Comparison stone-free rate and effects on quality of life of percutaneous nephrolithotomy and retrograde intrarenal surgery for treatment of renal pelvis stone (2–4 cm): A prospective controlled study

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Abstract
Objectives: The aim of our study was to compare the effects on quality of life (QoL) and stone-free rate (SFR) of percutaneous nephrolithotomy (PNL) and retrograde intrarenal surgery (RIRS) in patients with renal stones 2–4 cm.

Materials and methods: A total of 102 patients with renal pelvis stones were enrolled in this prospective controlled study, of which 52 were performed RIRS and 50 with PNL. The QoL was evaluated by using Short Form-36 pre- and post-operatively. Also, the surgical data of all patients during and after the operations were compared between the 2 groups.

Results: The mean age, body mass index, stone size and density of the patients in the 2 groups were statistically similar (p > 0.05). The SFR of PNL and RIRS were found 94% (47/50) and 73% (38/52), respectively (p < 0.01). There were no statistically differences between operation times, minor complication rates and Short Form-36 scores of the 2 groups. Hospitalization times were 1.13 ± 0.34 days for RIRS and 2.9 ± 5.7 days for PNL (p < 0.05). While the blood transfusion rate of PNL group was 8% (4/50), none patient was made blood transfusion in RIRS.

Conclusions: The results of our study show that the blood transfusion rates and hospitalization times of RIRS group are significantly lower than PNL for management of renal pelvis stone 2–4 cm. Despite these advantages of RIRS, the SFR is significantly lower than PNL for these stones. The effects on QoL of the both interventions before and after surgery were similar.

Keywords: Percutaneous nephrolithotomy; Quality of life; Renal pelvis stone; Retrograde intrarenal surgery; Stone-free rate

1. Introduction
The prevalence of urinary tract stone has been increasing. The options for treatment of renal stones include extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS), or percutaneous nephrolithotomy (PNL). Size, density, and localization of renal stones are important factors for the treatment options. While PNL is recommended for the treatment of larger renal stones (>2 cm) as first option by Urolithiasis Guideline of European Association of Urology (EAU), RIRS is advised as second option for these stones. Although PNL affords excellent success rates for the management of larger renal stone, it potentially causes severity complications such as adjacent organ injury, bleeding that can result in nephrectomy. Therefore, RIRS has begun to be performed for treatment of larger renal stones with improved technique instruments. In the literature, there are a few studies that compared to RIRS and PNL for treatment of larger renal stones; however all of them are designed as retrospective studies. To the best of our knowledge, there is no prospectively designed study that compares these interventions and evaluates the effects on quality of life (QoL) of them. The aim of our study was to prospectively compare stone-free rate (SFR), perioperative data and effects on QoL between PNL and RIRS for treatment of larger renal pelvis stones (2–4 cm).

2. Materials and methods
2.1. Study population
A total of 102 patients with renal pelvis stone (2–4 cm) were enrolled in the study between July 2016 and September 2018. All of the patients were explained the advantages and disadvantages of PNL and RIRS in detail. The patients decided which technique was performed for the treatment of their stones, in which 50 patients were performed PNL and 52 with RIRS according to their preference. Socio-demographic data of the patients and the size, density and side of the stones were recorded preoperatively. The operation time and surgical complications during the operation were also recorded. Position of the double J stent and stone fragments were assessed with a kidney, ureter and bladder X-ray graph at the first day after surgery. The stone-free
status was defined as no evidence of stone fragments or the presence of nonsymptomatic residual fragments less than 3 mm, evaluated with non-contrast computed tomography at the first month after surgery. All patients filled out Short Form (SF)-36 before and at the first month after operation. The validation and reliability study of Turkish version of the SF-36 was made by Kocyigit et al.[7] The exclusion criteria were bilateral renal stones, urinary tract infection, ureteral stones, all renal calyx stones except renal pelvis and the other urinary tract abnormalities including solitary kidney, ureteropelvic or ureterovesical stricture, horseshoe kidney, etc.

