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Short Term Renal Functional and Oncological Outcome of Nephron Sparing Partial Nephrectomy on >7 cm Renal Cell Carcinoma

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Abstract

Background: ***For larger Renal Cell Carcinoma (RCC), partial nephrectomy (PN) is gaining its feasibility, which facilitates conservation of functional renal tissue but keeping oncological outcome unaltered. Our aim is to study the short term i.e. one year oncological and renal functional outcome of > 7 cm RCC cases treated with PN.***

Methodology: ***A descriptive, prospective, observational study was designed and cases of RCC with size >7 cm, favorable anatomy, treated with PN were included. Preoperative and post-operative renal function, tumor characteristics, oncological clearance, cancer recurrence and post-operative complication were studied by following up for 12 months.***

Result: ***Total 22 patients was enrolled, 86.4% were male, mean age 58.73 + 6.69 years, mean BMI 24.34 + 2.7 kg/m2 and 02 (9.1%) patient had Chronic Kidney Disease (CKD). Mean maximum tumor diameter was 7.58 + 0.52 cm, and RENAL score was 9.86 + 1.12. Among them 21 (95.5%) patient were T2aN0M0 (Stage-ii) and 01 (4.5%) T2aN1M0 (Stage-iii). Pre-operative mean serum creatinine was 1.05 + 0.31 mg/dl and eGFR was 86.3+ 21.4 ml/min. After following up for one year the mean serum creatinine and eGFR was 1.0 + 0.24 mg/dl and 88.9 + 19.2 ml/min respectively. No significant alteration observed in concurrent variables like Hb%, ESR, alkaline phosphatase and LDH level. Seventeen cases (77.3%) was found to have clear cell variety of RCC, whereas 02 (9.1%) papillary RCC and 3 (13.6%) chromophobe RCC. While plotted on Clavien-Dindo Classification of post-operative complication, 05 (22.7%) patient developed Grade-1 complication. None of our cases had any recurrence of cancer within the 01 year of follow up.***

Conclusion: ***Our study supports expanding the role of partial nephrectomy beyond traditional size limits, demonstrating that even tumors >7 cm can be managed effectively with nephron-sparing surgery in selected patients. When performed in specialized centers, PN offers favorable short-term oncological outcomes while preserving renal function, underscoring its growing importance in modern RCC management.***

Keyword: Partial Nephrectomy , Renal Cell Carcinoma , Nephron Sparing Surgery.

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Introduction:

Renal Cell Carcinoma (RCC) is not uncommon, accounts for 2% - 3% of all new adult cancer cases worldwide[1] and represents almost 4% of all new cases of malignancies in United States.[2] Over the past few decades, there is a general shift toward the diagnosis of stage I (localized), smaller sized tumors[3] (≤4 cm) owing to the widespread use of advanced abdominal imaging modalities and diagnostic facilities (>50% detected incidentally)[4]. Along with the increased incidence of detection of early stage RCC, nephron-sparing strategy and minimally-invasive surgical techniques such as Partial Nephrectomy (PN) and Laparoscopic Radical Nephrectomy (LRN), have evolved over time as an alternative option, other than conventional standard open Radical Nephrectomy (RN) for the management of these patients, have been extensively studied by many international Urological and Oncological societies and associations.[4,5,6,7,8,9]

For a T1a (tumor confined to kidney, <4 cm) renal mass, the National Comprehensive Cancer Network (NCCN) guideline recommends partial nephrectomy. It also states that, RN should not be used when PN is possible. For clinical T1b (tumor confined to kidney, >4 cm but <7 cm)

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tumors, the NCCN guideline states that the standard of care is either RN or PN when possible.[9] According to the 2009 American Urological Association (AUA) management guideline, recommends discussing the potential advantages of PN with the patient, regarding avoidance of dialysis and reduced risk of chronic kidney disease. If PN is not technically feasible as determined by a urologic surgeon, then a RN should be considered as an alternate standard of care.[8]

