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ORIGINAL ARTICLE

Prospective randomized controlled trial comparing a ureteral stent crossing versus not crossing the bladder midline

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Abstract

Purpose To evaluate the correlation between the position of a ureteral stent and stent-related symptoms in a single-center randomized study.

Methods A total of 113 patients who required ureteral stent placement after lithotripsy were randomized at a 1:1 ratio into groups with stents crossing and not crossing the bladder midline. The ureteral stent remained in place until postoperative day 14, when we obtained each patient's International Prostate Symptom Score (IPSS), overactive bladder symptom score (OABSS), and visual analog scale (VAS) pain score.

Results Comparing changes from baseline IPSS and OABSS scores between the two groups, the midline crossing group had a worse OABSS total score than the not crossing group (3.0 ± 2.8 vs. 2.0 ± 3.3; $p = 0.032$). There was no significant difference between the crossing and not crossing groups in IPSS total score (6.8 ± 7.6 vs. 5.1 ± 8.5; $p = 0.14$). The OABSS urgency mean score was significantly lower in the not crossing than in the crossing group (1.1 ± 1.8 vs. 1.6 ± 1.8; $p = 0.042$). However, there was no significant difference between groups for remaining items of the IPSS and OABSS and the mean VAS total pain score (1.9 ± 2.7 vs. 1.2 ± 1.9; $p = 0.14$).

Conclusion A ureteral stent that crossed the bladder midline led to worse urinary symptoms. Choosing the appropriate stent length for each patient is important to minimize stent-related symptoms.

Trial Registration date 1 October 2018; number: UMIN000034067.

Keywords Lower urinary tract symptoms · Ureter · Stent · Ureteroscopy

Introduction

Since Zimskind et al. [1] introduced them in 1967, ureteral stents have become widely used for the maintenance of renal function, pain relief, and treatment of urinary tract infections. Ureteral stenting has also been used for the drainage of upper urinary calculi after ureteroscopic lithotripsy (URSL) and in the prevention of ureteral obstruction by stone fragments or hematomas. However, several complications related to ureteral stenting have been reported, such as incomplete emptying, bladder pain, frequency, hematuria, and migration. Additionally, ureteral stenting has been reported to diminish urination-related quality of life in 80% of patients who have undergone the procedure [2]. Several factors have been investigated for their effects on ureteral stent symptoms, namely, stent length [3, 4], diameter [5, 6], material [5], softness [7], position [8, 9], design [10, 11], and loop completeness [3].

Some studies have reported that placing an overly long ureteral stent can lead to worsening of urinary symptoms [3, 12, 13]. In a retrospective study, we previously reported that a ureteral stent crossing the bladder midline leads to worse urinary symptoms [9]. However, there is conflicting evidence regarding this issue. Abt et al. investigated the correlation between the position of a ureteral stent and

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stent-related symptoms using the ureteral stent symptom questionnaire (USSQ) in 73 patients who underwent URSL [14]. The authors concluded that the position of the ureteral stent was not associated with morbidity. Therefore, the association between ureteral stent position and stent-related symptoms remains unclear. In this randomized controlled trial (RCT), we evaluated the association between ureteral stent position and stent-related symptoms.

Materials and methods

Ethics statements

This study was a prospective, randomized, single-blind, single-center trial registered in the University Hospital Medical Information Network on 1 October 2018 (UMIN000034067). This study was approved by our institutional review board (No. 1809–3), and all patients provided written informed consent. We strictly followed the 2010 CONSORT (Consolidated Standards of Reporting Trials) statement guidelines to design and report this trial.[15].

Study participants

Eligible participants were adult patients ≥ 20 years of age who underwent unilateral URSL with planned ureteral stent insertion. The exclusion criteria were as follows: (1) active urinary tract infection; (2) concomitant medication with alpha blockers, antimuscarinics, analgesics, beta-3 agonists, and/or phosphodiesterase-5 inhibitors; (3) pregnancy; (4) ureteral stent placement before URSL; (5) bilateral ureteral stenting; (6) bladder cancer; (7) prostate cancer; (8) neurogenic bladder; (9) chronic prostatitis; (10) complications during ureteroscopy, such as ureteral perforation; and (11) lower ureteral calculi.

