

Électrochirurgie versus ligature mécanique dans le contrôle de l'artère mésentérique inférieure dans la sigmoïdectomie pour maladie diverticulaire

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Bertrand Trilling. Électrochirurgie versus ligature mécanique dans le contrôle de l'artère mésentérique inférieure dans la sigmoïdectomie pour maladie diverticulaire. Médecine humaine et pathologie. 2015. dumas-01674563

HAL Id: dumas-01674563

<https://dumas.ccsd.cnrs.fr/dumas-01674563>

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UNIVERSITE JOSEPH FOURIER
FACULTE DE MEDECINE DE GRENOBLE

Année : 2015

N°

**ELECTROCHIRURGIE VERSUS LIGATURE MECANIQUE DANS LE CONTROLE
DE L'ARTERE MESENTERIQUE INFERIEURE DANS LA SIGMOÏDECTOMIE
POUR MALADIE DIVERTICULAIRE.**

THESE
PRESENTEE POUR L'OBTENTION DU DOCTORAT EN MEDECINE

Bertrand TRILLING

[Données à caractère personnel]

THESE SOUTENUE PUBLIQUEMENT A LA FACULTE DE MEDECINE DE GRENOBLE*

Le : 10 novembre 2015

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TITRE : Electrochirurgie versus ligature mécanique dans le contrôle de l'artère mésentérique inférieure dans la sigmoïdectomie pour maladie diverticulaire.

CONCLUSION

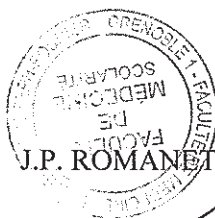
Cette étude rétrospective sur une cohorte de 200 patients a étudié deux modalités de ligature de l'artère mésentérique inférieure dans la sigmoïdectomie pour maladie diverticulaire.

Elle montre une baisse significative de la durée opératoire et de la durée d'hospitalisation dans le groupe des patients opérés avec l'électrochirurgie. Aucune différence n'a été identifiée en termes de complications, conversion, mortalité, hémorragie ou fistule.

Ce travail peut conclure que l'utilisation de l'électrochirurgie pour le contrôle de l'artère mésentérique inférieure est aussi efficace et sûre que la ligature mécanique conventionnelle avec un bénéfice pour la durée opératoire

VU ET PERMIS D'IMPRIMER
Grenoble, le 15/10/2015

LE DOYEN



LE PRESIDENT DE LA THESE

PROFESSEUR J.L. FAUCHERON



Remerciement

A *mi Chiqui* Elizabeth, qui a tout quitté pour me rejoindre en France et me supporte au jour le jour dans la vie à deux. Tu mets la vie dans notre foyer. Merci pour ta spontanéité et sincérité qui te sont propres. J'ai beaucoup de chance de t'avoir dans ma vie et j'espère de tout mon coeur que nos projets à deux se poursuivront.

A ma famille :

A Bruno, pour être disponible quand j'ai besoin de parler, se préoccuper de ce qui se passe dans ma vie et être un exemple de volonté.

A mes sœurs qui sont loin mais qu'on aimerait voir plus souvent.

Geneviève, l'ainée, seconde maman et relectrice médicale d'anglais professionnelle (songe à la reconversion)

Clémence, la Yogum non conforme et attachante

Lucie, la douce et aussi relectrice médicale

Lorraine, la motivée infatigable malgré sa vie hyper occupée.

A mes parents pour l'éducation « de roi » qu'ils nous ont donnée :

A ma mère, pour son incroyable gentillesse, sa créativité et sa disponibilité pour ses enfants.

A mon père, pour sa curiosité, ses convictions et pour avoir poussé ses enfants vers l'*étranger* (la meilleure chose qui ait pu nous arriver ! même si tu le regrettes parfois maintenant)

Aux Membres du jury

A Mr le Pr Faucheron, je vous remercie de l'intérêt que vous portez à mon apprentissage et de m'avoir accompagné au long de ce travail. Je vous serai toujours otre disponibilité et votre engagement dans ma formation. Votre dextérité chirurgicale, votre investissement auprès des patients et de la chirurgie en général sont un exemple pour nous. J'espère pouvoir continuer à travailler à vos côtés.

