



Use of the electrothermal bipolar vessel system (EBVS) in laparoscopic adrenalectomy: a prospective study

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Received: 4 January 2007/Accepted: 27 January 2007/Online publication: 4 May 2007

Abstract

Background: Since laparoscopic adrenalectomy (LA) has been adopted as the gold standard for the treatment of adrenal diseases, the development of technology for vascular control and dissection manoeuvres, amongst other things, may play a pivotal role in its further improvement. We report our experience with the electrothermal bipolar vessel sealing (EBVS) device for LA. **Methods:** From January 2004 to January 2006, 50 patients (pts) undergoing LA were selected and randomized for use of the EBVS (25 pts, group A) versus the UltraSonic Shears (USS) device (25 pts, group B). Age, sex, body mass index (BMI), previous surgery and associated diseases were similar between the two groups. The main surgical parameters collected for each patient (pt) concerned operative time, major and minor complications, conversion rate, blood loss, hospital stay and histology.

Results: There was no mortality in either group. The right adrenalectomy mean operative time (OpT) was 51.8 mins (range 40–90 mins) and 68.6 mins (range 50–130 mins) in group A and B, respectively (*P* not significant). The left adrenalectomy mean OpT was 72.2 mins (range 55–100 mins) and 94 mins (range 65–140 mins) for group A and B, respectively (*P* < 0.05). The mean blood loss was 83 ml (group A) and 210 ml (group B) (*p* < 0.05). Complications were not different for the two groups. The mean hospital stay was 2.9 and 3.1 days in group A and B, respectively (*P* not significant).

Conclusions: EBVS in LA may provide a significantly short operating time and blood loss.

Key words: Electrothermal bipolar vessel system — Laparoscopic adrenalectomy — Minimally invasive surgery

LA has been increasingly performed since its introduction in 1992, and has now become the gold-standard surgery for adrenal tumors. Laparoscopy has several advantages compared with habitual open access, including decreased postoperative pain, ileus, and hospitalization, faster return to daily activities, and better cosmetic results. Usual indications for adrenal removal include Conn's syndrome, Cushing's syndrome and Cushing's disease, pheochromocytoma and incidentaloma. The treatment of malignant diseases using minimally invasive approaches is still being debated, and, where acceptable, is limited to selected indications [3, 10, 16, 19]. To date, several different approaches have been devised to reach and remove the adrenal gland: flank and anterior transperitoneal or posterior retroperitoneal access [6, 13, 21]. According to the surgeon's preference, adrenal dissection from kidney fat and closure of its main vascular structures, especially the adrenal vein, are achieved by means of a wide range of tools, including monopolar/bipolar cautery, USS, staplers or clips, often employed at the same time [20, 22]. Recently, the use of EBVS sealing/cutting system was reported in various fields of laparoscopic surgery. The EBVS system, suitable for sealing vessels up to 7 mm in diameter, is based on a technology that fuses tissue bundles and vessels, reforming the collagen in vessel wall and connective tissue into a permanent seal. At present, there is not much data in the literature about the use of EBVS in adrenal surgery. Working in colorectal surgery, where we have used EBVS with success for some years, we perceived some possible benefits from the use of EBVS for LAs. This prospective randomized trial was therefore planned, aiming to compare the results of LAs performed by means of the EBVS LigaSure V to those conducted with a different tool for hemostasis and dissection (the USS), following the same surgical technique in both series of patients.

Table 1. Clinical characteristics of the patients

	Group A (<i>n</i> = 25)	Group B (<i>n</i> = 25)
Sex		
Male	11	8
Female	14	17
Mean age, years (range)	55.2 (29–74)	53.1 (27–72)
Mean BMI	28.3 (19–36)	26.6 (17–39)
Estimated tumor size, cm (range)	3.6 (1–8)	3.3 (1–6)
Tumour side		
Right, <i>n</i> (%)	12 (48)	16 (64)
Left, <i>n</i> (%)	13 (52)	9 (36)
Indication		
- Incidentaloma (<i>n</i>)	6	12
- Conn's syndrome (<i>n</i>)	6	4
- Cushing's syndrome (<i>n</i>)	5	2
- Pre-Cushing's syndrome (<i>n</i>)	3	0
- Pheochromocytoma (<i>n</i>)	4	4
- Virilizing adrenogenital syndrome (<i>n</i>)	0	1
- Adrenal cyst (<i>n</i>)	0	1
- Metastasis (<i>n</i>)	1	1

