Comparison of the Complications and the Cost of Open and Laparoscopic **Radical Nephrectomy in Renal Tumors** Larger than 7 centimeters

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Purpose: To compare the complications and the cost analysis of open radical nephrectomy (ORN) versus laparoscopic radical nephrectomy (LRN) in patients with renal tumors larger than 7 centimeters (cm).

Materials and Methods: A retrospective analysis was performed in 173 patients (ORN group, n = 140; LRN group, n = 33) who underwent surgery for kidney tumors between 2008 and 2011. Patients' age, tumor size, pre-operative surgical risk score (American Society of Anesthesiologists score), duration of hospitalization, complications and the costs of hospitalization were recorded. The complications in ORN group and LRN group were specified with Modified Clavien System in five grades.

Results: The mean age was found 58.52 ± 13.74 years in ORN group, and 58.15 ± 12.81 years in LRN group (P = .847). Post-operative pain necessitating analysesics was observed in all patients (100%) after early post-operative period in both groups (Grade 1 complications). Blood transfusions were required in 51 patients (36.42%) in the ORN group, and 7 (21.21%) patients in the LRN group (Grade 2 complications) (P = .185). Grade 3 complication was not observed in each groups. Grade 4 complications were occurred in 6 (4.28%) patients [aortic injury, acute tubular necrosis, the need for dialysis, respiratory arrest (2), atrial fibrillation] in the ORN group, and in 1 (3.03%) patient (pulmonary embolism) in the LRN group. Grade 5 complication was occurred in 1 (0.71%) patient (death) in the ORN group. By the cost analysis, the average cost of ORN group was \in 1328, whereas \in 1508 in LRN group (P < .05).

Conclusion: Laparoscopy is used in many clinics with an increasing frequency because of the improved patient comfort, better cosmetic results, less post-operative pain, lower transfusion rates, and early return to the daily activities. Besides these advantages, the negligible difference in the costs compared to the open surgery (mean difference = €180 per case) makes it even more attractive.

Keywords: kidney neoplasms; surgery; laparoscopy; nephrectomy; methods.

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INTRODUCTION

enal cell carcinoma (RCC) is a common malignant tumor of the genitourinary tract, accounting for 2% 3% of all adult malignant tumors. The increase in the incidence rates of the renal tumors all over the world in recent years is undoubtedly, the widely use of the ultrasound and the computerized tomography. Although the incidental diagnosis of the kidney tumors has become more frequent, the treatment policy is usually based on the clinical stage of the disease. (1) Partial or radical nephrectomy, is the mainly applied current method in the treatment of renal cell cancer. Laparoscopic radical nephrectomy (LRN) has been routine practice for localized RCC for indicated patients. (2,3) Most of studies about LRN were performed in small tumors. But few recent publications have showed that, LRN could be also performed for large renal tumors. Ritchie and colleagues emphasized that patients with stage T2 RCC were operated with LRN safely although more challenging procedure. (4) In addition to these; compared to open radical nephrectomy (ORN), LRN has advantages as decreased blood loss, less postoperative pain, improved cosmetics, and quicker return to daily activities. (5,6)

In our country, which is among the developing countries, there is rapidly increase in series of LRN. There is an increase in costs due to the instruments used during surgery, and this situation leads to financial problems in most centers. In our study, we aimed to compare complications and to make a cost analysis of ORN vs. LRN in patients underwent surgery due to large renal tumors larger than 7 centimeters (cm).

MATERIALS AND METHODS

A retrospective analysis was performed in 173 patients (ORN group, n = 140; LRN group, n = 33) who underwent surgery for kidney tumors between 2008 and 2011. Patients with T1 and T4 tumors were excluded from the study, because of they were treated with partial nephrectomy and ORN, respectively. Tumor staging was performed according to the 2009 American Joint Committee on Cancer (AJCC) TNM classification. Pre-operatively all patients were evaluated with posterior-anterior chest radiography, abdominal computerized tomography and/or magnetic resonance imaging. Of study