Study design

From October 2018 to December 2020, eligible patients were randomly and equally divided at a 1:1 ratio into a not crossing group and a crossing group (Fig. 1). Randomization was performed using computer-generated random tables before URSL, and the patients were blinded to the assignments throughout the study period. Sample size was calculated with the G*Power program using a priori analysis with an effect size of 0.5. The log-rank test with a two-sided significance of 0.05 had 80% power to detect differences between the groups with a sample size of 64 patients per group.

Intervention and postoperative follow-up

Unilateral URSL was performed with the patient under general anesthesia, using a semirigid or flexible ureteroscope with or without a ureteral access sheath. When used, the ureteral access sheath was a Navigator 11/13 F or 12/14 F (Boston Scientific, Natick, MA, USA). All surgeries were performed by a single surgeon, and a stent was inserted after URSL. All stents were Inlay Optima stents (CR Bard Inc., Murray Hill, NJ, USA), and the diameter was 6 F. There were four options for the stent length (22, 24, 26, and 28 cm). The length of the ureteral stent was chosen according to the patient's body height. Ho et al. divided patients into three populations according to their body height as < 160 cm, 160–175 cm, and > 175 cm, to choose the ideal length of a ureteral stent [16]. This was the method we used in this report. Among patients in the not crossing group, those with height < 160 cm received the 22-cm ureteral stent, patients with height between 160 and 175 cm received the 24-cm ureteral stent, and patients with height > 175 cm received the 26-cm ureteral stent. Among patients in the crossing group, those with height < 160 cm received the 24-cm ureteral stent, patients with height between 160 and 175 cm received the

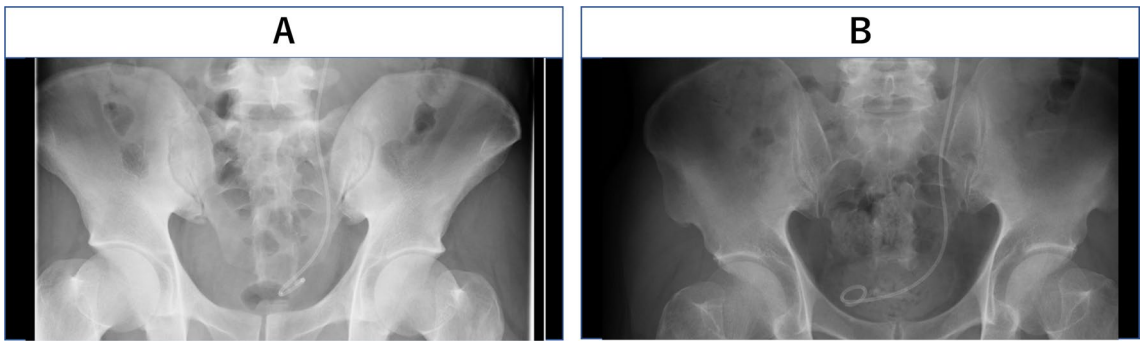

Fig. 1 Classification of the intravesical ureteral stent position. The intravesical ureteral stent in the not crossing group does not cross the midline of the bladder (**A**); the stent crosses the midline in the crossing group (**B**)

26-cm ureteral stent, and patients with height > 175 cm received the 28-cm ureteral stent.

The ureteral stent location and residual stone were evaluated using plain radiography on postoperative day (POD) 1 and 14; we removed the ureteral stent on POD 14. We obtained the International Prostate Symptom Score (IPSS) and overactive bladder symptom score (OABSS) for all patients before surgery at baseline and on POD 14. The IPSS and OABSS were self-administered by all patients. On POD 14, we also obtained visual analog scale (VAS) pain scores.

End points

The study primary end points were the IPSS total score and OABSS total score. The secondary end points were the VAS total pain score, the score for each item of the IPSS and OABSS, and the relationship between patient height and ideal stent length.

Statistical analysis

The chi-square test was used to compare nominal variables, and the Student *t* test was used to compare continuous variables between the two arms. We used IBM SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA) for the statistical analysis, and the significance level was set at $p < 0.05$.

This study failed to reach the required recruitment. Therefore, we calculated post hoc powers for the IPSS total score, OABSS total score, and VAS total pain score. The sample size was 51 and 62 patients; we used a two-sided *t* test for the percentage change from baseline between the two groups. Significance was defined as p < 0·05. Post hoc powers were 20%, 40%, and 35%.