Methods

From January 2004 to January 2006 all consecutive patients undergoing LA in our department were evaluated for eligibility in the randomized trial. According to our habitual diagnostic protocol, patients were preoperatively subjected to a baseline dynamic hormonal test, and additionally, when there was clinical suspicion of pheochromocytoma, a ¹³¹I metaiodobenzyl guanidine (MIBG) or ⁷⁵Se-cholesterol scintigraphy. The imaging study included abdominal ultrasound (US), computed tomography (CT) scan and/or magnetic resonance (MR). Inclusion criteria for randomization were a lesion diameter not exceeding 8 cm, ASA risk not over level III and age less than 80, while patients with well-founded suspect of adrenal carcinoma were excluded. Previous abdominal surgery was not considered among the exclusion rules. A cohort of 50 patients met the randomization criteria of the study. After obtaining consent, 25 patients (group A) were randomized to be operated on using the EBVS Ligasure V vessel sealing system (Tyco, Boulder CO, USA) and 25 (group B) by means of USS, assisted by monopolar high-frequency (HF) energy when necessary. The randomization assigned consecutive patients undergoing LA, who met the study inclusion criteria, to group A or B independently of adrenal lesion side. Therefore there were more right than left LAs, and more left LAs in group A than in group B. All procedures were performed by two attending surgeons (GM, CR). In group A, there were 14 women and 11 men, with a mean age of 55.2 years (range 29–74 years) and mean BMI of 28.3 (range 19–36). There were 12 right and 13 left adrenal masses. Indication for surgery were as follows: incidentaloma (six), Conn's syndrome (six), Cushing's syndrome (five), pre-Cushing's syndrome (three), pheochromocytoma (four), and metastasis (one). Seventeen LAs were performed by the usual anterior approach and eight by the anterior submesocolic approach. The patient with metastasis was a 65-year-old male who underwent right-lung lobectomy for pulmonary cancer two years previously. During follow-up, he presented with a 4 cm right adrenal tumor, detected by CT scan. In group B, there were 17 women and eight men with a mean age of 53.1 years (range 27–72) and mean BMI of 26.6 (range 17–39). There were 16 right and nine left adrenal masses diagnosed as: incidentaloma [12], Conn's syndrome (four), Cushing's syndrome (two), Pheochromocytoma (four), virilizing adrenogenital syndrome (one), adrenal cyst (one), and metastasis (1) (see Table 1). Out of the four patients with pheochromocytoma, one suffered from Von Recklinghausen fibromatosis. The metastasis patient was a 53-year-old male who had previously been operated on a open right nephrectomy by lumbar extra-peritoneal approach for a stage I clear cell kidney cancer. In this patient a CT scan revealed a 1.5 cm right adrenal mass close to the lateral wall of the inferior vena cava at 28 months follow-up. In spite of being conscious of how borderline this case seemed, this patient was included in the trial, above all to evaluate the posterior retro-peritoneal route for previous nephrectomy, leading

one to expect a considerable preservation of the main intra-peritoneal anatomical landmarks in the adrenal area, as in fact was the case. LA was performed in 21 patients by the anterior transperitoneal approach and in four by the submesocolic approach. OpT, blood loss, intraoperative and postoperative complications and postoperative hospital stay were analyzed in two groups comparing surgical route, size and histology of adrenal tumor. Surgical approach, by the submesocolic and anterior transperitoneal route, as well as relating technical details have been previously described [12, 13, 15]. For right adrenalectomy in group A when the adrenal vein was estimated to measure over 5 mm (four cases), titanium clips were used to close it, while in the remaining procedures, for both left and right LAs, the adrenal vein was sealed and cut by EBVS. Regardless of adrenal vein closing, adrenal gland dissection for group A was carried out exclusively by means of EBVS. In group B, four patients with a very small left adrenal vein, had this cut using USS, while in the remaining 21 LAs, titanium clips were used. Adrenal dissection was completed using USS. Monopolar HF energy in those patients was used only to refine hemostasis when bleeding persisted in peri-adrenal fat after adrenal dissection and removal by USS. It was deemed necessary to leave a 20 Fr drain for 24 hours in 11 pts (seven right, four left LA) and 14 pts (eight right, six left LA) in groups A and B, respectively. The amount of blood loss, which at first sight seems rather high, was actually deduced by collecting both intraoperative and drained bleeding. In order to restrict as much as possible the bias relating to empirical examination, we included only drained fluids having hematocrit over 20%, finding this in two and eight patients in groups A and B, respectively.