A Mr le Pr Chaffanjon, vous avez été un de mes premiers enseignants d'anatomie en 2004. Moi qui pensais m'inscrire en médecine pour être biochimiste, je n'imaginai pas à cette époque que je poursuivrais mon apprentissage vers la chirurgie. Travailler à vos côtés au laboratoire, au cours de mon projet de master 1 ou lors du passage dans votre service, a été très enrichissant. J'espère un jour avoir votre méticulosité.

A Mr le Pr Glehen, mon passage dans votre service a été une expérience inoubliable au point de vue médical, scientifique et humain. J'ai eu l'opportunité de m'initier à la prise en charge de cancers colorectaux complexes et de découvrir qui était Ennio Morricone!

A Mr le Dr Abba, Julio, tu es un mentor et un ami. Ton expérience chirurgicale est un "bien" que l'on doit tous valoriser. C'est un honneur d'avoir pu te rencontrer et d'avoir lié notre amitié. Tu étais là pour ma première garde (mon bip n'a pas sonné !), ma première hernie, ... J'espère pouvoir encore bénéficier de ton expérience !

A Mr le Dr Riboud, Romain, tu as accompagné mes premiers pas chirurgie

aux et su rattraper mes "bêtises" d'interna débutant. J'ai appris ce qu'était l'"eau de pluie l'eau de là haut". Merci pour ce travail que tu avais initié et que j'ai poursuivi par quelques visites aux archives et heures passées à Crystalnet.

A mes maitres d'internat

Madame le Pr Arvieux, je vous remercie de l'intérêt que vous portez à l'enseignement des internes et à la volonté que vous avez de nous former correctement à la pratique. Vous représentez nos intérêts nationalement.

Monsieur le Pr Letoublon, je vous remercie de m'avoir accueilli paternellement dans le service et de votre enseignement.

Olivier Risse, qui m'a fait peur lors de mes premiers jours dans le service mais qui est gentil au fond !

David « che » Voirin, merci de t'être battu pour la condition des internes. J'ai hâte de travailler de nouveau avec toi à la Clinique mutualiste.

Fabian, c'est un plaisir d'avoir pu retourner sur les bancs de la fac avec toi et te voir maîtriser les subtilités de LINUX!

A Edouard : Premier copain de médecine et binome durant toute ma formation. Merci pour tes idées et ton support. Je suis heureux de pouvoir encore travailler à tes côtés pour les prochaines années !

A mes exemples chirurgicaux grenoblois : Mr Rambeaud, Mr Descotes, Jean-Alex, Caroline, Bernard (relation médecin-malade !), Mr Brichon, Augustin, Mr Montbarbon, et lyonnais : Eddy, Mr Francois (PIM !!), Delphine, Guillaume et Colette (the bests !!)

A mes chefs de clinique : Fabien S, Alex AB, Marine, Seb G, Albé, Marion T, Pierre Alex, Hamza, Meriem, Laurence.

A mes cointernes de digestif : Pedro, Mouginho, Sandrine, Tatoon, Joliduvert, Mathieu S et aux plus jeunes. Les lyonnais qui m'ont formidablement accueilli : Michmich, Max, Momo, Nath, Mélanie Q, Guedjouille, Iris. Mes autres co-internes : spéciale dédicace à Carole, Spirou et Amandine ! Aux membres de l'AGGICL

Aux copains de la fac : Tom M, Yannou, Will, Clem, Sousou, Mag, AmL, Marinette, Marion, Julie, Thib P, Marco, l'Indien, les hyènes, Kantcheff, Fab, Rabot Maya et ceux qui m'excuseront de ne pas les avoir cités

