemia	4	5%	
Stone location	Calyx	9	12%	
	Renal pelvis	8	10%	
	UPJ	9	12%	
	Upper ureter	38	50%	
	Middle ureter	12	16%	
Laterality	Right	36	47%	
	Left	40	53%	
Stone diameter (mm)		13.3 ± 8.2		3.6–31

BMI, body mass index; UPJ, ureteropelvic junction.

Table 2 Changes in urinary parameters

	Mirabegron (−)	Mirabegron (+)	*p* value
IPSS total score	16.3 ± 7.1	14.3 ± 7.5	< 0.001
IPSS voiding score	7.2 ± 5.0	6.5 ± 5.0	0.074
IPSS storage score	9.1 ± 3.3	7.7 ± 3.6	< 0.001
IPSS-QoL	5.0 ± 1.2	4.6 ± 1.5	0.012
OABSS total score	7.7 ± 3.0	6.8 ± 3.3	0.006
Q3 (urgency score)	3.24 ± 1.3	2.68 ± 1.6	< 0.001
Q4 (urgency incontinence score)	1.08 ± 1.5	0.95 ± 1.5	0.4
VAS urinary bother	4.2 ± 2.7	3.8 ± 2.6	0.15
VAS pain	3.1 ± 2.5	2.5 ± 2.4	0.075
Nocturia	2.5 ± 1.3	2.2 ± 1.4	0.045

IPSS, international prostate symptom score; OABSS, overactive bladder symptom score; VAS, visual analogue scale.

Table 3 Studies of the outcomes of medical therapy for stent-related symptoms

Author	Reference number	Reported year	Number of patients	Drug used	Opinion/Conclusion
Deliveliotis	8	2006	100	alfzocin	Effective
Damiano	9	2008	75	tamsulosin	Effective
Beddingfield	10	2009	66	alfzocin	Effective
Valiere	11	2011	79	tamsulosin	Not effective
Lim	12	2011	168	tamsulosin, solifenacin	Combination was better.
Shalaby	13	2013	338	terazosin, tolterodine	Combination was better.
Tehranchi	14	2013	94	terazosin, tolterodine	Combination was better.
Lee	15	2013	140	solifenasin	Effective
Dellis	16	2014	150	alfzocin, tamsulosin	The both was effective.
Park	17	2015	81	tamsulosin, solifenacin	Neither combination nor monotherapy was effective.
Sivalingam	18	2016	80	tamsulosin, tolterodine	Add-on of tolterodine was not effective.
El-Nahas	19	2016	131	tamsulosin, solifenacin	Solifenacin was better than tamsulosin.
Liu	20	2016	100	solifenacin, tamsulosin	Combination was better within 4 days.
Ragab	21	2017	500	pregabalin, solifenacin	Pregabalin eased pain, solifenacin improved LUTS.
Lee	22	2017	71	belladonna and opium suppository	Effective
Dellis	23	2017	260	solifenacin, tamsulosin	The both was effective.
Maldonado	24	2017	51	tamsulosin, oxybutynin	Combination was better.
Tae	25	2018	96	mirabegron	Mirabegron eased pain.

LUTS, lower urinray tract symptoms.

Discussion

The results of our analyses revealed a significant improvement of SRSs after mirabegron treatment. At present, the most useful measure for the evaluation of SRSs is the ureteral stent symptom questionnaire (USSQ) established by Joshi [34]; however, the USSQ was not available in Japanese during the study period. We therefore used the OABSS, IPSS, and VAS to evaluate the patients' urinary bother and pain in daily life.

Of the 98 eligible patients, 76 patients (78%) experienced SRSs, whereas the other 22 did not. The location of calculi was confined to the upper ureter, ureteropelvic junction, renal pelvis, and calyces. We excluded patients with lower ureteral calculi because these calculi can cause LUTS and complicate the evaluations of symptoms.

The Polaris™ Ultra stent (Boston Scientific, Marlborough, MA, USA) is made of polyolefin with hydrophilic coating. The distal end of this stent is called the Nautilus™ Coil, which is convoluted inside the stent in order to reduce stimuli against the bladder

mucosa. In the present study, 78% of the patients experienced SRSs; this may be attributed to the rigidness of the Polaris Ultra stent design to prevent SRSs. Kawahara reported the usefulness of a loop-type stent to reduce SRSs [35]. The application of stents that are made of softer or thinner material might therefore have produced different results in this study.

Irani *et al.* reported changes in patients' tolerance to SRSs with time [36]. They assessed urinary symptoms at 24 h and again 1 week after placement, and on the day before stent removal. Although some symptoms (*e.g.*, dysuria and hematuria) improved significantly with time, the patients' general tolerance to SRSs remained unchanged. Some of the irritative symptoms observed a few days after the stent placement were suggested to be caused by the effects of instrumentation. In the present study, symptom assessments were performed > 2 weeks after the initial stent placement and a further 2 weeks after the URSL. Therefore, the symptom improvement with time seemed to be slight between the primary and the secondary assessments, and the amelioration of the patients' urinary symptom scores approximately reflected the symptom relief by mirabegron treatment.

The prior randomized controlled trials for medical therapy against SRSs are summarized in Table 3. The majority of the previous studies reported the usefulness of antimuscarinics and alpha-1 blockers for SRSs [8-10, 15, 16], and several research groups have indicated the efficacy of combination therapy [12-14, 20, 23, 24] and analgesics [21, 22]. Tae *et al.* demonstrated that compared to no treatment, mirabegron has the potential to reduce SRSs [25]. In their study, the postoperative USSQ body pain score and the overall pain score were lower in the mirabegron group compared to the no-treatment group. The USSQ urinary symptom scores, IPSS total scores, and QoL scores were lower in the mirabegron group, but the differences were not significant [25]; this might be due to the study's small sample size.

In the present study, mirabegron significantly reduced the total IPSS, OABSS, and IPSS storage symptom scores for patients with an indwelling ureteral stent. Urinary bother, as measured by the VAS, was not significantly improved ($p = 0.15$), but the patients' pain became less severe (although not significantly so; $p = 0.075$). The number of the patients' nocturia episodes per night decreased significantly from 2.5 to 2.2 ($p = 0.045$). Our findings thus indicated that mirabegron improves LUTS, reduces the number of nocturia episodes, and has the potential to alleviate pain due to an indwelling ureteral stent.

This study has some limitations. It was not a multicenter or placebo-controlled study. Other limitations are the study's small sample size (n = 76), the evaluation of SRSs without the use of the USSQ, the lack of an evaluation of the patients' sexual activity, the potential of the aggravation of LUTS due to instrumentation, and the lack of a urodynamic study.

In conclusion, mirabegron treatment for SRSs significantly decreased the patients' IPSS, IPSS-QoL, and OABSS scores and the number of nocturia episodes per night. Mirabegron alleviated urinary symptoms due to the patients' ureteral stents. Thus, mirabegron is a safe drug and is effective for improving stent-related symptoms.

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