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A Prospective Randomized Study Comparing Retrograde Intrarenal Surgery Under Spinal Anaesthesia Versus General Anaesthesia

Retrograd İntrarenal Cerrahide Genel Anestezi ve Spinal Anestezi Karşılaştırması: Prospektif Randomize Bir Çalışma

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ABSTRACT Objective: The aim of this study is to compare the intraoperative parameters, postoperative pain, surgical parameters, complication rates, and stone-free rates in patients who underwent retrograde intrarenal surgery (RIRS) under spinal anaesthesia (SA) versus general anaesthesia (GA). **Material and Methods:** A total of 100 patients treated with RIRS under SA (50) and GA (50) for renal stones were compared prospectively. The operative and postoperative outcomes of both groups were then analysed prospectively. **Results:** The demographic data was comparable between the two groups in terms of patient age, gender, and American Society of Anaesthesiologist (ASA) score as well as the size, lateralization, and location of the stones. And also, the mean operative times, fluoroscopy times, hospitalization times, and stone free rates were similar between the two groups. Postoperative Visual Analogue Scale (VAS) scores-measured only two hours after surgery-and rescue analgesia need were found statistically significantly lower in the SA group when compared with the GA group. Minor complication (Clavien 1-3) rates were 18% and 12% for the SA and GA group, respectively ($p > 0.05$). **Conclusion:** RIRS with SA can be performed safely and effectively to manage kidney stones, producing the same stone free rate (SFR) and complication rates when compared to GA.

Keywords: Anesthesia, spinal; kidney calculi; ureteroscopy

ÖZET Amaç: Bu çalışmada, spinal anestezi (SA) ve genel anestezi (GA) altında RIRS uygulanan hastalarda intraoperatif parametreleri, postoperatif ağrı skorlarını, cerrahi parametreleri, komplikasyon oranlarını ve taşsızlık oranlarını karşılaştırmak amaçlanmıştır. **Gereç ve Yöntemler:** Böbrek taşı olan toplam 100 hasta SA (50) ve GA (50) altında RIRS uygulandı ve her iki grup prospektif olarak karşılaştırıldı. Her iki grubun per-operatif ve postoperatif sonuçları prospektif olarak analiz edildi. **Bulgular:** Her iki grup demografik veriler açısından karşılaştırıldığında yaş, cinsiyet, boyut, taraf, taş yerleşimi ve hastaların ASA skorları açısından benzerdi. Ayrıca ortalama ameliyat süreleri, floroskopi süreleri, hastanede yatış süreleri ve taşsızlık oranları iki grup arasında benzerdi. Post op 2. saatteki VAS skorları ve kurtarma analjezi gereksinimi SA grubunda GA grubuna göre istatistiksel olarak anlamlı derecede düşük bulundu. Minör komplikasyon (Klavien 1-3) oranları SA ve GA grubu için sırasıyla%18 ve %12 idi ($P > 0.05$). **Sonuç:** SA ile yapılan RIRS, GA ile karşılaştırıldığında aynı taşsızlık ve komplikasyon oranlarına sahip olup, böbrek taşı tedavisinde güvenli ve etkili bir yöntemdir.

Anahtar Kelimeler: Anestezi, spinal; böbrek taşları; üreteroskopi

Along with the improvements in laser technology, endoscope miniaturization, deflection mechanisms, and optical quality, RIRS has been recommended as a standard therapy for renal stones smaller than 2 cm according to European urology guidelines.[1] Also, in recent studies, it has been shown

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to be an effective method for stones larger than 2 cm.[2,3] When compared with other surgical methods, RIRS has certain advantages, such as less bleeding, shorter hospitalization time, and lower complication rates. So, when percutaneous nephrolithotomy (PCNL) is not an option due to bleeding diathesis or the high risk of anaesthesia, RIRS has become the method of choice-even for renal stones greater than 2 cm.[4]

RIRS is usually performed under general anaesthesia (GA), which may be due to the minimal mobilization of the kidney during the operation and/or anxiety about the pain felt under spinal anaesthesia (SA) and conversion to GA.

