Randomized, comparative study between using harmonic scalpel with monopolar cautery versus cavitron ultrasonic surgical aspirator with bipolar cautery in liver resection

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Introduction
Over the last two decades, many studies have been done to assess the best technique and device for liver resection. On a trial to solve this issue, we conducted this study.
Materials and methods
Starting from January 2017, 60 patients underwent formal hepatectomies in Ain Shams University Hospitals using two different devices. A total of 30 patients with a mean age of 43 years underwent hepatectomy using cavitron ultrasonic surgical aspirator (CUSA) and the other 30 patients with a mean age of 45.53 years by using the harmonic scalpel. As for the sex, the women were more than men in the harmonic group (*n*=23 of 30) while in the CUSA group they were less (*n*=10 of 30). All patients underwent formal hepatectomies; in the CUSA group the majority had right hepatectomy (*n*=16 of 30) while in the harmonic group the majority had left hepatectomy (*n*=18 of 30).
Results
In the CUSA group, the mean operative time was 226.93 min and the resection time was 117.77 min while in the harmonic group, the mean operative time was 202.33 min and the resection time was 102.5 min. In the CUSA group, the mean amount of blood loss was 736.67 ml and the mean blood transfusion was 3.17 units of Packed red Blood Cells (PRBCs), while in the harmonic group, the mean amount of blood loss was 516.67 ml and the mean blood transfusion was 2.57 units of PRBCs.
In the CUSA group, 11 patients suffered from postoperative bleeding and seven patients had abdominal hematoma by ultrasound and four patients needed reexploration.
In the harmonic group, four patients suffered from postoperative bleeding and one patient had abdominal hematoma by ultrasound and one patient needed reexploration.
Conclusion
In our study, apart from the biliary complications, we believe that harmonic scalpel is faster and safer than the cusa. Yet another study should be conducted to assess the safety and efficacy of using both devices in combination.

Keywords:
cavitron ultrasonic surgical aspirator, harmonic scalpel, liver resection, liver surgery

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Introduction

Recent reports and consensus statements continue to discuss the safety, low morbidity, and minimal mortality rates associated with hepatic resection [1]. In part, better outcomes can be assigned to advances in the parenchymal transection techniques, which have led to a reduction in transection-related blood loss [2,3].

The mode of parenchymal transection in hepatectomy has been an issue of great debate for decades and many different technologies and techniques have been available to surgeons. Hepatic resections have now progressed from strictly open operations into laparoscopic and robot-assisted procedures [4,5].

Morbidity and mortality after hepatic resection have progressively declined over the years as a result of development of the equipment, operative technique, and anesthesia management [6,7].

The clamp–crush technique, first reported in 1974, has been used for many years and still remains the standard technique of parenchymal division for many surgeons [8].

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Many devices are now available to surgeons for division of the liver parenchyma in both open and minimally invasive surgery including: The cavitron ultrasonic surgical aspirator (CUSA) (Tyco Healthcare, Mansfield, Massachusetts, USA), harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, Ohio, USA), Ligasure (Valleylab, Tyco Healthcare, Boulder, Colorado, USA), TissueLink (Salient Surgical Technologies, Portsmouth, New Hampshire, USA), water-jet dissection, radiofrequency, microwave-assisted resection, vascular staplers, and others [9].

Still, there are no evidences to prove the ideal techniques for splitting the liver parenchyma [10].

Before 1980, the mortality rates were reported to be in the range of 10–20% and many mortalities were related to perioperative hemorrhage. Perioperative mortality has since dropped markedly to ~5% owned to the centers that are committed to excellence in liver surgery [11].

Control of intraoperative hemorrhage has been the most important technical challenge in advanced liver surgery. Excessive blood loss and intraoperative blood transfusions have been associated with increased perioperative morbidity and mortality, including an increased rate of hepatocellular carcinoma recurrence. Transfusions are also associated with high incidence of postoperative infection and with increased cost [12–14].