Despite these recommendations for smaller tumors, the applicability of PN in larger (T2) renal tumors remains controversial. For larger RCC, T2a (tumor confined to kidney, >7 cm but not >10 cm) and T2b (tumor confined to kidney, >10 cm), feasibility of PN was not clearly defined by such study groups and publications, probably due to high technical challenge in operation on such larger masses may endanger the tumor free margin and increase the rate of surgical complications due to increase vascularity, nearness to hilum, prolong warm ischemic time and blood loss. But we cannot deny the benefits of PN on the ground of better renal functional outcome and less complication rates of such approach by using current better pre-operative imaging, planning and advanced power tools. Survival advantage of PN compared to RN was reported in many non-randomized retrospective studies[10, 11, 12, 13]

Recently few studies have shown promising oncological and functional outcome within short follow-up period conducted over patients with low comorbidity, for elective NSS in selected cases presenting with, T2a and T2b renal tumors. [13, 14, 15]. Most of these studies incorporated highly selective patients, with low comorbidity rates in advanced centers, short follow up period and on small sample size. Thus we are yet to know about the long-term oncological outcome. The current available literature about PN in large renal masses is often biased and probably in a beginners stage. Most studies testing oncological outcome studied cohorts including different histological types of RCC or even benign renal lesions. Notably, no published study provides good comparability for elective PN and RN according to incidentally diagnosed cT2 RCC so far.

Under such, study on the outcome and effect of PN with nephron sparing approach on larger renal tumors are very time appropriate and necessary. Thus this study was conducted to determine the technical feasibility, short term renal functional and oncological outcome of NSS on > 7 RCC.

Materials and Method:

Descriptive, hospital-based, prospective, observational study was designed. Purposive sampling technique was used. All cases of RCC with Tumor size > 7 cm, with favorable location (cleavage from hilar vessels and adequate pelvis for drainage of left over kidney tissues), who was treated by PN in the department of Urology (CMH) Dhaka, started from January 2022 onward was purposively sampled and studied. Bilateral RCC, Recurrent RCC were excluded from this study.

The patients included in this study were counseled and informed written consent obtained. Detail history, physical examination and diagnostic work up and staging investigations were recorded. Pre-operative investigation and pre anesthesia checkup was done. All patients were discussed in a multidisciplinary tumor board and decision of PN was reviewed on the basis of tumor stage and technical feasibility by RENAL score. All radiological, hematological and biochemical (Serum creatinine, blood urea, eGFR, hemoglobin percentage, ESR, Serum Alkaline phosphatase, LDH and urinalysis) information were noted in a preformed data sheet. RENAL scoring was done with radiological information. All operations were performed by two of our experienced professor of Urology with vast training and experience in open PN in home and abroad. After operation all specimen were sent to affiliated laboratory for histopathology. Post-operative period was keenly observed, any complication and its management was noted in the data sheet. Follow up was given on 6th week, 3rd month, 6th month, 9th month and 12th month of post-operative period. Renal functional, hematological and biochemical test (Serum creatinine, blood urea, eGFR, hemoglobin percentage, ESR, Serum Alkaline phosphatase, LDH and urinalysis) as per the preset protocol for this study were advised and recorded. All patients underwent Ultra sonogram of whole abdomen and contrast enhanced CT scan of abdomen chest and pelvis to detect any recurrence at the same visits of post-operative follow up. The imaging frequency and protocol was set for this pilot study after through discussion in the tumor board. All investigations were performed in Armed Forces Institute of Pathology (AFIP) and Radiology Department of CMH Dhaka, where periodic audit of all instrument, reagent and electro-medical equipment are carried out as per set standard.

All information's were noted in preformed structured data collection sheet, transferred to IBM SPSS Version 25 software for statistical analysis. Mean with standard deviation and ranges were calculated by aforementioned software. Results were presented in tables, figures and charts. Results were aggregated; mean and percentage were calculated and presented in charts, tables and diagrams.