GA administration to patients with pulmonary atelectasis, chronic obstructive pulmonary disease, cardiovascular diseases, and higher ASA scores may be risky. It is also more expensive when compared to regional anaesthesia. Spinal anaesthesia (SA) provides better postoperative pain control and thus lesser analgesic drug consumption, which leads to the avoidance of side effects stemming from multiple medications used in GA.[5] We therefore consider that RIRS procedures can be performed safely and effectively under SA due to these advantages.

In this study, the primary outcome is to evaluate the applicability of RIRS under SA. Meanwhile as a secondary outcomes, success and complication rates, intra-operative parameters, postoperative pain scores, analgesia needs of patients who underwent RIRS under SA versus GA were compared.

MATERIAL AND METHODS

Between June 2016 and December 2017, 100 patients aged between 18-81 years-old and scheduled for RIRS were included in this study. This study was specifically approved by the Ethic Committees of Harran University (session 8/decision no. 32), and a written informed consent was obtained from all participants. This study was carried out in accordance with the principles of Helsinki. Patients were randomized into two groups on the basis of a random number table generated by a computer: RIRS under SA group 1 (n = 50) and RIRS under GA group 2 (n = 50) (Figure 1). Anaesthesia randomization was performed by the assistant doctors before the operation in the outpatient clinic. Surgeon learned the type of anaesthesia just before the surgical procedures. Sample size was determined statistical calculation with the help of biostatistic department of the university. Inclusion criteria were comprised of: patients with renal stones smaller than 2 cm, ESWL-resistant stones, and renal stones larger than 2 cm and did not accept PCNL procedures. Patients with spinal deformities, at a high risk for anaesthesia due to having cardiopulmonary disease, and coagulopathy were excluded from the study. Coagulation tests, urine cultures, and blood count and chemistry were calculated preoperatively. If infection was detected, antibiotherapy was initiated. All patients had sterile urine cultures prior to surgery and also had urinary system imaging such as urinary ultrasound, intravenous pyelography, and/or non-contrast tomography (NCCT). The longest axis of the renal stones in the NCCT imaging was defined as the stone burden of each patient. Patient demographics and preoperative information were collected, including gender, age, body mass index (BMI), stone burden, stone location (renal pelvis, inferior calyx, middle calyx, superior calyx), prior renal surgery history, haemoglobin and creatinine levels, and ASA scores. Fluoroscopy (minutes) and operation time (minutes/time from application of a rigid ureteroscope to the completion of DJ stent insertion) SFRs, stone composition, complications, and hospitalization period (measured from day of operation to day of discharge following surgery/whenever patients are ready to discharge) were recorded for each patient.

ANAESTHESIA TECHNIQUE

An intravenous catheter was introduced with a 18-gauge (G) cannula on the right hand and an infusion of 10 mL kg-1 0.9% NaCl-1 was administered to the patients in both Group 1 (SA) and Group 2 (GA). Patients were premedicated with 0.03 mg/kg midazolam before entering operation room. Non-invasive blood pressure, electrocardiogram (ECG), heart rate, and peripheral oxygen saturation (SpO_2) were monitored.

In patients undergoing GA, induction was initiated with 2 mg/kg of propofol, 0.6 mg/kg of rocuronium, and 2 µg/kg of fentanyl, and laryngoscopy and tracheal intubation was attempted. For general anaes-

thesia maintenance, a mixture of 6-8% Desflanted, 50% O_2 and air (1:1), and 50 µg of fentanyl together with 10 mg of rocuronium was administered at every 30 minutes.

SA was performed with 3.5 mL of 0.5% heavy bupivacaine and 0.25 mL of fentanyl injected intrathecally at the L2-L3 interspaces with a 25 G pencil point spinal needle to patients in a sitting position. Patients were eligible for surgery if reaching T4-6 sensory dermatome levels determined via a pinprick test.