subjects 140 patients underwent ORN and in 33 patients LRN was performed. Recommendations and surgeon experience were affected the choice of surgical method. Patients with tumor invasion of the renal vein and the inferior vena were included in the ORN group. ORN was performed through hemi-chevron incision. After the dissection and division of subcutaneous tissues and abdominal muscles; the peritoneum was incised and colon was medialized. Then retroperitoneal space was entered from posterior peritoneum. After the hilar area was reached, first renal artery, then the renal vein and ureter were sutured and cut, respectively. The kidney was extracted en-bloc with perinephric fat and Gerota's fascia, and a 20 French Foley drain was left at the renal space. When an enlarged lymph node (hilar, para-aortic, paracaval) was detected radiologically before surgery or largish during the operation; lymph node dissection was also performed.

The transperitoneal approach was preferred in all patients who underwent LRN. After pneumoperitoneum was performed with a Veress needle, 3 or 4 laparoscopic trocars were sited under direct vision. Laterocolic tissue was dissected and colon was medialized. Then approaching the renal hilum, the renal vein and artery was isolated. First renal artery, subsequent renal vein were separately ligated with Hem-o-Lok clips. Three or 4 clips or vascular stapler were used to control the renal vein. We performed nephrectomy, with surrounded by the perinephric fat and Gerota's fascia, with or without a simultaneous adrenalectomy. The specimens were extracted with Endo Catch bag and a 20 French Foley drain was left in the retroperitoneal area.

In all patients receiving transperitoneal laparoscopic procedure, two 10-11 mm trocars for the camera, the endobag and the clip applicator, and for the non-dominant hand one 5 mm trocar to suspend ureter, where necessary one 5 mm trocar for the retraction of the liver or the spleen were used during the procedure. In all cases, three clips were placed on the renal artery and vein, and one on the ureter (Hem-o-lok, Weck Closure Systems, Research Triangle Park, NC, USA). For minimizing the operation time and to ensure adequate hemostasis, LigaSureTM (Valleylab, Tyco Healthcare Group LP, Longbow Drive Boulder Colorado, USA) was used. For each patient, monopolar scissors, bipolar dissector and gear holder were used. To reduce the costs, LigaSureTM, the monopolar

Table 1. Classification of surgical complications according to the Modified Clavien Grading System.

Grade 1. Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are as follows: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.

Grade 2. Requiring pharmacological treatment with drugs other than such allowed for grade 1. complications. Blood transfusions and total parenteral nutrition are also included.

Grade 3. Requiring surgical, endoscopic, or radiological intervention.

3a. Intervention not under general anesthesia.

3b. Intervention under general anesthesia.

Grade 4. Life-threatening complication (including central nervous system) requiring intensive care unit stay.

4a. Single organ dysfunction (including dialysis).

4b. Multi organ dysfunction.

Grade 5. Death of a patient.

scissors, the bipolar dissector, the gear holder, and the trocars were re-sterilized in solution and used at least for four laparoscopic interventions. All the transperitoneal or laparoscopic procedures were performed using surgical techniques as described in other publications. (7)

Patients' age, tumor size, pre-operative surgical risk score (American Society of Anesthesiologists score: ASA score), duration of hospitalization, complications and the costs of hospitalization were recorded. The complications in both groups were specified with Modified Clavien System in five grades (Table 1).⁽⁸⁾

The cost analysis was performed by scanning the hospital bills in the automation system and the calculations were made in Euro's. All the expenses starting from the patient's hospitalization until the discharge [consumables used during surgery, laboratory, radiologic imaging, drugs, intravenous (IV) fluids, analgesics, bed costs, surgeons, and anesthesia] were included in this bill.

Comparison of two independent groups was performed with Mann Whitney U-Test. For the categorical data chi-square test was used. The statistical package for the social science (SPSS Inc, Chicago, Illinois, USA) version 11.5 was used for analysis and P values lower than .05 were accepted as significant.

