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Stenting *versus* non-stenting following uncomplicated ureteroscopic lithotripsy: comparsion and evaluation of symptoms

Poređenje i vrednovanje simptoma nakon nekomplikovane ureteroskopske litotripsije kod bolesnika sa i bez ugrađenog stenta

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Abstract

Background/Aim. Currently, ureterorenoscopic (URS) stone fragmentation and removal is the treatment of choice for managing ureteral stones, especially mid and distal ones and is advocated as initial management of ureteric stones. The aim of this work was to evaluate the symptoms, necessity, potential benefits and adverse effects of ureteral stent placement after uncomplicated ureteroscopic lithotripsy. **Methods**. This retrospective-prospective study evaluated a total of 125 patients who had underwent ureteroscopic lithotripsy (URSL). The patients were divided into two groups: stented (59 patients) and unstented (controls, 66 patients). The outcomes measured and compared between the two groups included: stone free rate, postoperative patient pain validated by scale, lower urinary tract symptoms (LUTS), the need for unplanned hospital care, stent related complications, and functional recovery in the form return to normal physical activities. **Results.** A successful outcome, defined as being stone-free after 12 weeks, was achieved in all 125 (100%) patients. The stone-free rate showed no significant differences between the two groups. LUTS was a frequent complaint in the stented group, with statistically significant difference in the domain of frequency/urgency (p = 0.0314). There was a statistically significant difference between the groups in the mean operative time and mean hospitalization time, mean pain visual analog scale (VAS) score and in the use of non-narcotic analgesic. On the day of the surgery and until postoperative day 3 (POD 3) and postoperative day 5 (POD 5), the pain score was much higher among stented patients than among the controls (p = 0.0001) and non-narcotic analgesic use (p = 0.001) was frequently required in the stented group. **Conclusion**. Routine placement of ureteral stent after URSL is not mandatory and may be associated with stent side effects. Uncomplicated URSL is safe without stent placement after the treatment.

Key words:
ureteroscopy; lithotripsy; stents; lower urinary tract symptoms; comparative study.

Apstrakt

Uvod/Cilj. Ureterorenoskopsko sitnjenje i uklanjanje kamena predstavlja lečenje izbora prilikom zbrinjavanja ureteralnog kamena naročito srednjeg i donjeg uretera, i smatra se osnovnim zbrinjavanjem. Cilj rada bio je da se ocene simptomi, neophodnost potencijalne koristi i neželjeni efekti plasiranja ureteralnog stenta nakon nekomplikovane ureteroskopske litotripsije (URSL). **Metode**. U ovoj retrospektivno-prospektivnoj studiji, ispitano je 125 bolesnika koji su bili podvrgnuti URSL. Bolesnici su podeljeni u dve grupe: sa ugrađenim stentom (ispitivani bolesnici, 59) i bez stenta (kontrole, 66 bolesnika). Ishodi koji su mereni i poređeni između dve grupe obuhvatali su: stopu odsustva kalkulusa, postoperativni bol kod bolesnika ocenjen pomoću skale, simptome donjeg urinarnog trakta (SDUT), potrebu za neplaniranim bolničkim lečenjem, komplikacije povezane sa stentom i funkcionalni oporavak u formi povratka na uobičajene fizičke aktivnosti. **Rezultati.** Povoljan ishod, definisan kao odsustvo kalkulusa nakon 12 nedelja, postignut je kod svih 125 (100%) bolesnika. Nije bilo statistički značajne razlike između dve grupe u stopi odsustva kalkulusa. SDUT su bili češći u grupi sa plasiranim stentom, sa statistički značajnom razlikom u domenu učestalosti mokrenja, odnosno urgencije (p = 0,0314). Postojala je statistički značajna razlika između grupa u prosečnom trajanju operacije i prosečnoj hospitalizaciji, srednjoj vrednosti ocene bola na vizualnoj analognoj skali (VAS) i u upotrebi neopijatnih analgetika. Na dan operacije i sve do trećeg postoperativnog dana (POD 3), odnosno petog postoperativnog dana (POD 5), ocena bola (p = 0,0001), kao i potreba za neopijatnim analgeticima (p = 0.001) bila je viša među bolesnicima sa stentom u poređenju sa kontrolama. **Zaključak.** Rutinsko ugrađivanje ureteralnog stenta nakon nekomplikovane URSL nije obavezno i može biti povezano sa neželjenim efektima stenta. URSL je bezbedna procedura i bez ugrađivanja stenta na kraju intervencije.

