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CLINICAL STUDY

## Retrograde Intrarenal Surgery is equally efficient and safe in patients with different American Society of Anesthesia physical status

Ozer Guzel<sup>a</sup>, Altug Tuncel<sup>a</sup>, Melih Balci<sup>a</sup>, Nihat Karakoyunlu<sup>b</sup>, Yilmaz Aslan<sup>a</sup>, Anil Erkan<sup>a</sup> and Cagdas Senel<sup>a</sup>

<sup>a</sup>Third Department of Urology, Ministry of Health, Ankara Numune Research and Training Hospital, Ankara, Turkey; <sup>b</sup>Department of Urology, Ministry of Health, Diskapi Yildirim Beyazit Research and Training Hospital, Ankara, Turkey

### ABSTRACT

**Objective** To assess the efficacy and safety of Retrograde Intrarenal Surgery to treat renal stones in patients with different American Society of Anesthesia (ASA) physical status. **Material and methods** We performed a retrospective analysis of 150 patients who underwent Retrograde Intrarenal Surgery for renal stone between October 2013 and December 2014. Patients were categorized into three groups according to their ASA physical status: ASA Class 1 (Group 1,  $n = 23$ ), ASA Class 2 (Group 2,  $n = 113$ ) and ASA Class 3 (Group 3,  $n = 14$ ). We documented and stratified the per-operative and postoperative complications according to modified Satava Classification System and Clavien–Dindo Classification. **Results** The mean age of the patients was 44 years. The total stone-free rate was 81.2%. According to the groups, the stone-free rate was 75% in Group 1, 82.5% in Group 2, and 83.3% in Group 3 ( $p = 0.340$ ). Per-operative and postoperative complications were recorded in 12% ( $n = 18$ ) and 5.3% ( $n = 8$ ) of the patients. We did not find significant difference in terms of per-operative and postoperative complication rates among patients with different ASA physical status ( $p_{\text{per-operative}} = 0.392$  and  $p_{\text{postoperative}} = 0.136$ ). **Conclusions** Retrograde Intrarenal Surgery is an effective and safe surgery with high stone-free rates and low morbidity in patients with different ASA physical status.

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### Introduction

Retrograde Intrarenal Surgery (RIRS) has been used for the last three decades. RIRS in the kidney has become possible due to the development of appropriate accessories for stone retrieval and fragmentation. With this surgical procedure, a significant segment of difficult and complex cases with upper tract pathology has become the routine indication for this new minimally invasive treatment. Although RIRS has improved the safety and efficacy in treating renal stones, even for higher stone burdens in recent years,<sup>1</sup> it is still not a complication-free procedure.

In the international literature, most of the publications investigated the complications of semirigid ureteroscopy<sup>2–4</sup> but a few series focused on the complications of RIRS.<sup>5–8</sup> A recent study reported modified Satava Classification System (SCS) that categorizes the complications of RIRS.<sup>6</sup> The authors stated that the modified SCS can facilitate patients to understand the safety of RIRS.

American Society of Anesthesia (ASA) score has been described the physical status classification of

preoperative patients for anesthetic risk assessment.<sup>9</sup> In the international literature, previous researchers have mainly examined the safety of RIRS using per-operative and postoperative complication assessment scales. However, no attention has been paid to understand relationship between patient's physical status and safety of this surgery.

The objective of the present study was to assess the efficacy and safety of RIRS to treat kidney stones in patients with different ASA physical status.

### Material and methods

Between October 2013 and December 2014, a total of 150 (92 males and 58 females) patients underwent RIRS for renal stone in our clinic. Patient evaluation included medical history, anamnesis, physical examination, microscopic urine analysis, urine culture, blood count test, serum biochemistry analysis, intravenous urography, and/or computerized tomography (CT) with/without contrast material. Stone size was determined by measuring the longest axis on preoperative radiologic investigation; in cases of multiple renal calculi, stone size was defined as the sum of the greatest dimensions of each stone.

The study was approved by local ethics committee. After written informed consent was obtained from all the patients, all surgeries were performed using 7.5-Fr flexible ureteroscope (Karl Storz Flex-X<sup>2</sup>™, Karl Storz, Tuttlingen, Germany) through a 9.5-Fr ureteral access sheath (Cook™, Cook Medical, Dublin, Ireland). Stones were fragmented with a 30W Holmium:YAG laser device (SphinxX™, Lisa, Katlenburg-Lindau, Germany) until the fragments were small enough to pass out spontaneously. We did not use basket retrieval during the operation. A 4.8-Fr JJ stent (Geotek™, Geotek Inc., Ankara, Turkey) was placed at the end of the operation if the surgeon thought necessary. The operation duration was calculated using a timer. The device was started at the beginning of the operation and stopped at the end of the procedure.