Materials and methods

Trial design

This prospective, randomized controlled study included 60 patients who underwent formal hepatectomy. The study population was divided into two groups according to the method of liver transection: group A (30 patients) by CUSA/bipolar diathermy combination and group B (30 patients) by harmonic scalpel (HS)/monopolar diathermy combination. The surgical procedures were held at Al Demerdash University Hospital and Ain Shams University Specialized Hospitals, the study started at January 2017, and the patients were followed up for at least 3 months.

The randomization was done by the software program (Randomizer for Clinical Trial Lite, Cairo, Egypt).

Inclusion criteria

(1) All adult patients undergoing either left or right formal hepatectomy, so that the cut surface area are nearly the same and the speed of resection can be compared.
(2) Noncirrhotic liver or in the presence of cirrhosis, the liver function was Child–Pugh class A.
(3) Elective liver resection.

Exclusion criteria

(1) Patients undergoing nonanatomical resections.
(2) Pediatric group.
(3) Child B or C cirrhotic liver.
(4) Emergency cases of liver trauma.

Outcomes

The following outcomes will be evaluated.

Early outcomes

Operative time, time of resection, intraoperative blood loss, and requirements for blood transfusion.

Late outcomes

Hospital stay, bile leakage, postoperative bleeding, reexploration, and mortality.

This study needed to be approved by the ethics committee of Ain Shams University Hospital. Informed consent was required for any patient participating in this study.

Technique

In this study, we compared using CUSA/bipolar diathermy combination versus using HS/monopolar diathermy combination in liver resection.

CUSA utilizes ultrasonic energy to fragment and aspirate the parenchymal tissue. This exposes vascular as well as biliary structures that can then be closed in a variety of ways at the surgeon's discretion. It permits a precise transection plane allowing preservation of normal liver tissue [9].

The HS uses ultrasonic vibration of two blades causing destruction of hydrogen bonds. This disruption of hydrogen bonds causes protein denaturization coagulating small blood vessels of 3–4 mm diameter. The parenchyma is also cut when the two blades move in a saw-like manner [9]. In this study, we evaluated the safety and efficacy of the two different techniques described above for resection of the hepatic parenchyma in order to improve perioperative outcomes.

Inflow occlusion was not used routinely in any of these procedures, and low central venous pressure (0–5 mmHg) was maintained by the anesthesiologist during resection.

Blood transfusion data were gathered from both the anaesthesia and medical record data. Blood loss was extracted from anaesthesia record and was calculated by adding the amount of blood in all suction containers after subtraction of all irrigating fluids and weighing surgical sponges.

Postoperative management

All patients were admitted to the ICU during the early postoperative period. Postoperative parameters of hepatic damage and recovery, including serum total bilirubin, alanine aminotransferase, aspartate transaminase, prothrombin time, and albumin were measured daily till discharge from the ICU, and then every other day after that. Also, pelviabdominal ultrasound was done at least once after 1 week or when necessary to exclude any collection.

The drain was removed when the amount was less than 100 ml/day and no bile leak or infection.

The decision to discharge from the hospital was based on the patient's general condition, clinical parameters, absence of any complication, and abdominal ultrasound.

Postoperative bile leakage was diagnosed by the following findings: detection of bile from the wound or the drain (total bilirubin level in the drain fluid >3 times that in the serum), intra-abdominal accumulation of bile confirmed by drainage, or demonstration of bile leakage on postoperative MRCP.

Postoperative bleeding and hematoma was diagnosed when there is accumulation of greater than or equal to 300 ml frank blood in the abdominal drains (confirmed by measuring hemoglobin and hematocrit in the drain fluid) or in the ultrasound, respectively.

Reexploration due to bleeding was done according to the following criteria: the patient becomes vitally unstable+continuous bleeding in the drains or expanding hematoma by ultrasound±drop of the hemoglobin level more than 3 mg/dl.

Statistical analysis

Data were collected, revised, coded, and entered to the Statistical Package for the Social Sciences (IBM SPSS) version 23. The quantitative data were presented as mean, SD, and ranges when their distribution found parametric and median with interquartile range when their distribution found nonparametric. Also qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data was done by using χ^2-test.

