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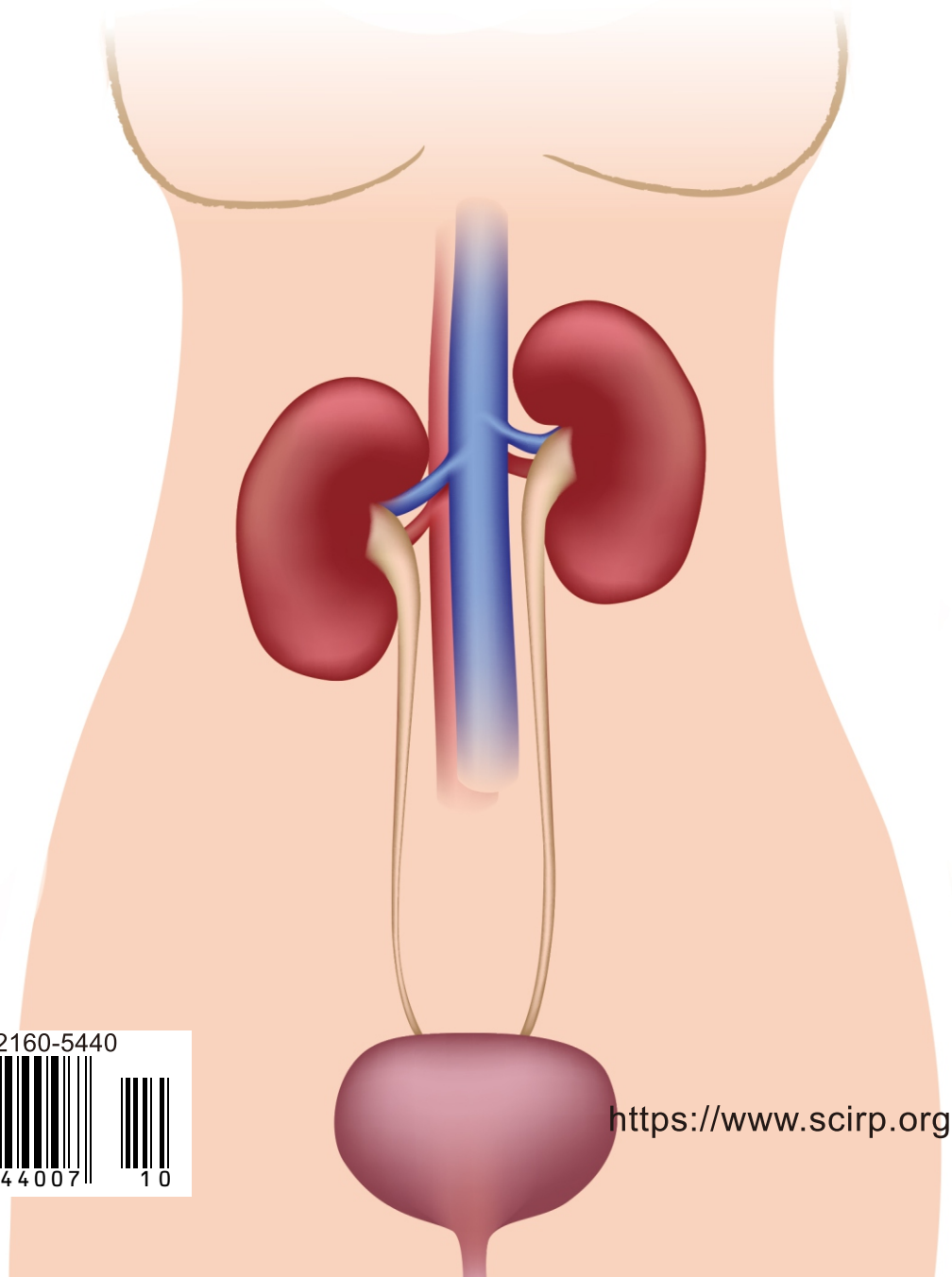

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Evaluation of Outcome of Ureteroscopic Pneumatic Lithotripsy in Single Lower Ureteric Calculus and Its Association with CT Parameters

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Abstract

Objective: To evaluate the outcome of ureteroscopic pneumatic lithotripsy in single lower ureteric calculus and correlate its success with different CT parameters like HU, size of calculus and hydrnephrosis, if present. **Patients and Methods:** This study was conducted from October 2017 to March 2019 in Department of General Surgery, Maulana Azad Medical College, New Delhi. 30 patients (out of which 6 were excluded due to spontaneous passage of calculus), with single lower ureteric calculus were chosen and the outcome of URSL was compared with respect to CT parameters of Size, HU and Hydronephrosis and intra-operative clearance of calculus. **Results:** Success rate of URSL in single lower ureteric calculus was found to be 75%. Lower HU (774.12 ± 212.85) was associated with higher success rate. Similarly smaller size of calculus (9 ± 2.1) mm was associated with success group. Patients with gross hydronephrosis had a poor outcome of URSL. Lower urinary tract infection (8.33%) was the most common complication. **Conclusion:** Patients with small size calculus, low HU and absence of hydronephrosis have a better outcome of URSL.

Keywords

Computed Tomography (CT), Ureteroscopic Lithotripsy (URSL), Hounsfield Unit (HU), Hydronephrosis (HDN)

1. Introduction

Ureteral stones are common (5% - 12%) urologic condition [1]. They are commonly made up of Calcium salts, while others are also made of other compounds like triple phosphates, cysteine and uric acid [2]. Due to this variability in its

composition, the stones themselves can occur in various shapes, sizes and hardness. The stone may lie at different anatomical positions within the ureter, hence they are also classified as upper, middle and lower ureteric stone. Lower ureteric calculus (distal ureter + UVJ) is most common, more than 60% of all ureteric calculus [3].

Non Contrast Computed Tomography (NCCT) is accepted as one of the best imaging modality for detection and evaluation of ureteric calculus with sensitivity as high as 96% [4]. It is the imaging modality of choice during acute renal colic. Other than the anatomical details, we can rule out other pathologies that may mimic renal colic [5]. CT also helps in knowing about the nature or the hardness of the stone measured in terms of Hounsfield unit (HU) [6] [7]. In terms of position it tells the exact distance of the stone from PUJ/VUJ.

Ureteroscopic lithotripsy (URSL) is a good intervention modality for treatment of ureteric stones [8]. Its outcome is affected by size, position and nature of stones. In our study we are evaluating the outcome of URSL in lower ureteric calculus and its association with CT parameters. The parameters used are dimensions and HU of stone which depict the nature and size of stone.