Result:

Table-I

Distribution of demographic variables (n=22)

Variable	Frequency	Percentage
Age (in years)		
Mean+ Std Dev	58.73 + 6.69	
Range	48 - 70	
Sex		
Male	19	86.4%
Female	03	13.6%
BMI (kg/m^2)Mean+ Std. Dev	24.34 + 2.7	
Range	20- 29	
Condition of opposite kidney		
Normal	18	81.8%
Simple cyst	02	9.1%
CKD	02	9.1%

BMI- Body Mass Index, CKD- Chronic Kidney Disease

Table-II

Distribution of pathological variables (n= 22)

Variable	Frequency	Percentage
Maximum tumor diameter (cm)		
Mean+ Std. Dev	7.58 + 0.52	
Range	7 – 9 cm	
Exophytic/ Endophytic property of tumor		
> 50% Exophytic	07	31.8%
<50% Exophytic	15	68.2%
Entirely Endophytic	0	00%
Nearness to collecting system or sinus (mm)		
>7 mm	00	00%
>4 mm but < 7mm	06	27.3%
<4mm	16	72.7%
Anterior/ Posterior location of tumor at coronal plane		
Anterior	05	22.7%
Posterior	06	27.3%
Neither	11	50.0%
Location relative to polar lines		
Entirely above or below	00	00%
Crosses a polar line	12	54.5%
>50% across polar line	10	45.5%
Crosses axial renal midline	00	00%
Entirely between polar lines	00	00%
RENAL Nephrometry Score		
Mean+ Std. Dev	9.86 + 1.12	
Median	10	
Mode	11	
Range	8-11	
Preoperative TNM staging		
T2aN0M0	21	95.5%
T2aN1M0	01	4.5%
AJCC Stage		
Stage ii	21	95.5%
Stage iii	01	4.5%

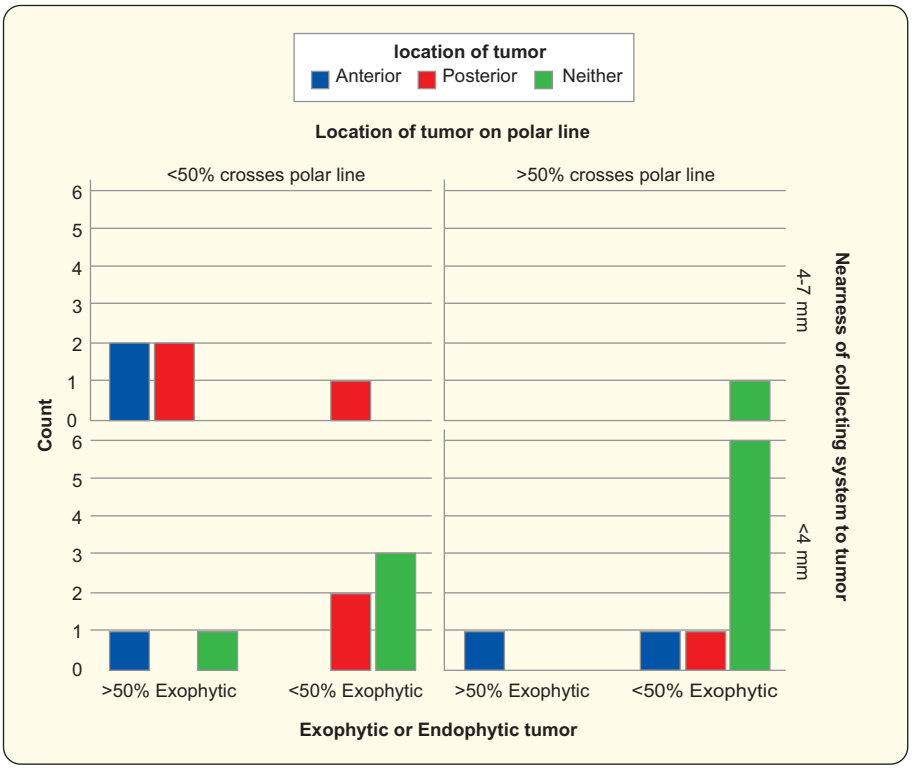

Figure 1: *Grouped bar diagram showing inter-relation of variables of RENAL Score*

This bar diagram shows inter-relation of RENAL score parameters in our study population. Tumors that are neither anterior nor posterior were found to be more endophytic and had more nearness i.e <4 mm, to the collection system, reflecting more assumed difficulties and complexities at operation.

