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EFFICACY OF FLOSEAL® VERSUS TACHOSIL® VERSUS NO HEMOSTATIC AGENTS FOR NEPHRON SPARING SURGERY: A PROSPECTIVE MULTICENTER COMPARATIVE STUDY (RECORD PROJECT)

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Aim of the study

To evaluate the efficacy of FloSeal® versus TachoSil® versus no hemostatic agents for nephron sparing surgery (NSS) in a prospective multicenter dataset.

Materials and methods

The RECORD Project is a 4-year prospective observational multicenter study promoted by SIU. The study includes all patients who underwent open or laparoscopic NSS between January 2009 and January 2011 at 19 Italian centers. Approval of the study protocol by the local ethical committee was obtained. All intraoperative data including whether or not to clamp the renal vessels, type of haemostatic agent and intraoperative blood loss were recorded. Postoperative bleeding requiring blood transfusion/reintervention and cardiovascular complications occurring within 30 days, were recorded. Univariable analysis was used to evaluate the association between type of hemostatic agent used and both the need for blood transfusion/reintervention and the risk of cardiovascular complications. Multivariable logistic regression model was applied to analyze predictors of postoperative blood transfusion/reintervention for bleeding.

Results

A total of 418 patients were recruited, following exclusion of patients with incomplete data on the type of haemostatic agent adopted and of patients treated with both haemostatic agents (FloSeal® and TachoSil®). Overall 231 had FloSeal® NSS; 116 TachoSil® NSS and 71 had pure NSS without the adoption of any haemostatic product. Clinical dimension did not differ among the three groups. Overall, 41 postoperative bleeding requiring blood transfusion/reintervention (9.8%) and 7 cardiovascular events (1.7%) occurred. Overall, 9.3% of FloSeal® NSS, 7.9% of TachoSil® NSS and 15.7% of pure

NSS had postoperative bleeding requiring blood transfusion/reintervention (FloSeal® and TachoSil® vs. pure, $p=0.05$). Moreover, 0.9% of FloSeal® NSS, 0.9% of TachoSil® NSS and 5.7% of pure NSS had cardiovascular complications (FloSeal® vs. pure, $p=0.035$; TachoSil® vs. pure, $p=0.05$). Multivariate analysis showed that factors correlated with postoperative bleeding requiring blood transfusion/reintervention were preoperative haemoglobin level, ECOG score (≥ 1), the lack of haemostatic agents and tumor growth pattern ($>50\%$ endophytic) while it was not influenced by the tumor location (polar vs. mesorenal), the surgical approach (open vs. laparoscopic), the surgical technique (Standard PN vs. SE) and the decision whether or not to clamp the renal vessels.

Discussion

This study represents the first prospective comparative multicenter study between FloSeal® NSS, TachoSil® NSS and pure NSS with no hemostatic agents.

Conclusions

In our series the risk of postoperative bleeding was significantly and independently associated with the lack of any hemostatic agents. Both FloSeal® and TachoSil® seem protective against postoperative bleeding and are used in different settings according to tumor characteristics, surgical approach and surgeon's attitude.

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OPEN VERSUS ROBOTIC-ASSISTED PARTIAL NEPHRECTOMY: MULTICENTER COMPARATIVE STUDY OF SURGICAL RESULTS AND COMPLICATIONS (AGILE GROUP)

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Aim of the study

To compare surgical and perioperative outcomes of open partial nephrectomy (OPN) with those of robotic assisted partial nephrectomy (RAPN).

Materials and methods

This is a 2-year multicentric study derived from a prospective database promoted by AGILE group, who included all patients treated

with OPN or RAPN for renal cell carcinoma between January 2010 and December 2011 at six Italian urologic centers. All clinical variables, including tumor nephrometry (PADUA score) and laboratory analyses, were recorded. Surgical results and complications, occurred within 30 days after surgery and stratified with Clavien system, and pathological data were registered. All significant differences in each variable in OPN versus RAPN group were assessed with univariate analysis. Independent predictors of surgical complications were evaluated with multivariate analysis.

Results

Overall, 198 and 104 patients were enrolled in the OPN and RAPN group, respectively. Distribution of gender, age, body mass index, ASA score, tumor nephrometry (PADUA score) and preoperative serum haemoglobin and creatinine, was not significantly different in the two groups. Charlson comorbidity index was significantly higher in RAPN group while clinical tumor diameter was higher and imperative surgical indication was more frequent in OPN group. Pedicle clamping was used in 48% and 62.5% of OPN and RAPN group, but in 11.5% (12/104) of RAPN a selective arterial clamping was used. In RAPN group, one case needed conversion to OPN. At univariate analysis, there was no significant difference in warm ischemia time, intraoperative complications, postoperative medical complications, delta of serum creatinine, positive surgical margins and benign tumor rates. The operative time resulted significantly higher in RAPN group.

Discussion

Further studies are needed to evaluate the functional and oncological results of RAPN as in this analysis, from an oncological viewpoint, we were able to evaluate only the surgical margin rate.

Conclusions

In our analysis the robotic approach clearly improved the safety of conservative surgery in terms of postoperative complication and the reintervention rates. RAPN had longer operative time but a not significantly different warm ischemia time compared to OPN.

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GENITOURINARY INFECTIONS

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IN VITRO BACTERIAL BIOFILM PRODUCTION FROM PATIENTS WITH CHRONIC BACTERIAL PROSTATITIS (NIH-II) BIOLOGICAL FLUIDS

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Aim of the study

Increasing prevalence of prostatitis (P) in young males has been recently reported in international literature, with subsequent relevant impact on fertility and patient's quality of life. Category II-NIH chronic bacterial prostatitis (CBP) in particular seems to be more frequent than in the last years probably thanks to detailed microbiological analysis. It usually involves a wide range of bacterial species such as *Escherichia coli* and other *Enterobacteriaceae*, *Enterococci*, *Staphylococci* and *Ureaplasma spp.* All these bacteria are able to form biofilms and infect prostate cells although no previous studies demonstrated the presence of biofilm in prostate tissue or prostate fluids. Aims of the present study were to isolate potentially biofilm-producing bacteria from urinary samples, total ejaculate, prostate/seminal vesicle secretions from CP-NIH-II-patients, then evaluate their ability to produce *in vitro* biofilms.

Materials and methods

150 clinical bacterial strains isolated from CBP-NIH-II-patients afferent to our Centre for Prostatitis in 2008. Bacterial strains consisted were: 50 *Enterococcus faecalis*; 50 *Staphylococcus spp.*; 30 *E. coli*; 20 gram- miscellanea. Their characterization and antibiotic chemosensitivity were determined by Vitek II System (Bio-Merieux, Italy). Quantitative assay of biofilm production and adhesion was performed according to classic Christensen et al. micro well assay (*J. Clin. Microb.*, 1985). Isolates were classified into "non producer, weak, moderate and strong producer".

Results

The majority of *E. coli*, gram negatives, *Staphylococci* and *Enterococci* strains were strong or medium producer: 63-30, 75-15,