2. Material and Methods

The study was conducted in department of General Surgery, Maulana Azad Medical College and Lok Nayak hospital, New Delhi from October 2017 to March 2019. It was a prospective study. A total of 30 patients were taken for study, which was done for a period of 1.5 years. Inclusion criteria was all adults (>18 years) with diagnosis of single lower ureteric calculus on X-Ray KUB (**Figure 1**). Exclusion criteria were presence of ureteral injury/stricture, urinary tract infection, single kidney, renal failure. Out of the 30 patients, 6 were excluded due to spontaneous passage of stone. Remaining 24 patients underwent unenhanced helical computed tomography scan (**Figure 2** & **Figure 3**). The images were reviewed at a Picture Archiving and Communication System (PACS) workstation.

The size of the stone was measured using the dimension tool of Radiant DICOM software. The longest transverse diameter of stone was taken as the size of stone. Other stone factor used was height of stone in form number of axial cuts images of stone (slice thickness 5 mm). The Hounsfield units (HU) for each stone were calculated for the cross-section with the largest diameter and the secondary sign like hydronephrosis was graded between 0 - 3. All the CT studies were reviewed by radiologist who was blindfolded to pre and postoperative CT parameters.

Hydronephrosis was graded as follows: 0 = absent, 1 = prominence of the intrarenal pelvis or mild ureteral dilatation, 2 = dilatation of the renal calices or moderate ureteral dilatation, and 3 = severe dilatation of the collecting system [9].

Using a 10 F rigid ureteroscope, a guide wire was introduced in lower ureter and ureteroscope was advanced in lower ureter. Using pneumatic lithotripter the stone was broken and extracted using dormia basket or forceps.

Figure 1. X-Ray KUB showing right lower ureteric calculus.

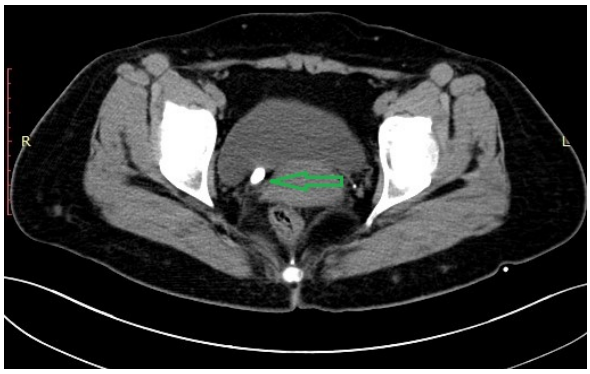

Figure 2. CT KUB showing right lower ureteric calculus.

Figure 3. CT KUB with calculus in right lower ureter.

Statistical analysis was performed to evaluate the association between the outcome of URSL and patient's age and gender. We also evaluated the association between the outcome of URSL and CT parameters of the stone like size of the stone, Hounsfield unit. We also included hydronephrosis as secondary sign, duration and complication of the procedure as statistical parameters in our study.

All values are expressed as the mean ± standard deviation. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by

Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. A *p* value of less than 0.05 was considered significant.

3. Results

Data from 24 patients with single lower ureteric stone were analyzed. Outcome was classified as successful or failure, based on intra-operative clearance of stone and post operative CT findings. In our study 18 patients had complete removal of stones and 6 patients had failed outcome of URSL. The overall rate of treatment success was 75% (n = 18) and the failure rate was 25% (n = 6). The outcome of URSL was correlated with duration of the procedure and CT parameters such as size of stone (diameter and height), Hounsfield unit and presence of hydronephrosis. In group 1 (success group) the mean duration of URSL was 25.56 ± 6.49 minutes and mean Hounsfield unit of stone was 774.12 ± 212.85 HU. In group 2 (failure group) the mean duration of URSL was 40.75 ± 4.95 minutes and mean Hounsfield unit of stone was 1193.12 ± 327.51 HU (Table 1).

Out of 24 patients, 18 had positive outcome of URSL with mean size of stone 9 ± 2.1 mm and 6 had negative outcome with mean size of stone 12.5 ± 3.3 mm. The **p value** for stone size in relation to outcome was **<0.0004** which was **statistically significant** (Figure 4).

In our study population the shortest duration of URSL was 15 min and the longest duration was 48 min. Out of 24 patients, 18 had positive outcome of URSL with mean duration of procedure 25.56 ± 6.49 and 6 had negative outcome with mean duration of 40.75 ± 4.95. The **p value** for procedure duration was **<0.0001** which was **statistically significant** (Figure 5).

Out of total sample size of the study 58.33% of patients had moderate hydronephrosis (HDN), 29.17% had gross HDN and 12.50% had mild HDN. Patients with gross HDN had a poor outcome of URSL (Figure 6 & Figure 7).

The patient's sex, age, height, weight, BMI and previous stone history did not differ significantly between group 1 and group 2 (Table 2).

The most common complication seen was lower urinary tract infection, which accounted for 8.33%. Second most common complication was hematuria which accounted for 4.16%. There was no evidence of any other known complication including ureteric perforation (Table 3).

4. Discussion

The success rate of URSL depends on the location of stone in the ureter, size of the stone, the use of surgical instruments including the ureteroscope, and the operator's surgical technique.

The stone size factors that were included in the study were longest diameter, transverse diameter, and height by CT axial cuts. Most studies have focused on the longest stone diameter for measuring stone size. However, Abdelrahim *et al.* [10] considered the transverse stone diameter, as this dimension generates the most resistance to the downward force applied by a basket or forceps.

Table 1. Comparison of outcome of URSL in respect to duration of procedure, size and HU of calculus and Hydronephrosis.

	Success (Group 1) Sample size 18	Failure (Group 2) Sample size 6	P value
Duration (minutes)			<0.0001
Mean ± SD	25.56 ± 6.49	40.75 ± 4.95	
HU			0.001
Mean ± SD	774.12 ± 212.85	1193.12 ± 327.51	
Size (mm)			0.004
Mean ± SD	9 ± 2.1	12.5 ± 3.3	
Hydronephrosis (grade 0/1/2/3)	0/3/13/2	0/0/1/5	0.001

Table 2. Comparison of various parameters in success and failure group.

Parameters	Success (group 1)	Failure (group 2)	p value
Sex (m/f)	14/4	5/1	>0.05
Age (years)	26.75 ± 6.2	26.80 ± 6.1	>0.05
Height (cm)	160.66 ± 9.3	160.56 ± 9.6	>0.05
Weight (kg)	65.3 ± 8.7	66.1 ± 8.3	>0.05
BMI (kg/m^2)	25.2 ± 3.4	24.6 ± 3.2	>0.05
Previous stone history (present/not)	6/13	2/4	>0.05

Table 3. Complications after URSL.