The comparison between two independent groups with quantitative data and parametric distribution was done by using independent *t*-test.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *P* value was considered significant at a level of less than 0.05.

Results

As regards the demographic data, there was no significant difference in the age group with the mean age in the CUSA group being 43 years and in the harmonic group 45.53 years. As for the sex, women were more than men in the harmonic group (*n*=23 of 30) while in the CUSA group they were less (*n*=10 of 30), although it is highly significant but we do not have clinical implication for this difference.

All patients underwent formal hepatectomies, in the CUSA group the majority had right hepatectomy (*n*=16 of 30) while in the harmonic group the majority had left hepatectomy (*n*=18 of 30) but the difference was insignificant (Table 1).

As regards the indication of resection, it was mainly due to hepatocellular carcinoma (10 cases in the CUSA

Table 1 Demographic data of the patients

Preoperative data	CUSA group (*n*=30)	Harmonic group (*n*=30)	Test value	*P* value	Significance
Age					
Mean±SD	43.00±8.85	45.53±8.76	−1.114•	0.270	NS
Range	33–77	40–66			
Sex [*n* (%)]					
Female	10 (33.3)	23 (76.7)	11.380*	0.001	HS
Male	20 (66.7)	7 (23.3)			
Type of hepatectomy [*n* (%)]					
Right	16 (53.3)	12 (40.0)	1.071*	0.301	NS
Left	14 (46.7)	18 (60.0)			

CUSA, cavitron ultrasonic surgical aspirator; HS, highly significant. *χ^2-test. •Independent *t*-test. *P*>0.05, non significant; *P*<0.05, significant; *P*<0.01, highly significant.

group and 11 cases in the harmonic group) but all cases were noncirrhotic and in the presence of cirrhosis, the liver function was Child–Pugh class A (Table 2).

As for the early outcome, the time of resection and overall operative time were significantly less in the harmonic group. In the CUSA group, the mean operative time was 226.93 min and the resection time was 117.77 min, while in the harmonic group, the mean operative time was 202.33 min and the resection time was 102.5 min (Fig. 1).

Also, the intraoperative blood loss and blood transfusion were in favor of the harmonic group with significantly less amount than the other group. In the CUSA group, the mean amount of blood loss was 736.67 ml and the mean blood transfusion was 3.17 units of PRBCs; while in the harmonic group, the mean amount of blood loss was 516.67 ml and the mean blood transfusion was 2.57 units of PRBCs (Table 3).

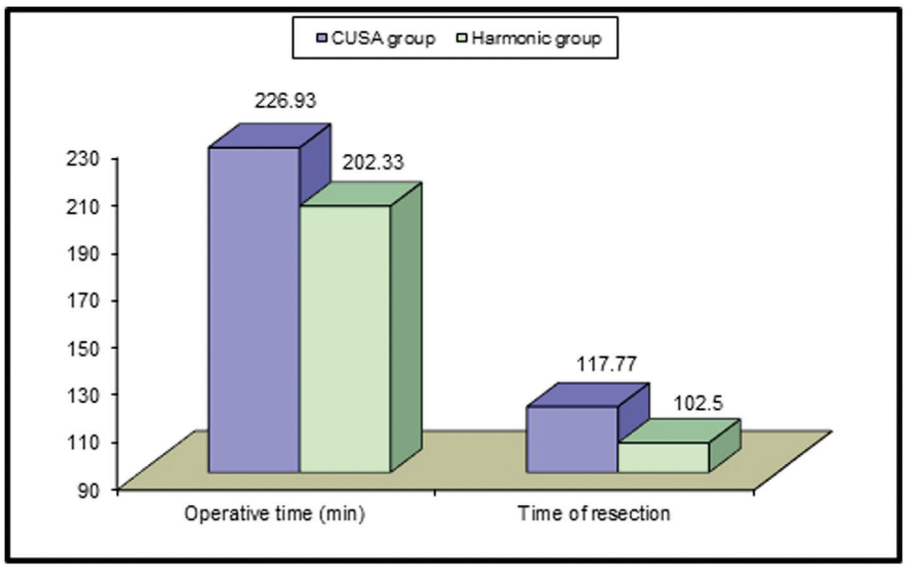
As regards the late outcome (the postoperative course), the occurrence of postoperative bleeding and

