Randomized clinical trial

Prospective randomized study of monopolar scissors, bipolar vessel sealer and ultrasonic shears in laparoscopic colorectal surgery

M. Hubner, N. Demartines, S. Muller, D. Dindo, P.-A. Clavien and D. Hahnloser

Department of Visceral and Transplantation Surgery, University Hospital of Zurich, Ramistrasse 100, 8091 Zurich, Switzerland
Correspondence to: PD Dr D. Hahnloser (e-mail: dieter.hahnloser@usz.ch)

Background: **Many instruments are used for laparoscopic dissection, including monopolar electrosurgery scissors (MES), electrothermal bipolar vessel sealers (BVS) and ultrasonically coagulating shears (UCS). These three devices were compared with regard to dissection time, blood loss, safety and costs.**

Methods: **Sixty-one consecutive patients undergoing laparoscopic left-sided colectomy were randomized to MES, BVS or UCS. The primary endpoint was dissection time.**

Results: **Patient and operation characteristics did not differ between the groups. Median dissection time was significantly shorter with BVS (105 min) and UCS (90 min) than with MES (137 min) ($P < 0{\cdot}001$). With BVS and UCS, significantly fewer additional clips were required (MES 9 *versus* BVS 0 *versus* UCS 3; $P < 0{\cdot}001$) and there was a trend towards lower blood loss (125 *versus* 50 *versus* 50 ml respectively; $P = 0{\cdot}223$) and a reduced volume of suction fluid (425 *versus* 80 *versus* 110 ml; $P = 0{\cdot}058$). Overall satisfaction was similar for the three instruments. Dissection with BVS and UCS was significantly cheaper than with MES, assuming a centre volume of 200 cases per year ($P = 0{\cdot}009$).**

Conclusion: **BVS and UCS shorten dissection time in laparoscopic left-sided colectomy and are cost-effective compared with MES. Registration number: NCT00517608 (http://www.clinicaltrials.com).**

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Introduction

Laparoscopic colorectal surgery has gained wide acceptance for benign and oncological indications[1–3]. Conventional monopolar electrosurgery scissors (MES) have several shortcomings in this type of surgery, including the risk of thermal injury, difficult haemostasis and smoke production, necessitating the use of additional tools such as bipolar graspers, sutures and clips[4]. To overcome these problems and to reduce the number of instrument changes, trocars and operating time, several multifunctional tools have been developed. The most popular devices are electrothermal bipolar vessel sealers (BVS)[5,6] and ultrasonically coagulating shears (UCS)[6–8]. Both of these instruments are well established in laparoscopic surgery[9–14], but their practicability and cost-effectiveness compared with conventional methods remain undetermined as findings from randomized trials and cohort studies published to date are controversial, and comprehensive cost analyses are lacking[9–13,15].

The aim of this prospective randomized study was to compare MES, BVS and UCS in laparoscopic colorectal surgery with regard to dissection time, blood loss, technical aspects, surgeon comfort and costs.

Methods

All consecutive patients admitted for elective laparoscopic left-sided colorectal resection were evaluated for entry into the study. Eligibility criteria included age above 18 years, reasonable communication ability and signed informed consent. Patients requiring a right-sided or total colectomy were excluded. Previous laparotomy was not an exclusion criterion. Sixty-one consecutive eligible patients were randomized to undergo laparoscopic colorectal resection using one of the three dissection devices (no

financial support was received from the manufacturers). The procedure was approved by the institutional ethics committee. Randomization was performed by sealed envelopes on the day before surgery to allow nursing staff to prepare the allocated instruments.

When using MES (Endo Shears^{TM} 5 mm, Covidien, Mansfield, Massachusetts, USA; trigger switch and cord, Valleylab, Boulder, Colorado, USA), electrical energy is applied between the shears and a reference electrode is placed distantly on the body surface. The advantage of sharp dissection is outweighed by high heat production with thermal spread in surrounding structures and charring. Potential risks are direct coupling to another metal instrument, direct sparking and the passage of current from recently coagulated, electrically isolated tissue[4].

With the BVS (LigaSure^{TM} 5 mm; Valleylab), high current and low voltage results in the denaturation of collagen and elastin components within the vessel wall and surrounding tissue. According to the manufacturer, secure sealing of vessels for up to 7 mm can be obtained. Thermal spread is minimal compared with conventional electrocautery. The instrument can be used as coagulator, dissector and grasper, thus reducing instrument traffic[5,6].