Complications	Number	Percentage
Ureteric perforation	0	Zero
Hematuria	1	4.16
Lower urinary tract infection	2	8.33

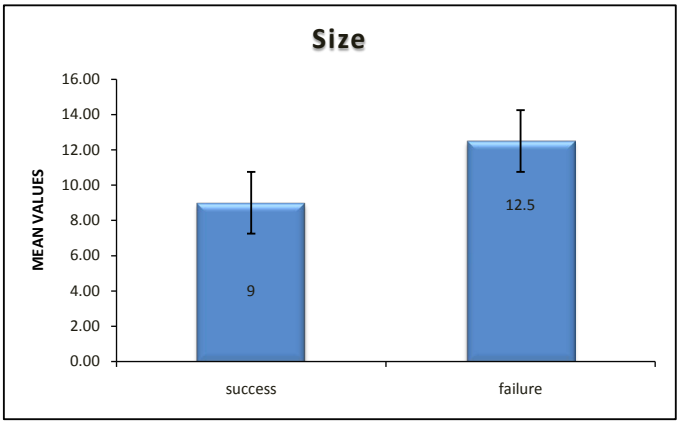

Figure 4. size of stone with outcome of URSL.

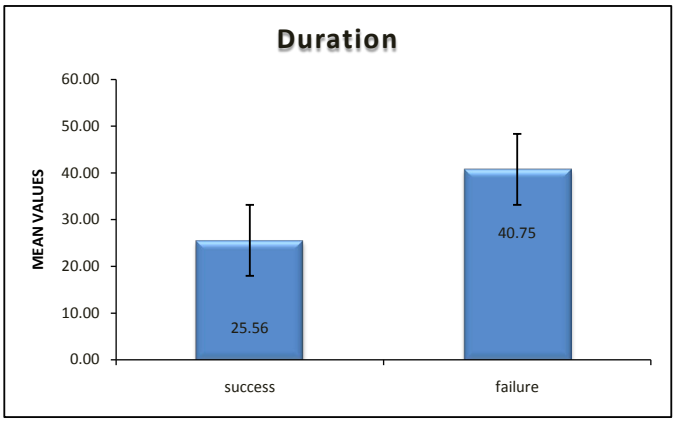

Figure 5. Duration with outcome of URSL.

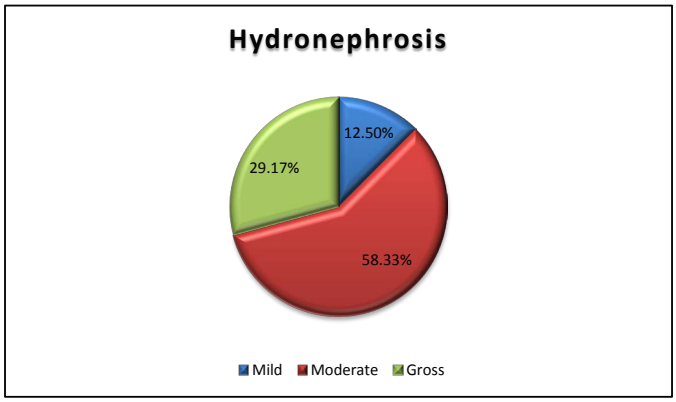

Figure 6. Distribution of Hydronephrosis.

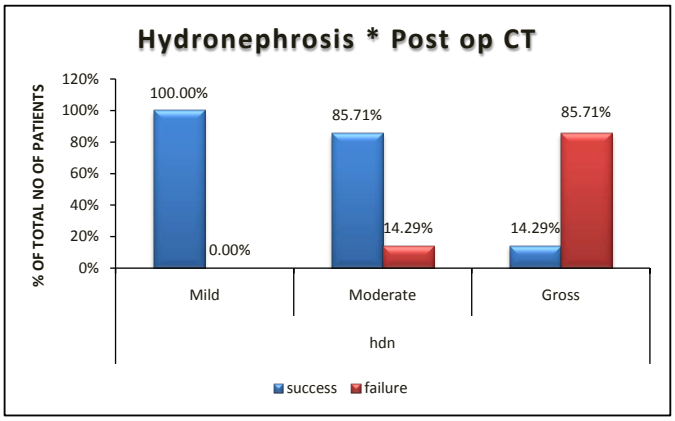

Figure 7. Hydronephrosis and outcome of URSL.

There is still controversy whether the secondary signs can predict outcome in patients with ureteral stones or not. In a report on the incidence rates of secondary signs and their influences on patient management, Ege *et al.* [11] identified hydroureter, hydronephrosis, periureteral edema, and unilateral renal enlargement as the most reliable signs for endoscopic removal of stones. Takahashi *et al.* [12] reported that the severity of perinephric edema correlates with the probability of stone expulsion spontaneously. He also suggested that the degree

of edema indicated the seriousness of ureteral obstruction. Seitz *et al.* [13] reported that the presence of secondary signs before URSL did not correlate with the preoperative stone-free rate. In our study 7 out of 24 patients had gross HDN and among them 6 had failed outcome of URSL. Patients with gross HDN had poor outcome of URSL. This was because patients with gross HDN has longer duration of stone disease which resulted in impaction of stone and thus resulting in failure of URSL.

In our study the stone with higher HU had a negative outcome as compared to stones with a low HU. The result was in concordance with the study done by Magnunson *et al.* [14] who showed that Hounsfield unit reflects the stone's composition and hardness and correlates with the rate of successful ESWL.

Our study compares well with other world literature in terms of outcome of URSL. In our study the overall success rate was 75% and complication rate of 16.67%. Knispel *et al.* had a success rate of 73.7% in his series of 135 patients who were treated with lithocast [15] Shrestha *et al.* had a success rate of 88.5% in 52 patients with lower ureteric calculi when treated with pneumatic lithotripter [16]. Oktay *et al.* and Leidi *et al.* also showed the success rate of 91% in lower ureteric calculi [17] [18]. Another study done by Salman *et al.* compared pneumatic lithotripsy and laser lithotripsy. Out of 50 patients taken for pneumatic lithotripsy, 41 patients had successful outcome giving a success rate of 82% [19]. In our study we were not able to include the later complications such as stricture formation, which has been documented in literature, due to difficulties in the further follow up.

5. Conclusions

Size of the stone and Hounsfield units of the stone are the factors which directly influence the outcome of URSL; the bigger the stone or the higher the HU of stone, the less the chances of complete removal of stone. Gross hydronephrosis is associated with poor outcome of URSL.

This study also points towards higher incidence of ureteric stones in males as compared to females with mean age of presentation between 20 - 40 years. We found that ureteroscopy is safe with minimal complications in the management of lower ureteric calculus.

Ethical Clearance

Study was approved by institutional ethics committee.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Management of Bladder Exstrophy: A Case Report in the Urological Ward at Saint Elizabeth General Catholic Hospital SHISONG

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Abstract

Bladder Extrophy is a rare urogenital malformation of the penis and bladder. This is an impressive fact at birth, due to the absence of the anterior bladder wall and the dorsal side of the penis. We report the clinical observation of a 21-month-old child who consults for urine incontinence from birth, when physical examination showed complete bladder extrophy. The reconstructive surgery allowed forming a bladder reservoir associated with a repair of the penis at the same time. Bladder extrophy is a benign condition whose operative consequences can be simple but urinary incontinence is not uncommon after reconstitution.