RIRS TECHNIQUE

The procedures were performed in a lithotomy position under spinal or general anaesthesia according to the randomization. Optical dilation was performed via semi-rigid ureteroscopy as a routine procedure before inserting the 9.5 Fr ureteral access sheath (UAS). If the UAS did not pass from the orifice, a DJ stent was inserted for passive dilatation of the ureter for 2-4 weeks, and the procedure was planned for four weeks later. The UAS was inserted over the guidewire and checked with fluoroscopy in the meantime. A 7.5 Fr flexible ureteroscope (f-URS, Karl Storz, Germany) was advanced through the UAS. The stones were fragmented into small pieces via a Holmium-YAG laser fibre. Basket catheters were used to pick up a sample for stone analysis only. If the deflection manoeuvre of the flexible ureteroscope was not sufficient to reach the lower pole stone, repositioning was performed with a nitinol basket. At the end of the procedure, a double-J stent (4.7 fr 26 cm/28 cm) was routinely inserted in all patients. DJ catheters were removed four weeks after the procedures.

On the first postoperative day, kidney-ureter-bladder graph was performed to check the DJ stent positions and residual stone fragments. NCCT or ultrasound and kidney-ureter-bladder graph was performed three months after surgery. SFR was accepted as complete stone clearance or residual stone fragments ≤ 3mm at three months via NCCT. The DJ stent was removed one month after the operation if there were no residual fragments. In the case of residual fragments, re-RIRS or ESWL was planned according to the location and size of the stone. At one month postoperatively, all patients underwent metabolic evaluations for renal stones.

Perioperative anaesthesia related complications were recorded.

A postoperative visual analogue scale (VAS) was used, which is a scoring system that attempts to measure patient pain experienced. The patient marks the point on paper that corresponds with their current amount of experienced pain, ranging from a minimum of one point to a maximum of 100 points. This was recorded at two, six, 12, and 24 hours after surgery.

RESULTS

One hundred and eight eligible patients underwent randomization, and five from the SA group and three from the GA group dropped out of the study due to renal anomalies and loss to follow-up (Figure 1). The demographic data was comparable between the two groups in terms of age, gender, stone size, stone lat-

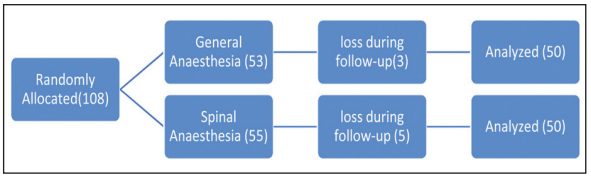

FIGURE 1: Flow chart of the patients.

TABLE 1: Patients' demographics and preoperative data.

	SA	GA	p value
No. patients (%)	50	50	
Gender (male/female)	32/18	22/28	> 0.05
Mean age ± SD (years)	45.08 ± 14.89	48.87 ± 15.95	> 0.05
Mean stone size ± SD (mm)	18.06 ± 5.31	17.30 ± 4.11	> 0.05
ASA Scores			> 0.05
I	32 (64%)	36 (72%)	
II	13 (26%)	11 (22%)	
III	5 (10%)	3 (6%)	
Prior Renal Surgery	9 (18%)	6 (12%)	
Stone Location			> 0.05
Renal pelvis	11 (22%)	10 (20%)	
Lower pole	16 (32%)	20 (40%)	
Middle pole/upper pole	18 (36%)	17 (34%)	
Partial/complete staghorn	5 (10%)	3 (6%)	
Laterality L/R	31/19	28/22	> 0.05

GA: General anaesthesia, SA: Spinal anaesthesia.

TABLE 2: Comparison of intraoperative and postoperative parameters of patients.