Table 2 Pathology of lesions resected in the study population

Pathology	CUSA group	Harmonic group
HCC	10	11
Adenoma	4	3
Hemangioma	8	7
Liver metastasis	6	6
Cholangiocarcinoma	2	3

CUSA, cavitron ultrasonic surgical aspirator; HCC, hepatocellular carcinoma.

Fig. 1



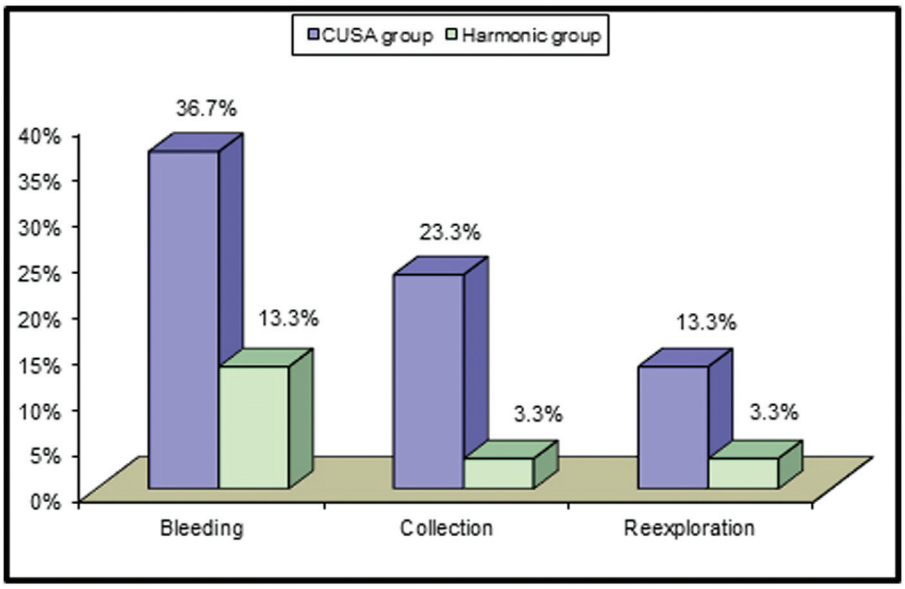
Comparison between operative time and resection time in both groups.

Table 3 Operative data

Operative	CUSA group (*n*=30)	Harmonic group (*n*=30)	Test value•	*P* value	Significance
Operative time (min)					
Mean±SD	226.93±38.68	202.33±45.31	2.262	0.027	S
Range	180–300	120–290			
Time of resection					
Mean±SD	117.77±22.25	102.50±24.31	2.537	0.014	S
Range	80–160	50–150			
Blood loss (ml)					
Mean±SD	736.67±301.13	516.67±342.49	2.642	0.011	S
Range	200–900	200–900			
Blood transfusion					
Mean±SD	3.17±0.99	2.57±0.97	2.375	0.021	S
Range	1–4	1–4			