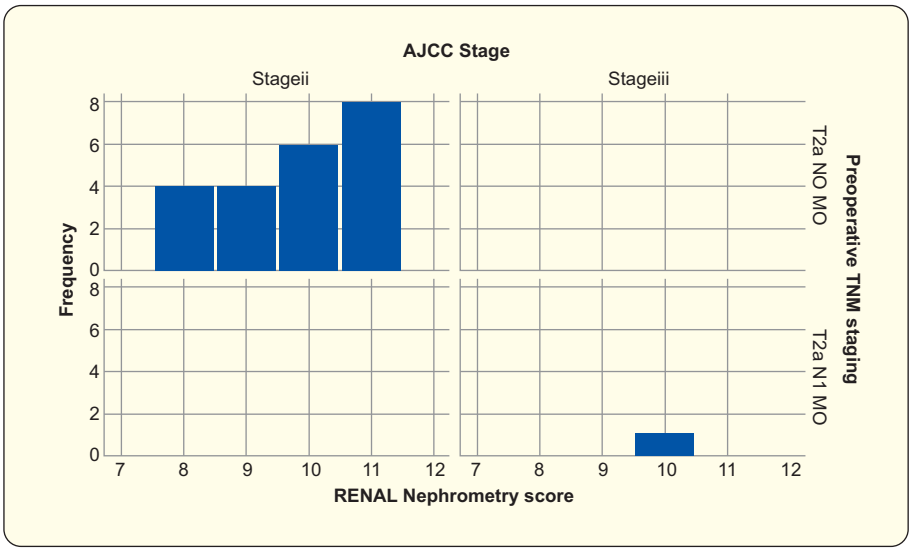

Figure 2: *Histogram showing distribution of TNM and AJCC staging according to RENAL Score*

In our study group, one patient (4.5%) was clinically stage-iii wit RENAL score 10. But 8 (36.4%) patient had Renal score 11, but were clinically in stage-ii.

Table-III

Distribution of preoperative and postoperative renal functional variables (n= 22)

Variable	Pre Operative level (Mean + SD)	Postoperative level(Mean + SD)				
		6th Week	3rd Month	6th Month	9th Month	12th Month
Blood urea (mg/dl)	35.5 + 6.2	35.22 + 5.4	36.8 + 8.1	34 + 4	47.3 + 6.3	34.3 + 3.5
Serum Creatinine(mg/dl)	1.05 + 0.31	1 + 0.29	1 + 0.25	1 + 0.29	1 + 0.22	1 + 0.24
eGFR	86.3+ 21.4	86.9 + 19	88.6 + 19.9	88.5 + 19.8	87 + 17	88.9 + 19.2
Haemoglobin (g/dl)	12.9 + 1.1	13 + 1	13.2 + 0.9	13 + 1	13.1 + 0.9	13.2 + 0.9
ESR(mm in 1st hr)	20+ 3	18.7 + 6.9	18.7+ 6.9	17.5+ 6.3	16.9 + 5.1	18.4 + 4.5
Serum Alkaline Phosphatase (IU/L)	119.3 + 23.7	119 + 26	121 + 23	121+ 24	114 + 31	118.6 + 24
LDH (U/L)	172 + 28	172 + 36	172 + 26	170 + 24	171 + 21	172 + 20
Urinalysis Normal	20 (90.9%)	22(100%)	22(100%)	22(100%)	22(100%)	22(100%)
Haematuria	02(9.1%)	00(00%)	00(00%)	00(00%)	00(00%)	00(00%)

eGFR- Estimated Glomerular Filtration Rate, ESR- Erythrocyte Sedimentation Rate, LDH- Lactate Dehydrogenase

Table-IV

Distribution of final histological and staging variables (n= 22)

