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Surgery in Motion

Safety Study of Umbilical Single-port Laparoscopic Radical Prostatectomy with a New DuoRotate System

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Abstract

Background: Laparoendoscopic single-site (LESS) radical prostatectomy (RP) has been performed through different approaches. A new DuoRotate manual system developed by Richard Wolf (KeyPort; Richard Wolf GmbH, Knittlingen, Germany) can be applied to RP.
Objectives: Our aim was to describe the surgical technique and report early outcomes of KeyPort LESS-RP to determine if this procedure is feasible and safe.
Design, setting, and participants: Prospective study performed between October 2011 and January 2012 to standardize LESS-RP. A total of 31 procedures were performed (10 with and 21 without neurovascular preservation, 8 with and 23 without pelvic lymph node dissection).
Surgical procedure: LESS-RP was performed using the methods outlined in the manuscript. All patients underwent LESS RP by the same surgical team. Access was achieved via a tri-channel reusable KeyPort and one 3.5-mm extra port to facilitate urethrovesical anastomosis and drainage extraction.
Outcome measurements and statistical analysis: Preoperative, perioperative, and pathologic outcomes data are presented.
Results and limitations: The mean age of the patients was 64 yr; mean body mass index: 30.7 kg/m^2; mean prostate-specific antigen level: 7 ng/ml; mean operative time: 207 min; and mean estimated blood loss: 258 ml. The average length of stay was 2.9 d and visual analog pain score (range: 0 [no pain] to 10) at day 2 was 1.2. Five focal positive margins (16.7%) were encountered (4.4% for pT2 and 57.1% for pT3). Five cases (16.7%) were pT2a, 3 (10%) were pT2b, 15 (50%) were pT2c, and 7 (23.3%) were pT3a. Lymph node dissection results were negative in all patients. Major complications occurred in two patients (6.5%) (hypercapnia with respiratory acidosis and rectourethral fistula) and minor complications in four (12.9%) (atrial fibrillation, orchitis, transfusion, and vomiting). No case required additional analgesia. Incision was totally hidden in the umbilicus. Study limitations included short follow-up (mean: 20.2 ± 4.1 wk), premature functional data, and absence of a comparative cohort.
Conclusions: The KeyPort system allows performance of umbilical RP with few complications, a low positive-margin rate, excellent aesthetic results, and very low postoperative pain levels.

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1. Introduction

Laparoendoscopic single-site surgery (LESS) is the latest progression of laparoscopic surgery. It has significantly evolved since its first urologic application, nephrectomy, was described in 2007 [1] to become, in a short time, effective and safe for many procedures and in multiple hospital settings [2]. However, its diffusion has been limited

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by the lack of development of appropriate instruments that avoid clash and allow for ergonomic triangulation. New technical developments that include the application of robots (eg, robotic LESS) and more precise manual systems will contribute to further development of this new field.

The umbilical approach implies cosmetic benefit because the scar is easily concealed within this embryonic natural orifice. But apart from the cosmesis, benefits in pain management and recovery also have been demonstrated for simple nephrectomy [3] and robotic radical nephrectomy [4] models and have been anticipated for many other procedures but remain to be proven [5].

Patient selection [6,7] and difficulty in conducting comparative prospective trials of techniques that use recent technological achievements are major problems in demonstrating the logical advantages of LESS or robotic LESS (R-LESS) over conventional laparoscopy or robotics. Nevertheless, fewer and smaller-caliber ports are associated with shorter length of stay and very low visual analog pain (VAP) scores in different procedures [7–9]. Difficulty in performing surgery and increased cost related to the use of disposable elements must also be taken into account with LESS. In this sense, LESS radical prostatectomy (LESS-RP) is one of the least frequently performed procedures (2.3%) in an ordinary clinical setting, according to a multi-institutional series recently published [2].

Kaouk et al. [10] published a very preliminary, pioneering experience with LESS-RP though the Uni-X port (Pnavel Systems Inc., Morganville, NJ, USA) and rapidly moved to robotics though a SILS port (Covidien, Dublin, Ireland) [8], thus reducing the difficulties encountered with conventional LESS-RP.

We have systematized LESS-RP performed with KeyPort, a new, reusable, manual, single-port umbilical system developed by Richard Wolf (Richard Wolf GmbH, Knittlingen, Germany) that incorporates bent instruments with double rotation [11]. It allows precise movements and more space, triangulation is recovered, and clashing of instruments is avoided. We also have incorporated a lateral 3.5-mm trocar to ease intracorporeal suturing and drainage extraction. Our initial experience with this technique and early outcomes are presented.

