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Bleeding Control and Vascular Preservation in Laparoscopic Living Donor Nephrectomy. Powered *vs.* Mechanical Vascular Stapler: A Possible Real Advantage

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Abstract

Kidney transplantation (KTx) is the treatment of choice for end stage renal disease (ESRD), improving both quality, and quantity of life in the recipients. Living Donor Kidney Transplantation (LDKT) is both related to a longer patient and graft survival, and laparoscopic donor nephrectomy (LDN) is the procedure of choice by most transplants Centers. Even though many techniques have been used to secure both the renal artery and vein during laparoscopic nephrectomy (Hem-o-lock clips, titanium clips or Vascular Stapler), ligation and division of the renal hilum remain two critical steps, entailing a certain risk of serious complications. Mechanical EndoGIA *vs.* iDrive™ Ultra Powered Stapling System (Autosuture; Covidien Surgical, Mansfield) have been compared. iDrive™ is a reusable, handled stapler computer-controlled stapling systems that runs on battery and can be used on multiple-patients. It comprises a hand-held control unit, and a loading unit, which consists in a powered EndoGIA cartridge. We evaluated safety, efficacy, maneuverability and ergonomics for renal vascular control during LDN. Moreover, the differences in costs between the two procedures were also analyzed. There were no malfunctions or complications related to the use of iDrive™ requiring conversion to open procedure. Advantages in maneuverability and costs were also observed. The total timing related to the use of the devices was statistically significant shorter for the iDrive™ than for the EndoGIA being respectively 3.4 ± 0.4 minutes *vs.* 4.2 ± 0.4 minutes (p=0.0014). In our experience, iDrive™ is safe and feasible for separate ligation and accurate division of renal artery and vein during LDN. The system also helps to minimize the need for additional maneuvers to secure the renal hilum. Furthermore, it allows greater precision of cutting on the kidney vessels that will have to be used for transplantation.

Keywords: Kidney transplantation; End stage renal disease; Laparoscopic donor nephrectomy; Powered Stapler; Mechanical stapler; Living donor kidney transplantation

Introduction

Kidney transplantation (KTx) remains the only treatment for end stage renal disease (ESRD) [1]. Transplantation from a living donor is a valid alternative for multiple reasons, but particularly for a shorter waiting list period, and a longer patient and graft survival [2]. The ideal nephrectomy technique from a living donor should ensure donor safety, and maximize graft quality for the recipient [3]. Laparoscopic nephrectomy suited the method of choice of living kidney donation in most transplant centers [4]. The laparoscopic technique is the gold standard for kidney removal from a living donor because its performance equals that of the open technique [5]. Besides, its outcome is a more likable cosmetic result, a better controlled analgesia, and a shorter hospital stay and convalescence if compared to open surgery [6,7].

A vast range of techniques have been used to secure the renal artery and vein during laparoscopic nephrectomy (Hem-o-lock or titanium clips, Vascular stapler), but ligation and division of the renal hilum remain critical steps during any laparoscopic procedure [8,9]. Vascular staplers are probably the most widely used device to manage vessels in laparoscopic nephrectomy due to their feasibility and safety [10,11]. Thus, their use has progressively been set as a standard practice [12,13].

Materials and Method

A total of 14 kidney living donors were randomized for powered or mechanical vascular stapler in a monocentric pilot study. All donors were similar for clinical characteristics, and type of operation (trans-peritoneal left nephrectomy with no vascular or ureteral abnormalities). Data collected included demographic data, preoperative American Society of Anesthesiologist physical status scores (all donors were in ASA 1 classification), total operative time, complication and bleeding during surgery, and during the immediate perioperative period. Furthermore, the value of hemoglobin and serum creatinine before, the day after and 1 month after surgery have been also considered.

We utilized Mechanical EndoGIA *vs.* iDrive™ Ultra Powered Stapling (Autosuture; Covidien Surgical, Mansfield, MA) with 45 mm power linear cutter type (blue vascular cartridge, tri-staple technology) for the ligation and division of renal hilum. iDrive™ is a reusable, handled and computer-controlled stapler that runs on battery and can be used on multiple patients. Function commands are controlled by pushing a button on the anterior part of the handle; iDrive™ is equipped with a control unit which verifies the right assembly of the cartridge by orientating the tip of the rigid shaft; the same control unit verifies the closure of the stapler and the firing. Ergonomic, fingertip control offers

points of articulation between the 45-degree left and right limit. We assessed the differences in the safety and efficacy during ligation techniques. We also compared warm ischemia time, and time after closing the hilum between the two devices. Evaluated stapler's maneuverability and surgeon's comfort, as well as the entire cost of the device, have been also taken into consideration.

Comparison has been performed using the Student's t-test and chi-square as appropriated. A p-value of less than 0.05 was considered significant.

Results

Demographics characteristics, operative time, renal function, post-operative complications and hemoglobin level of the iDrive™ and EndoGIA patients are reported in Table 1 and showed no statistically significant differences. All donations were concluded laparoscopically with no intraoperative problems in all patients. In all cases, the renal vessels were ligated close to the origin of the vena cava and the aorta respectively, using 45 mm three-stage vascular technology for each one. We have never used the "en-block" procedure.