Results

Study population

The CONSORT diagram of this study is shown in Fig. 2. The planned number of participants was 128, but owing to the COVID-19 pandemic, recruitment was terminated at the halfway point; 113 patients were randomized. No patients were excluded, and all 113 patients were included in the analysis, 51 in the not crossing group and 62 in the crossing group.

The patients' baseline characteristics in each group were comparable regarding sex, age, body height, body

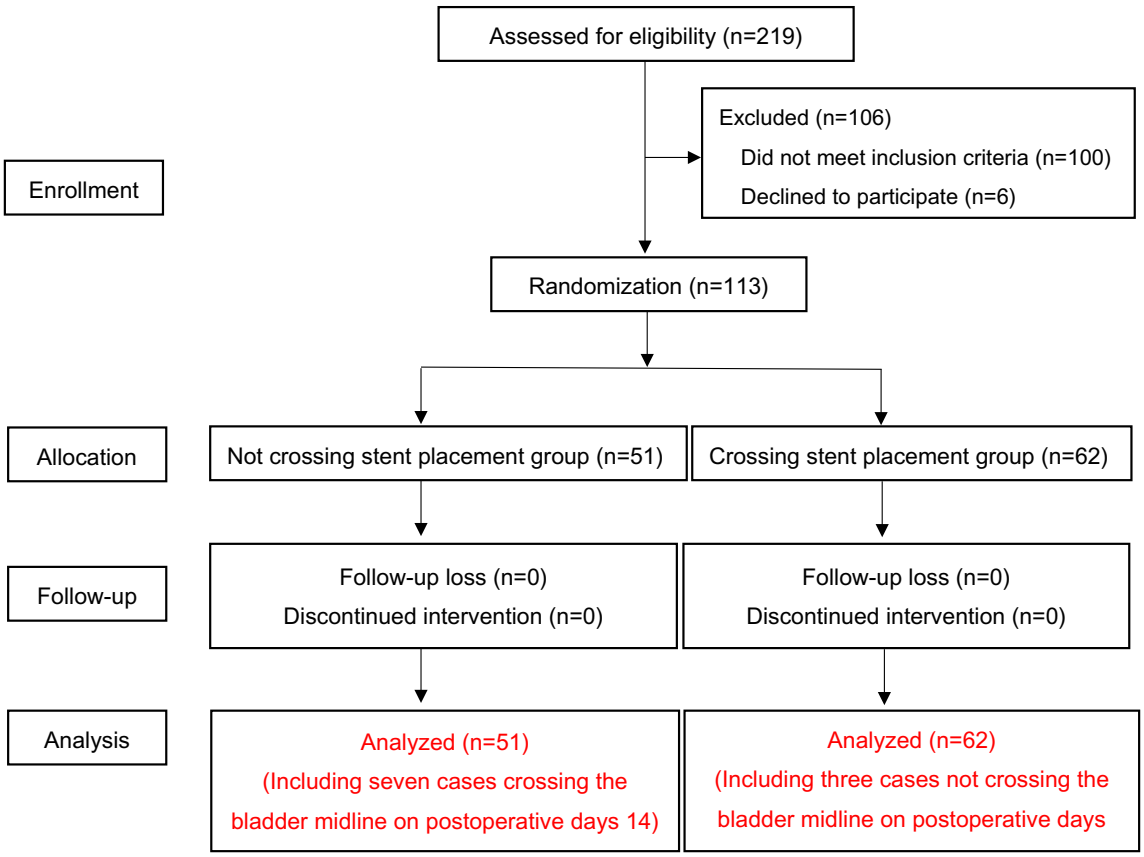

Fig. 2 CONSORT diagram of this study

weight, body mass index, stent side, stone location, stone size, urine culture, ureteral access sheath, operation time, and IPSS and OABSS scores (Table 1).