Aux copains d'enfance : GC (Oliv, Alex F B C, Had, Pierrot, Sam, Titi, Trincat, Gui, Kev, Mickael et toutes les "valeurs ajoutées"), Béné, les 3Tchiottes (Alex W, Etienne C, Thomas F le limogeois),

Aux membres de TIMC pour m'accueillir dans leur équipe : Mr Cinquin, Sandrine, Mme Troccaz et aux thésards! (Armand, Cecilia, Antho, Paul, Sonia, Johan, Mathieu et les autres)

Résumé

OBJECTIF : Avec le développement de nouveaux dispositifs médicaux, les techniques de ligature de l'artère mésentérique inférieure en chirurgie colorectale ont été modifiées, passant d'une ligature mécanique au contrôle vasculaire par électrochirurgie (EC). L'objectif de cette étude est de déterminer si la ligature de l'artère mésentérique inférieure par électrochirurgie est aussi efficace que la ligature mécanique dans la chirurgie sigmoïdienne programmée.

METHODES : De 2001 à 2014, 200 patients (110 hommes) consécutifs, avec un âge moyen de 54.1 ans, ont été opérés pour une maladie diverticulaire symptomatique par voie coelioscopique. La ligature artérielle était réalisée, pour 100 patients de manière mécanique (LM), soit à l'aide de clip, agrafes ou fil intracorporel, ou, à partir de 2006, à l'aide d'EC (100 patients). La ligature de l'artère mésentérique est réalisée systématiquement à son origine pour des raisons d'enseignement. Les résultats techniques étaient recueillis de manière prospective en per et post opératoire.

RESULTATS : La mortalité était nulle. Le temps opératoire moyen était 253,7 et 200.7 minutes dans les groupes LM et EC respectivement ($p < 0.001$). La durée moyenne d'hospitalisation était 10.4 et 8.1 jours ($p < 0.001$). Une complication post opératoire est survenue dans les 30 jours chez 31% versus 25% des patients ($p = 0.29$). Une fistule anastomotique est survenue chez 3 patients dans le groupe LM. Un évènement hémorragique est survenu dans les 2 groupes (3 dans le groupe LM et 2 dans le groupe EC). Les limites de cette étude sont son caractère rétrospectif et les biais inhérents à l'étude de deux cohortes historiques.

CONCLUSION : L'électrochirurgie pour le contrôle de l'artère mésentérique inférieure est aussi efficace et sûre que la ligature mécanique et permet une baisse significative de la durée opératoire.

Energy Vessel Sealing Systems versus Mechanical Ligature of inferior mesenteric artery in laparoscopic sigmoidectomy.

Abstract

AIM: With the development of new devices, our ligation technique of the inferior mesenteric artery changed from mechanical ligature (ML) to energized vessel sealing systems (EVSS) ligature. The aim of this study was to determine if EVSS could be considered as safe and effective as the more convention ML of the inferior mesenteric vessels division during elective laparoscopic left colectomy.

METHODS: Between 2001 and 2014, 200 consecutive patients (111 males) of mean age 54.1 years were operated on laparoscopically for a symptomatic sigmoid diverticulitis. Vascular interruptions were performed using mechanical ligatures including double clipping, staples or surgical thread (100 patients) or, starting from 2006, with EVSS thereafter (100 patients). Section of the inferior mesenteric artery is performed systematically at its origin in our institution for teaching purpose. Technical results were prospectively collected per and postoperatively.

RESULTS: There was no mortality. Mean operating time was 253.7 and 200.7 minutes in the ML and EVSS groups, respectively ($p < 0.001$). Mean hospital stay was 10.4 and 8.1 days ($p < 0.001$). Thirty-day complications occurred in 31% versus 25% of patients ($p = 0.29$). Leakage with peritonitis occurred in 3 patients in the ML group. Hemorrhagic events occurred in both groups (3 in ML group versus 2 in EVSS group). Limitations of the study are its retrospective design and the bias due to the comparison of two historical cohorts.