2.2. PNL technique

The patients were placed in the lithotomy position under general anesthesia and were advanced a hydrophilic-tipped guidewire into their ureters with the help of cystoscope under fluoroscopic guidance. A 6F open-ended ureteral catheter was inserted via the guidewire to the collecting system. Then, the collecting system was filled with contrast material and the ureteral catheter was fixed on the urethral Foley catheter. The patients were replaced to the prone position on a table compatible with C-arm fluoroscopy (Philips BV 25 Gold Endura, Netherlands). PNL procedures of the patients were performed in the standard prone position. An 18 gauge needle was entered into favorable calyx with the help of C-arm fluoroscopy guidance. After a guidewire was inserted and fixed, dilatation was performed serially with standard Amplatz dilatation equipment (Cook Medical, USA) up to 18F and a 30F sheath was placed through the tract. Then, the 26F nephroscope (Karl Storz GmbH & Co, Tutlingen, Germany) in accordance with 30F sheath was used for visualization. Stone fragmentation was performed using pneumatic (Calculith, Me-Se Medikal, Izmir, Turkey) and/or laser lithotripsy (Litho, Quanta System, Istanbul). Fragments were extracted with some endoscopic equipment such as forceps and basket catheters, or by a flushing process. An 18F nephrostomy tube was inserted into the collecting system at the end of the surgery in all of the patients and usually extracted in the 3 days after surgery, provided that there was no complication or the nephrostomy tube is draining clear urine. A 4.8F double J stent was placed from the renal pelvis to the bladder routinely. The stent was extracted under local anesthesia at the third week after operation.

2.3. RIRS technique

The patients were placed in the lithotomy position under general anesthesia and were advanced a hydrophilic-tipped guidewire into their ureters with the help of cystoscope under fluoroscopic guidance. Ureteroscopy was performed over this guidewire with the aid of rigid ureteroscopy (9.5F, Karl Storz Endoscopy) for the purpose of excluding ureteral abnormalities and performing ureteral dilatation. Then, a ureteral access sheath (UroPass 10–12F, 46 cm) was advanced via the guidewire to the proximal ureter under C-arm fluoroscopy (Philips BV 25 Gold Endura, Netherlands). A 7.5F flexible ureteroscope (Karl Storz Endoscopy, FLEX-X2) was placed into the access sheath and advanced to the renal pelvis. If the procedure was unsuccessful because of ureteral stricture and/or other causes, a double J stent would be placed and the surgery would be performed after 2 or 3 weeks again. A 272-μm holmium laser fiber was used for stone fragmentation until the stones were able to fall spontaneously. The laser device (Litho, Quanta System, Italy) was set at the rate of 5–10 Hz and energy of level 1.0–2.1. A 4.8F double J catheter was routinely placed the ureter of patient at the end of the surgery and it was removed after 3 weeks.

2.4. Statistical analyses

Statistical analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, IL). All the variables of the 2 groups were compared using by the chi-square or independent t test. The scores of SF-36 of patients in each group before and after the surgery were compared by using the independent t test. A p value < 0.05 was considered statistically significant.

3. Results

The mean age, body mass index and gender distribution in PNL and RIRS groups were statistically similar (p > 0.05). There were no statistically differences between the mean stone size and density of patients in the PNL and RIRS groups (p > 0.05). The mean operation times in the PNL and RIRS groups were 61 ± 43 and 74 ± 25 minutes, respectively (p > 0.05). The complication rates of PNL (4/50) and RIRS (4/52) groups according to the modified Clavien classification[8] were statistically similar (p > 0.05). All of these data were given in Table 1. The SFR of patients in the PNL and RIRS groups were 94% (47/50) and 73% (38/52), respectively (p < 0.01). The mean hospitalization time of patients in the RIRS group (1.13 ± 0.34 days) were significantly lower than PNL group (2.9 ± 5.7 days) (p < 0.05). While the blood transfusion rate of PNL group was 8% (4/50), there were no blood transfusion requirements for the patients in RIRS group. None of the patients who had blood transfusion was performed embolization. There were no statistically differences between SF-36 scores before and at the third months after the procedure in each group (p > 0.05). The mean SF-36 scores of patients before and at the third months after the PNL and RIRS were given in Tables 2 and 3, respectively.

4. Discussion

The European Association of Urology Guidelines on urolithiasis[12] and The American Urological Association/Endourology Society Guidelines on surgical management of stones[13] recommend that PNL is the first option for the treatment of larger renal pelvis stones >2 cm. Moreover, although RIRS is recommended as second-line treatment for these stones, it is advised as first-line therapy.
Zengin et al. [3] on their comment regarding the similar 73% and 94%, respectively. However, we do not agree with similar to their study. In our study, the SFR of RIRS and PNL are prospective studies. The outcomes of our prospective study are authors noticed that RIRS for the management of larger renal pelvis stones. Their study showed that the hospitalization time in the (stone-free) rate was 80.6% in the RIRS group and 95.5% in the success rate for sub-anterior minor calyceal stones might be more difficult to remove than sub-posterior minor calyceal stones with RIRS and might require re-operation. They also reported that the RIRS method could be performed more safely than PNL with less bleeding. Similarly, the results of our study show that blood transfusion requirements in RIRS procedure are lower than PNL.

