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Renal Disease

Perioperative Morbidity of Laparoscopic Cryoablation of Small Renal Masses with Ultrathin Probes: A European Multicentre Experience

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Abstract

Background: Low morbidity has been advocated for cryoablation of small renal masses.

Objectives: To assess negative perioperative outcomes of laparoscopic renal cryoablation (LRC) with ultrathin cryoprobes and patient, tumour, and operative risk factors for their development.

Design, setting, and participants: Prospective collection of data on LRC in five centres.

Intervention: LRC.

Measurements: Preoperative morbidity was assessed clinically and the American Society of Anaesthesiologists (ASA) score was assigned prospectively. Charlson Comorbidity Index (CCI) and Charlson-Age Comorbidity Index (CACI) scores were retrospectively assigned. Negative outcomes were prospectively recorded and defined as any undesired event during the perioperative period, including complications, with the latter classed according to the Clavien system. Patient, tumour, and operative variables were tested in univariate analysis as risk factors for occurrence of negative outcomes. Significant variables ($p < 0.05$) were entered in a step-forward multivariate logistic regression model to identify independent risk factors for one or more perioperative negative outcomes. The confidence interval was settled at 95%.

Results and limitations: There were 148 procedures in 144 patients. Median age and tumour size were 70.5 yr (range: 32–87) and 2.6 cm (range: 1.0–5.6), respectively. A laparoscopic approach was used in 145 cases (98%). Median ASA, CCI, and CACI scores were 2 (range: 1–3), 2 (range: 0–7), and 4 (range: 0–11), respectively. Comorbidities were present in 79% of patients. Thirty negative outcomes and 28 complications occurred in 25 (17%) and 23 (15.5%) cases, respectively. Only 20% of all complications were Clavien grade ≥ 3 . Multivariate analysis showed that tumour size in centimetres, the presence of cardiac conditions, and female gender were independent predictors of negative perioperative outcomes occurrence. Receiver operator characteristic curve confirmed the tumour size cut-off of 3.4 cm as an adequate predictor of negative outcomes.

Conclusions: Perioperative negative outcomes and complications occur in 17% and 15.5%, respectively, of cases treated by LRC with multiple ultrathin needles. Most of the complications are Clavien grade 1 or 2. The presence of cardiac conditions, female gender, and tumour size are independent prognostic factors for the occurrence of a perioperative negative outcome.

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1. Introduction

The increasing incidental diagnosis of small renal masses [1] poses a clinical dilemma: Some recommend a watchful waiting policy, while others advocate active treatment [2]. Small renal masses may be benign or low-grade malignancy, but aggressive potential cannot be ruled out by means of radiologic examinations [3–5]. Although the accuracy of percutaneous biopsy has improved [6,7], indeterminate biopsies still exist and are subject to interobserver variability [6,8,9]. Furthermore, elderly patients with significant comorbidities are seeking counselling and, in some cases, active treatment [2]. Radical nephrectomy is overtreatment for most of these small masses and may prompt renal insufficiency in this already-compromised population [10]. Partial nephrectomy (PN), which should be considered the treatment of choice, may not be an adequate first-choice treatment in this group of patients [11,12].

In an attempt to prevent side-effects and complications, ablative therapies are emerging as a viable option. Throughout the last decade, technical refinements resulted in smaller probes able to deliver the ablative energy efficiently. Ultrasound devices evolved, and, currently, intracavitary real-time monitoring of the ablative process is possible. Laparoscopic renal cryoablation (LRC) is the best studied of the ablation techniques; however, until enough long-term studies support its oncologic safety, the major argument to treat using LRC is its low complication rate. Besides institutional studies, only one multicentre retrospective series reported a low complication rate, mostly attributable to the cryoablation process [13–18].

Our objectives are to describe the negative perioperative surgical outcomes of cryoablation of small renal masses with third-generation ultrathin cryoprobes and to assess possible patient, operative, and tumour risk factors for their development.

2. Materials and methods

Consecutive patients treated using cryoablation from September 2003 to August 2007 in five European centres were included in this study. The same surgical protocol was agreed for eventual data merge, and data were prospectively collected.