We documented and stratified the per-operative complications according to modified SCS as described by Tepeler and coworkers for semirigid ureterorenoscopy complications.<sup>4</sup> The categorization is divided into the following four grades. *Grade 1* includes minor risk events not requiring therapy and includes mild degree of bleeding, mild degree of mucosal injury, inability to reach the stone in the kidney and no additional treatment required after the intervention. *Grade 2* complications are treated per-operatively with endoscopic surgery. *Grade 2a* complications are defined as events which could be treated with endoscopic surgery per-operatively as mucosal injury treated by placing a ureteral stent, inability to reach the stone in the kidney and treated by percutaneous nephrolithotomy (PNL) in the same session, ureteral perforation managed by placing a ureteral stent, inability to reach the stone due to the narrow ureter and to treat by shockwave lithotripsy/with or without ureteral stent. *Grade 2b* complications include events which were treated with endoscopic treatment in another session, like treatment with semirigid ureteroscopy or PNL, inability to reach the stone due to the narrow ureter and to re-treat by RIRS after ureteral passive dilation with ureteral JJ stent, and severe degree of bleeding causing postponement of the surgery. *Grade 3* complication is defined as the events requiring laparoscopic or open surgery.

In the present study, postoperative complications were recorded according to modified Clavien–Dindo Classification.<sup>10</sup> The categorization is divided into the following four grades. *Grade 1* included minor risk events not requiring therapy (with exceptions of analgesic, antipyretic, antiemetic, and antidiarrheal drugs or drugs required for lower urinary tract infection). *Grade 2* complication is defined as potentially life-threatening complications with the need of intervention or a hospital stay longer than twice the median hospitalization for the

same procedure. *Grade 2* is divided into two subgroups based on the invasiveness of the therapy selected to treat the complication; *Grade 2a* complications required medications only and *Grade 2b* is an invasive procedure. *Grade 3* complications are defined as complications leading to lasting disability or organ resection, and finally, *Grade 4* complication indicates death of a patient due to a complication.

ASA proposed the physical status classification of preoperative patients for anesthetic risk assessment in 1963.<sup>10</sup> The ASA score is a subjective assessment of a patient's overall health that is based on five classes (I–V): *Class 1*, patient is a completely healthy fit patient; *class 2*, patient has mild systemic disease; *class 3*, patient has severe systemic disease that is not incapacitating; *class 4*, patient has incapacitating disease that is a constant threat to life; *class 5*, a morbid patient who is not expected to live 24 h with or without surgery.

In the current study, patients were categorized into three groups according to their ASA physical status: ASA class 1 (Group 1,  $n = 23$ ), ASA class 2 (Group 2,  $n = 113$ ) and ASA class 3 (Group 3,  $n = 14$ ). The patients with ASA class 4 and 5 were not included in the study due to anesthesiology and reanimation clinic's decision. We compared the three groups with regard to stone size and locations, stone-free rates, operative parameters, postoperative outcomes and complications. ASA physical status was determined by an anesthesiologist in pre-operative patient evaluation.

Stone-free status was evaluated in an outpatient clinic setting at 4–6 weeks after the operation with low-dose spiral CT. Success is defined as a complete stone-free status or residual stone  $<4$  mm on imaging modality.

### Statistical analysis

Statistical analysis was performed using Statistical Packet for Social Sciences (SPSS) 16.0 for Windows software (SPSS Inc., Chicago, IL). A comparison among the groups was performed by using *Student t-test*. A  $p$ -value less than 0.05 was considered significant.

### Results

The mean age of the patients was 44 years. The mean ages in Groups 1, 2 and 3 were  $29.7 \pm 8.8$ ,  $45.5 \pm 14.4$ , and  $54.9 \pm 11.5$ , respectively ( $p < 0.01$ ). In Groups 1, 2 and 3, the mean body mass indexes were  $23.2 \pm 3.2$ ,  $25.3 \pm 3.6$ , and  $30.5 \pm 5.9$ , respectively ( $p < 0.01$ ).