CONCLUSION: EVSS for the inferior mesenteric artery are as safe and effective as ML in elective sigmoidectomy for diverticular disease with lower operative time and hospital stay.

Introduction

When indicated, laparoscopic elective colectomy for sigmoid diverticular disease has become widespread as a minimally invasive procedure because of its benefits, such as decreased pain, faster recovery, favorable short term outcomes, shorter hospital stay, and decreased costs when compared to open surgery [1–4].

Today, several available instruments are used for dissection and division of the major mesenteric vessels during laparoscopic colectomy [5]. The conventional mechanical ligature (ML) devices (vascular staplers, titanium or plastic clips, or surgical thread knot) are available. More recently, new energized vessel sealing systems (EVSS) such as ultrasonic coagulating shears (UCS) and electrothermal bipolar vessel sealers (EBVS) have been developed [6]. Both are currently used for vascular control according to the surgeon's preference. In 2006, we started to use EVSS (Ligasure™ 5mm, Covidien) in our colorectal department.

A recent review from the Cochrane Collaboration assessed the safety and effectiveness of these instruments for laparoscopic colectomy [7]. The limitations of this review, as pointed out by the authors, were the few number of randomized controlled trials found (six, including only 446 participants), heterogeneity of trials, of chosen primary outcome (blood loss, morbidity, operative time, hospital stay, etc), of involved pathology types (benign and malignant conditions), of procedures (right colectomy, left colectomy, total colectomy, anterior resection of the rectum), of the instruments used during different steps of the procedures (for example, dissection with monopolar or bipolar scissors, peeling of the main vessels with UCS, and vascular section with use of vascular staplers or clips) and the small number of participants included in each trial. The authors of the review concluded it was not possible to demonstrate

which the best instrument for a laparoscopic colectomy was. To our knowledge, no study compared mechanical ligature of the inferior mesenteric artery versus EBVS of "small size", such as LigasureTM 5mm. More recently, Sankaranarayanan *et al.* published a comprehensive review on energy devices in surgery, and also concluded "there is no consensus as to which device is optimal for a given procedure" [8].

The aim of this study was to narrow the population and provide an analysis on a more selected group of patients and determine if EVSS could be considered as safe and effective as the more traditional ML, regardless of the standardized procedure, to control the inferior mesenteric vessels division during elective laparoscopic left colectomy for diverticulitis.

Patients and methods

Patients

Between 2001 and 2014, 200 consecutive patients (110 males) of median age 54.9 years (17-84) were operated on for symptomatic sigmoid diverticulitis in a single surgical team. Diverticulitis was diagnosed on abdominal symptoms such as left inferior quadrant pain and constipation or diarrhea with fever, and biologic inflammatory syndrome. The diagnosis of diverticulitis was confirmed on CT scan in every instances, and included thickening of the sigmoid colon, presence of diverticulas, and corresponding inflammatory mesocolon. Patients with colorectal cancer, ulcerative colitis, volvulus or other sigmoid conditions were excluded from this study, along with patients with diverticular bleeding or sigmoid undetermined stenosis. Emergency procedures were also excluded.

The elective procedure for sigmoid diverticulitis has long been standardized in our institution, and consisted in complete mobilization of the left colon including the splenic flexure, dissection of inferior mesenteric artery (IMA) using a medial approach, ligation of the IMA at 2 cm from its origin, ligation of the inferior mesenteric vein at the inferior border of the pancreas, rectosigmoid resection, and stapled side-to-end colorectal anastomosis on the high portion of the rectum. Operating time was considered from first incision to end of wound closure.