Ključne reči:
ureteroskopija; litotripsija; stentovi; urinarni trakt, donji, simptomi; komparativna studija.

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Introduction

Currently, ureterorenoscopic (URS) stone fragmentation and removal is the treatment of choice for managing ureteral stones, especially mid and distal ones and is advocated as initial management of ureteric stones [1]. There is a controversy regarding the need for ureteral stent insertion after uncomplicated URS stone surgery due to the possibility of complications. Saltzman [2] recommended stenting in patients following URS stone therapy and Aoyagi et al. [3] continued to advocate routine stenting as a security measure. On the other hand, reports in the literature suggest that the use of stents was associated with complications with the incidence of stent-related symptoms and morbidity of 10–85% [4]. As Richter et al. [5] stated, placement of a ureteral stent is "a friendly procedure with unfriendly morbidity" [5]. The key question is the definition of the word 'uncomplicated', and so is the indication for not placing a stent, as well as the decision on which patients can safely be left unstented. Denstedt et al. [6] defined uncomplicated URS as "no evidence of perforation or lack of clinically important edema".

The aim of this study was to evaluate the diference in the postoperative course between stented and nonstented groups, comparing patient's characteristics, stone features, treatment outcome, and functional recovery.

Methods

Patients and study design

This retrospective-prospective chart analysis was conducted at the Department of Urology of Dr. Dragiša Mišović Hospital in Belgrade, Serbia. Between January 2011 and December 2014, a total of 213 patients underwent ureteroscopic lithotripsy (URSL) for ureteral calculi. The eligible patients for this study were adults who underwent URSL without dilatation for ureteral stones, and who had no history of previous ureteroscopy or failed treatment for the same stone. The results thus included 125 patients.

The patients were categorized into two groups depending on whether they received a stent at the end of a procedure or not. When used, stent was placed routinely, without strict indications.

Clinical procedure

All interventions were carried out under general (n = 15) or spinal (n = 110) anesthesia, using semi-rigid single channel OLYMPUS 9.8 Chureteroscope with a 5.5 Fr working channel width, 7° lens, and length of 430 mm. A ballistic (pneumatic) generator, LithotronWalz EL-27 Compact was used. In the cases (stented) group, a double pigtail ureteral 6 Fr polyurethane stent was placed following URSL and removed after 2 weeks. The patients assigned to one day surgery were admitted to the day case ward on the morning of surgery, or one day before surgery. The patients were fully evaluated using routine lab tests, accompanied with ultrasonography (US) and plain abdominal X-ray. Intravenous urography (IVU) and retrograde ureteropyelography were performed in patients optionally.

All the patients were discharged after overnight hospitalization. The discharge criteria included stable vitalparameters, ability to void spontaneously, and satisfactory pain control using oral non-narcotic analgesics. URSL was performed in hemodynamically stable patients.

Follow-up procedure

The patients were initially evaluated in a recovery room and then followed up on postoperative days (POD) 1, 3, 5, and 7, four weeks and three months postoperatively. All events were measured and evaluated using plain abdominal X-ray, renal US, urinalysis and urine culture, laboratory analysis and patient questionnaire. All these analyses were performed on days of follow-up visits during the immediate postoperative period and 12 weeks postoperatively.

The evaluated outcomes were stone free rate, patient reported pain using a validated scale, need for analgesia, LUTS (dysuria, frequency/urgency), postoperative complications (hematuria, fever > 37°C, urinary tract infection…), unplanned medical visits or readmission to a hospital due to postoperative complications and patient functional recovery.

Procedures were considered successful if fragmentized calculi were smaller than the probe tip width and in the absence of residual stones on a plain radiographic film or US 2 weeks after initial lithotripsy. Stone diameters ≤ 4 mm as stone-free rate (SFR) were established as success criteria.