Variable	Frequency	Percentage	
Specimen Maximum tumor diameter (cm)			
Mean+ Std. Dev	7.58 + 0.52		
Range	7 – 9		
Histological subtype			
clear cell RCC	17	77.3%	
papillary RCC	02	9.1%	
chromophobe RCC	03	13.6%	
Furham nuclear gradeG1	18	81.8%	
G2	04	18.2%	
G2	00	00%	
G4	00	00%	
Sarcamatoid featuresAbsent	21	95.5%	
Present	01	4.5%	
Tumor necrosisAbsent	14	63.6%	
Present	08	36.4%	
Renal capsule involvement			
Absent	20	90.9%	
Present	02	9.1%	
Margin involvement			
Clear	22	100%	
Involved	00	00%	
WHO/ ISUP Grade	G1	18	81.8%
G2	04	18.2%	
G3	00	00%	
G4	00	00%	
Final AJCC Stage			
Stage ii	21	95.5%	
Stage iii	01	4.5%	

WHO- World Health Organization, ISUP- International Society of Urologic Pathologist, AJCC- American Joint Committee on Cancer

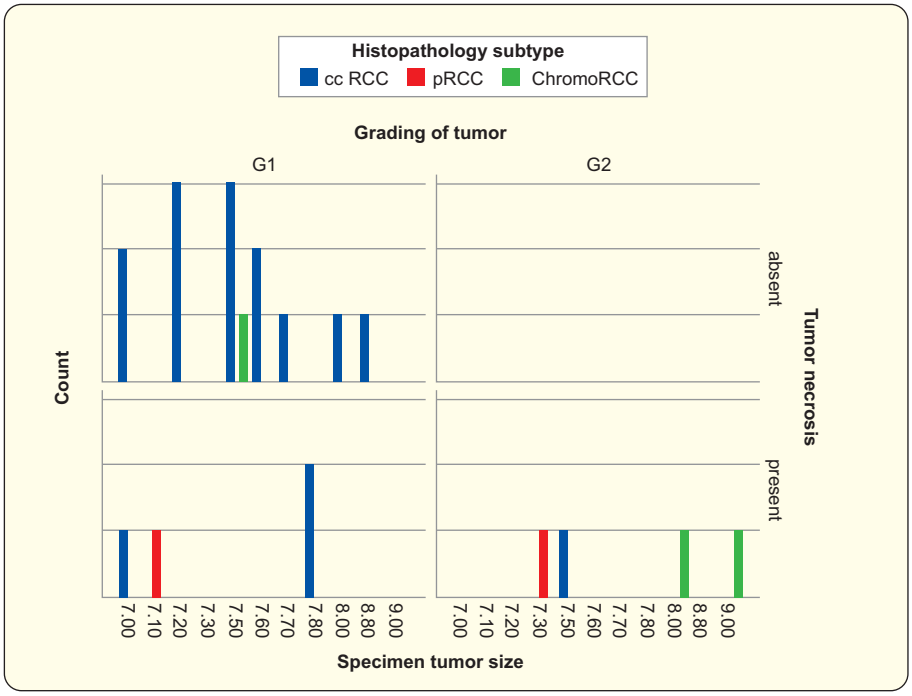

Figure 3: *Grouped bar diagram showing inter-relation of histological variables (n=22)*

In our study, 4 (18.2%) was found to have WHO G2 differentiation at final histopathology report and 8 (36.4%) specimen was found to have tumor necrosis

Five (22.7%) patient had grade-I post-operative complication. Larger tumor size was not found associated with post-operative complication. During follow up of one year post operatively, none of our patient was found to have any local or distant recurrence detected by USG or Contrast enhanced CT scan of chest, abdomen and pelvis.

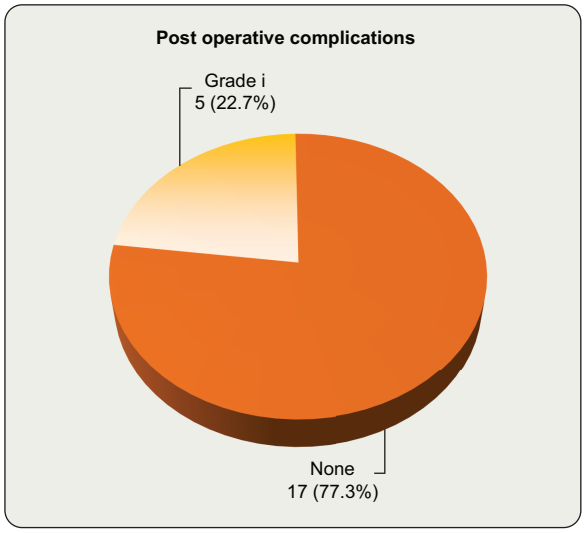

Figure 4: *Pie chart showing distribution of Post-operative complication according to Clavien-Dindo Classification (n=22).*