	SA (n = 50)	GA (n = 50)	P value
Mean operative time ± SD (min)	48.23 ± 11.87	45.28 ± 9.70	> 0.05
Mean fluoroscopy time ± SD (sec)	3.85 ± 1.38	4.05 ± 1.18	> 0.05
Mean hospitalization time ± SD (day)	1.80 ± 0.77	1.45 ± 0.58	> 0.05
Initial stone-free rate	38 (76%)	36 (72%)	> 0.05
Stone free rate after additional therapy	46 (92%)	45(90%)	> 0.05
Additional procedures			
ESWL	7	9	
Re-RIRS	5	5	
Mean VAS score 2 h after surgery, SD	9 ± 8	38 ± 12	< 0.05
Mean VAS score 6 h after surgery, SD	17 ± 11	21 ± 9	> 0.05
Mean VAS score 12 h after surgery, SD	14 ± 4	13 ± 5	> 0.05
Mean VAS score 24 h after surgery, SD	12 ± 5	10 ± 9	>0.05
No. pts. (%) requiring “rescue” analgesic consumption, n/%	1 (2%)	6 (12%)	< 0.05
Minor (Clavien I-III) complications	9 (18%)	6 (12%)	> 0.05
Intraoperative vomiting	1	0	
Intraoperative shivers	1	0	
Intraoperative pain	3	0	
Conversion to GA	1		
Ureteral mucosal injury	1	2	
Postoperative fever	2	4	
Major (Clavien IV-V) complications	1 (2%)	2 (4%)	> 0.05
Steinstrasse	1 (2%)	2 (4%)	
Stone Composition			> 0.05
Uric acid	5 (10%)	4 (8%)	
Cystine	7 (14%)	5 (10%)	
CaOx-CaP	16 (32%)	14 (28%)	
Struvite	6 (12%)	4 (8%)	
Unknown	16 (32%)	23 (46%)	

GA: General anaesthesia, SA: Spinal anaesthesia.

eralization, stone location, and ASA scores (Table 1). The intraoperative and postoperative parameters of the patients in each group are shown in Table 2.

The mean operative, fluoroscopy, and hospitalization times were 48.23 ± 11.87 minutes, 3.85 ± 1.38 seconds, and 1.80 ± 0.77 days in the SA group and 45.28 ± 9.70 minutes, 4.05 ± 1.18 seconds, and 1.45 ± 0.58 days in the GA group, respectively ($p > 0.05$).

The initial stone free rates (SFR) in the SA group and the GA group were 76% and 72%, respectively (p> 0.05). Twelve patients needed supplementary procedures (seven ESWL, five Re-RIRS) for residual stones in the SA group. Eight of these 12 patients were stone-free, and these supplementary interventions increased the overall SFR from 76% to 92%. SFR increased from 72% to 90% after the supplementary procedures (five re-RIRS, nine ESWL) performed in the GA group.

The mean VAS scores were calculated as 9±8 at two hours after surgery, 17±11 at six hours after surgery, 14±4 at 12 hours after surgery, and 12±5 at 24 hours after surgery in the SA group and 38±12 at two hours after surgery, 21±9 at six hours after surgery, 13±5 at 12 hours after surgery, and 12±5 at 24 hours after surgery in the GA group. A statistically significant difference was found between the two groups in terms of VAS scores only at two hours after surgery ($p < 0.05$).

In terms of major complications, steinstrasse was only diagnosed in one patient in the SA group

and two patients in the GA group. Overall, patients in the SA group had higher rates of minor (I-III) complications, but this was not statistically significant (*p>0.05*). One patient in the SA group had intraoperative vomiting and shivers. Three patients in the SA group felt intraoperative pain, one of which converted to general anaesthesia due to intractable flank pain. Two patients in the SA group and four patients in the GA group experienced upper urinary tract infection. They were treated with parenteral antibiotics for 14 days. Surgeries were postponed for four weeks and a DJ catheter was inserted after ureteral mucosal injury, which was observed in one patient in the SA group and two patients in the GA group.