For ultrasonic dissection with UCS (Harmonic ACE^{TM}; Ethicon Endo-Surgery, Cincinnati, Ohio, USA), piezoelectric transducers transform electrical energy at the functional tip into frictional energy (movement of the tips at 55 kHz), allowing cutting and coagulation of vessels for up to 3–5 mm. Additionally, tissue dissection is eased by a cavitational effect. No surgical smoke is generated during ultrasonic dissection, but visibility may be hindered by dispersed non-viable tissue particles ('storm' effect)[6–8].

Surgical procedures

All operations were performed or supervised by two expert laparoscopic colorectal surgeons (D.H., N.D.), who had each performed more than 200 laparoscopic colectomies using any of the three devices. No surgeon had a preference for a particular device. The operative technique was standardized before starting the protocol and differed only with regard to the technology allocated for dissection and haemostasis. For evaluation purposes the colorectal dissection was divided into three phases, each with three or four steps. Phase A involved dissection of the inferior mesenteric vessels, identification of the left ureter, and transection of the inferior mesenteric vessels. Phase B comprised mobilization of the sigmoid colon, opening of the presacral space (preserving the nerves), presacral mobilization (if necessary), and dissection of the distal margin; it ended with laparoscopic stapling and transection of the colon/rectum. Phase C consisted of lateral and medial mobilization of the descending colon, mobilization of the splenic flexure and great omentum (if necessary), and ended with the complete mobilization of the descending colon.

The specimen was retrieved through a 4-cm Pfannenstiel incision, and resected. The end-to-end-anastomosis was performed laparoscopically using a circular stapling device.

Outcome measures

Dissection time (phases A–C), which served as the primary endpoint of the study, was documented by the operation nurses, together with the amount of suction and rinsing fluid used immediately after each phase. At the end of the operation, the surgeon documented the use of the allocated instrument and the need for additional devices in each phase and each step. Intraoperative blood loss was estimated by the surgeon based on his subjective appraisal; perioperative blood transfusions and the difference in haematocrit (value before surgery minus that on the second postoperative day) were recorded. Frequency of lens cleaning and the time-related carbon dioxide consumption were measured as surrogate parameters for the generation of surgical smoke and vapour respectively. Postoperative complications were assessed for up to 30 days after surgery using a validated five-point scale classification[16]. The operating surgeon graded the practicability of each instrument using a visual analogue scale (VAS) from 0 (poor) to 10 (outstanding) with regard to main features such as dissection capacity, sealing, cutting, management of bleeding, handling and overall satisfaction. Twelve surgeons were equally involved in the evaluation process.

Cost analysis

Actual costs were calculated in euros as described previously[17], including operating theatre time, costs of the allocated device and for the additional instruments used for haemostasis or dissection. Briefly, device-related costs comprised a capital charge (5-year depreciation) for the generator, maintenance charges and disposals. Costs were calculated for four different centre volumes (20, 50, 100 and 200 laparoscopic colorectal resections per year) using the median values for the sum (material costs, costs for operating theatre time and for additional instruments) of each case in each group. Operating theatre costs were €7·77 per min; one red blood cell unit was €127·00. Plastic clips (Hemo-o-lok®; Teleflex® Medical, Research Triangle Park, North Carolina, USA; €4·06 for six clips)

or titan clips (Soma Medical, Feusisberg, Switzerland; €66·50 for ten clips) were used for ligation of large vessels and haemostasis. Costs were provided by the institutional accounting department and reflect the actual values for the year 2007.

Statistical analysis

Descriptive statistics are expressed as median (range). Comparison of continuous variables between the three groups was performed with the Kruskal–Wallis test. The χ^2 test was employed for comparison of categorical variables. According to the Bonferroni adjustment for three groups analysed, $P < 0{\cdot}017$ was considered to indicate statistical significance.

The sample size calculation was based both on the authors' experience with the three devices and on published findings[10,13,14]. The standard deviation for dissection time was assumed to be 45 min, and a 30-min reduction in dissection time (phases A–C) was considered to be clinically relevant. To find this difference in at least one of the groups with a level of statistical significance of 0·017 (according to the Bonferroni adjustment) and a power of 0·80, calculations included 20 patients in each group. Statistical analysis was performed using standard software package SPSS® version 14.0 (SPSS, Chicago, Illinois, USA).

