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Tri match comparison of the efficacy of Floseal® vs Tachosil® vs no hemostatic agents for partial nephrectomy: Results from a large multicenter dataset

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INTRODUCTION & OBJECTIVES: The aim of this study is to investigate the efficacy of hemostatic agents (HA) in Nephron Sparing Surgery (NSS). A three-matched comparison between patients treated with no HA, with Tachosil® and with Floseal® was performed.

MATERIAL & METHODS: Observational multicentre study (RECORd Project) collects the data of 1055 patients who underwent PN between January 2009 and December 2012 at 19 Italian centres. Surgical technique, including hemostasis on bedside renal parenchyma, was performed according to surgeon's and centre's preference. Cases treated with more than one HA or with HA other than Floseal® or Tachosil® were excluded.

A tri-match propensity score analysis was applied to create 66 triplets - no HA group, Floseal® group, Tachosil® group balanced for pre and intra operative variables. The three groups were compared regarding the main intra and post-operative outcomes.

RESULTS: The study excluded 255 patients treated with more than one HA and were submitted 131 cases to no HA group, 200 to Tachosil® group, 489 to Floseal® group. In the original cohort significant differences among groups in terms of patient, tumor and surgical features were detected, so that a tri-match analysis for 66 triplets well balanced triplets were performed. The three matched cohorts presented a significant difference in EBL, lower in the Floseal® group, but this result lost significance if important clinical EBL was considered (>400 cc). No significant difference was found between three groups regarding medical and surgical post-operative overall complications, surgical haemorrhagic Clavien 2 and 3 complications, variation of haemoglobin and creatinine values between preoperative and 3rd post-operative day.

CONCLUSIONS: Since epidemiologic, clinical and surgical features were similar, no differences in terms of overall and bleeding complications were detected among patients submitted to NSS without using HA, using Floseal® or Tachosil®. There is no clear evidence that the use of HA, in addition to sutures, can improve haemostasis after PN.

Intra and post-operative Variables		No haemostatics		Tachosil ®		Floseal ®		p	p*	p**	p***
Approach, n. %	Open	50	75,8%	48	72,7%	52	78,8%	0,72	0,69	0,42	0,68
	Minimally invasive	16	24,2%	18	27,3%	14	21,2%				
Technique, n. %	Simple Enucleation	17	25,8%	16	24,2%	19	28,8%	0,83	0,84	0,55	0,70
	Standard PN	49	74,2%	50	75,8%	47	71,2%				
Intraoperative time, median IQR		132,5	104-210	127,5	105-170	130,0	100-160	0,70	0,69	0,70	0,45
EBL, median IQR		200	100 -300	200	120-300	135	50-250	0,003	0,73	0,003	0,01
EBL, n %	< 400 cc	57	86,4%	59	89,4%	59	89,4%	0,73	0,85	0,99	0,85
	≥ 400 cc	9	13,6%	7	10,6%	7	10,6%				
Ischemia time, mean SD		15,2	7,3	16,0	7,1	17,5	6,4	0,38	0,65	0,36	0,17
Hilar clamping, n. %	Not performed	27	40,9%	23	34,8%	28	42,4%	0,64	0,47	0,37	0,86
	Performed	39	59,1%	43	65,2%	38	57,6%				
Medical Complications, n.%	Absent	61	92,4%	63	95,5%	62	93,9%	0,76	0,47	0,70	0,73
	Present	5	7,6%	3	4,5%	4	6,1%				
Surgical Complications, n.%	Absent	56	84,8%	61	92,4%	57	86,4%	0,37	0,29	0,46	0,27
	Present	10	15,2%	5	7,6%	9	13,6%				
Surgical haemorr. Clav. 2 complic. ,n.%	Absent	61	92,4%	62	93,9%	61	92,4%	0,93	0,73	0,73	0,99
	Present	8	12,1%	3	4,5%	4	6,1%				
Surgical haemorr. Clav. 3 complic. ,n.%	Absent	65	98,5%	66	100,0%	64	97,0%	0,36	0,32	0,15	0,56
	Present	1	1,5%	0	0,0%	2	3,0%				
Preop-3rd day Δ haemoglobin, mean SD		2,7	1,6	2,1	1,2	2,5	1,3	0,23	0,10	0,26	0,51
Preop-3rd day Δ eGFR, median IQR		8,9	0,0-17,8	10,6	0,0-23,4	10,2	0,0-25,6	0,88	0,50	0,88	0,42

p*: No haemostatics vs Tachosil ® p**: Tachosil ® vs Floseal ® p***: Floseal ® vs no haemostatics