DISCUSSION

According to European urology guidelines, percutaneous nephrolitotomy (PCNL) is recommended for the management of renal stones > 2 cm, whereas RIRS and ESWL should be the preferred method for stones smaller than 2 cm in the current management of renal calculi.[6-8] In recent publications, it has been shown that RIRS can be applied in repeated sessions to kidney stones larger than 2 cm in certain patients, like anti-coagulant users and high-risk patients.[9]

The advancement of technology and the miniaturization of surgical instruments have made kidney stone surgeries a minimally invasive method of treatment, and, likewise, regional anaesthesia applications are a minimally invasive method of anaesthesia, because GA has serious complications, such as intubation difficulty, aspiration pneumonia, pneumothorax, and ventilation problems.[10] Also, SA techniques are advantageous over GA in terms of pulmonary/vascular complications, cost, and pain control.[11] In addition, it is not always possible to apply general anaesthesia to patients with severe comorbidities and high ASA scores.[12]

GA was the generally preferred method of anaesthesia in the early stage of the RIRS procedures. General anaesthesia is preferred to control the diaphragm movements and tidal volume so surgeons can focus and fragment renal stones more precisely.[13,14] First, Zeng et al. performed RIRS under combined spinal-epidural anaesthesia (CSEA) and concluded that RIRS with CSEA could be administered with the similar efficacy and safety when compared to GA.[15] After this first study RIRS with regional anaesthesia, Karabulut et al. first compared SA versus GA for RIRS and also found that SA was as effective and safe as GA as well as advantageous due to its low cost.[16]

One of the most important independent variables in studies comparing SA versus GA is the VAS. In our study, VAS scores were statistically significantly lower in the SA group only at two hours after surgery, and the need for rescue analgesic, which indicates the need for analgesic other than routine postoperative analgesia administration, was also significantly lower in the SA group. On the other hand, Karabulut et al. found a statistically significant difference between the two groups in terms of VAS scores at all the times (15th minute, first hour, fourth hour, and 24th hour).[16] Contrary to this, Oztekin et al. and Zeng et al. evaluated VAS scores 8.-24. and 6.-24. hours respectively postoperatively and found no statistically significant difference between the groups.[15-17]

In the literature, the first series RIRS, residual stones were found in 9.3% and 14% in the SA group and GA group, respectively. Oztekin et al. evaluated spinal, epidural, and general anaesthesia on ureteral access and RIRS outcomes in primary surgery.[17] They achieved a complete SFR of 85.7% in the GA group and 91.4% in the SA group. A retrospective evaluation was conducted by Baran et al. in 1,467 cases, and they obtained a SFR of 85.3% in the SA group and 83.5% in the GA group, a difference which was statistically insignificant.[18] On the other hand, in a prospective randomized study by Kwon et al., SFR after RIRS with SA and GA was 71% and 92.3%, respectively. They concluded that manoeuvrability and accessibility during SA without sedation were poorer than during GA; so, overall SFR after GA was higher than that after SA.[19] In our study, SFR increased from 76% to 92% after supplementary procedures in the SA group and from 72% to 90% in the GA group. Parallel to the literature on RIRS with SA, the SFR of our patients was similar to that in published studies.

Complications were almost similar after RIRS between SA and GA in our study. Three patients felt flank pain during the operation due to hydrodistension of the kidney, two were relieved with intravenous analgesics, and only one patient converted to GA. In the literature on anaesthesia type for RIRS, mucosal injury, postoperative haematuria, infection, and steinstrasse have been recorded as complications. In all published studies, there has been no statistically significant difference in terms of the complication rates between RIRS with SA versus GA.[16-19]

The main limitation of the present study was its lack of cost calculation between both groups.

CONCLUSION

RIRS with SA can be performed safely and effectively to treat renal stones, producing the same SFR and complication rates as GA. Flank pain and intraoperative nausea must be kept in mind during the operation. RIRS under SA provides surgeons with a SFR as high as that of RIRS under GA.

Source of Finance

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Eyyup Sabri Pelit, Orhan Binici,* ***Design:*** *Eyyup Sabri Pelit, Bülent Katı,* ***Control/Supervision:*** *Eyyup Sabri Pelit, Halil Çiftçi,* ***Data Collection and/or Processing:*** *Eyyup Sabri Pelit, Adem Tunçekin,* ***Analysis and/or Interpretation:*** *Orhan Binici, Halil Çiftçi,* ***Literature Review:*** *Adem Tunçekin,* ***Writing the Article:*** *Eyyup Sabri Pelit, Erkan Arslan,* ***Critical Review:*** *İsmail Yağmur, Mehmet Demir.*

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