Results

Between August 2005 and December 2006, 70 consecutive patients undergoing laparoscopic left-sided colectomy were evaluated. Seven patients refused to participate and two did not meet the inclusion criteria (*Fig. 1*). The remaining 61 patients (25 men), of median age 62 (range 33–84) years, were randomized to one of the three study groups. No patient was excluded subsequently.

The three groups were similar with regard to age, body mass index, sex ratio, American Society of Anesthesiologists grade, co-morbidity (as assessed by the Charlson index[18]), indication for surgery and type of operation (*Table 1*).

Operative parameters

Primary and secondary outcomes are shown in *Table 2*. The median dissection time was significantly shorter with BVS or UCS than with MES ($P < 0{\cdot}001$), due mainly to faster transection of mesenteric fat or omentum (phase C). Similarly, significantly more clips were required in the MES group than in the other two groups ($P < 0{\cdot}001$). With BVS and UCS, intraoperative blood loss was lower and less suction fluid was collected than in the MES group, although not significantly so. Relative carbon dioxide consumption was lowest in the BVS group, and frequency of lens cleaning did not differ between the groups (data not shown).

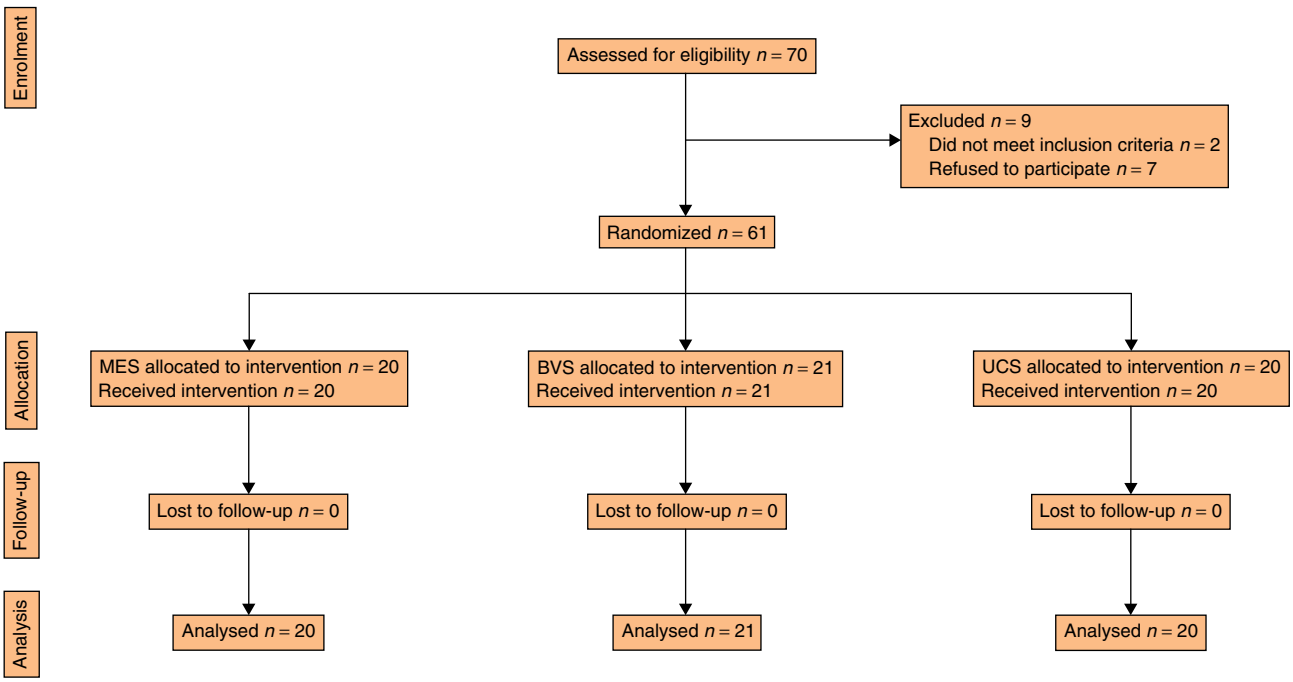

Fig. 1 Study flow chart of patients admitted for elective laparoscopic colonic surgery. MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears