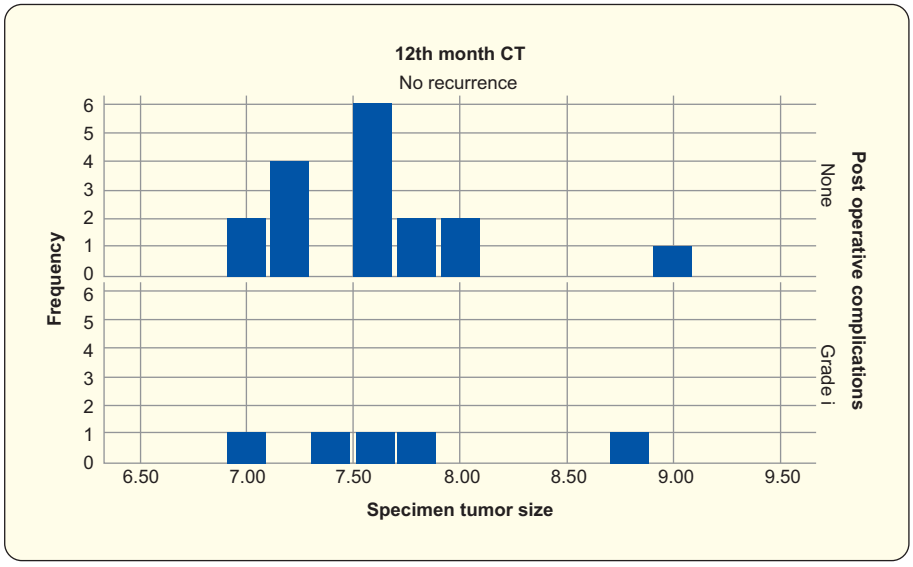

Figure 5: *Histogram showing distribution of post-operative complications with specimen tumor size and recurrence at 01 year of follow-up (n=22).*

Discussion:

In this study, we included total 22 patient of RCC (>7 cm), who fills the inclusion criteria and completes total one year of follow up as per the study design. Most of our cases i.e. 86.4% were male, mean age of diagnosis was 58.3 years and BMI 24.3 kg/m^2. Many of our patients had comorbid conditions and few had more than one comorbidity but two of the (9.1%) patients had CKD (Table 1). In their multi-center cohort study, Janssen MWW et al[15] observed mean age of PN group was 57 years, but male female ratio was 1:1. Veys R et al[16] found mean age of NSS group in their study was 63.8 years and mean BMI was 26 kg/m2 but 72.4% of their cases were male patient others female. The demographic variables are prone to vary according to the region and ethnicity. In our study we purposively sampled our cases over a brief period of time to complete one year of follow up period. Small number of cases in our study is not likely to reflect the overall situation but comparing with published researches, shows near similar findings in many demographic variables.

In table 2 we depict pathological variables of our cases. Mean maximum size of tumor was 7.58 cm, ranging from 7 to 9 cm. twenty one cases (95.5%) in our study was staged ii (T2aN0M0) and 01 (4.5%) patient was staged iii (T2aN1M0). Median RENAL nephrometry score was 10 and ranging from 8 to 11. Median tumor diameter in the study of Janssen MWW et al [15] was 8 cm which ranged from 7 cm to 16 cm and 61.1% cases were pT2a disease with 16.6% pT3 in their NSS group. A retrospective review[17] by Shin et al, of RCC treated by surgery reviewed complexity of renal masses, measured using the RENAL nephrometry scoring system with CT or MRI, showed the trend of gradual lowering RENAL scores at diagnosis over the period of 07 years and gradual uprising of PN for the treatment. Most of our cases i.e. >7 cm RCC, however was scored cautiously and shows the maximum tumor diameter around 7.5 cm. Veys R et al[16] performed 76 PN on RCC stages ≥cT1b, among which 24.5% was cT2, 3.9% cT3a and 1.3% cT4, observed no significant difference in oncological outcomes between the PN and RN groups at medium-term follow ups.