Postoperative pain was defined by the need for oral analgesics in the 1st week and the dose of required analgesics, and in this study was evaluated by how much analgesia was required by patients each day, in addition to the number of readmissions to a hospital for pain control. At follow-up visits on days 3, 5 and 7, postoperative pain was measured using a 10 cm visual analog scale (VAS), where 0 represented no pain and 10 extreme pain. The analgesics that were used were diclofenac sodium tablets 50 mg and patients were instructed to take it only for pain episodes. The patients who reported pain were classified into three groups: those who reported pain score within or at three days, those who reported pain at five days, or after day seven following the procedure.

In an analysis of symptoms of LUTS, we used the IPSS questionnaire that patients were asked to complete two weeks after intervention.

The modified Clavien-Dindo Classification of Surgical Complications (CCS) was used for evaluation of intraoperative and postoperative complications within 15 perioperative days.

Functional recovery was evaluated using specifically tailored questionnaire. The questionnaire was filled out by patients themselves at clinical visits or by doctor during telephone interview at the time of ultimate stone-free status 12 weeks after surgery in the non-stented group and 10 weeks after stent removal in the stented group. The questionnaire used to evaluate patient satisfaction with provided treatment modalities included overall satisfaction (5 choices: very sati-

sfied, satisfied, acceptable, dissatisfied, very dissatisfied) and satisfaction or dissatisfaction with return to normal physical activities, as well as patient willingness to undergo a repeated procedure.

This study protocol was approved by the Ethics Committee of the Hospital Dragiša Mišović and the research was carried out in accordance with Helsinki Declaration. Before inclusion and undergoing ureteroscopy, all the patients provided written informed consent.

Statistical analysis

The Statistical Package for the Social Sciences software (SPSS, version 10.0; SPSS Inc. Chicago, IL, USA) was used for statistical analysis. The results are presented as mean ± SD. The groups were compared using parametric 2 tailed *t*-test and nonparametric Mann-Whitney *U*-test for continuous and semi-continuous variables, as appropriate. We used χ2-test and Fisher's exact test to assess differences in categorical variables between cases and the controls. A *p*-value < 0.05 was considered as statistically significant.

Results

This study included 125 patients. Patient demographic data and stone characteristic are shown in Table 1. The two patient groups were comparable regarding the baseline variables. Table 2 summarizes the results of stone removal. There were no differences between the groups in any of technical aspects or stone-free rates.

Among the total of 125 patients, our study showed 113 (90%) stone-free rate (clearance rate) in the ureter at all levels on the first POD. The stone-free rate was 52 (88%) in the cases group, and 61 (92%) in the control group. When the stone free rate was compared between the groups, there was no statistically significant difference. Plain abdominal X-ray on the 12th postoperative week showed the stone-free rate of 100% (n = 59) among cases and 100% (n = 66) among controls – completely stone free with no ultrasound evidence of obstruction.

The mean operative time was longer in cases of stent placement, and the difference was significant ($p < 0.001$, $t = 6.584$). Furthermore, there was a significant difference in the mean hospitalization time between the groups ($p < 0.001$, $Z = -5,66$).

On the first postoperative day, flank pain rate experienced by stented patients was higher [29 (49%)] than that reported by the patients in the unstented group [12 (18%)], ($p = 0.003$). Suprapubic pain and urethral irritation occurred more often in the cases group.

Table 3 shows the mean visual analog pain scores and analgesic use in the two groups at 3, 5 and 7 days. At the day 3 and 5, the mean visual analog pain score in the cases was significantly higher than in the controls. On the 7th day, the

Table 1

Age, sex and ureteral stone characteristics – distribution of patients

Patients	Cases (stented)	Controls (unstented)	Results
Mean age ± SD (years)	51.97 ± 12.77	52.73 ± 12.58	$p = 0,783$ $t = -0.335$
Males/females (n)	26/33	27/39	$p = 721$ $\chi^2 = 0.127$
Mean stone size ± SD (mm)	10.49 ± 1.06	10.20 ± 1.46	$p = 0.070$ $Z = -1.813$
Stone side: left/right (n)	24/35	32/34	$p = 0.381$ $\chi^2 = 0.768$
Stone level (%)			
iliac	24	33	
pelvic	34	27	$p = 0.065$ $\chi^2 = 5.421$
pelvic and iliac (n)	1	6	

SD – standard deviation.