Keywords

Extrophy, Penis, Bladder, Malformation

1. Introduction

Bladder exstrophy is a urogenital malformation characterized by an abnormality of the cloacal membrane that forms the intra-umbilical abdominal wall during the first weeks of embryonic life.

It presents itself under 3 aspects: the classical form or complete vesical extrophy, the partial form which is rare and the extended form known as extrophy of the cloaca also very rare [1] [2] [3].

In Africa, the presence of an apparent malformation is often interpreted as a

curse or the result of witchcraft.

In addition, there are also socio-economic factors and the lack of qualified medical personnel in peripheral health facilities with the result that pregnant women cannot properly follow their pregnancies in a health facility in order to detect possible malformation in time during the antenatal period

Bladder exstrophy, diagnosed during the morphological examination in the 2nd trimester of pregnancy may be a reason for voluntary termination of pregnancy [4] [5].

Bladder exstrophy is a rare pathology; its frequency is estimated at 1 in 10,000 to 50,000 births [6].

It affects about one in 40,000 infants according to the Boston Children's Hospital in the United States of America [5].

We report the clinical case of a newborn having a complete bladder exstrophy received and treated in our hospital and make a review of the literature.

2. Observation

It was a 21-month-old male child who had been referred to us from a rural health center on the outskirts of Bamenda in North West Region of Cameroon.

At birth, the malformation was obvious and after several unsuccessful consultations in health facilities in the region, he was sent to us for management

The study of his antecedents had revealed that he was the last born in family of three and no malformation had been revealed in his brothers. Similarly, there was no concept of consanguinity between the parents. No ultrasound examination documented the pregnancy follow-up of the mother, who said that she had done her prenatal consultations correctly.

The clinical examination revealed a conscious child in good general condition with normal reflexes.

At the hypogastric level, the presence of a reddish plate was noted with the presence of the two ureteral orifices measuring 11 cm long axis each through which intermittently flowed urine associated with the absence of the dorsal face of the penis (**Figure 1**). There was also a diastasis of the right muscles in the lower abdominal wall, a displaced navel. The examination expanded to other organs did not reveal other apparent malformations.

The renal blood test was normal with serum creatinine at 5 mg/L and there was no urinary infection on the cyto-bacteriological examination of the urine. The abdominal and pelvic ultrasound did not visualize the bladder because of acoustic window and there was no renal dilation.

In order to obtain a reservoir, a primary surgical closure of the exstrophy and epispadia associated with reconstruction of the anterior abdominal wall without osteotomy was performed. The patient was seen at 3 months with a micturition jet but we could not judge the urinary continence because at this age the child does not yet have micturition autonomy (**Figure 2**). It was planned a control at 6 months, 1 year, and 5 years but the appointment was not respected.

Figure 1. Before intervention.

Figure 2. After intervention.

3. Discussion

Exstrophy of the bladder is a birth defect. It is a rare malformation that affects about one in 40,000 infants according to the Boston Children's Hospital [6].

Exstrophy of the bladder is an apparent malformation discovered at birth. In our case the patient was consulted after 21 months of birth with a bladder dry and retracted.

In developed countries, this pathology is diagnosed during the antenatal life and this intervention is carried out, ideally at 24 - 48 after birth.

The clinical examination of our patient revealed: a diastasis of the straight muscles in the lower abdominal wall, a displaced navel, an inflammatory bladder plate and an associated penile epispadia.

In the literature, in addition to the clinical data of our patient, there is often a diastasis of the associated pubis and in the girl a short urethra, extended labia and a narrow vaginal opening [6] [7]. We did not observe any diastasis of pubic bones in our patient who had good walking.

The work up (urea and blood creatinine, cytobacteriological examination of the urine, radiography of the pelvis and ultrasound of the urinary system) were to check urinary infection, signs of renal insufficiency and the presence of other associated malformations.

Therapeutically, two positions are opposed in the literature:

The first consists of primary closure of the bladder and urethral plate, reconstruction of the lower abdominal wall, and approximation of the pubic bones with or without osteotomy. This has the advantage that it realizes a bladder tank early enough, thus ensuring good healing of the bladder plate and good recovery of continence later. However, it has the disadvantage of being a heavy surgery at

this age requiring a long anesthesia, and traumatizes the children.

The other approach is to correct the malformation by successive interventions carried out at different ages of the child:

- Closure of the bladder and urethral plate and reconstruction of the lower abdominal wall at first leaving the child with epispadia and incontinence at maximum 48 hours of birth,
- Correction of the epispadia at 6 months after hormonal stimulation in a second time and
- Surgery for the incontinence and vesical-kidney reflux at 4 - 5 years of age [8] [9].

In our case, the patient's non-compliance with appointments did not reveal the possibility of performing an enlargement cystoplasty or an uretero-vesical reimplantation.

In any case, taking into account the parents' expectations and the psychosocial discomfort that this malformation may cause in the child, this surgery must be performed at best by a qualified surgeon with a certain experience in the field and with equipment adapted to this type of surgery, which is not always the case in some African countries [5].

In our case, despite the fact that it was a 21-month-old child, the operative follow-ups were a success, particularly the repair of the bladder and the urethra as first-line treatment.

The long-term follow-up of our patient would have allowed us to judge the opportunity to perform an ureterovesical reimplantation. The latter, however, is almost always indicated because the majority of these children still have vesico-renal reflux, which can lead to a deterioration of renal function [8].

4. Conclusions

Bladder exstrophy is an apparent malformation that can be diagnosed on prenatal ultrasound in the first trimester and can lead to pregnancy termination in countries with low skills.

When diagnosed at birth, well-managed surgical management can give a good morpho-functional result.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Salvage Transrectal High-Intensity Focused Ultrasound Therapy for Patients with Recurrence of Vesico-Urethral Anastomosis after Radical Prostatectomy

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Abstract

Background: Salvage radiotherapy has been used as the treatment for patients with local recurrence after radical prostatectomy. However, the therapy is time-consuming and it experiences adverse effects of some kind. Simple and less invasive treatment is highly anticipated. **Objectives**: To evaluate the outcomes of salvage transrectal high-intensity focused ultrasound (HIFU) therapy for patients with localized recurrence of a vesicourethral anastomosis (VUA) after radical prostatectomy. **Material and methods**: Sixteen patients with suspected local recurrence of a VUA after prostatectomy were treated with HIFU. All patients had prostate-specific antigen (PSA) failure (>0.2 ng/ml), positive findings of a VUA with biopsy and/or MRI, TRUS and CT, and no distant metastasis by CT, MRI and bone scintigraphy before HIFU. Recurrence after HIFU was determined by PSA failure (>0.2 ng/ml), histological findings, metastasis and start of systemic therapies. **Results**: HIFU treatments were performed in 16 patients, and followed-up for 7 - 159 months (median 46.5). The pre-HIFU PSA levels ranged from 0.318 to 3.1 ng/ml. Sonication time ranged from 9 - 42 min. All patients had a decline of PSA after HIFU, and 88% of the PSA nadir was <0.2 ng/ml. Recurrence free survival (RFS) rates of 5 year were 31.3%. Nadir PSA was significantly associated with recurrence, whereas initial PSA, pre-HIFU PSA, duration and risk group after prostatectomy were not. There were no intraoperative adverse effects. In the 1 - 3 months after HIFU, there was some difficulty voiding in 4 cases (grade 1), urgency incontinence in 3 cases (grade 1 or 2). **Conclusion**: HIFU therapy for local recurrence after prostatectomy may become a feasible salvage therapeutic option because of its ease and simple procedure. For salvage HIFU therapy, further research and additional follow-up are required to

evaluate and correct the diagnosis of recurrence areas and to provide the sufficient sonication.