RESULTS

The mean age was found 58.52 ± 13.74 years in ORN group, and 58.15 ± 12.81 years in LRN group (P = .847). In ORN group, 103 (73.5%) patients had ASA II scores, and 37 (26.4%) patients had ASA III scores. In LRN group, 22 (66.6%) patients had ASA II scores, and 11 (33.3%) patients had ASA III scores (P = .432). Tumor size was calculated 9.90 ± 2.04 (7-15) cm in ORN group, and 9.54 ± 1.43 (7-12) cm in LRN group (P = .692). In the ORN group, T2 tumors were found in 106 (75.71%) patients, and T3 tumors in 34 (24.28%) patients. In the LRN group, T2 tumors were identified in 28 (84.84%) patients, and T3 tumors in 5 (15.15%) patients (P = .242). There was no significant difference between the two groups in terms of mean age, ASA score, mean tumor size, and the tumor stages (P > .05) (Table 2).

Post-operative pain necessitating analgesics was observed in all patients (100%) after early post-operative period in both groups (Grade 1 complications). Blood transfusion were required in 51 patients (36.42%) in the ORN group, and 7 (21.21%) patients in the LRN group (Grade 2 complications) (P = .185). Grade 3 complication was not observed in each groups. Grade 4 complications were occurred in 6 (4.28%) patients [aortic injury, acute tubular necrosis, the need for dialysis, respiratory arrest (2), atrial fibrillation] in the ORN group, and in 1 (3.03%) patient (pulmonary embolism) in the LRN group. Grade 5 complication was occurred in 1 (0.71%) patient (death) in the ORN group (Table 3).

The mean hospital stay was 3.75 ± 2.26 days in ORN group, and 3.27 ± 1.39 days in LRN group (P = .601). The total cost per patient for open surgery was calculated €1328, whereas the total cost per patient for laparoscopic surgery was €1508 (P = .011) (Table 2).

The mean follow up period was calculated 33 months for the

T3: 5 (15.15)

 3.27 ± 1.39

P = .242

P = .601

Table 2. Demographic data of patients in study groups.			
	ORN (n = 140)	LRN (n = 33)	р
Age (years)	58.52 ± 13.74	58.15 ± 12.81	P = .847
Tumor size, cm (range)	9.90 ± 2.04 (7-15)	9.54 ± 1.43 (7-12)	P = .692
T	T2: 106 (75.71)	T2: 28 (84.84)	D 242

T3: 34 (24.28)

 3.75 ± 2.26

Key: ORN, open radical nephrectomy; LRN, laparoscopic radical nephrectomy.

ORN group, and the 23 months for the LRN group. Local recurrence was occurred in 2 (1.4%) patients in the ORN group. Two patients in ORN group and 2 patients in LRN group were died during follow-up period.

DISCUSSION

Tumor stage, n (%)

Hospitalization (days)

The laparoscopic dissection of large tumors highly depends on the experience of the laparoscopic surgeon. Although the limitation of the working space, more bleeding, and the neovascularization of the larger tumors constitute a disadvantage for the laparoscopic technique, today LRN is often performed for T2 tumors. After Gill and colleagues⁽⁹⁾ have reported in 2000 that they have successfully implemented LRN in tumors larger than 12 cm (mean 14.6 cm), Dunn and colleagues⁽¹⁰⁾ have published the results of laparoscopic radical nephrectomy in a series of 61 patients with kidney tumors larger than 10 cm. In these studies, the authors have found more advantageous results in the laparoscopy group than the open surgery group, such as less pain, faster recovery and similar efficacy. These results have encouraged the urologists to perform laparoscopic surgery, to all stage T2 tumors, regardless of tumor size.

Steinberg and colleagues have compared a series of 62 patients with stage T2 tumors (mean diameter 9.2 cm) treated with LRN; with a series of 32 patients treated with ORN. In this study, laparoscopic intervention was found to be associated with a shorter hospital stay, less blood loss compared to the open group.⁽¹¹⁾ Hemal and colleagues retrospectively compared 41 patients performed LRN with 71 patients per-

formed ORN between 1998 and 2006 with tumor stage T2. The average tumor size was about 10 cm in both groups. The transfusion rate was 15% and 32%, and the hospital stay was 3.6 days and 6.6 days for LRN and for ORN groups respectively. The postoperative complications were similar (12% and 15% in LRN and ORN groups, respectively). The LRN was thus found to be more advantageous than the ORN. These results were in concordance with the results obtained in our study. Although the difference was not statistically significant, the transfusion rates in ORN (36.42% vs. 21.21%) was higher and the hospitalization time (3.75 days vs. 3.27 days) in ORN was also longer.