The mean stone size was 15.1 mm. The mean stone sizes were  $12.7 \pm 4.3$  (range 5–20) mm in Group 1,  $13.9 \pm 5.3$  (range 7–29) mm in Group 2, and  $14.9 \pm 4.9$  (range 10–25.2) mm in Group 3 ( $p = 0.525$ ). Stones were

located in the renal pelvis in 81 (54%), lower pole calices in 29 (19.3%), middle pole calices in 27 (18%), and upper pole calices in 13 (8.7%) patients. According to the groups, the stone-free rates after a single procedure were 74% ( $n = 17$ ), 80.5% ( $n = 91$ ), and 78.5% ( $n = 11$ ) in Groups 1, 2 and 3, respectively ( $p = 0.472$ ). In the Group 1, four patients underwent additional treatments (three patients with a second RIRS and one patient with shock wave lithotripsy [SWL]); in Group 2, 14 patients underwent additional treatments (11 patients with a second RIRS and three patients with SWL); and in Group 3, two patients underwent additional treatment (second RIRS). After additional treatments, final stone-free rates were 75% in Group 1, 82.5% in Group 2, and 83.3% in Group 3 ( $p = 0.340$ ). A JJ stent was placed in 142 (94.7%) patients at the end of the operation based on the surgeon's preference. The stent was removed four weeks after the surgery. The mean operation durations were  $38.2 \pm 9.4$ ,  $40.8 \pm 12.4$ , and  $39.5 \pm 15.8$  min, respectively ( $p = 0.604$ ). The mean lengths of hospital stay were 1, 10.2 and 1.7

**Table 1.** Patient, stone and operation characteristics.

Mean age, year (range)	44 $\pm$ 14.9 (18–81)
Gender	
Male	92
Female	58
Mean stone size, mm (range)	15.1 $\pm$ 3.6 (5–29)
Stone location	
Renal pelvis	81 (54%)
Lower pole calices	29 (19.3%)
Middle pole calices	27 (18%)
Upper pole calices	13 (8.7%)
Ureteral access sheath, $n$	138 (92%)
Mean operation duration, min (range)	41.4 $\pm$ 7.7 (21–52)
Number of postoperative JJ stents, $n$	142 (94.7%)
Success rates, $n$	121 (81.2%)
Mean hospital stay, day (range)	5.3 $\pm$ 4.4 (1–12)

days, respectively ( $p < 0.01$ ). Patient, stone and operation characteristics are summarized in Table 1.

Per-operative complications were recorded in 12% ( $n = 18$ ) of the patients. The per-operative complications are summarized in Table 2. In Group 1, three patients had *grade 1*, two patients had *grade 2* complications. In Group 2; five patients had *grade 1*, four patients had *grade 2* complications. In Group 3; two patients had *grade 1*, two patients had *grade 2* complications. We did not find significant difference in terms of complications rate among the groups ( $p = 0.392$ ). *Grade 3* complication was not detected in any of the patients.

Postoperative complications were observed in 5.3% ( $n = 8$ ) of the patients. The postoperative complications are shown in Table 3. In Group 1; two patients had *grade 1*, one patient had *grade 2* complications. In Group 2; one patient had *grade 1*, one patient had *grade 3* complications. A 54-year old man had *grade 3* complications (septicemia) after the operation and he underwent intensive antibiotic treatment for 11 days. He was uneventfully discharged on the 12th postoperative day. In Group 3, one patient had *grade 1*, two patients had *grade 2* complications. No significant difference was found in terms of complication rates among the groups ( $p = 0.136$ ).

**Table 3.** Postoperative complications of the patients.

Grade	Complications	$n$ (%)
1	Fewer	4 (2.6)
2a	Urinary infection	2 (1.3)
2b	JJ stent migration	1 (0.6)
3	Septicemia	1 (0.6)

**Table 2.** Per-operative complications of the patients.

Grade	Complications	$n$ (%)	
1	Complications (incidents without consequences)	3 (2)	
	Mild degree bleeding	2 (1.3)	
	Minimal mucosal injury of ureter (mucosal tears)	2 (1.3)	
	Inability to reach stone requiring observation	3 (2)	
2	Complications (incidents treated with endoscopic surgery)	1 (0.6)	
	2a	Complications (incidents treated intraoperatively with endoscopic surgery)	2 (1.3)
2a	Inability to reach stone treated with shockwave lithotripsy ( $\pm$ stent insertion)	0	
	Mucosal injury requiring stent insertion	0	
	Inability to reach stone treated with percutaneous nephrolithotomy in the same session	0	
	Ureteral perforation managed by placing ureteral stent	0	
	2b	Complications (incidents requiring endoscopic re-treatment)	0
	Inability to access ureter or reach stone requiring secondary retrograde intrarenal surgery	3 (2)	
	Inability to reach stone treated with secondary percutaneous nephrolithotomy	0	
	Secondary ureteroscopy due to ureteral stone fragments	1 (0.6)	
	Severely bleeding requiring termination of the procedure and secondary retrograde intrarenal surgery	1 (0.6)	
	3	Complications (incidents requiring open or laparoscopic surgery)	0
Severely bleeding requiring open or laparoscopic surgery		0	
Inability to access ureter or reach Stone requiring conversion to open surgery		0	
Ureteral perforation requiring conversion to open surgery		0	
Ureteral intussusception		0	
Ureteral avulsion		0	

## Discussion

RIRS marked the beginning of a new era in urology and it renders kidney stones more accessible and upper urinary tract tumors treatable, using minimally invasive methods. RIRS is an effective and safe surgical procedure with high stone-free rates. According to our results, the stone-free rate of this surgery was 81.2% and between 70% and 97% in the international literature.<sup>4-7,11-14</sup> These studies mentioned above showed that our results were consistent with the international literature.