Keywords

High-Intensity Focused Ultrasound (HIFU), Prostate Cancer, Recurrence of Vesicourethral Anastomosis (VUA), Radical Prostatectomy, Salvage Therapy

1. Introduction

For the past quarter-century, with the high incidence of prostate cancer worldwide, the proportion of early stage prostate cancer has increased. Several treatment options for localized prostate cancer are available including the two standard treatment options, radical prostatectomy, and radiation therapy. Although the treatment outcomes have improved the procedure and devices, the biochemical recurrence rate had not decreased yet [1] [2] [3]. Recently, many alternative and less invasive treatments have been developed for localized prostate cancer [4] [5]. Since the first clinical application of HIFU for the treatment of localized prostate cancer by Madersbacher *et al.* [6] (using the Sçonablate™ 200), several investigations of HIFU therapy using Ablatherm or Sonablate systems have been reported for patients with this disease [7] [8] [9]. HIFU is a less invasive technique for thermal ablation of tissue that can induce complete coagulation necrosis of a targeted tumor without requiring surgical exposure or insertion of invasive instruments [10]. Since 2003, we have performed transrectal HIFU therapy for patients with localized prostate cancer, and we have reported the efficacy and safety of HIFU ablation for patients with localized prostate cancer [11] [12]. According to these experiences, we think HIFU therapy has the advantages of fewer complications, the potential for a repeat treatment, simplicity of the procedure, and shorter treatment times [11]. Beginning in 2005, we performed focal HIFU at the VUA for 4 patients with PSA failure without distant metastasis after prostatectomy [13]. Since then, we have experienced an additional 12 cases. Here we retrospectively examined the prognosis and long-term outcomes of the salvage HIFU for total 16 patients with the suspected recurrence of at the VUA.

2. Methods

From May 2005 to May 2016 in our Takanobashi central hospital, we performed salvage HIFU in 16 patients (57 - 83 years old). All patients had PSA failure (over 0.2 ng/ml) after radical prostatectomy. These patients' characteristics before prostatectomy and before salvage HIFU are shown in **Table 1**. The median PSA level before radical prostatectomy was 8.4 ng/ml (range; 4.2 - 18). The postoperative pathological stage ranged pT2a - pT3b and Gleason score ranged 5 - 9. The median follow-up period after prostatectomy in these cases was 18

months (range; 8 - 144). Over two-thirds of these prostatectomy patients failed within 12 months after treatment using PSA > 0.2 ng/ml definition. The median PSA level of these 16 patients before HIFU was 0.978 ng/ml (range; 0.318 - 3.1) without androgen deprivation therapy (ADT) after prostatectomy. No distant metastasis or regional lymph node swelling by CT (including 2 PET CTs), MRI (including 4 multiparametric MRIs) and bone scintigaraphy was found before salvage HIFU (Table 2). However, soft mass lesions at the VUA region were found in 6 patients by CT, 13 by MRI, 4 by TRUS and 2 by urethrocystoscope, which caused us to suspect local recurrence. Positive cancer lesion by biopsy was found in 3 patients.

Table 1. Characteristics of 16 patients with salvage focal HIFU.

			No. pts.	Median (range)
Before prostatectomy	PSA (ng/ml)		16	8.4 (4.2 - 18)
		3 + 3	4	
		3 + 4	6	
	Gleason score	4 + 3	2	
		4 + 4	2	
		4 + 5	2	
		T1c	8	
	Clinical stage	T2a	6	
		T2b	2	
		Low	2	
	Risk group (D'Amico)	Intermediate	10	
		High	4	
Before HIFU	PSA (ng/ml)		16	0.98 (0.318 - 3.2)
		3 + 3	2	
		3 + 4	8	
	Gleason score	4 + 3	3	
		4 + 4	1	
		5 + 4	2	
		pT2a	3	
	Pathological stage	pT2b	9	
		pT3a	3	
		pT3b	1	
	Risk group (after prostatectomy)	Intermediate	10	
		High	6	

HIFU: high-intensity focused ultrasound, PSA: prostate specific antigen, D'Amico: D'Amico classification.

Table 2. Data of examinations before therapies in patients with salvage HIFU.

Examination	Local findings	Total pts.	Positive pts.	Negative pts.	Metastasis	No. pts
CT	Soft mass	14	6	8	Distant	0
MRI	S/o recurrence	16	13	3	Pelvic LN	0
Bone scintigraphy	Bone metastasis	4	0	4	Bone	0
Transrectal echo	Soft mass	14	4	10		
Urethrocystoscopy	Regional mass	12	2	10		
Transrectal biopsy	Finding of cancer	9	2	7		
TUR-biopsy	Finding of cancer	5	1	4		

CT: computer tomography, MRI: magnetic resonance imaging, TUR: transrectal resection, LN: lymph node.

Fifteen patients were treated using Sonablate 500® and/or version 4 (Sonacare Medical, Inc., Indianapolis, IN, USA) device under spinal anesthesia, and one with caudal anesthesia. HIFU therapy was performed using the standard transrectal procedure [14]. In order to confirm the position of the external sphincter at the time of the HIFU treatment, we placed biopsy forceps as a marker at the distal portion of the external sphincter under urethroscopic visualization [14]. We performed HIFU sonication on the VUA region from the proximal portion of the external sphincter to the bladder neck under ultrasound visualization (**Figure 1**). Recurrence after salvage HIFU was determined based on PSA failure (PSA > 0.2 ng/ml), histological findings, metastasis and start of ADT. Recurrence free survival (RFS) rate was calculated using Kaplan-Meier curves and a log-rank test was used to evaluate differences between these curves. Mann-Whitney test was used to evaluate statistical difference of two groups. P-value of <0.05 was considered to indicate statistically significant differences. Patient status and treatment-related complications in the Japanese version of the National Cancer Institute-Common Toxicity Criteria version 4.0 [15] were evaluated.

All patients received informed consent of the diagnosis and treatments for suspected recurrence of a VUA lesion. The patients who chose HIFU therapy were provided with the informed consent for particular HIFU treatment and agreed to pay privately for the uninsured therapy in Japan, and the institutional review board for Takanobashi Central Hospital approved these studies.