Primary and secondary end points

Table 2 shows a comparison of the changes from baseline in the IPSS and OABSS between the two groups. The crossing midline group had a worse OABSS total score than the not crossing group (3.0 ± 2.8 vs. 2.0 ± 3.3; $p = 0.032$). The IPSS

Table 1 Baseline characteristics of all patients and comparison between the two study groups

	All *n* (%) or mean ± standard deviation	Not crossing group	Crossing group	*p*-value
Patients	113	51	62	
Sex				0.69
Male	84 (74.3)	37 (72.5)	47 (75.8)	
Female	29 (25.7)	14 (27.5)	15 (24.2)	
Age	62.3 ± 14.1	62.3 ± 14.9	61.1 ± 13.3	0.52
Body height (m)	1.62 ± 0.09	1.59 ± 0.09	1.63 ± 0.10	0.67
Body weight (kg)	65.2 ± 13.4	64.9 ± 15.9	65.5 ± 10.8	0.14
BMI (kg/m^2)	24.9 ± 3.9	25.2 ± 4.8	24.6 ± 3.0	0.49
Stent side				0.52
Left	65 (57.5)	31 (60.9)	34 (54.8)	
Right	48 (42.5)	20 (39.1)	28 (45.2)	
Stone location				0.73
Renal pole	44 (38.9)	18 (35.3)	26 (41.9)	
Renal pelvis	6 (5.3)	3 (5.9)	3 (4.8)	
Proximal ureter	43 (38.1)	18 (35.3)	25 (40.3)	
Mid ureter	24 (21.2)	13 (25.5)	11 (17.7)	
Stone size (mm)	7.9 ± 5.2	8.2 ± 5.3	7.8 ± 5.0	0.60
Positive urine culture	19 (16.8)	10 (19.6)	9 (14.5)	0.64
Ureteral access sheath				0.33
Not used	12 (10.6)	7 (13.7)	5 (8.1)	
11/13 F	98 (86.7)	42 (82.4)	56 (90.3)	
12/14 F	3 (2.7)	2 (3.9)	1 (1.6)	
Operation time (min)	60.8 ± 33.5	62.6 ± 38.4	59.3 ± 28.2	0.97
IPSS (preoperative)				
Q1, Incomplete emptying	0.7 ± 1.3	0.5 ± 1.1	0.9 ± 1.5	0.27
Q2, Frequency	1.4 ± 1.6	1.6 ± 1.7	1.2 ± 1.4	0.38
Q3, Intermittency	0.6 ± 1.2	0.6 ± 1.1	0.7 ± 1.3	0.64
Q4, Urgency	0.7 ± 1.3	0.7 ± 1.4	0.6 ± 1.3	0.58
Q5, Weak stream	1.1 ± 1.6	1.1 ± 1.5	1.1 ± 1.7	0.66
Q6, Straining	0.5 ± 1.1	0.4 ± 1.1	0.6 ± 1.2	0.35
Q7, Nocturia	1.5 ± 1.2	1.6 ± 1.3	1.4 ± 1.1	0.36
Total score	6.5 ± 5.9	6.6 ± 5.5	6.4 ± 6.3	0.65
QOL	2.6 ± 1.8	2.8 ± 1.8	2.5 ± 1.8	0.59
OABSS (preoperative)				
Q1, Daytime frequency	0.5 ± 0.5	0.6 ± 0.5	0.5 ± 0.6	0.19
Q2, Nocturia	1.4 ± 1.0	1.5 ± 1.0	1.3 ± 1.0	0.35
Q3, Urgency	0.8 ± 1.2	0.8 ± 1.3	0.8 ± 1.2	0.54
Q4, Urgency incontinence	0.4 ± 1.0	0.5 ± 1.1	0.4 ± 0.9	0.91
Total score	3.2 ± 2.8	3.4 ± 2.9	2.9 ± 2.6	0.47

BMI body mass index, *IPSS* International Prostate Symptom Score, *QOL* quality of life, *OABSS* overactive bladder symptom score, *Q* question

Table 2 Comparison of changes from baseline in the IPSS and OABSS scores between the two groups