Table 2

Results of stone removal

Variables	Cases (stented)	Controls (unstented)	Results
SFR – POD 1, n (%)	53 (88.1)	92.4 (61)	$p = 0.416$ X = 0.660
SFR –POD 15, n (%)	56 (94.9)	95.5 (63)	$p = 1.000$ X = 0.200
SFR – 12 weeks, n (%)	59 (100)	100 (66)	-
Mean operative time ± SD (min)	41.53 ± 5.10	37.02 ± 1.21	$p = 0.001$ $t = 6.584$
Mean hospitalization time ± SD (hours)	24.88 ± 0.89	26.03 ± 1.20	$p = 0.001$ Z = -5.667

SFR – stone-free rate; POD – postoperative day; SD – standard deviation.

Table 3

Visual analog pain scores – postoperative pain score

Variables	Cases (stented)	Controls (unstented)	Results
Mean pain score on the day 3 (0–10[a]) ± SD	4.78 ± 0.911	2.83 ± 0.376	$p = 0.0001$ Z = -9.439
Mean pain score on the day 5 (0–10[a]) ± SD	3.34 ± 0.576	2.68 ± 0.469	$p = 0.0001$ Z = -6.115
Mean pain score on the day 7 (0–10[a]) ± SD	2.32 ± 0.600	2.53 ± 0.503	$p = 0.038$ Z = -2.080
POD 3 analgetic usage 1/2/3 tbl	2.14 ± 0.495	1.64 ± 0.485	$p = 0.0001$ Z = -6.911
POD 5 analgetic usage 1/2/3 tbl	2.02 ± 0.293	1.30 ± 0.463	$p = 0.0001$ Z = -7.615
POD 7 analgetic usage 0/1/2 tbl	0.98 ± 0.347	0.26 ± 0.441	$p = 0.038$ Z = -7.618

[a] No pain (0) to extreme pain (10); SD – standard deviation, POD – postoperative day.

patients in overall had few symptoms and the mean visual analog pain scores were not statistically different between the two groups. In the stented group, on POD 5 and POD 7, the rates of patients who required two or more analgesic tablets a day for pain control were 57% and 27%, respectively, but none of them required hospitalization for intractable pain. Analyses of International Prostate Symptome Score (IPSS) on postoperative day 14 showed a significant difference between the groups (Table 4). Dysuria was observed in 33 (56%) of the patients in cases group and 30 (45%) of the patients in the control group ($p = 0.2840$), while frequency/urgency was present in 37 (63%) of the patients among the cases and in 28 (41%) of the patients among the controls ($p = 0.0314$).

The modified Clavien system has been proposed to grade perioperative complications (Table 5). Urinary tract infections (UTI) occurred in 16 (13%) of the patients (symptomatic with positive urine culture results; the most common pathogen was *Escherichia coli*, present in 15 culture samples) which were successfully treated with antibiotic. In the first 24 hours, mild macroscopic haematuria was observed in 11 (18.6%) of the patients among the cases and 8 (12%) of the patients among the controls, and it did not require treatment. The rate of fever (37.5–38°C) was higher among the cases, where 8.5% of the patients developed upper UTI related fever and were treated with oral antibiotics accompanied with excellent response.

Return to emergency room during the first week was necessary in 11 (8.8%) of the patients, 6 (10%) from the cases group and 5 (7.5%) from the control group ($p = 0.7547$). Thirty six hours after URS, one patient from the stented group developed fever due to pyelonephritis (urinanalysis, sonography), without signs of septicemia (nausea, vomiting) and was treated with antibiotics (initially with parenteral fluoroquinolon, and after improvement, the patient was switched to oral regimen).

Figure 1 shows the overall subjective patient satisfaction with the procedure that generally reflects treatment success.

Table 4

International Prostate Symptom Score (IPSS)

IPSS	Stent	n	Arithmet. mean	SD	Median	Min	Max	Result
Obstructive	no	66	5.14	1.487	5.00	2	8	$t = 12.311$
	yes	59	9.19	2.161	9.00	4	14	$p < 0.001$
	total	125	7.05	2.732	7.00	2	14	
Irritative	no	66	3.27	0.869	3.00	1	5	$t = 4.937$
	yes	59	4.08	0.970	4.00	2	7	$p < 0.001$
	total	125	3.66	1.001	4.00	1	7	
Total	no	66	8.39	2.089	8.00	3	12	$t = 11.148$
	yes	59	13.27	2.784	13.00	6	20	$p < 0.001$
	total	125	10.70	3.448	11.00	3	20	

SD – standard deviation.