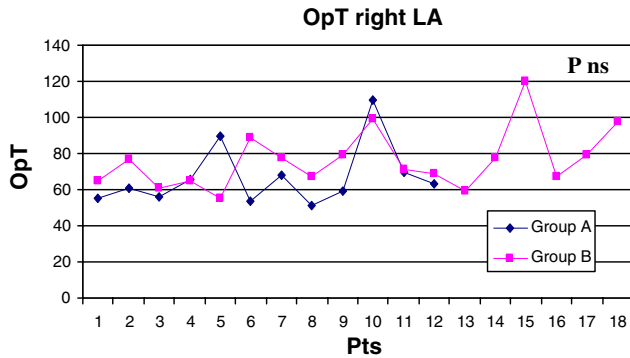
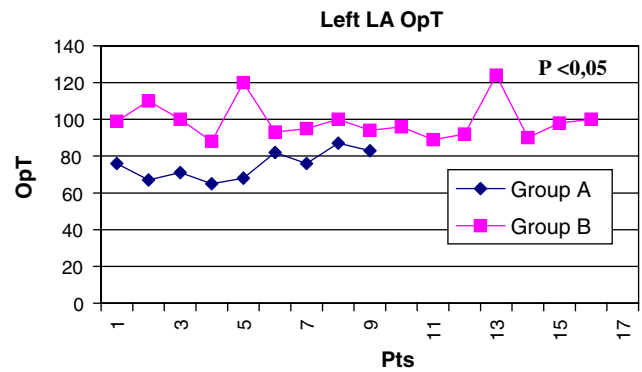
Statistical analysis was carried out using the Primer statistics software. Clinical findings (OpT, blood loss, hospital stay, etc.) were reported as consecutive numbers, and were processed as a mean for each group of patients. The unpaired two-tailed Student's *t*-test was used to compare the two means. A *p* value less than 0.05 at 95% confidence intervals was considered significant.

Results

No intraoperative complications or conversions to open surgery occurred in either group. The right adrenalectomy mean OpT was 51.8 mins (range 40–90 mins) and 68.6 mins (range 50–130 mins) in groups A and B, respectively (*P* not significant) (see Table 2, Picture 1). For the left adrenalectomies the mean OpT was 72.2 mins (range 55–100 mins) and 94 mins (range 65–140 mins) for groups A and B, respectively (*P* < 0.05) (see Table 2, Picture 2). The mean blood loss was 83 ml (range 50–100 ml) in group A and 210 ml (range 100–300 ml) in group B (*P* < 0.05). Among A group, a patient treated for right adrenal pheochromocytoma presented a significant increase of blood pressure and cardiac rhythm, requiring two temporary interruptions of laparoscopy for 10 mins. In both groups, except for this case, there was no peculiarity ascribed to the differences in OpT or blood loss. In all patients the drain was removed on the first postoperative day and the patients were ambulating freely and tolerating oral intake within 24 hours. No major postoperative complications or mortality within 30 days were observed. Two minor complications, one in each group, occurred: a wound infection on the trocar site (group A), and an intra-abdominal collection, resolved with antibiotic treatment (group B) (see Table 3). The average diameter of the adrenal tumours removed in group A was 3.6 cm (range 1–8 cm) and was 3.3 cm (range 1–6 cm) in group B. Separately collecting the left adrenal removed size, there was no significant difference between the mean size in group A and B: 3.9 and 3.4 cm, respectively. Histology is reported in Table 4. In one case of group A

Table 2. Operative time

	Group A (n = 25)	Group B (n = 25)	P value
Right LA	(n = 12) 51.8 mins (range 40–90 mins)	(n = 16) 68.6 mins (range 50–130 mins)	NS
Left LA	(n = 13) 72.2 mins (range 55–100 mins)	(n = 9) 94 mins (range 65–140 mins)	0.023

**Picture 1.** Operative time comparing Right LA of group A and B (P ns)**Picture 2.** Operative time comparing Left LA of group A and B (P < 0.05)**Table 3.** perioperative, postoperative and hospital stay for the two groups

	Group A (n = 25)	Group B (n = 25)	P value*
Intraabdominal collection (n)	0	1	
Wound infection (n)	1	0	
Conversion (n)	0	0	
Blood transfusion (n)	0	0	
Mean blood loss (range)	83 mL (50–100)	210 mL (100–300)	< 0.05
Mean size at pathology	3.9 cm	3.4 cm	NS
Mean hospital stay, days	2.9 (range 1–9)	3.1 (range 1–8)	NS