3. Results

HIFU therapy was performed in 16 patients. Intraoperative and perioperative results are shown in **Table 3**. The median HIFU exposure time was 28 min. (range; 9 - 42). The median hospital stay was 2 days (range; 2 - 7) and the median periods of catheterization were 5.5 days (range; 4 - 21). There were no adverse effects observed in the period from HIFU treatment to removal of the indwelling catheter.

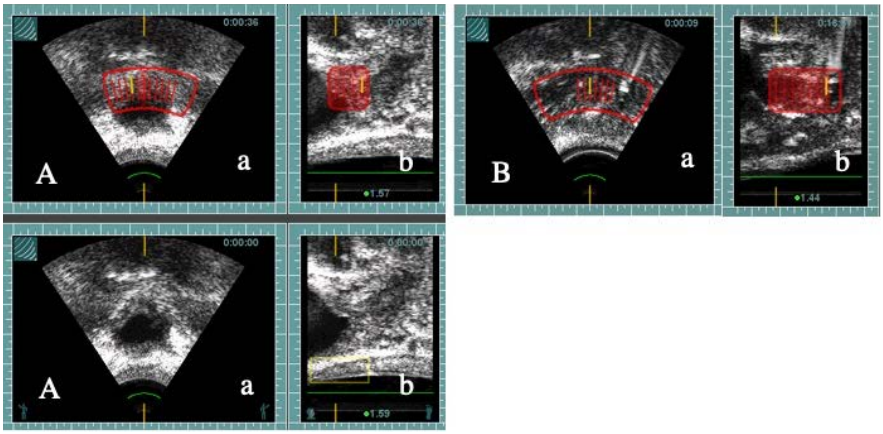

Figure 1. Ultrasound images during HIFU. (A) Sonication field in upper half of the urethra in case 2. (B) Marking the distal portion of the external sphincter with a biopsy forceps. (a) Sector section view (b) Linear section view.

Table 3. Intraoperative and perioperative results of HIFU therapy.

No. of patients:	16	
No. of sessions:	16 times	
Anesthesia:	Spinal 15 times, caudal 1 time	
HIFU exposure time:	Median 28 min.	Range 9 - 42 min.
Hospital stay (post OP):	2 days	2 - 7 days
Catheterization period:	5.5 days	4 - 21 days
Adverse effects:	None	

The median follow-up period of this study was 46.5 months (range; 7 - 159). As shown in **Table 4**, the median PSA nadir after HIFU was 0.088 ng/ml (range; 0.008 - 0. 789) at 1.5 median month (range; 1 - 21), and 88% of these PSA were <0.2 ng/ml. The curve of RFS rates were analyzed using the Kaplan-Meier method with PSA level > 0.2 indicating recurrence in **Figure 2(A)**. The RFS rates of 1, 2, 3 and 5 year were 50%, 37.5%, 31.3% and 31.3%. Patients were categorized according to risk group with initial PSA, pathological Gleason score and T-stage in **Figure 2(B)**. There was no difference in the RFS between the intermediate risk (30%) and the high risk (33%) group. Of the 16 patients with salvage HIFU, 4 patients' PSAs were under 0.2 ng/ml at the latest PSA, one patient's PSA was <0.2 ng/ml until 115 months after HIFU, and 11 patients' PSAs were over 0.2 ng/ml until 36 months after HIFU. A small mass was detected by CT and/or MRI before HIFU recurred in ten cases (77%) of the 13 patients. We compared the five effective cases with the early recurrence 11 cases. Although there was no difference in initial PSA (P = 0.141), pretreatment PSA (P = 0.257) and the time to salvage HIFU after prostatectomy (P = 0.363) between the effective 5 cases and the recurrent 11 cases, we recognized significant difference (P = 0.014) in the nadir PSA after HIFU.

Table 4. Results of HIFU therapy in 16 patients with recurrence of vesicourethral anastomosis.

Follow up period after HIFU	7 - 159 months (median 46.5)	No. of patients
PSA nadir (PSA ng/ml)	0.008 - 0.789 (median 0.088)	
	1 - 21 months (median 1.5)	
	<0.01	4
	0.01 - <0.2	10
	0.2 - <0.4	1
	≥0.4	1
Disease free survival rate	1 year 50.0%	
	2 year 37.5	
	3 year 31.3	
	4 year 31.3	
	5 year 31.3	
PSA result of salvage HIFU		
	<0.2	4
	<0.4 over 24 months	5
	<0.4 under12 months	4
	>0.4 under 12 months	3
Adverse effects at 1 - 3 months after HIFU		
	Difficult voiding	G1 2, G2 3
	Urinary incontinence	G1 2, G2 1
	Recto-urethral fistula	0

G: Grade of CTCAE v4.

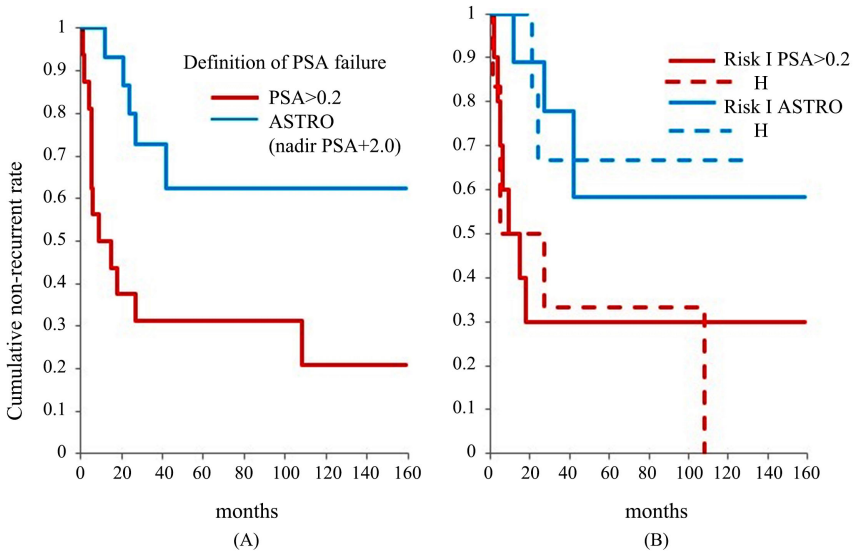

Figure 2. Non-recurrent curves in 16 cases with salvage HIFU. (A) According definition of PSA failure; (B) According risk group with iPSA, p-Gleason score and p-Stage.

The changes of the PSA levels in non-recurrent cases (cases No. 4, 8 and 9) are shown in Figure 3. Their PSA stayed under <0.2 ng/ml for the follow-up periods. Figure 4 shows the changes of the PSA in non-recurrent within 2 years (cases No. 1 and 13). Their PSA remained < 0.4 ng/ml for over 3 years. A temporary rise was usually observed in the PSA level in all patients on the first day after HIFU and a rapid decrease of PSA was seen thereafter.