Parameters	iDrive™ Ultra Powered (7 pts)	Mechanical EndoGIA	p-value
Gender (Male/Female)	1/6	3/4	0.21
Age (years)	49 ± 5	56 ± 5	0.18
Operative time (min)	216 ± 78	223 ± 78	0.76
Intraoperative complications	0	0	ns
Pre-operative creatinine (mg/dl)	0.9 ± 0.10	0.9 ± 0.15	0.86
1-month creatinine (mg/dl)	1.21 ± 0.23	1.43 ± 0.23	0.17
Pre-operative Hb (g/dl)	12.5 ± 0.9	13.2 ± 0.9	0.34
1-day Hb (g/dl)	10.6 ± 0.85	11.7 ± 0.85	0.1
1-month Hb (g/dl)	12.1 ± 1	12.7 ± 1	0.39

Table 1: Demographics characteristics and operative and post-operative parameters analyzed.

No malfunctions or complications related to the use of the iDrive™ have been evidenced. The total timing related to the use of the devices was statistically significant shorter for the iDrive™ than for the EndoGIA being respectively 3.4 ± 0.4 minutes *vs.* 4.2 ± 0.4 minutes (p=0.0014).

Maneuverability of iDrive™ resulted high because its handle allows with one-handed the control push-button operation that eliminates manual firing force, increasing the sense of stability, and consequently the cutting precision.

No statistically significant differences have been found between the iDrive™ and the EndoGIA in terms of length of renal vein and artery being respectively 7.5 ± 0.4 cm *vs.* 7.4 ± 0.5 cm for the renal vein (p=0.6) and 4.8 ± 0.4 cm *vs.* 4.6 ± 0.4 cm (p=0.3) for the renal artery.

In our series, surgeon's evaluation, and comfort appears also greater with iDrive™ comparing with EndoGIA (Table 2).

Parameters (score 1-10)	Powered iDrive™	Mechanical EndoGIA
Ergonomics	8.5	7
Manoeuvrability	9	7
Ease of use	9	8
Stability during vascular section	9	7.5
Bleeding on the suture rhyme	9	8.5
Renal vessels characteristics on the back-table	9	8
Total score	53.5	46

Table 2: Surgeon's evaluation: powered *vs.* mechanical vascular stapler. Legenda: Score 1: low efficiency; Score 10: high efficiency.

Moreover, although iDrive™ has a greater initial cost than EndoGIA (14250 Euro *vs.* 630 Euro), the device is reusable for about 50 applications. The initial cost of the suturing machine is then depreciated, and each procedure costs about 280 Euro. There are no price differences as far as recharging is concerned.

Discussion

Many techniques have been used to secure the renal artery and vein during laparoscopic nephrectomy (like Hem-o-lock clips, titanium clips or Vascular Stapler) [14-16], but ligation and division of the renal hilum are critical steps during any procedure with any techniques of vascular control for the risks of serious complications [17,18]. EndoGIA staplers are widely used to manage vessels in laparoscopic nephrectomy because of their feasibility and safety and their use has become standard practice [19-21].

This is the reason why, we preferred EndoGIA from the beginning of our experience in patients underwent LDN [22]. Recently, we used iDrive™ Ultra Powered Stapling System Autosuture in a randomized trial to evidence possible advantages for donor in terms of safety, and for the subsequent transplant.

There were no malfunctions or complications related to the use of the iDrive™ Ultra Powered Stapling System requiring the surgery to be converted to an open procedure.

iDrive™ offers one-handed push-button operation that eliminates manual firing force improving manoeuvrability, during vascular compression and clamping. Ergonomic, fingertip control offers points of articulation between the 45-degree left and right limit.

The control unit that controls the accurate placement of the cartridge by orientating the tip of the rigid shaft, and controlling the closure of the stapler and the firing, improve the ease of use of the device. Manoeuvrability of the iDrive™ has proved high because its handle allows with one-handed the control push-button, operation that eliminates excessive thickness of the tissue and manual firing force and increasing the stability with consequently high cutting precision. Device stability during and after vascular stapling is more evident despite to mechanical device, and this is very important because the vessels should also be stored for subsequent transplantation.

The total timing related to the use of the devices (insertion into the abdomen through the port, time to set the angle, time of section in separate time of renal hilum vessel and the realignment and extraction from the abdomen) was statistically significant shorter for the iDrive™ than for the EndoGIA.

Moreover, at the back table the vessels of kidney taken with iDrive™ were in all cases longer if compared with EndoGIA (1.6 mm for renal vein and 1.8 mm for renal artery respectively). Despite it is not statistically significant, anyway in our opinion it seems important for the subsequent kidney transplantation.

The ease of use of a device is important for surgeons, for reproducibility of the outcome of a surgical intervention and it can even play a role in the wellbeing and safety of the patient. Is difficult to achieve a quantitative assessment of the surgeon's comfort, because there is no single parameter for its assessment, but the ease of iDrive™ must be taken into consideration when you can easily appreciate the advantages offered by this automatic system.

Conclusion

In our series, that use of vascular stapling iDrive™ in trans-peritoneal laparoscopic nephrectomy is a safe and effective procedure that offers a better chance than mechanical stapler, with more stability and an improved precision of the cut, without any cost increase.

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