Table 1 Patient demographics and surgical characteristics

	MES ($n = 20$)	BVS ($n = 21$)	UCS ($n = 20$)	P
Sex ratio (F : M)	11 : 9	9 : 12	10 : 10	0·736†
Age (years)*	62 (33–80)	62 (42–84)	60 (44–80)	0·709‡
ASA grade				0·052†
1 or 2	13	14	16	
3 or 4	7	7	4	
Charlson score[18]*	1 (0–6)	2 (0–6)	1 (0–5)	0·440‡
BMI (kg/m^2)*	26 (20–40)	26 (16–34)	26 (19–35)	0·674‡
Type of lesion				0·896†
Malignant	9	9	10	
Benign	11	12	10	
Type of resection				0·871†
Rectosigmoid	15	17	15	
Low anterior	5	4	5	
Mobilization of splenic flexure				0·926†
Yes	16	16	15	
No	4	5	5	

*Values are median (range). MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears; ASA, American Society of Anesthesiologists; BMI, body mass index. †χ^2 test; ‡Kruskal–Wallis test.

No patient received intraoperative or postoperative blood transfusions.

Complications and hospital stay

Twenty-six of the 61 patients had at least one postoperative complication (MES, ten; BVS, ten; UCS, six; $P = 0·375$) (*Table 3*). Eight patients had complications that required an intervention or stay in the intensive care unit (grade 3 and 4 according to the classification of Dindo *et al.*[16]). Two (one each with MES and BVS) were postoperative episodes of ventricular arrhythmia in patients with cardiopathy who needed Intensive care (grade 4a). The remaining six surgical complications were two anastomotic leaks (grade 3b, grade 4a) in the BVS group, one iatrogenic small bowel lesion (grade 3b) and one recurrent colovesical fistula (grade 3b) in a cachectic patient in the MES group, one stoma necrosis following a Hartmann operation (grade 3b; BVS) and one infected intra-abdominal hematoma requiring relaparoscopy (grade 3b, BVS). The overall median (range) hospital stay was 8 (3–31) days, and was similar in the three groups ($P = 0·446$).

Influence of the device on costs

The factors impacting on overall costs are shown in *Table 4*. Lower material-related costs in the MES group

Table 3 Postoperative complications and hospital stay

	MES ($n = 20$)	BVS ($n = 21$)	UCS ($n = 20$)	P
No. with complications†	10	10	6	0·375‡
Grade 1	3	4	4	
Grade 2	4	1	2	
Grade 3	2	3	0	
Grade 4	1	2	0	
Grade 5	0	0	0	
Hospital stay (days)*	8·5 (5–29)	7 (3–31)	7 (3–28)	0·446§

*Values are median (range). †According to a validated five-scale classification system[16]: grade 1, any deviation from normal postoperative course with no need for specific drugs or intervention; grade 2, requiring specific pharmacological treatment; grade 3, requiring surgical, endoscopic or radiological intervention; grade 4, life-threatening complications requiring intensive care; grade 5, death from complication. MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears. ‡χ^2 test; §Kruskal–Wallis test.

Table 2 Operative parameters related to the dissection device used

	MES ($n = 20$)	BVS ($n = 21$)	UCS ($n = 20$)	P
Dissection time (min)	137 (65–230)	105 (58–195)	90 (45–177)	< 0·001¶
Phase A	30·5 (11–110)	27 (10–95)	22 (10–80)	0·148¶
Phase B	55·5 (20–155)	42 (16–80)	38·5 (15–132)	0·205¶
Phase C	36 (14–95)	23 (6–60)	23 (10–55)	0·022¶
Instrument use (0–11)*	9·5 (1–11)	9 (6–11)	9 (8–11)	0·777¶
Other instrument used†	6	3	5	0·472#
No. of sutures or clips	9 (4–28)	0 (0–3)	3 (0–11)	< 0·001¶
Estimated blood loss (ml)	125 (0–450)	50 (0–600)	50 (0–500)	0·223¶
Haematocrit (%)‡	5·5 (0–11)	5 (0–11)	4·5 (0–11)	0·684¶
Suction fluid (ml)	425 (0–1600)	80 (0–8200)	110 (0–1400)	0·058¶
Carbon dioxide/time (l/min)§	1·18 (0–2·48)	0·54 (0–2·60)	0·99 (0·34–1·74)	0·042¶

Values are median (range). *Number of predefined operation steps (of a total of 11) performed using the allocated instrument. †Number of operations where an instrument additional to the allocated one was used. ‡Haematocrit difference (before minus postoperative day 2). §Time-related carbon dioxide consumption (surrogate parameter for smoke generation). MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears ¶Kruskal–Wallis test; #χ^2 test.

were outweighed by higher costs for longer operating time and the increased need for additional material. A comprehensive cost analysis that gives the median price per patient according to the device employed is dependent on the centre volume (*Table 4*). Colonic dissection by BVS and UCS was less expensive than with MES when a centre volume of 200 patients per year was assumed ($P = 0{\cdot}009$).