	Not crossing group Mean (standard deviation)	Crossing group	*p*-value
IPSS			
Q1, Incomplete emptying	1.0 ± 1.8	1.1 ± 1.8	0.78
Q2, Frequency	0.9 ± 1.9	1.3 ± 2.0	0.37
Q3, Intermittency	0.7 ± 1.6	0.7 ± 1.4	0.84
Q4, Urgency	0.8 ± 2.1	1.5 ± 1.9	0.11
Q5, Weak stream	0.5 ± 1.6	0.5 ± 1.4	0.86
Q6, Straining	0.6 ± 1.9	0.9 ± 1.6	0.29
Q7, Nocturia	0.5 ± 1.4	0.8 ± 1.4	0.37
Total score	5.1 ± 8.5	6.8 ± 7.6	0.14
QOL	0.8 ± 2.4	1.4 ± 2.5	0.50
OABSS			
Q1, Daytime frequency	0.3 ± 0.6	0.4 ± 0.7	0.56
Q2, Nocturia	0.3 ± 0.9	0.6 ± 1.0	0.14
Q3, Urgency	1.1 ± 1.8	1.6 ± 1.8	0.042
Q4, Urgency incontinence	0.4 ± 1.3	0.3 ± 0.9	0.99
Total score	2.0 ± 3.3	3.0 ± 2.8	0.032

IPSS International Prostate Symptom Score, *QOL* quality of life, *OABSS* overactive bladder symptom score
[a]Voiding symptoms: Questions (*Q*) 1 + 3 + 5 + 6; [b]Storage symptoms: Questions 2 + 4 + 7

total score in the crossing midline group was also worse; however, there was no significant difference compared with the not crossing group (6.8 ± 7.6 vs. 5.1 ± 8.5; $p = 0.14$).

Regarding the secondary end points, the OABSS urgency mean score was significantly lower in the not crossing group than in the crossing group (1.1 ± 1.8 vs. 1.6 ± 1.8; $p = 0.042$). However, no significant difference was found between the not crossing and crossing groups for mean scores on the remaining items of the IPSS and OABSS surveys (Table 2). The mean VAS total pain score was not significantly different in the not crossing group and crossing group (1.9 ± 2.7 vs. 1.2 ± 1.9).

In this study, the stent position of ten patients (8.8%) had deviated on plain radiographs at POD 14, from not crossing to crossing in seven patients (13.7%) and from crossing to not crossing in three patients (4.8%). We primarily analyzed our data according to initial randomization (intention-to-treat analysis) (Fig. 2). We also analyzed our data in per-protocol analysis (excluding data for the ten patients with a deviated stent position; Supplemental Table 1) and in as-treated analysis (converting the ten deviated patients into the other group according to the actual stent position at POD 14; Supplement Table 2). In both analyses, there were significant differences in IPSS urgency (0.7 ± 2.1 vs. 1.6 ± 1.9, $p = 0.03$; 0.6 ± 2.0 vs. 1.7 ± 2.0, $p = 0.005$), IPSS total score (4.8 ± 8.4 vs. 7.2 ± 7.6, $p = 0.048$; 4.3 ± 8.2 vs. 7.3 ± 7.8, $p = 0.01$), OABSS urgency (0.8 ± 1.6 vs. 1.7 ± 1.7, $p = 0.004$; 0.7 ± 1.6 vs. 1.8 ± 1.8, $p < 0.001$), and OABSS total score (1.7 ± 2.9 vs. 3.2 ± 2.8, $p = 0.005$; 1.5 ± 2.9 vs. 3.3 ± 2.9, $p = 0.001$).

All patients except two (one patient in each group) with small fragments in the kidney showed no residual stone on plain radiography at POD 14.

Discussion

In this randomized controlled trial, we evaluated the association between ureteral stent position and stent-related symptoms. The group with stent placement crossing the bladder midline had a worse OABSS total score than the not crossing group, and the OABSS urgency mean score in the crossing group was significantly worse than that in the not crossing group. In secondary end points, although the OABSS urgency mean score was significantly worse in the crossing group, we failed to detect differences in all items of the IPSS and OABSS Q1, Q2, and Q4. One reason would be owing to the protocol deviation. In this study, the stent position at POD 14 in seven and three patients had migrated from not crossing to crossing the bladder midline and from crossing to not crossing the midline, respectively. When these patients were excluded (per-protocol analysis) or re-grouped according to the actual position (as-treated analysis), there were significant differences in IPSS urgency, IPSS total score, OABSS urgency, and OABSS total score (Supplemental Tables 1 and 2).