Major complications secondary to RIRS are less common and decrease in time compared to PNL. Recently, with the decreasing size of instruments, significant complications such as ureteral avulsion are extremely rare. In addition, RIRS is a safe intervention in patients with high risk and co-morbidities such as pregnant woman, morbid obesity, bleeding diathesis and in whom PNL may be contraindicated.[14] Akman et al.[15] compared 2 methods (RIRS, PNL) in elderly patients. RIRS was applied to 28 patients and PNL was applied to 79 patients over 65 years old who had a single kidney stone with a diameter of 1.5–3 cm. The minor complication rates were 7.1% in the RIRS group and 10.7% in the PNL group. In our study, there are no geriatric patients; nevertheless we have found that minor complication rates of RIRS and PNL are similar to the outcomes of their study.[15]

Our study also evaluates the QoL of patients after PNL and RIRS differently from other studies. We have found that both of the procedures do not influence the QoL of patients after the operations. However, we did not perform subgroup analyses to assess the QoL in patients who had residual stone after surgery. Because the number is very small in both PNL (n=3) and RIRS (n=14) groups. Perez-Fentes et al.[16] investigated short- and long-term effects on health-related QoL of PNL. They found that there was a minimal clinically important difference in bodily pain at third month after PNL. They also noticed that physical aspects of QoL get better at a year after PNL.

The most important limitation of our study is that the QoL of patients were evaluated at 1 month after surgery. This period may not be long enough to assess QoL after surgery. The other important limitation is the small number of patients, so we could not perform subgroup analysis of patients who had unsuccessful surgery. We suggest comparing between RIRS and PNL in studies that have larger patient groups and long-term follow-up prospectively.

### Table 2

|                          | Before PNL | After PNL | p    |
|--------------------------|------------|-----------|------|
| SF-physical              | 78.22±15.27| 81.29±13.28| 0.28 |
| SF-mental                | 70.47±19.01| 72.69±14.45| 0.29 |
| SF-physical functioning  | 74.14±22.47| 77.38±19.01| 0.19 |
| SF-role functioning/physical | 85.72±28.38| 87.26±29.54| 0.37 |
| SF-pain                  | 88.32±12.58| 90.56±11.98| 0.78 |
| SF-general health        | 65.59±14.74| 69.62±16.35| 0.13 |
| SF-energy/tired          | 61.34±12.56| 63.23±12.69| 0.37 |
| SF-social functioning    | 92.01±13.25| 87.82±15.19| 0.32 |
| SF-role functioning/emotional | 74.29±24.10| 78.15±22.34| 0.19 |
| SF-mental health         | 61.11±15.02| 62.61±11.25| 0.47 |

SF = short form; PNL = percutaneous nephrolithotomy.

Treatment for renal pelvis stones <2 cm by the EAU Guideline.[22] Currently, with technological improvement and increasing surgical experience, RIRS seems to become one of treatment options for the management of larger renal pelvis stones. There are few comparative studies related to this topic in the literature[3,4,6,10–13] and most of them have compared to PNL and RIRS in the management of lower pole renal stones. Only 1 study has compared these interventions in renal pelvis stones so far, however, this study was designed as a retrospective study.[13]

To the best of our knowledge, there is no prospective study that compares to PNL and RIRS in the treatment of larger renal pelvis stones. Zengin et al.[14] evaluated the medical data of 154 patients (74 PNL, 80 RIRS) who had renal pelvis stones 2–3 cm in diameter retrospectively. They found that the complete success (stone-free) rate was 80.6% in the RIRS group and 95.5% in the PNL. Their study showed that the hospitalization time in the RIRS group was shorter than PNL group. Consequently, the authors noticed that RIRS for the management of larger renal pelvis stones was as effective as PNL and they suggested further prospective studies. The outcomes of our prospective study are similar to their study. In our study, the SFR of RIRS and PNL are 73% and 94%, respectively. However, we do not agree with Zengin et al.[13] on their comment regarding the similar effectiveness of PNL and RIRS for the treatment of larger renal pelvis stones. Because the results of the both studies show that the SFR of RIRS are lower than PNL and this difference is approximately 15–18%. On the other hand, the success rate of 73% means that RIRS is unsuccessful in 1 of every 4 patients for the management of larger renal pelvis stone.