Surgeon evaluation

The subjective evaluation of the three instruments is illustrated in *Fig. 2*. Overall median satisfaction for the three instruments was equally high, as determined by VAS (MES 7·7 *versus* BVS 8·0 *versus* UCS 7·7; $P = 0{\cdot}425$). Major advantages of BVS and UCS were seen for bleeding control (MES 5·1, BVS 8·4, UCS 7·9; $P < 0{\cdot}001$) and safety aspects (6·0 *versus* 8·6 *versus* 7·8 respectively; $P < 0{\cdot}001$). Handling was assessed as a significant drawback of UCS (8·8 *versus* 7·9 *versus* 4·8; $P < 0{\cdot}001$).

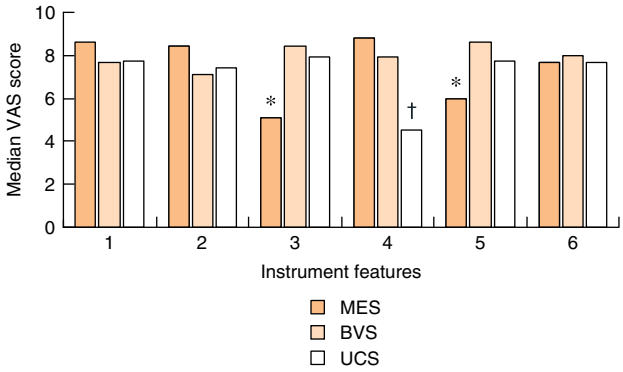

Fig. 2 Surgeon evaluation of the main features of instruments used. 1, Dissection capacity; 2, cutting ability; 3, control of bleeding; 4, handling; 5, safety aspects; 6, overall satisfaction. VAS, visual analogue scale; MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears. *$P < 0{\cdot}001$ *versus* BVS and UCS; †$P < 0{\cdot}001$ *versus* MES and BVS (Kruskal–Wallis test)

Discussion

In this prospective randomized study, the time taken to perform laparoscopic colonic dissection was significantly shorter with the BVS or UCS than with MES. This can be attributed to the type of instrument, as adherence to the surgical protocol was similarly high in all three groups. The difference in dissection time can be explained by reduced instrument traffic, lower clip application and less blood loss, as well as by the need for less rinsing and fluid suction. Another factor may be the reduced smoke production when using BVS, as deduced from a lower relative carbon dioxide consumption in this group. All three instruments can be considered to be safe, as complication rates were comparable. Finally, BVS and UCS were both cost effective.

Only a few, heterogeneous, studies of laparoscopic dissection devices in colorectal surgery have been published, making comparison with the present findings difficult. One study of only 38 patients reported reduced operating time and blood loss with BVS and UCS *versus* MES[15], but patient numbers in the three groups were different and the randomization process was not stated. Furthermore, these authors compared BVS 10 mm with UCS 5 mm, and endostaplers were used for vessel control in the UCS group whereas clips were employed in the MES and BVS groups. Two randomized studies[10,11] compared BVS alone with MES and stapler or clips respectively, and found a slightly reduced operating time for BVS as well as a lower failure rate regarding haemostasis and vessel sealing, with no significant difference in blood loss. Comparisons with the present study are not easy to make, as these studies evaluated a BVS device for open gastric resection[10] or a BVS 10-mm device in laparoscopic colectomy[11]. One larger trial of 146 patients found a shorter operating time and minimally reduced blood loss for UCS compared

Table 4 Material-related costs per patient for each device

	MES	BVS	UCS
Instrument costs according to centre volume (€)*			
20 cases/year	180	549	620
50 cases/year	180	429	499
100 cases/year	180	389	435
200 cases/year	180	369	403
Theatre time costs (€)	1045 (505–1786)	812 (450–1515)	699 (350–1375)
Additional costs (€)†	102 (4–635)	0 (0–127)	13 (0–131)

Values are median (range). *Calculated on the basis of capital charge for generator (5-year depreciation), and costs for maintenance and disposal of material. †For additional instruments, clips and blood transfusions. MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears.