Adverse effects at 1 - 3 months after HIFU (Table 4) were difficulty with voiding in 4 patients (grade-1) and urinary urgency or incontinence was observed in 3 cases (grade-1; 2, grade-2; 1).

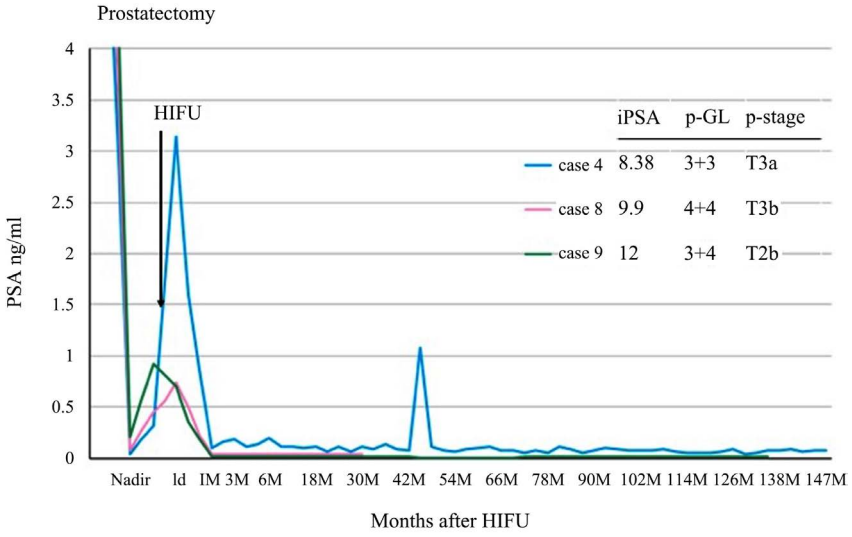

Figure 3. Changes in PSA levels following salvage HIFU therapy in patients with excellent outcome. iPSA: initial PSA -GL: pathological Gleason's score p-stage: pathological stage.

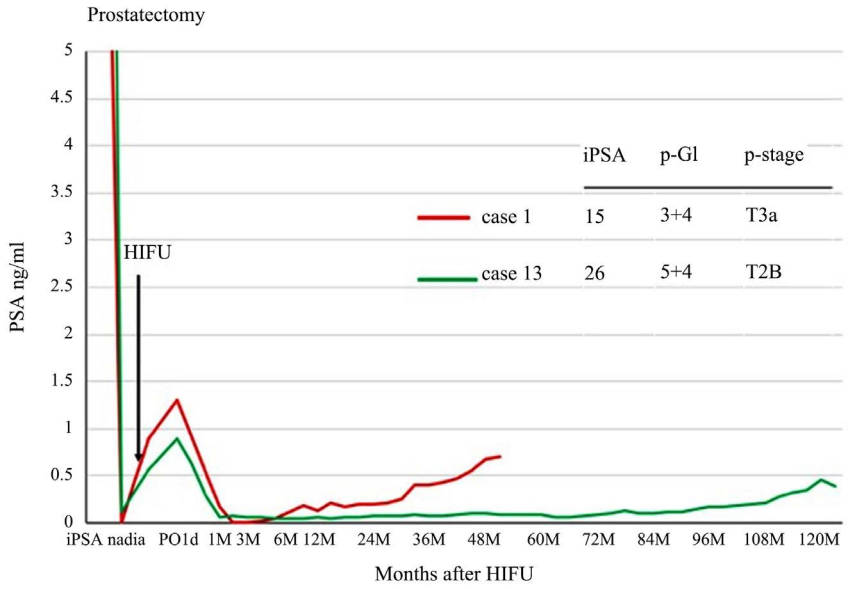

Figure 4. Changes in PSA levels following salvage HIFU therapy in patients with good outcome.

For the prognosis of these salvage HIFU patients, 6 of 12 patients with PSA failure underwent ADT, 3 underwent re-treatment with HIFU, one was followed-up without therapy and two were unknown. No patients died of prostate cancer, but two died of cardiovascular disease and three patients were lost to follow up. A recto-urethral fistula was not observed in this series.

4. Discussion

There are some salvage therapies for recurrence after radical treatment of localized prostate cancer [16] [17] [18]. For salvage HIFU therapy, although there are many reports for radio-recurrent prostate cancer in recent years [19] [20] [21], there are only a few reports [22] [23] for recurrence after prostatectomy available besides our reports [13] [14] and those of Murota-Kawano [24]. After our first report of salvage HIFU therapy for four patients after prostatectomy [13], we performed salvage focal HIFU on lesions at the VUA in a total of 16 cases. The advantages of salvage HIFU therapy as well as whole grand HIFU for primary prostate cancer include the following [10]: no bleeding, less infection, ease of procedure, shorter treatment times, and the possibility of administering repeat treatments. As shown in **Figures 3-5**, a temporary rise is observed in the PSA level of nearly all patients on the first day after HIFU. These PSA changes appear to confirm the fact that the residual prostate tissue was destroyed in the sonication fields. Further, the rapid decrease of PSA after a temporary rise indicates the effectiveness of HIFU therapy.

The biochemical recurrence free survival (BRFS) of the salvage HIFU after radiation therapy was based on Phoenix definition. In the two large volume reports [20] [21] about salvage HIFU after failed radiotherapy, the BRFS rates were 48% at 3 years and 49% at 5 years for the entire group. The BRFS rates were 100%, 61% and 32% at 3 years and 58%, 51% and 22% at 5 years in the low-, intermediate- and high-risk groups on pre-salvage HIFU, respectively. Conversely, the salvage HIFU after prostatectomy results in other reports [22] [23], effectiveness of this therapy was defined as <0.4 ng/ml PSA level or PSA nadir level. The success rate of these reports at 4 years was 45% - 47%. Although there are differences of proportion of stage, risk group and duration of follow-up as compared to these reports [22] [23], our RFS rates using the criteria of 0.2 ng/ml PSA were 31.3% at 3 or 5 years after HIFU. With PSA < 0.4 ng/ml, our RFS rate was 43.8% and 31.3% at 3 and 5 years after HIFU. On the other hand, our RFS rate was 72.7% and 62.3% by the ASTRO definition. Our outcomes were similar to the RFS rate of these reports [22] [23].

The main complications for salvage HIFU after radiotherapy are urethral and/or bladder neck stricture at 8% - 18%, and RUF at 2% - 2.3% [20] [21]. For salvage HIFU after prostatectomy in other reports [22] [23], although urethral stricture rate was similar (5% - 10%), the urinary incontinence was higher (21% - 25%) and RUF was not observed. At 1 - 3 months after HIFU, difficulty in voiding and urinary urgency or incontinence was similar (25% and 19% respectively).