Table 5

Comparsion of complications, classified according to the modified Clavien-Dindo classification system (CCS) between the groups

CCS grade	Total	Cases (stented)	Controls (unstented)	*p*-value
Grade 1, n (%)				
fever	10 (8)	5 (8.5)	5 (7.6)	1.0000
hematuria –mild	19 (15)	11 (18.6)	8 (12)	0.3306
Grade 2, n (%)				
UTI	16 (13)	8 (13.5)	8 (12)	1.0000
pyelonephritis	1 (0.78)	1 (1.7)	-	0.4720

UTI – urinary tract infection.

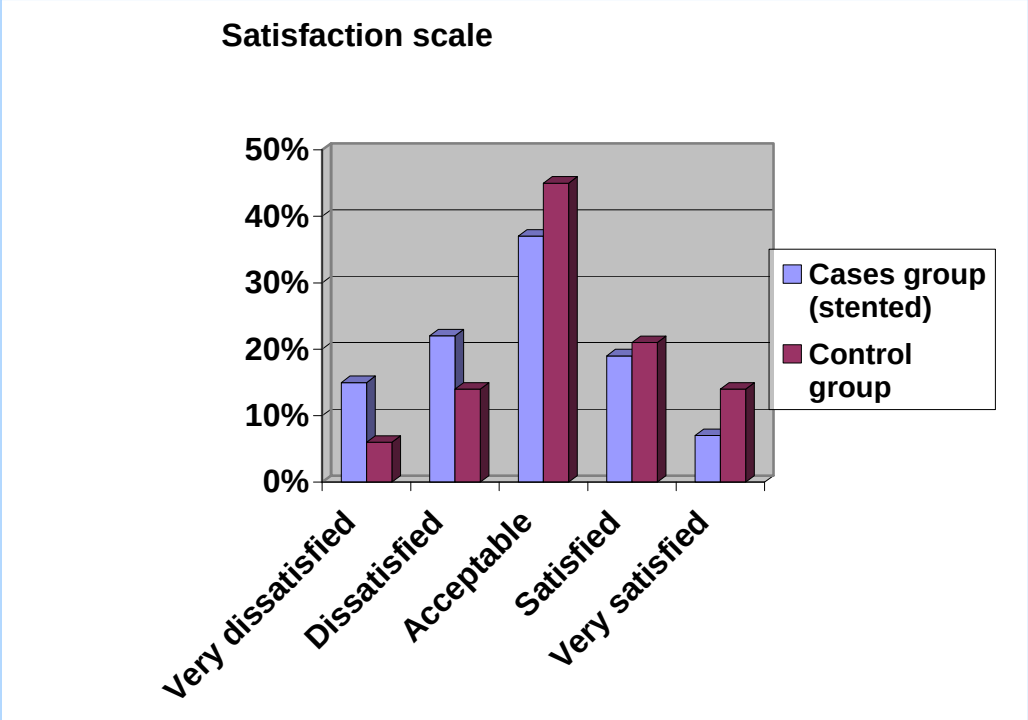

Fig. 1 – Overall subjective satisfaction of patients with treatment outcomes.

According to our results in 90 (72%) of the patents, their expectations were met by the specific treatment, meaning that they were satisfied with chosen therapeutic modality and that they would recommend it to others. There was a significant statistical difference among the patients who were dissatisfied with chosen therapeutic modality (p = 0.0452). Specifically, 22 (37%) of the patients from the stent group were dissatisfied because of discomfort and pain and expressed that they would have not accepted a stent if they had to undergo a repeated procedure. In the group of patients without stent, total dissatisfaction with treatment was lower at 13 (20%) of them. Return to normal physical activities one day after the procedure was reported by 36 (61%) of the stented patients and 52 (79%) of the unstented patients (p = 0.0330).

Discussion

In this study, the overall stone-free rate of URS was comparable to other studies with stone-free rates ranging from 75% to 93% [7]. The stone site has always been noted as an important determinant. In our study, there were 83 (66%) of lower and 39 (31%) of mid ureteric stones. Lower ureteric stones were more easily handled than upper ureteric stones primarily because of accessibility and anatomical reasons.