Table 5 Comprehensive costs per patient for each device, analysed by centre volume

Centre volume (cases/year)	MES	BVS	UCS	*P**
20	1382 (752–2368)	1364 (999–2190)	1323 (969–2003)	0·610
50	1382 (752–2368)	1243 (880–2071)	1202 (849–1882)	0·089
100	1382 (752–2368)	1204 (840–2031)	1138 (784–1818)	0·021
200	1382 (752–2368)	1185 (820–2011)	1105 (752–1786)	0·009

Values are median (range). MES, monopolar electrosurgery scissors; BVS, electrothermal bipolar vessel sealer; UCS, ultrasonically coagulating shears in brackets. *Kruskal–Wallis test.

with MES[12]. Two cohort studies comparing BVS with UCS in laparoscopic colectomy reported a slightly reduced operating time and blood loss in the BVS group[9,13]. All of these studies showed a slight advantage for BVS or UCS compared with MES, but operations and outcome measures were not standardized.

The present authors have previously demonstrated the safety and advantages of BVS 5 mm *versus* 10 mm in a prospective randomized study[14]. In the present study, all three instruments were compared in one type of laparoscopic colectomy (left-sided). The operation was standardized and divided into specific steps, allowing a detailed analysis of the advantages and disadvantages of each instrument.

BVS and UCS are advertised by the manufacturers for their multifunctionality, secure haemostasis, small risk of collateral damage and minimal smoke production. Based on animal studies, vessel sealing with BVS is secure for up to 6–7 mm for arteries and 12 mm for veins[6,19–21]. Seal strength and failure rate (3–18 per cent) vary considerably between the available BVS products[19–21]. UCS devices effect secure sealing of vessels for up to 3–5 mm[6,20]. Thermal spread for BVS and UCS is small (2–3 mm), but should not be ignored[6,19–21]. Furthermore, ultrasonically induced injury is not visible macroscopically during surgery. Power settings and activation time should therefore be adapted when operating close to important anatomical structures, especially when using UCS[6–8]. Another advantage of BVS and UCS is the potentially reduced smoke production during dissection, as shown in a recent *in vitro* study in which the best visibility conditions were achieved with BVS[22]. This is in accordance with the present findings, although relative carbon dioxide consumption and frequency of lens cleaning are only surrogate parameters for smoke production. The authors are not aware of any other *in vivo* study that has evaluated smoke production by these devices.

Costs for operations depend mainly on operating time and material costs. Despite being expensive devices, BVS and UCS may be cost effective compared with MES, as shown in the present study. The higher material-related costs for BVS and UCS are balanced by a reduced operating time and a decreased need for additional material such as clips. Furthermore, for BVS and UCS the material-related costs per patient decrease with a higher annual caseload, whereas costs for MES (disposals alone) remain the same. With an annual caseload of more than 200 patients, BVS and UCS incur significantly lower costs than MES.

In the literature, cost analyses regarding laparoscopic devices are controversial and have been less detailed than in the present study[11,12,15]. One small study showed no differences between costs for the three devices[15], although only operating time and disposals were analysed, with no consideration of the expense of the BVS and UCS generators. Others reported a minor advantage for BVS over stapling devices, or slightly higher costs for UCS compared with MES, without considering operating time[11] or providing a detailed cost analysis[11,12]. As related costs and use of materials differ considerably between countries and even hospitals, cost analyses should be interpreted with caution.

To minimize possible bias in the study, each operation was performed in a standard manner by or under supervision of two experienced colorectal surgeons who were familiar with all three devices. The three groups were well matched by randomization and the vast majority of eligible patients were included in the study, minimizing selection bias. However, some points need consideration when interpreting the results. First, the sample size was not sufficiently large to detect or exclude minor differences in the secondary endpoints. Larger studies would be needed to evaluate differences in complication rates and hospital stay. Second, the surgeons' individual preference for one of the instruments might entail a bias concerning the subjective instrument evaluation using a VAS. However, evaluation was performed by 12 different surgeons and overall results were fairly similar for the three devices.

In conclusion, BVS and UCS are safe and shorten dissection time in laparoscopic colectomy compared with MES, due mainly to reduced instrument traffic.

They can usually be employed without the need for additional devices, and are cost effective. BVS and UCS do not differ significantly regarding dissection time and costs.

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