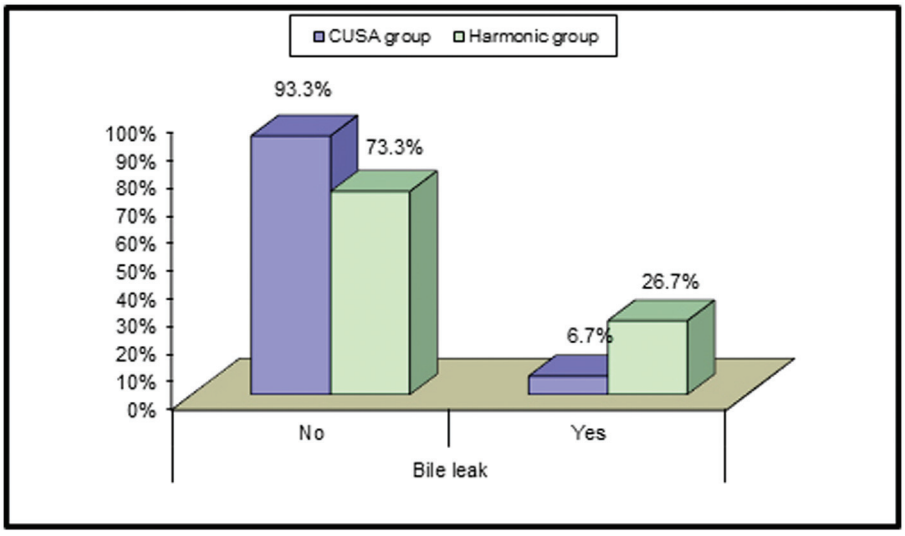
CUSA, cavitron ultrasonic surgical aspirator; S, significant. •Independent *t*-test. $P>0.05$, nonsignificant; $P<0.05$, significant; $P<0.01$, highly significant.

Fig. 2



Comparison between late outcomes in the two groups.

Fig. 3



Occurrence of bile leak.

hematoma (collection) was significantly less in the harmonic group and, in consequence, necessity of reexploration was less in this group. In the CUSA group, 11 patients suffered from postoperative bleeding and seven patients had abdominal hematoma by ultrasound and four patients needed reexploration due to bleeding, two of them in the first 24 h postoperatively and the other two were in the second day of operation. In the harmonic group, four patients suffered from postoperative bleeding and one patient had abdominal hematoma by ultrasound and one patient needed reexploration in the same day of operation (Fig. 2).

The bile leakage was significantly more in the harmonic group as it occurred in eight cases while in the CUSA group it occurred only in two cases; all cases were managed conservatively (Fig. 3).

The postoperative hospital stay was longer in the CUSA group (mean=8.5 days) while in the harmonic it was significantly shorter (mean=6.43 days).

The perioperative mortality occurred in two cases only in the whole study group, both were in the CUSA group and were related to bleeding and reexploration.

Table 4 Late outcomes in the two groups

Postoperative	CUSA group (*n*=30) [*n* (%)]	Harmonic group (*n*=30) [*n* (%)]	Test value	*P* value	Significance
Bleeding					
No	19 (63.3)	26 (86.7)	4.35*	0.037	S
Yes	11 (36.7)	4 (13.3)			
Collection					
No	23 (76.7)	29 (96.7)	5.192*	0.023	S
Yes	7 (23.3)	1 (3.3)			
Re-exploration					
No	26 (86.7)	29 (96.6)	5.455*	0.020	S
Yes	4 (13.3)	1 (3.3)			
Hospital stay (days)					
Mean±SD	8.50±3.48	6.43±1.01	3.124•	0.003	HS
Range	5–20	6–10			
Bile leak					
No	28 (93.3)	22 (73.3)	4.320*	0.038	S
Yes	2 (6.7)	8 (26.7)			
Perioperative mortality					
No	28 (93.3)	30 (100.0)	2.069*	0.150	NS
Yes	2 (6.7)	0 (0.0)			

CUSA, cavitron ultrasonic surgical aspirator; S, significant. *χ^2-test. •Independent *t*-test. $P>0.05$, nonsignificant; $P<0.05$, significant; $P<0.01$, highly significant

One of them happened 3 days after reexploration due to rebleeding and the other one 5 days after reexploration due to severe decompensation (Table 4).

Discussion

There is evident controversy concerning which of the techniques used in parenchymal resection is safest and most efficient in open and minimally invasive liver surgery. The parenchymal transection step in the operation has a great effect on intraoperative bleeding, blood transfusion, postoperative blood loss, bile leakage and survival, which is why this topic remains under scrutiny [15].