Vascular interruptions were performed either using ML devices (100 patients), as double clipping (n=82), surgical thread (n=11), or intra-abdominal stapling device (n=7) until 2006, or with EVSS (100 patients), as UCS (n=5) or EBVS (n=95) thereafter. After some patients had been operated on with UCS, members of our department chose to use systematically EBVS. Using such devices, dissection and division of the mesenteric trunk seemed faster and safe. In the first group, dissection was made with bipolar forceps and scissors, and vascular section was secured mechanically. In the second group, dissection and vessels sealing were made using the EVSS device only.

Demographic and operative data

Age, gender, operating time and hospital stay were prospectively collected. Type of ligature was retrieved from the operative report.

Complications

Preoperative and postoperative hemoglobin level, transfusion requirement, need and reasons for conversion, intraoperative complications, early postoperative surgical and medical complications (classified following Dindo [9] classification taking into account the most severe complication), and late complications including sexual dysfunction in males, were

retrospectively reviewed from the prospectively collected database, for the purpose of this study. Hemorrhagic events were defined by loss of blood related to operative site bleeding (preoperatively and during the postoperative course).

Cost Analysis

Costs were calculated in Euros (€), including operating time and instruments costs. Costs were estimated by actual prices of available devices. Theatre costs included professional fees. Hospital expenses were calculated on billed costs. Comparison was realized with and without considering hospitalization costs.

Statistical analysis

Data were analyzed by using R statistical package. Results were given as percentage, mean and standard deviations, or median and ranges. Quantitative and qualitative variables were compared with Student's t-test and Pearson's chi squared test or Fischer's exact test, respectively. A p value < 0.05 was considered significant.

Results

Age, gender, mean operating time and length of hospital stay are reported in Table 1. Operating time and hospital stay in the EVSS group were significantly shorter ($p < 0.001$ for both items).

There was no difference for mean hemoglobin level differential (preoperative hemoglobin *minus* postoperative hemoglobin), transfusion or number of blood units transfused for each group (Table 2). Hemorrhagic events occurred in 3 patients in the ML group (two abdominal wall hematomas, one rectal anastomosis bleeding treated conservatively) and 2 patients in the

EVSS group (one cautery insufficiency and one hematuria on a partial cystectomy). Conversions are reported in Table 3. They were needed in 11.5% of cases with no significant difference between both groups. Most frequent cause of conversion was dissection difficulties (exposure or extended adhesiolysis).

Table 1: Demographic, intra- and post-operative data

	Mechanical ligature	Energy vessel sealing system	Global	p value
Female patients (n)	47	42	89*	
Male patients (n)	52	59	111*	p=0.70
Mean age (years)	54.5	53.7	54.1 [§]	p=0,45
Mean surgery duration (min.)	253,74	200,72	227,23 [§]	p<0.001
Median surgery duration (min.)	245	198	215	
Length of hospital stay (days)	10.4	8.1	9.3 [§]	p<0.001

* Total or [§]mean for the entire cohort

Table 2: Hemoglobin loss and need for transfusion

	Mechanical ligature	Energy vessel sealing system	Global	p value
Mean Hb differential (g/L)	-13.16	-12.78	-13.0 [§]	p=0.82
Transfusion requirement (n)	1	3	4*	p=0.56
Blood Clot number (n)	2	6	8*	p=0.22
Hemorrhagic event (n)	3	2	5*	P=0.65

* Total or [§]mean for the entire cohort; Hb: hemoglobin; N: number of patients

There was no 30-day mortality in either group. Overall 30-day complications rates were respectively 31% and 25% (p=0.29) for ML and EVSS (Table 4). Two patients suffered from complications greater than class IIIb from the Dindo classification (one respiratory failure and one septic shock requiring Intensive Care). Most frequent complications were infection (24 in ML group and 16 in EVSS group, p=0.21) and represented mainly by abdominal wall abscess

(11 in each group), pelvic abscess (6 in ML group and 2 in EVSS group) and urinary tract infection (2 in each group). There was no difference between the two procedures in terms of complications severity.