It is important to choose an appropriate ureteral stent length for each patient to minimize stent-related symptoms, but deciding the length is also challenging. Several methods have been reported for choosing an appropriate ureteral stent

length for each patient. One method is direct measurement of the ureter itself using a guide wire or ureteral catheter [17–20]. The other method is based on the date of retrograde or intravenous pyelography [20, 21]. These methods are substantially invasive. Patient height is reportedly a more reliable guide for obtaining an appropriate ureteral stent length than direct ureteral measurement using a guide wire or ureteral catheter [17–20]. Therefore, in this RCT, the length of the ureteral stent was chosen according to the patient's body height; however, the stent in ten patients (8.8%) was located in an unintended position on POD 14. Other methods have also been reported, such as using computed tomography [22] or plain radiography [23]. However, there is no reliable method for determining ureteral stent length.

Although several reports [24] indicate that ureteral stenting is unnecessary after uncomplicated URSL, many urologists routinely insert a ureteral stent after URSL [25]. In these patients, minimizing stent-related symptoms is important for their quality of life. Medical therapies, such as alpha blockers, antimuscarinics, and beta-3 agonists, have been widely used to improve stent-related symptoms [26–28]. However, these medical therapies may be associated with drug-related complications, such as headache, dizziness, gastrointestinal problems, dry mouth, constipation, and allergic reactions. Furthermore, medical therapies can be costly.

Several factors have been reported to be correlated with ureteral stent symptoms. Among them, stent position is considered very important. Giannarini et al. reported that stent position had the strongest impact on most domains of the USSQ [13]. Rane et al. reported that a ureteral stent crossing the bladder midline leads to worse urinary symptoms (particularly urgency) owing to trigonal irritation [3], because the trigone of the bladder has a large number of sensory nerve fibers [29]. Two RCTs have evaluated the stent position and stent-related symptoms. Liatsikos et al. demonstrated that stent-related symptoms such as urgency were decreased in the group with the proximal stent end located in the upper pole compared with in the renal pelvis [8]. Al-Kandari et al. compared stent-related symptoms, such as flank pain, dysuria, and urgency, in groups with a longer stent (proximal end in the upper pole and distal end crossing the bladder midline) versus a shorter stent (proximal end in the renal pelvis and distal end just beyond the vesicoureteral junction) [4]. Those authors showed that the group with a longer stent had significantly worsening of dysuria, urgency, and quality of life. However, those two RCTs did not report data for stent migration. In our RCT, we simply focused on the position of the distal end of the stent and demonstrated that it strongly influenced stent-related symptoms. Furthermore, our data revealed the rate of stent migration (8.8%). In this type of prospective study, it is important to note that stent migration may have a negative impact on detecting the difference between intervention groups.

This study had some limitations. First, this was an open label, single-center, RCT with a relatively small sample size. Second, the stent position shifted from the allocated position in ten patients. In future studies, it is necessary to choose the optimal ureteral stent length using more reliable methods. Third, we used the IPSS and OABSS instead of the USSQ, which is globally considered the gold standard for evaluating ureteral stent-related symptoms. However, there is no validated Japanese version of the USSQ available. Data on quality of life using the IPSS rather than the USSQ may be insufficient, and hematuria as a stent-related symptom were not evaluated this study. Fourth, recruitment was terminated at the halfway mark owing to the COVID-19 pandemic; therefore, this study might be underpowered. However, we found a significant difference between the groups in OABSS total score and OABSS urgency score as primary end points.

Conclusions

The present study indicated that when inserting a ureteral stent, the stent should not cross the bladder midline. Choosing the appropriate ureteral stent length for each patient is important to minimize stent-related symptoms.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00345-022-03978-5.

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Author contributions MT: project development, data collection/management, data analysis, manuscript writing. KY: data analysis, manuscript editing. HK: project development, data analysis, manuscript editing.

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Availability of data and materials The data that support the findings of this study are available from the corresponding author upon reasonable request.

Code availability Not applicable.

Declarations

Conflict of interest None declared.

Ethics approval This study was approved by our institutional review board (authorization number: 1809–3). Informed consent was obtained from all individual participants included in the study. All methods were performed in accordance with approved guidelines.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication Written informed consent for publication of the participants' clinical details and/or clinical images was obtained from each patient or the patient's parent(s)/guardian(s)/relative(s).

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