2. Methods

2.1. Study design

The new KeyPort system was experimented with both in pelvitrainer and porcine models (Fig. 1) following the regulations of the Autonomous Community of Madrid for animal care. Once 200 h of training were individually achieved by two experienced surgeons (FC and PMC), who have performed >300 previous laparoscopic procedures, several low-risk human LESS surgeries (cryptorchidism, pyelolithectomy, ureterectomy in duplicated cranial-ending ureter, and pyeloplasty) were performed before renal and prostate surgeries were accomplished. Patient data were prospectively entered in an institutional review board-approved database that included demographic data, patient age, body mass index (BMI), prostate-specific antigen (PSA) level, Gleason score, D'Amico risk classification, and Sexual Health Inventory for Men (SHIM) score. Complete preoperative evaluation was performed. A nerve-sparing technique was intended in all patients with T1c or T2a tumor and SHIM score ≥21.

Consecutive patients diagnosed with prostate cancer and willing to receive surgical treatment were offered LESS-RP. After discussion with the patient, written informed consent was obtained in every case. All patients who accepted the procedure were informed that additional incisions might be made if necessary. No patient had received radiotherapy. Previous abdominal surgery was not a contraindication for the procedure.

Estimated blood loss (EBL); operative time; conversion to standard laparoscopy; intra- and postoperative complications, following Clavien-Dindo classification [12]; hospital stay; and VAP score at day 2 were recorded. Patients were followed after discharge from day 10, when the patient's catheter was removed; at month 1, to receive the histopathologic report; and every 3 mo for PSA, continence, and erectile function assessment. Patient satisfaction with the wound on a visual analogue

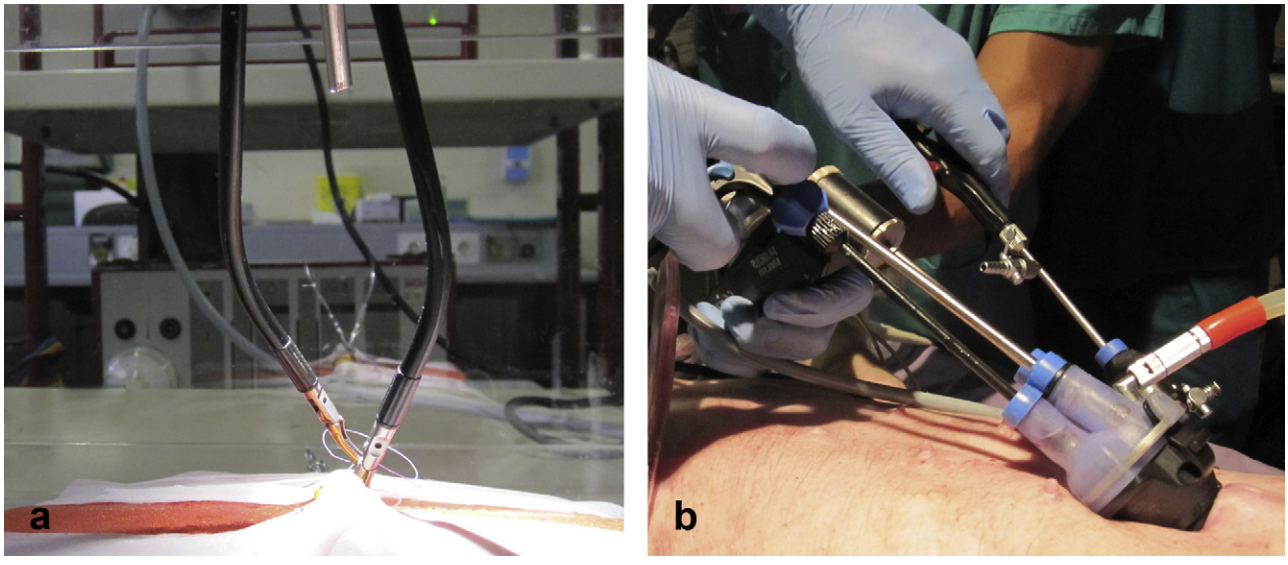

Fig. 1 – (a) Dry lab and (b) porcine surgery facilitate learning and progression in human surgery with the KeyPort (Richard Wolf GmbH, Knittlingen, Germany).