Table 3: Conversion and causes

Conversion causes	Mechanical ligature	Energy vessel sealing system	Global*	p value
Dissection difficulties	12	7	19	
Hemorrhage	0	1	1	
Abcess	1	0	1	
Bowel ischemia	1	0	1	
Non planified bladder partial resection	0	1	1	
Total	14	9	23	P=0.27

*Total

Table 4: Complications regarding Dindo classification

Dindo Classification	Mechanical ligature	Energy vessel sealing system	Overall	p value
I	12	11	23	
II	8	9	17	
IIIa	3	0	3	
IIIb	7	4	11	
IVa	1	1	2	
IVb	0	0	0	
Total	31	25	56	p=0.29
Minor events (I-II)				
Minor events (I-II)	20	20	40	
Major events (III-V)				
Major events (III-V)	11	5	16	p=0.68

Fistulas, defined by the apparition of septic pelvic collection related to an anastomotic leakage, occurred in 3 patients in the ML group, and in no patients in the EVSS group ($p=0.25$). Two patients required surgery (end colostomy) and one was treated by controlled with conservative measures (antibiotics).

Anastomotic stenosis requiring surgery developed in 4 cases at long-term follow-up in the mechanical ligature group ($p=0.12$). Two patients required anastomosis resection and two patients were treated by endoscopic dilation.

No short or long term sexual dysfunction compared with the preoperative status in the 110 male patients were recorded in either group.

Taking into account hospitalization costs (Table 5), price reduction was 3919€ in favor of EVSS ($p= 0.001$). Considering hospitalization costs (Table 6), price reduction was 239€ in favor of ML ($p< 0.001$).

Table 5: Cost analysis without hospitalization consideration

	Mean (Min-Max) in Euros	Standard deviation
ML	1125 (514-1739)	280
EVSS	1364 (834-2161)	270
Total	1244 (514-2161)	299

Table 6: Cost analysis with hospitalization consideration

	Mean (Min-Max) in Euros	Standard deviation
ML	19899 (8012-64301)	9969
EVSS	15980 (8501-40711)	6845
Total	17939 (8012-64301)	8753

Discussion

This study included all patients operated on for diverticular disease in a single institution. All sigmoidectomies were performed by senior surgeons in a standardized fashion. In 2006, the dissection and ligation of inferior mesenteric artery were progressively modified with the release of new devices. After some surgery performed with UCS, members of our department decided to use Ligasure™ for all colorectal surgeries. Comparison of the type of vascular ligation either with ML or EVSS was realized and shows that use of EVSS for inferior mesenteric artery in sigmoidectomy for diverticulitis is as safe as ML with a shorter operating time.

High tie, meaning before the division of the left colic artery, is still debated in colorectal cancer for oncologic benefits (when opposed to low tie) [10] and is even more debated in diverticular disease [11]. In our institution, we chose to apply this approach systematically for every left colon resection since 1995. The IMA is actually sectioned at 2 cm from its origin, leaving absolutely free the sympathetic innervation lying on the aorta. This technique has the advantage of facilitating teaching (of younger surgeons) and accelerates learning curve since the same technique applies to all left colonic pathologies (cancer, inflammatory bowel disease, diverticular disease, etc.). No patient reported sexual dysfunction following such a proximal ligation of the inferior mesenteric vessels in our series. Moreover, high tie of the IMA and ligation of the inferior mesenteric vein at the lower border of the pancreas allow easy mobilization of a well vascularized colon towards the pelvis, for safe anastomosis.

Advanced EBVS such as Ligasure™ (Covidien) or ENSEAL™ (Ethicon) are multifunctional tools that can seal and cut vessels up to 7 mm in diameter using electrothermal bipolar energy

to denature elastin and collagen in vessel wall [12]. Those devices are widely used in both open and laparoscopic urologic [13], hepatobiliary [14], endocrine [15], and gynaecologic [16] surgery.