Table 4. Definitive histology

	Group A (n = 25)	Group B (n = 25)
Adrenocortical adenoma, n (%)	19 (76)	19 (76)
Pheochromocytoma, n (%)	5 (20)	4 (16)
Adrenocortical carcinoma, n (%)	1 (4)	0
Adrenal cyst, n (%)	0	1 (4)
Metastasis, n (%)	0	1 (4)

pathology demonstrated unsuspected adrenocortical carcinoma, completely margin-free, excised by laparoscopy. In this case, the preoperative indication to LA was based on a CT scan suspected incidentaloma of left adrenal, measuring about 5 cm, without radiology evidence of signs of malignancy. The tumour staging did not reveal local invasion, nodal or distant metastases, resulting therefore in stage I disease. The mean hospital stay for groups A and B was, respectively, 2.9 (range 1–9) and 3.1 days (range 1–8) (*P* not significant). At 7 and 30 days following their discharge, patients were evaluated clinically and hormonally. Subsequent follow-up controls were based on histology results. Patients treated for metastasis and unexpected carcinoma underwent postoperative chemotherapy and at 18 and 12 months after surgery, respectively, were disease free. Patients

treated for secreting adrenal lesion presented normalization of the endocrine profile, or at least a significant reduction, unless drug therapy was suspended.

Discussion

Multiple retrospective comparative studies and case series have demonstrated the benefits of minimally invasive surgery for adrenalectomies, including decreased analgesic requirements, and shorter hospital stay and recovery time, compared with open surgery. Beyond recovery and cosmetics, attempts have been made to assess associated morbidity, the functional outcome for hormonally active lesions, and the results for large and malignant tumours compared with conventional open surgery [4, 9, 14]. Performing open adrenalectomy, the majority of surgeons prefer the anterior transabdominal approach. This technique has some advantages, such as exposure of the operating field, exploration of the abdominal cavity and early control of the adrenal vein. As a consequence, and considering our experience with LA, we chose the laparoscopic transperitoneal anterior access. LA has progressively become a safe, effective treatment for a variety of adrenal diseases, overcoming initial scepticism over

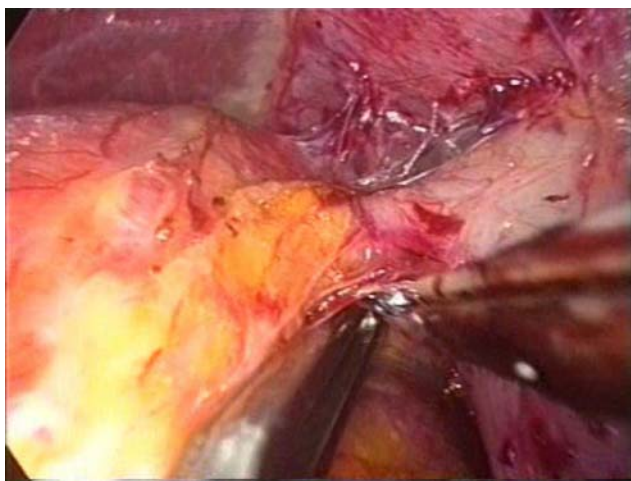


Fig. 1. Dissection of the main adrenal right vein by LigaSure V.

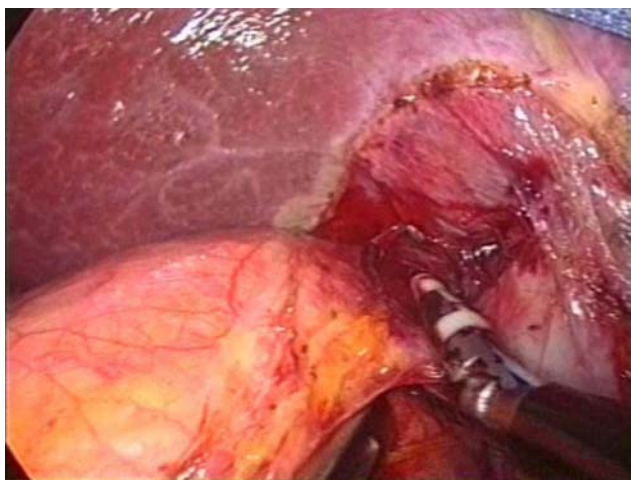


Fig. 2. Closure of the adrenal vein by LigaSure V.