RENAL score developed by Kutikov A[18] was used extensively over past decades for patients who were not eligible for radical nephrectomy. In this context, imperative indications for partial nephrectomy included anatomical or functional compromised kidney, CKD or bilateral RCC's. Mass size, extent of exophycity, relation to collecting system and hilar structure—determines the suitability of PN. The RENAL nephrometry score (RNS) was developed to quantify the anatomic features of solid renal masses in an objective and reproducible manner. In Figure 1 by a grouped bar diagram we

presented inter-relation of variables of RENAL score of our cases (n=22). We assessed how renal mass complexity influenced surgical choices by applying the RENAL scoring system to our patient data base and evaluated how individual components contributed to the operative approach chosen and final outcome. Endophytic tumor clearly shows (Figure 1) nearness to collecting system and crosses polar line are also neither anterior, nor posterior, in this graphical representation shows how they scores high in RENAL score and increases susceptibility to operative complexity. Moreover 01 (4.5%) patient in our study was found node positive and staged iii by AJCC system having RENAL score 10. Whereas 08 (36.4%) patient with RENAL score 11 were staged ii (Figure 2). The AJCC and TNM staging, plotted with RENAL score in figure-2 shown no interrelation among this variables. Mean pre-operative eGFR of our cases was 86.3 + 21.4 and post-operative eGFR calculated on 6th week, 3rd month, 6th month 9th month and finally on 12th month (Table 3) as per our follow up plan, shows no significant change in renal functional status, though there were variable results on many occasions. Two (9.1%) patient in our study had established CKD and their post-operative renal functional status was same as before, no deterioration was noted. Statistical analysis of final post-operative i.e. at the end of 01 year of follow up showed no significant change. Along with renal functional status, we plotted hemoglobin percentage, ESR, Serum Alkaline phosphatase, LDH and urinalysis. None of these parameters had shown any significant change over the course of 01 year follow up. Few variability that observed, are most likely due to other factors such as physical, biochemical, nutrition, infection, hydration that influence their result. Veys R et al [16] reported mean serum creatinine 1.04 mg/dl (0.9-1.34 mg/dl) in their 75 PN series, with pre-operative eGFR 69.43 (26.6–87.6). Post-operative serum creatinine and eGFR shows no significant change in their study. Moreover shift towards higher CKD stages post-operatively (p = 0.01), was seen in RN group but not in the PN-group (p = 0.4). Similarly, Huang et al.[19] showed in a series of 662 patients with a normal serum creatinine and RCC who underwent PN or RN that even on multivariate analysis, RN was an independent risk factor for the postoperative development of CKD. Kopp et al[20] further demonstrated a lower decline in GFR following PN in this cohort; however, this was not seen in patients with more complex and endophytic tumours in whom less parenchyma may be preserved.

In our study, 17 (77.3%) patient was diagnosed off clear cell type RCC (ccRCC) and papillary (pRCC) and chromophobe (chRCC) variety was seen in 02 (9.1%) and 3 (13.6%) patient (Table 4). All patient had free tumor margin but 8 (36.4%) patient had tumor necrosis, 02 (9.1%) had capsular involvement and 04 (18.2%) patient was found having G2 on furham nuclear grading system. Such histological findings on final specimen are independent prognostic factor in cancer treatment outcome. Many studies have proved that gross resection of all tumour, as assessed intra-operatively by the surgeon, with microscopically negative margins, allows excellent local control without increased risk of recurrence, even without the need for a 1-cm margin of normal renal parenchyma [21, 22]. During surgery in all our cases all macroscopic tumors were cleared and minimum 0.3 cm margin[23] was ensured in all cases and 1 cm margin was taken where possible[21, 22]. Such intraoperative maneuvers ensured and ended up with a final histological tumor free margin in all our cases. Routine frozen section of the resection bed is also no longer recommended[22]. Investigators from Mayo Clinic and MSKCC reported that a positive surgical margin (5.5% in a series of 1344 patients) had no association with an increased risk of tumour recurrence or metastatic disease[24]. Figure- 3 also depicts that all the cases of our study with tumor necrosis present, were actually were G2 on WHO/ ISUP grade group. Though no relation of variant histology could be identified inter related with the histological prognostic factors.