The outbreak of those new energized vessel sealing systems in colorectal surgery has been one of the major innovative steps forward of the last years, reducing blood loss and operating time [17–19]. In this study, we found a significant shorter operating time (mean difference of 53 minutes in favor of EVSS). Certainly, this improvement can be partially credited to the use of EBVS that hasten the dissection steps[20]. Other factors such as the improvement of the learning curve of the surgeon along with his surgical team could also impact. Nevertheless, Tou *and al* [7], in a large metanalysis reviewing energy source instruments in colectomy, found a similar difference of operating time when comparing EBVS versus standard dissection with monopolar scissors. Mean difference of 40 minutes was observed in Hübner *and al* [20], in a trial comparing 61 patients undergoing left-sided hemicolectomy with either EBVS, UCS or monopolar scissors. Surgeon's overall satisfaction of the instruments were similar. Targarona *and al* [5] described a median operating time of 110 minutes in the EBVS group and 180 min in the monopolar dissection group ($p < 0.001$) for 38 patients undergoing left-sided colic resection. Marcello *and al* [21] did not find any difference in term of operating time in a study comparing 101 patients who underwent laparoscopic colectomy using ML (titanium clips or staplers) or EBVS with Ligasure AtlasTM (10mm) for division and ligation of major vascular pedicles. However, this study included various types of colectomies (right, left, total colectomy, proctectomy) for benign and malignant diseases using laparoscopy or hand-assisted laparoscopy techniques performed by senior or junior surgeons and results could be therefore altered by those factors.

Length of hospital stay was significantly shorter in the EVSS group in our study. Various studies[5, 19, 22, 23] comparing UCS, EBVS or ML did not find any difference. Our series compares two groups of patients operated on for diverticular disease. Nevertheless, we implemented an *Enhanced Recovery After Surgery* Program [24] for colorectal surgery in 2011. With the avoidance of drain and tubes, early mobilization and feeding and adequate analgesia, hospital stays decreased drastically with a median hospital stay of 5 days (range 4-14 days) in 2014.

No differences were found in terms of blood loss (hemoglobin differential), blood transfusion requirements or hemorrhagic events. A larger trial including 146 patients compared UCS with standard electrosurgery for dissection (ML was performed for vascular ligation) and showed only a difference in reduced intra operative blood loss in UCS group [22]. Hübner *and al* [20] reported also a significant decreased intra operative blood loss using EVSS. We could not evaluate precisely intraoperative blood loss as this data was not recorded in our prospective database and decided to assess two information of clinical value, differential hemoglobin and number of transfusions. No difference existed between the two groups.

One cautery insufficiency was described in the EVSS group, related to an insufficiency of electrofusion with Ligasure™ 5mm in our early experience. Marcello *and al* [21] described 3% device failure using Ligasure™ Atlas 10mm and reported a higher rate of dysfunction in the clip/stapler group (9.8%, $p < 0.001$). All dysfunction were manageable with EVSS or ML laparoscopically. Adamina *and al* [18] didn't find any significant difference in a prospective trial comparing clip/staplers and EVSS in 100 interventions. Other existing trials did not discuss this event. More recently, Martin *and al.* reported their experience of 802 consecutive unselected patients who had a resection for colorectal cancer using EBVS device only (5 and

10mm) [25]. Division of major mesenteric vessels was achieved in 99.8% of the cases. Two patients were converted from laparoscopy to laparotomy for uncontrolled hemorrhage. The authors recommended extreme caution with elderly atherosclerotic patients, particularly when using the 5 mm Ligasure™ device.

Conversion to open surgery representing 11.5% of surgeries was not significant between the two groups. Similar rates are found in the literature [18, 22]. Targarona *and al* [5] reported however that conversion to other endoscopic techniques was higher in the conventional electrosurgery group. In this series, the main cause of conversion was surgical adhesion attributable to the numerous diverticulitis crisis prior to surgery. Only one conversion was needed to control hemorrhage in the EVSS group.