In this study, there was no statistically significant difference in the success rate between the groups. Similarly, none of the previous trials reported a significant difference in stone-free rates between participants with and without stent [8]. Compared with other published trials, the mean stone size and the number of stones between the two groups in our study are similar. The mean operative time recorded during this study was comparable between the two groups with a significant difference.

Patients with indwelling ureteral stents have a wide range of urinary symptoms that affect their quality of life [9]. Stent discomfort can vary from one patient to another in an idiosyncratic manner, but it is reported to affect over 80% of patients [8]. It has been suggested that irritative symptoms are the result of irritation of neuronal-rich trigone mucosa and flank pain, related with reflux [10]. We noted that patients without stents had fewer postoperative complications in the form of LUTS, which is also consistent with other studies [11]. Pollard at Macfarlane [12] evaluating symptoms associated with ureteral stent, confirmed that the symptoms disappeared after stent removal. Similarly, Bregg and Riehle [13] found that 22 (44%) out of 50 patients experienced moderate to intolerable discomfort that was relieved by removal of the stent [13]. Kuyumcuoglu et al. [14] in their work highlight that the frequency of LUTS increase in patients in whom the double-J stent was applied, with an increase in the International Prostate Symptom Score (IPSS) Quality of life question (IPSS-QOL) and Overactive Bladdetr Questionnaire (OABq) scores. In other words, discomfort continues as long as the stent stays in the body. Stented patients have been documented to have significantly higher pain scores [6, 15]. Our study showed that the presence of stent significantly affected postoperative pain, requiring analgesics.

The ureteroscopic procedure itself often has little impact on patient's quality of life, but the method of ureteral drainage after the procedure may have a significant negative effect on the patient's quality of life. Leibovici et al. [16] suggested that the use of double-J stents can lead to several side effects and cause negative effects on quality of life. Joshi et al. [9, 17] indicate that 76%

of stented patients experienced negative symptoms and 42% had to reduce their activity by half. Stenting adds to the medical expense of the ureteroscopic procedure, and cystoscopy is usually required for stent removal unless a string is attached to the distal end of a stent [18]. By analyzing patient perceptions about the outcome of the treatment, together with the clinical parameters, our results indicate the importance of patient subjective satisfaction. This should be considered as an important parameter when making a decision to place a stent, except in the presence of very strict indications. Although clinical parameters are of major importance, considerations about quality of life and subjective satisfaction assessed by standardized questionnaire are also essential.

Stents can be viewed as kind of insurance policy against postoperative complications, especially those that require intervention. Given the imperative of sending patients home on the day of the procedure, it is not surprising that many urologists choose to stent routinely [19]. Therefore, it may be suggested that stenting should be limited to selective cases, such as patients with a single kidney, urinary tract infection, complications during surgery, and large stones with large residual fragments [20]. Uncomplicated ureteroscopy for removing *calculi* is safe without stenting after treatment, and after considering complications and side effects, routine use of ureteric stents after uncomplicated ureteroscopy for stone extraction may be unnecessary [21]. Patients without stents have significantly fewer lower-urinary symptoms, such as pain, urgency, and dysuria, and are not at risk of increased rate of complications [22].

Some limitations of our study must be highlighted, such as partly retrospective, lack of randomization, decision to put stent intraoperatively. We are well aware that our study does not provide a definitive answer to the actual question, stent or not after URSL. However, we believe that, even the known limitation of our current study, the results can suggest to consider advantages or/and disadvantages of each treatment. Although, further study/investigations, including comparison of long term complications are warranted to clarify, confirm or deny, the need for routine stenting after URSL.

Conclusion

Being stone-free after submitting to the risks and pain of a surgical procedure would be the most important outcome for most, if not all, patients. Most bothersome symptoms and side effects following URS originate from ureteral stent placement. Most untoward effects associated with ureteral stents persist during the entire stenting dwell time and that must be kept in mind when deciding on stent placement.

After analysis of complications and side effects, we consider the routine use of ureteric stents after uncomplicated ureteroscopy for stone extraction to be unnecessary and that it should be used very selectively. In this context, surgeons should be aware of high patient expectations for treatment success and reluctant patient attitudes toward ancillary treatment after surgery.

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