In this study, 05 (22.7%) patient developed Clavien-Dindo Grade-I post-operative complication. Most of the patients developed post-operative fever and thrombo-phlebitis at cannula site and one patient developed electrolyte imbalance, which were managed with supportive treatment only. No major complication was recorded in post-operative period in our study. Janssen MWW et al [15] reported 44% grade ii and 16.7% grade iii post-operative complication in their study. Veys R et al [16] reported 6.6% in each grade-i and grade-ii complications, followed by 3.9% complication in each grade-iii and iv group. But there was no difference in complication rates between the RN and PN groups (p = 0.3) in their study. They also concluded no significant

raise in postoperative complications for such PN and concluded PN as a safe and sound technique for management of RCC's. The low rate of complications in the present study can be explained by the highly selective tumor character, careful patient selection and surgical technique and facility. As the primary outcome of this study was to detect cancer recurrence and renal functional outcome, the study excluded few major factors such as warm ischemic time and operative blood loss, which are to be considered as a major limitation.

We followed up for 01 year as per the set protocol, with the contrast CT scan to detect any local recurrence or distant metastasis. But none of our patient had developed so. None of our patient expired within this time duration, neither reported with any other complications. Due to small number of patient and relatively shorter follow up time i.e. 01 year, we could not calculate cancer specific survival (CSS) or overall (OS) survival by any of the popular method of calculation such as Kaplan–Meier curve or survival statistic. Janssen MWW et al [15] had a median follow up time of 163 months in their study, 6% death was reported due to RCC in PN group and local or distant recurrence was seen in 5.5% cases of >7cm RCC after PN. Kaplan-Meier analysis showed significant differences in OS (p = 0.014) and CCS (p = 0.036) between the PN and RN groups in favor of the PN group in their study[15]. Breau RH et al [25] had high recurrence rate 27%, while followed up for 38 months. Kopp RP et al [20] reported 86.7% CSS and 83% OS after 05 years follow up, in their series of PN on Larger RCCs.

Highly selective cases and carefully judged favorable anatomy of tumor restricted our study from selecting more samples. Also, the study was completed within aforementioned period of time as per the set time limit of study design. All the surgeries were carried out by two highly experienced surgeons in a standard of care tertiary level hospital with highly equipped facilities such as modular operation theater and advanced power tools for hemostasis. Free access to radiology and imaging facility in our center, facilitated us for repeated imaging when necessary along with expert opinion in case selection. Such standard of care and dedicated surgical team encouraged us to plan such a study. These may not me the reflection of the whole country or in this geographical region. Any cancer study needs adequate time and number of patient to conclude in a compliant manner, which our study was lacking, but even with this small number of cases and comparing those with internationally published reports and researches encourage us to carry forward this study in a larger volume and longer duration. Near similar findings in such studies in same cohort, clearly reflects the logical suitability of our study. Another limitation was non availability of a comparison group of RN in our study.

Conclusion:

This study demonstrates that elective partial nephrectomy (PN) for renal cell carcinoma (RCC) >7 cm is technically feasible and safe when performed in highly selected patients by experienced surgeons at specialized centers. Despite the small sample size (n=22) and short one-year follow-up, our results—including stable renal function, no cancer recurrences, and a low rate (22.7%) of only Grade I complications—align closely with recent international studies. While definitive conclusions are limited by the absence of a radical nephrectomy comparison group and the short observation period, our findings support that nephron-sparing surgery for larger RCC can achieve acceptable oncological and functional outcomes. Rigorous patient selection, meticulous surgical technique, and experienced multidisciplinary teams remain imperative. Longer-term, larger-scale studies are needed to confirm these promising results.

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Conflict of interest: We have no conflict of interest to declare.

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