Other well designed studies [5, 18, 20, 23] evaluating different dissection and ligation instruments reported a post-operative complication range of 17-46% (28% in present studies). One of the main concern are the thermal injuries [12] to the adjacent organs (mainly bowel and ureter) that can develop up to 36-48h after sealing [26]. Even if, energy devices create damage up to 2 mm to the surrounding tissues [27], no direct thermal injuries were reported in the studies. Anastomotic dehiscence were similar regardless of dissection instruments [18, 20]. Most of reported complications were infectious [18, 20], mainly surgical site infections, inherent to colorectal surgery. Recent prevention strategies have been proposed such as combined mechanical and oral antibiotic bowel preparation [28], povidone-iodine application on the extraction site wound [29] or use of new wound retractor/protector of the abdominal wall [30].

Two cost analysis were realized in this study including or not hospital length reduction as this results could have been biased by other factors. Results were discordant whether hospitalization costs were considered. Three studies compared different EVSS with monopolar scissors for dissection. Cost analysis were planned as secondary outcome. Price reduction was significant using EVSS (range 83\$-267\$)[7, 18, 20, 21] for high caseload institution. Lower costs of material in the monopolar scissors group were out weighted by the saving performed by reducing operating costs and need for additional instruments [7, 18, 20, 22].

Our series is a comparative study of two historical cohorts comparing 2 periods: before and after the introduction of EVSS (mainly the LigasureTM 5mm) used for inferior mesenteric vessels ligation during elective laparoscopic colectomy for sigmoid diverticulitis, in consecutive patients, using the same procedure, for the same condition, by the same surgical team. A significant advantage in terms of operating time and length of hospital stay with similar morbidity was found in favor of the EBVS device. The analysis was done retrospectively, however the data were recorded prospectively in all cases.

Conclusion

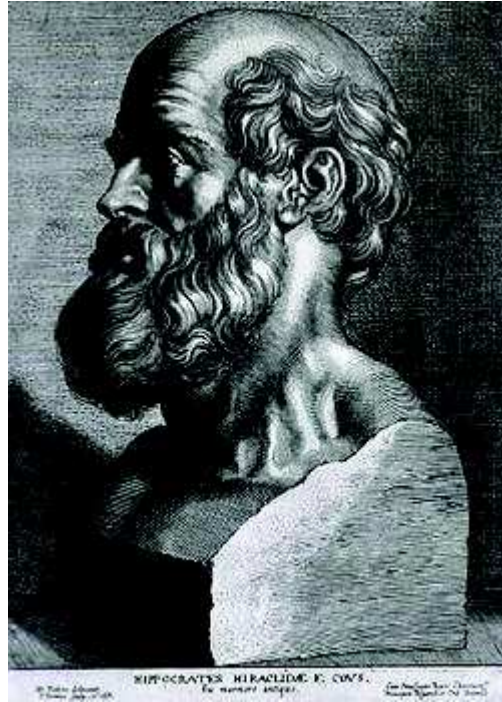
Energy vessel sealing at the origin of the IMA is safe and may be as effective as mechanical ligation using clips in the surgical treatment of sigmoid diverticulitis. Patients in whom this device was used had significant advantages in terms of operating time with similar morbidity.

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SERMENT D'HIPPOCRATE

En présence des Maîtres de cette Faculté, de mes chers condisciples et devant l'effigie d'HIPPOCRATE,

Je promets et je jure d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la Médecine.

Je donnerais mes soins gratuitement à l'indigent et n'exigerai jamais un salaire au dessus de mon travail. Je ne participerai à aucun partage clandestin d'honoraires.

Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y passe ; ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.

Je ne permettrai pas que des considérations de religion, de nation, de race, de parti ou de classe sociale viennent s'interposer entre mon devoir et mon patient.

Je garderai le respect absolu de la vie humaine.

Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.

Respectueux et reconnaissant envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les hommes m'accordent leur estime si je suis fidèle à mes promesses.

Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.