The only mandatory inclusion criterion was a solid, contrast-enhancing renal mass suspected for renal cell carcinoma. A largest tumour diameter of 4.0 cm was recommended, but there were no size limitations. Similarly, there were no age or comorbidity limitations, provided the patient was suitable for general anaesthesia. Watchful waiting and other surgical options were discussed in all cases, although most of the patients were specifically referred for cryoablation.

2.1. Surgical protocol

The choice of the access route (retroperitoneal, transperitoneal, or open) depended on the surgeon's preferences and on anaesthesia limitations. Regardless of the route, sufficient mobilisation of the kidney and perineal fat to allow localisation of the mass and placement of the probes was carried out. Intracavitary real-time ultrasound was used to verify tumour location and diameters, the position of the cryoprobes, and the

development of the ice ball during freezing. Cryoablation was performed using 1.47-mm (17-gauge) cryoprobes. Two types of cryoprobes, IceSeed and IceRod (Galil Medical, Tel Aviv, Israel), were used. IceSeed needles form a small ice ball of 19×10.5 mm in diameter, and IceRod needles form a larger ice ball of 41×16 mm in diameter (in vitro, for the -40°C isotherm). A tumour biopsy was taken during the procedure and prior to ablation. Ice-ball formation was monitored by intracavitary ultrasound until the whole tumour and approximately a 1-cm margin around were engulfed. Two freezing cycles separated by a thaw period were performed in all cases. After a second passive/active thaw, the probes were carefully retrieved, avoiding traction from the tissue. If necessary, haemostatic agents, compression, or stitches were used to control haemorrhage at the puncture sites. The number of thermal probes for monitoring temperature during the procedure was surgeon dependent.

2.2. Method

Demographic data, comorbidity data, and American Society of Anaesthesiologists (ASA) scores were prospectively collected. Weighted and age-related comorbidities were retrospectively assigned according to the Charlson Comorbidity Index (CCI) and Charlson-Age Comorbidity Index (CACI) [19,20]. For calculation of the CCI and CACI, the renal mass was not considered malignant, as pathology was still unknown in the preoperative period. Perioperative negative outcomes until day 30 after cryoablation were prospectively assessed and, when appropriate, retrospectively graded as complications according to the last modification of the Clavien criteria [21]. A negative outcome was defined as any undesired event, conversion to open procedure, complication, or deviation from the normal operative and postoperative course, sequel, or failure to cure [21,22]. Conversion to open surgery followed by cryoablation was recorded as a negative outcome [21]. Conversion to open nephrectomy or PN was categorised as conversion but also as a complication. Other laparoscopic procedures than cryoablation were also considered complications. Patient, operative, and tumour characteristics were evaluated as predictors of negative outcome (Tables 1 and 2).

A cardiac condition was defined as a history of cardiac insufficiency, aortic valve replacement or stenosis, atrial fibrillation, arrhythmia, angina pectoris, and acute myocardial infarction treated with or without percutaneous transluminal coronary angioplasty in regular controls by a cardiologist. Hypertension was defined as the need for at least one drug to control blood pressure, and obesity was defined as a body mass index ≥ 30 . Renal insufficiency was defined as creatinine (Cr) $>110 \mu\text{mol/l}$ and further classed into mild (Cr $111\text{--}200 \mu\text{mol/l}$), moderate (Cr $201\text{--}300 \mu\text{mol/l}$), and severe (Cr $>301 \mu\text{mol/l}$ or dialysis). Access was classed in transperitoneal laparoscopy, retroperitoneoscopy, and open. Location of the tumour was defined as upper, mid-, or lower pole.

2.3. Statistics

Incidence of negative outcomes and complications was expressed as a percentage over the total number of procedures. Spearman rank correlation was used to correlate categorical and ordinal variables.

We defined the dependent variable *perioperative negative outcome* as the presence or absence during cryoablation and until 30 d. All cases were analysed by intent to treat. Univariable analysis was performed. Significant variables ($p < 0.05$) were entered in a step-forward multivariate logistic regression model to identify independent risk factors for one or more perioperative negative outcomes. The confidence interval was settled at 95%. For statistical purposes, only the larger tumour was considered when two ipsilateral tumours were treated during the same procedure. Calculations were done using the 16.x Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA).

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