There have been more many studies associated with comparing to PNL and RIRS in lower pole stones than renal pelvis. Donaldson et al.[17] published a very comprehensive review and meta-analysis to compare the benefits and harms of ESWL, RIRS, and PNL techniques in the treatment of medium-sized (≤2 cm) lower pole stones in adults, 12 articles reporting on 7 randomized controlled trials recruiting a total of 691 patients in this meta-analysis. SFR favored PNL (96.3%) over RIRS (91.7%), and over ESWL (54.5%). Stone size subgroup analyses revealed PNL and RIRS were considerably more effective than ESWL for >1 cm stones. The major limitation of this review was the lack of evidence for the comparison of PNL versus RIRS. Also, the difference from our study was that the lower pole stone size was considered to be <2 cm.[11]

Jung et al.[15] compared RIRS and PNL for the management of larger stones (15–30 mm) in lower poles. This study showed that sub-anterior minor calyceal stones might be more difficult to remove than sub-posterior minor calyceal stones with RIRS and might require re-operation. They also reported that the RIRS method could be performed more safely than PNL with less bleeding. Similarly, the results of our study show that blood transfusion requirements in RIRS procedure are lower than PNL.

Major complications secondary to RIRS are less common and decrease in time compared to PNL. Recently, with the decreasing size of instruments, significant complications such as ureteral avulsion are extremely rare. In addition, RIRS is a safe intervention in patients with high risk and co-morbidities such as pregnant woman, morbid obesity, bleeding diathesis and in whom PNL may be contraindicated.[14] Akman et al.[15] compared 2 methods (RIRS, PNL) in elderly patients. RIRS was applied to 28 patients and PNL was applied to 79 patients over 65 years old who had a single kidney stone with a diameter of 1.5–3 cm. The minor complication rates were 7.1% in the RIRS group and 10.7% in the PNL group. In our study, there are no geriatric patients; nevertheless we have found that minor complication rates of RIRS and PNL are similar to the outcomes of their study.[15]

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The most important limitation of our study is that the QoL of patients were evaluated at 1 month after surgery. This period may not be long enough to assess QoL after surgery. The other important limitation is the small number of patients, so we could not perform subgroup analysis of patients who had unsuccessful surgery. We suggest comparing between RIRS and PNL in studies that have larger patient groups and long-term follow-up prospectively.

### Table 3

|                          | Before RIRS | After RIRS | p    |
|--------------------------|------------|-----------|------|
| SF-physical              | 77.18±16.19| 80.14±11.18| 0.26 |
| SF-mental                | 70.29±15.33| 72.64±13.13| 0.24 |
| SF-physical functioning  | 74.14±19.74| 77.28±12.68| 0.21 |
| SF-role functioning/physical | 84.89±29.15| 88.88±29.49| 0.33 |
| SF-pain                  | 87.89±14.76| 90.23±14.87| 0.47 |
| SF-general health        | 64.24±15.56| 68.48±13.87| 0.13 |
| SF-energy/tired          | 61.38±13.28| 63.27±15.27| 0.42 |
| SF-social functioning    | 90.28±14.37| 87.46±11.25| 0.30 |
| SF-role functioning/emotional | 75.27±23.42| 78.52±15.23| 0.25 |
| SF-mental health         | 62.99±14.29| 65.21±14.32| 0.31 |

SF = short form; RIRS = retrograde intrarenal surgery.
renal pelvis stones are less bleeding rates and hospitalization times than PNL, its success rates in the treatment of these stones are lower than PNL. Although RIRS may be considered as the first option in renal pelvis stones <2 cm diameters, it cannot replace PNL in stones >2 cm diameters according to the outcomes of this study. Therefore, we suggest that PNL have to be preferred as the first option in larger renal pelvis stones, like the recommendation of urolithiasis guidelines of EAU.

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None.

Statement of ethics
The Ethics Committee of Celal Bayar University approved the study protocol, with an approval number 20478486-244. Informed consent was obtained from all patients. All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest statement
There are no conflicts of interest to be stated for the corresponding author and all co-authors.

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Author contributions
All authors contributed equally in this study.

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