In their study comparing the ORN and LRN for masses larger than 7 cm, Jeon and colleagues have not found significant differences in complication (pre-operative; vascular/hemorrhage, bowel, spleen, liver complications, post-operative; delayed bleeding, ileus, respiratory, and cardiac complications) rates between the groups. (12) Similar to our study, major complications were occurred in 6 (4.28%) patients (aortic injury, acute tubular necrosis, the need for dialysis, respiratory arrest, and atrial fibrillation) in the ORN group, and in 1 (3.03%) patient (pulmonary embolism) in the LRN group. Unfortunately, 1 (0.71%) patient was died in the ORN group due to respiratory arrest.

Although the difference between ORN and LRN groups in terms of complications was not statistically significant, due to the high costs and the payments done according to the package standard prices, most centers have to deal with the financial aspects when they decide to switch to laparoscopic

Table 3. Comparing complications of ORN and LRN by Clavien Classification. ORN, n (%) LRN n (%) р NS Grade 1 33 (100) 140 (100) Grade 2 51 (36.4) 7 (21.2) 185 Grade 3 0 Grade 4 6 (4.28) 1 (3.03) NS Grade 5 1 (0.71) 0 NS

Key: ORN, open radical nephrectomy; LRN, laparoscopic radical nephrectomy; NS, not significant.

surgery, in our country. Postoperative complications result in high costs due to the extended the duration of hospital stay and additional treatment. When the published data are analyzed, the complication rates are similar in open and laparoscopic kidney surgery. For this reason, we think that the complication rates do not have any effect on the cost calculation. Today, the factors determining the costs of the open and the laparoscopic kidney surgery are the operating time, the number of transfusions, the medications, the hospital stay and the additional costs resulting from the complications. However, the main factor that increases the costs of the laparoscopic procedures are the high prices of the instruments. Although the use of LigaSure™ results in additional costs, it has a number of advantages such as the user-friendliness, the possibility of blunt dissection with the tip, the effective bleeding control and ability to reduce the duration of the surgery. Furthermore, the possibility of sterilization and the repeated usage of the LigaSure™ reduces the additional cost. In our procedures, we have used each LigaSure™ device in about four cases after sterilization.

The Hem-o-lok polymer clips are preferred by many urologists due to the lower in price compared to the endovascular-GIA stapler, and higher reliability than the titanium clips with a comparable price. Guazzoni and colleagues have reported a cost reduction of €805 per patient after 2003 by using the Hem-o-lok clip instead of the endovascular-GIA stapler. (13) We have used the endovascular-GIA stapler only in three cases in our procedures. We have tried to minimize the costs

by placing three clips on the renal artery and vein; and one polymer clip on the ureter (Hem-o-lok, Weck Closure Systems, Research Triangle Park, NC, USA), in all cases.

The studies comparing the costs of the open and laparoscopic procedures, performed outside our country, Holligsworth and colleagues have reported \$5808 for ORN and \$5157 for LRN. (14) In another study, Lotan and colleagues reported that the cost of LRN is \$1211 cheaper than ORN. (15) In the publications showing the financial burden brought by the laparoscopic renal interventions in our country, Basok and colleagues have calculated that the costs of LRN to be 20% higher than ORN. (16) In our study, the costs of ORN was €1328, whereas LRN was calculated to cost €1508, with a difference of 13.5% (P < .05).

This study has certain limitations. Our study was retrospective nature, and because of this, we could not perform randomization. We compare the expenses starting from the patient's hospitalization until the discharge. Only intra-operative cost may be more important to assess cost effectiveness of these two techniques.

CONCLUSION

Laparoscopy is used in many clinics with an increasing frequency because of the improved patient comfort, cosmetic display, post-operative pain reduction, lower transfusion rates, and early return to the daily life. Besides these advantages, similar complication rates even in larger renal masses and the negligible difference in the costs compared to the

open surgery (mean difference = €180 per case) makes laparoscopy even more attractive.

CONFLICT OF INTEREST

None declared.

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