Up to date, no specific classification system has been described for per-operative complication of RIRS. For categorizing per-operative adverse events of surgeries, SCS has been used by some studies. Two previous published studies used this system for laparoscopic pyeloplasty in pediatric population.<sup>15-17</sup> Dogan and associates used SCS for semirigid ureterorenoscopy in children.<sup>17</sup> In 2014, Tepeler et al. modified SCS for the semirigid ureterorenoscopy complications in 1208 patients so the authors separate moderate complications from catastrophic ones.<sup>4</sup> In this study, overall stone-free and complication rates were 88.3% and 12.6%, respectively. According to modified SCS, 4.5% *grade 1*, 4.4% *grade 2a*, 3.2% *grade 2b* and 0.57% *grade 3* complications were reported. The authors noted that modified SCS is a quick and simple system for describing the degree of preoperative ureterorenoscopy complications and this grading system will facilitate a better comparison for the surgical results. In 2014, Oguz et al. used modified SCS for assessing per-operative complications in 230 patients who underwent RIRS.<sup>6</sup> In their series, the overall stone-free and per-operative complication rates were 81% and 30.4%, respectively. *Grade 1*, *2a*, *2b* and *3* complications were 15.9%, 5.6%, 8.9% and 0%, respectively. The authors claimed that the modified SCS is quick and easy to apply for grading preoperative RIRS complications. Also they stated that modified SCS can facilitate patients to understand the safety of this surgery as much as its success. A recent study assessed the efficacy and safety of RIRS to treat kidney stones in 947 patients.<sup>8</sup> In this study, per-operative complication rate was reported as 8.9%. In a study by Bozkurt et al., stone-free and per-operative complication rates were reported as 89.2% and 5.4% (*grade 1 and 2*) in 37 patients who underwent RIRS.<sup>12</sup> In a review by Breda and Angerri, 10 studies were assessed and overall stone-free and per-operative complication rates were reported as 89.3% and 8%, respectively.<sup>7</sup> They noted that major complication rate was 1.9%. The authors concluded that RIRS may offer an acceptable efficacy with low morbidity. In the current study, our stone-free and per-operative complication rates were 81.2% and 12%, respectively.

Most of our patients had minor (*grade 1 and 2*) per-operative complications. Our study supports previous findings. Moreover, we showed that per-operative complication rates were similar among patients with different ASA physical status.

The Clavien–Dindo classification system is widely used for postoperative complications of different endoscopic interventions. In a recent study, postoperative complications were assessed using Clavien–Dindo classification system in 437 patients who underwent SWL ( $n = 251$ ), PNL ( $n = 140$ ), or RIRS ( $n = 46$ ).<sup>18</sup> The overall complication rates for the SWL, PNL and RIRS were reported as 7.6%, 22.1% and 10.9%, respectively. No major complication (*grade 3–4*) was reported in SWL and RIRS groups. In a study by Gulpinar and associates, postoperative complication rate was 5.8% in 947 patients who underwent RIRS.<sup>8</sup> In the present study, postoperative complication rate was 5.3%. Our results were consistent with the international literature. Additionally, we did not find significant difference in terms of postoperative complication rate among patients with different ASA physical status.

According to our results, hospitalization time per patient was significantly longer in the ASA 2 physical status group compared to ASA 1 and 3 physical status groups. This result occurred to develop a major complication (septicemia) in a patient. However, the complication did not relate with the patient's physical status.

Finally, RIRS has been demonstrated as an alternative treatment option to SWL and PNL with high success rates and minimal complication rates in kidney stones. To our knowledge, no previous study has evaluated the results of RIRS in patients with different ASA physical status. According to our results, RIRS is an effective and safe surgery with high stone-free rates and low morbidity in patients with different ASA scores. High ASA physical status did not alter the success rate and did not increase the per-operative and postoperative complications. Hence, ASA physical status might not be considered as a limitation factor for RIRS. We believe that this issue should be studied further with more patients.

## Disclosure statement

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

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