

Antonelli A.¹, Cindolo L.², Sandri M.³, Furlan M.¹, Veccia A.¹, Palumbo C.¹, Simeone C.¹, Sessa F.⁴, Facchiano D.⁴, Serni S.⁴, De Concilio B.⁵, Zeccolini G.⁵, Celia A.⁵, Ingrosso M.², Giommoni V.⁶, Annino F.⁶, Pizzuti V.⁷, Nucciotti R.⁷, Dandrea M.⁸, Angelo P.⁸, Minervini A.⁴

¹Spedali Civili Hospital of Brescia, Dept. of Urology, Brescia, Italy, ²San Pio Da Pietrelcina Hospital, Dept. of Urology, Vasto, Italy, ³University of Brescia, Data Methods and Systems Statistical Laboratory, Brescia, Italy, ⁴Careggi Hospital, Dept. of Urology, Florence, Italy, ⁵San Bassiano Hospital, Dept. of Urology, Bassano del Grappa, Italy, ⁶San Donato Hospital, Dept. of Urology, Arezzo, Italy, ⁷Misericordia Hospital, Dept. of Urology, Grosseto, Italy, ⁸Policlinico Di Abano, Dept. of Urology, Abano Terme, Italy

INTRODUCTION & OBJECTIVES: The impact of ischemic damage on kidney function residual to partial nephrectomy (PN) remains a controversial issue. The clamping of the artery is more frequent during minimally invasive PN compared with the open counterpart. The CLOCK study (CLamp vs Off Clamp the Kidney during partial nephrectomy, clinicaltrial.gov registration n° NCT02287987) is a perspective, randomized, multicentre trial, started in September 2014, still ongoing, with a goal of 200 patients which primary outcome is the comparison of renal function preservation. Local ethical committee approval was obtained by every center. The present study is an ad interim analysis after the first 137 patients to compare perioperative morbidity of the two procedures.

MATERIAL & METHODS: Up to September 2016 137 patients were centrally randomized to be submitted to clamp vs off-clamp robotic PN at 6 institutions. Inclusion criteria were normal coagulative function, healthy contralateral kidney, eGFR ≥ 60 ml/min, R.E.N.A.L score ≤ 10 and surgeon experience >50 robotic PN. Split renal function was evaluated pre and post-operatively after 4-6 months by DTPA renal scan. Peri-operative data were collected in a dedicated e-crf, centrally managed. Any deviation from the assigned technique was recorded and explicitly motivated.

RESULTS: No significant differences between groups were observed in terms of baseline features, duration of surgery, oncological outcomes and complications, whereas there was a difference in the severity of bleeding as perceived by the surgeon and in estimated blood loss (table no.1). A shift from an off-clamp to clamp technique was observed in 29/67 patients (43.3%): the decision was taken preoperatively in 3 cases (10.3%), intraoperatively before the resection in 10 (34.5%) and during the resection because of prohibitive bleeding in 16 (55.2%). Among the patients randomized to a clamp procedure a shift to off-clamp was observed in 10/70 (14.3%), on the basis of a pre-operative decision.

Perioperative morbidity of clamp vs off-clamp robotic partial nephrectomy: Preliminary results from a multicentre randomized clinical trial (the CLOCK study)

Eur Urol Suppl 2017; 16(3);e1356

Preoperative features	Clamp =70	Off-Clamp=67
Gender F/M, n	39/42	25/42
Mean Age, (yrs)	66.6	63.7
Mean BMI (kg/m ²)	26.2	26.9
Charlson Comorbidity Index, n (%)		
≤ 1	60 (85.7)	46 (71.6)
≥ 2	10 (14.3)	19 (28.4)
Mean Clinical Tumor diameter (cm)	3.0	2.8
Mean Preoperative Creatinine (mg/dL)	0.9	0.8
Mean Preoperative Hemoglobin (g/dL)	14.1	14.1
Median R.E.N.A.L. score (range)	6 (4-9)	7 (6-10)
Spinal fluid function of the affected kidney	48%	48%
Mean eGFR (ml/min)	88.5	94.6
% Study attrition		
% Shift to off-clamp, n (%)	10 (14.3)	-
% Shift to clamp, n (%)	-	29 (43.3)
Intra-operative outcomes		
Surgical Approach, n (%)		
- transperitoneal	56 (80)	53 (79)
- retroperitoneal	14 (20)	14 (21)
Quintiles of severity of bleeding (0-5), n (%)		
0	15 (21.4)	11 (16.4)
1	24 (34.3)	12 (17.9)
2	23 (32.9)	25 (37.3)
3	3 (4.3)	9 (13.4)
4	6 (7.1)	10 (14.9)
5	0 (0)	0 (0)
Mean Estimated Blood Loss (mL)	102.1	160.5
Post-operative outcomes		
Median SIB score, n (range)	3 (0-5)	3 (0-5)
Histotype, n (%)		
- ccRCC	28 (40)	29 (43.3)
- pRCC	6 (8.6)	11 (16.4)
- chrRCC	6 (8.6)	6 (9)
- colRCC	0 (0)	0 (0)
- rnsocytoma	16 (22.8)	5 (7.5)
- ANL	7 (10)	8 (11.9)
- other	7 (10)	8 (11.9)
Clavien-Dindo Complications grade, n (%)		
0	62 (74.3)	53 (79.1)
1	11 (15.7)	8 (11.9)
2	4 (5.7)	4 (6)
3	3 (4.3)	0 (0)
4	0 (0)	2 (3)
Positive Margins rate, n (%)	3 (4.3)	1 (1.5)
Mean Pathological Tumor diameter (cm)	2.9	2.8
OR time (min)	122.4	132.1

CONCLUSIONS: Off-clamp and clamped robotic PN are equally safe procedures in terms of oncological outcomes and complications. However, even for tumors with a low/intermediate complexity, in high-volume centers and for skilled surgeons, despite the firm indications given into the setting of a RCT, in a relevant rate of cases off-clamp PN is not feasible due to bleeding, and, on the opposite in a few cases clamping the artery can be redundant.