There has been a sum of randomized control trials as well as retrospective studies looking at the efficacy and safety of many techniques and technologies in hepatic resection (Table 5). Some reviews showed limited differences in postoperative outcomes [23,24]; however, in one of the randomized, controlled trials, the clamp–crush technique with continuous inflow occlusion was shown to be better than other technologies in terms of transection time, blood loss, and overall cost [25].

We decided to study which of the dissecting devices, CUSA or HS, in combination with the bipolar or monopolar diathermy, respectively, without inflow occlusion would have a benefit in terms of blood loss, blood transfusion, operative time, and resection time while decreasing postoperative complications.

Table 5 Comparison between different methods of resection in literatures

References	Patients (*n*)	Devices compared	Conclusions from study
Takayama *et al.* [16]	132	Crush clamp vs. ultrasonic dissection	No technical difference
Burdio *et al.* [17]	8	Radiofrequency-assisted device	Decreased blood loss
Lesurtel *et al.* [18]	100	Crush clamp vs. CUSA vs. hydrojet	Crush clamp was the most efficient device in terms of resection time, blood transfusion and blood loss
Torzilli *et al.* [19]	76	Monopolar floating ball (MFB) vs. bipolar forceps (BF)	MFB has no significant benefit over BF
Jagannath *et al.* [20]	NA*	Multiple instruments	No convincing evidence for the superiority of any single technique
Nanashima *et al.* [21]	33	Combination of crush clamping and vessel sealing	Safe and allows rapid completion
Gehrig *et al.* [22]	14	LigaSure vs. conventional	LigaSure is feasible and safe and may lead to reduction in cost

CUSA, cavitron ultrasonic surgical aspirator; NA, not available.

The median blood loss of 516.67 ml in the HS/monopolar diathermy group, in our study, compares favorably with other studies looking at single and two-device parenchymal resection including reports of blood loss ranging from 300 ml to greater than 1000 ml [26,27].

The decrease in blood loss in the harmonic group over the CUSA group might be explained by the fact that the HS has more coagulating properties while the CUSA has the manual ability to coagulate at the surgeon's discretion even when combined with the bipolar, still the harmonic seems to be superior in coagulation and sealing of blood vessels.

Our study's median operative time is significantly shorter in the harmonic/monopolar group as it was 202.33 min, while in CUSA/bipolar group it was 226.9 min. In a similar study that compares the usage of CUSA and harmonic but in combination with TissueLink, the median operative time in the HS and CUSA groups was 185 and 290 min, respectively [28]. Our combination of devices appears to provide comparable or faster operative times when compared with the clamp–crush technique at 259 min and the dissecting sealer alone at 264 min as previously stated by another study [15].

Our study demonstrates a statistically highly significant decrease in hospital stay in the HS group (6.43 days) compared with the CUSA group (8.5 days); however, these results compare similarly to other studies [29]. One of them, by Bodzin *et al.* [28], stated that the length of stay was shorter in the HS group as it was 6 days compared with the 7 days in the CUSA group.

The complication of bile leakage in liver resection has been always a worrisome complication and may be affected by the technique used for parenchymal transection. Literature show conflicting data regarding bile leak with the HS. Biliary fistula rates as high as 24% with the HS are reported in a study which compared with a 7% rate with the clamp–crush technique [30].

This was clearly a concern when we looked at our data; however, we demonstrated a 26.7% biliary leak rate with the HS and 6.7% in the CUSA group. This results come in contrast to the results of Bodzin *et al.* [28], which showed a 5% bile leak in the harmonic group and 11.1% in the CUSA group. Our explanation for decreased bile leak by the CUSA group is that using CUSA help in better identification of the bile ducts so that it can be securely ligated, while the harmonic coagulate them temporarily and the sealed tissues slough later on leading to bile leak.

Conclusion

In our study comparing cusa and harmonic in liver resection, the results are in favor of using HS. Apart from the biliary complications, we believe that HS is faster and safer than the cusa yet another study should be conducted to assess the safety and efficacy of using both devices in combination.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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