its reliability. For instance, lesion size can no longer be considered an absolute contraindication, because Gagner and other authors did have performed LA for 10 cm lesions, reporting the feasibility of this kind of surgery [5, 14, 19]. Indeed, large masses often have an increased risk of cancer, leaving open to question whether they can be treated reliably by laparoscopic access. In contrast to this observation on size, we unexpectedly found an adrenocortical carcinoma with a 5 cm diameter, in which the preoperative contrast-enhanced spiral CT scan failed to show significant findings of malignancy. In fact, in the case in point the lesion was completely encapsulated with a few, small necrotic areas, which are atypical malignant features. Some authors report malignant adrenal masses measuring more or less than 4 cm, suggesting that the role and timing of surgery for their treatment should be reassessed, particularly in young patients [2, 14]. Approaching these masses, as for pheochromocytomas, one often faces increased vessel supply, increasing the risk of operative bleeding and increasing operative time [7]. Laparoscopic surgeons are well aware that laparoscopy requires a clean operative field, so that reducing bleeding as much as possible be-



Fig. 3. Section of the adrenal vein by blade contained in the LigaSure V device. Picture 1. Operative time comparing right LA of group A and B (P not significant) Picture 2. Operative time comparing left LA of group A and B ($P < 0.05$).

comes imperative for intra- and postoperative good results. Hemostasis is even more necessary in LA, where the operating area is narrow and close to major vessels, for instance the cava vein. Assalia and Gagner reported bleeding as the most common problem both during and after operation (40% of total complications). The most frequent vascular injury found in their series was to the adrenal vein [1]. The approach to adrenal vessels may sometimes be difficult, especially in obese patients. During right LA, when the adenoma extends to and/or the adrenal vein flows behind the inferior vena cava the dissection could be difficult. Only by careful movements and close attention to the main anatomical landmarks in a clear operating field can the task be performed without dramatic complications (Figure 1). On the left side the adrenal vein can be identified with difficulty when the lesion is large and is approached from the flank position after a significant, potentially bleeding, dissection. There are a range of tools in laparoscopy as well as in open surgery to achieve hemostasis and reduce blood loss, including ligatures, titanium clips, USS and monopolar/bipolar coagulation. Harold, comparing hemostasis techniques, concluded that clips are easily placed but require accurate vessel dissection, with a considerable risk of dislodgement during tissue manipulation. Standard bipolar and ultrasonic coagulation can be used to coagulate small blood vessels in the 1 to 3–5 mm range, but can be slow and may result in unsafe lateral thermal spreading [8]. The EBVS Ligasure vessel sealing system achieves vascular control by sealing vessels up to 7 mm in diameter. EBVS is an energy system for sealing blood vessels in laparoscopic and open surgical interventions, and has been in use since 2000. This energy, applied at high current and low voltage, using bipolar pressure and thermal energy simultaneously (Figure 2) creates seals in large vessels, including mesenteric vessels, that have burst strengths at least three times the physiologic norm. In recent literature EBVS has been successfully used for both abdominal and urologic surgical approaches [11, 17, 18, 22]. As reported by Romano et al. (18) it was our impression that EBVS allows some perceivable advan-

tages, such as minimal sticking and charring as well as reducing instrument interchange or interference in the operating field, and being used as a grasper, dissector, coagulating and cutting tool. Moreover it permits one to seal small vessels without dissection or isolation, which may otherwise prolong the operative time. For these reasons, EBVS has the potent to shorten the operating time and reduce blood loss in both laparoscopic and open procedures. In fact, in this study a statistically significant difference was found between the EBVS and USS series for the operative time required for left adrenalectomy and volume of blood loss. Indeed, in this trial there was a significant difference between the number of left LAs performed as well, with 13 and nine in series A and B, respectively. Moreover, eight patients in the EBVS series and four in the USS series were approached from the submesocolic route, raising suspicion about the bias represented by this imbalance. In fact, stating that the range in size of the masses removed as well as the histology was similar among two groups and there were not significant differences concerning pts inside two series, there is a consideration, in our opinion, able to strengthen our results reducing at the same time the supposed bias role. Since the dissection required during left LA is usually greater than on the right side and in our overall series from 1992 (more than 250 LAs) the OpT in left LAs was about one and a half hours, it is reasonable to suppose that more left LA cases in group B, balancing the EBVS left procedures, could not have wander the expected results off the currents (refl comments).

Conclusions

The present trial was conceived to compare two series of LA, focusing attention on dissection and vessel control tools and their effectiveness in terms of OpT and bleeding in minimally invasive surgery. Analyzing the results, LAs carried out using the EBVS tool appeared to show a statistically significant decrease in OpT, on the left side, and blood loss, on both sides, although both the number of procedures and their distribution between the left and right and sides prevents any firm statement. However, in spit of cautiousness, the results for OpT and blood loss from the present series seem to encourage the use of EBVS in LA.

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