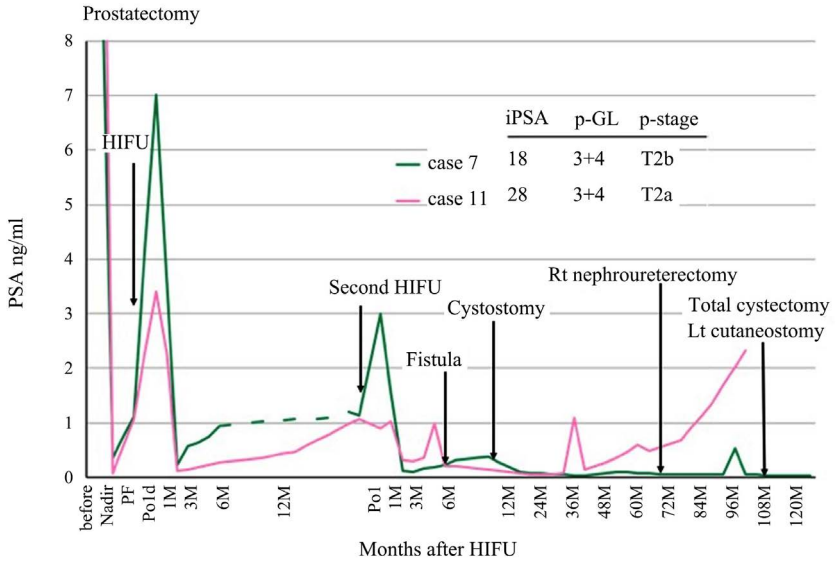

Figure 5. Changes in PSA levels following second salvage HIFU therapy in patients with recto-urethral fistula.

Although a recto-urethral fistula (RUF) was not observed in this series, we experienced a RUF in 2 of the 3 patients with a second HIFU treatment. As these adverse events were important, we are presenting the two cases with serious side effects. The changes of PSA levels in the patients (case No. 7, 11) are shown in Figure 5. They underwent a second salvage HIFU treatment because of early recurrence, and a recto-urethral fistula occurred after removal of the urethral catheter. Though they had suprapubic cystostomy, an artificial colostomy and trans-rectal closure, the RUF were not closed completely during follow-up. Patient (No. 7) also underwent a TUR for bladder tumor, and a right nephroureterectomy for ureteral cancer after the second HIFU, and then a total cysto-urethrectomy and left cutaneous ureterostomy due to the recurrence of bladder cancer. The fistula almost healed by the time of the total cystectomy, and no adenocarcinoma was found in the VUA. The RUF of second patient (No. 11) did not close during follow-up. He has undergone ADT and his PSA is still under 2 ng/ml.

We inferred from the experience of our two patients with RUF that the RUF may have been caused by the second HIFU with its high power energy and the delay of treatments for dysuria. Topazio *et al.* [25] reported success for RUF with conservative treatment. But our patients could not obtain complete closure even with surgical procedures.

We performed a second salvage HIFU treatment for 3 patients with recurrence, and followed them-up from 112 to 144 months. Although all patients had recurrence, one patient had PSA < 0.2 for more than 4 years and the patient (No. 7) with RUF had PSA < 0.3 ng/ml for more than 4 years and <0.1 ng/ml after cystectomy. Though we cannot evaluate the effectiveness of re-treatment with salvage HIFU because there were only three cases, users should be aware of the risk of RUF.

The limitation in our retrospective study is that there were many patients without biopsy-confirmed local recurrence. As for the histological confirmation, it was difficult to confirm by early biopsy after prostatectomy, especially with PSA < 1.0 ng/ml [26] or with PSA < 0.5 ng/ml and negative digital rectal examination [27]. In our cases with no malignancy by biopsy, it is necessary to confirm with another test, such as digital rectal palpation, TRUS or MRI [28]. Recently, fusion biopsy with TRUS and multiparametric MRI is recommended for diagnosis or recurrence after radical therapy of prostate cancer [29]. Therefore, we performed these from the proximal portion of the external sphincter to the bladder neck by the placement of a biopsy forceps as a marker, which was inserted to the distal portion of the external sphincter (**Figure 1(B)**).

In the latest two cases of salvage HIFU, there was suspicion of recurrence on the VUA region by multiparametric MRI, but these lesions could not be proven by transrectal biopsy. In one of the cases discovered by multiparametric MRI, we found that the positive findings disappeared by MRI at 7 months after HIFU. After that, when the PSA rose over 2.0 at 26 months after HIFU, the positive finding appeared in the proximity of the residual seminal vesicle located by MRI.

Asimakopoulos *et al.* [22] reported on 19 patients that those patients with lower Gleason scores and lower PSA values had a better outcome than those patients with higher scores and values. In our patients, there was no difference in the RFS rate between the intermediate and the high risk groups. In the comparison with effective cases and early recurrent cases, there was significant difference only in the nadir PSA after HIFU. From these results, we consider that the effectiveness of salvage HIFU is due to sufficient sonication of recurrence areas rather than PSA levels or malignant grade. So it is critical to correctly diagnose the area of recurrence and perform sufficient sonification. Although the predictive factor is a nadir PSA, we cannot determine in advance the patients that will respond favorably to HIFU.

In the cases with no malignancy determined by biopsy, it is necessary to confirm with TRUS and multiparametric MRI. However in the case of prostatectomy, it is hard to diagnosis because of minimal tumor mass (PSA < 1.0 ng/ml) [26] [27] [30]. Moreover, HIFU therapy is sensitive surrounding blood flow or urine for achieving sufficient temperature [6] [10]. It is also critical to determine the accurate distance from the rectal mucosa to the VUA.

HIFU therapy for local recurrence after prostatectomy may become a feasible therapeutic salvage option because of its easy and short procedure time. As our study was a retrospective analysis with a low volume cases, further research and additional follow-up are required to evaluate this salvage therapy. Moreover for the best outcomes, correct diagnosis of recurrence areas, sufficient sonication and careful follow-up are necessary.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations & Acronyms

ADT = androgen deprivation therapy
ASTRO = American Society for Therapeutic Radiology and Oncology
BRFS = biochemical recurrence free survival
CT = computed tomography
HIFU = high-intensity focused ultrasound
MRI = magnetic resonance imaging
PSA = prostate-specific antigen
RFS = recurrence free survival
RUF = recto-urethral fistula
TRUS = transrectal ultrasound
TU-biopsy = transurethral biopsy
VUA = vesicourethral anastomosis

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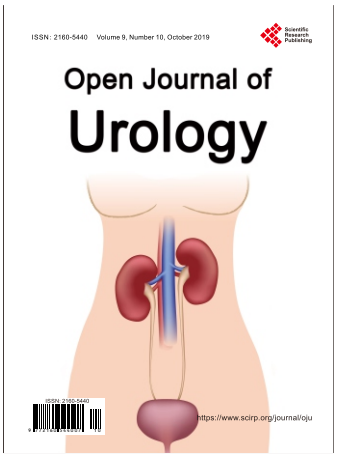

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