A clinical comparative analysis of crush/clamp, stapler, and dissecting sealer hepatic transection methods

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Abstract

Introduction. Several methods for hepatic parenchymal division exist. The primary aim was to assess differences in postoperative bile leaks, operative blood loss, and margin status between three transection methods: crush/clamp (CC), stapler (SP), or dissecting sealer (DS). *Methods*. A single institution, retrospective cohort study was performed on data collected over a three-year period in patients undergoing elective liver resection using the CC, SP, or DS. Patients were excluded if multiple methods of transection were used or for intraoperative death. The association of bile leak with transection type was assessed. A logistic regression model was tested to assess if blood loss was associated with the covariates of transection method, use of portal inflow occlusion, extent of liver resection, and other concurrent major operations. *Results*. Analyses included 141 patients. The stapler method was quicker than the other methods (p = 0.01). The risk of postoperative bile leak was no different between CC, SP, and DS transection methods (p = 0.23). There was no difference in mean blood loss or transfusions; however, hepatectomies performed with DS were associated with an increased risk of blood loss ≥ 1000 mL compared to CC (p = 0.04). There were no differences in mean surgical margin between the three methods. *Conclusion*. The risk of bile leaks was not different between the three methods. While mean blood loss was similar, hepatectomy performed with the DS was associated with an increased risk of having operative blood loss ≥ 1000 mL compared to CC. Margins were equal by all methods. The stapler method was quicker.

Key Words: hepatectomy, stapler, crush/clamp, dissecting sealer, tissue link, bile leak

Introduction

The impact of blood loss during liver transection and the need for perioperative blood transfusions have previously been shown to negatively impact perioperative morbidity and mortality as well as long-term outcomes [1–3]. Therefore, several "technological" advances over the past decades have focused on ways of decreasing blood loss during parenchymal transec-

Portions of this project were presented at the World Congress of the International Hepato Pancreato Biliary Association (27 February–2 March 2008) and the Annual Meeting of the American Hepato Pancreato Biliary Association (27–30 March 2008).

tion [4–9]. These techniques share the same objectives: rapid division of hepatic parenchyma, minimization of blood loss, sealing of bile ducts to prevent postoperative biliary leaks, and avoidance of unintended damage to adjacent structures. Each of these techniques used for the division of hepatic parenchyma comes with unique sets of advantages and disadvantages.

Postoperative bile leaks also negatively impact perioperative morbidity and mortality. And patients with bile leakage have been shown to have significantly increased intraoperative blood loss compared to patients who did not have a bile leakage [10], linking those two complications of liver resection.

(Received 3 April 2008; accepted 1 July 2008) ISSN 1365-182X print/ISSN 1477-2574 online © 2008 Informa UK Ltd. DOI: 10.1080/13651820802320040

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A limited number of trials, with few being prospective and randomized, have been performed attempting to assess outcomes using varying methods of resection, but unfortunately arriving at different conclusions [11–14].

At our institution, methods used for hepatic parenchymal division include the crush/clamp (also known as Kelly clamp, finger fracture, or digitoclasia), stapler, or dissecting sealer. The primary aim of this study was to determine if differences exist in outcomes after hepatectomies performed by crush/clamp, stapler, or the dissecting sealer method (Tissue Link). The primary outcomes of interest were that of postoperative bile leak, blood loss \geq 1000 mL, and margin status for operations performed for malignancy.

Methods

After approval was granted by the Vanderbilt Institutional Review Board, a retrospective cohort study of elective liver resections in which the crush/clamp, stapler, or dissecting sealer were utilized as the primary method of hepatic parenchymal transection was performed. To be included, resections occurred between 1 July 2002 and 30 June 2005 at Vanderbilt University Medical Center. Patients were excluded from the study if multiple methods of transection were used or if methods other than crush/clamp, stapler, or dissecting sealer were used for transection. To determine if multiple methods of transection were used, operative reports were reviewed. If any mention of more than one technique for parenchymal resection occurred, then that resection was excluded. Resections performed for trauma were excluded. Additionally, patients who expired prior to completion of the operation were excluded. Over 95% of resections were performed by one of five experienced surgeons trained in hepatobiliary surgery (n = 110) or surgical oncology (n = 25).

Data were collected using a standardized data collection sheet including patient age, sex, diagnosis, preoperative laboratory profile, method of transection, operation/s performed, use of portal inflow occlusion, total operative time, margin status if malignant disease, estimated blood loss, blood product transfusion requirement, days spent in intensive care, length of hospital stay, bile leaks, and mortality. All patient records were evaluated for 30 days postoperatively. Patients hospitalized for >30 days had follow-up extended through discharge.

For purposes of the analysis, a bile leak was defined if one of the following occurred: (1) bilious drainage into operatively placed drains for > seven days after the hepatic resection; (2) postoperative imaging demonstrating a fluid collection confirmed to be bile with percutaneous drainage; or (3) subsequent reoperation noting a bile leak. Additionally, blood loss was dichotomized into minor blood loss (<1000 mL) or major blood loss (\geq 1000 mL). Hepatic resections were considered major if \geq two Couinaud segments were resected and minor if <two Couinaud segments were resected.

The association of bile leak with transection technique was assessed with a chi-squared test. Patients who required biliary enteric reconstruction with their initial operation were not included to avoid this confounding variable (n = 13). A multiple logistic regression model assessed the association of blood loss $\geq 1000 \text{ mL}$ (the outcome parameter of interest) with the covariates transection technique, extent of hepatic resection, presence or absence portal inflow occlusion, and the presence or absence of other concurrent major operations. The Kruskal-Wallis test was used to determine if differences in margin status existed between the three transection techniques in hepatic resections performed for malignant disease. For purposes of analyses, the crush/clamp group was considered the reference group. Demographic data were analyzed with one-way analysis of variance (and post hoc comparisons when the Fstatistic was significant) and the chi-square test of proportions. Power was calculated post hoc on the basis of the observed sample sizes in each group. Data were analyzed using the Statistical Package for the Social Sciences 14.0 (SPSS, Inc., Chicago, IL) with an alpha level of < 0.05 taken as statistically significant. Summary data are presented throughout as mean + standard deviation or percentages.

Results

There were 190 patients who underwent a first time hepatic resection over the course of the study time period at our institution, 141 of whom met inclusion criteria. The reasons for exclusion were as follows: multiple methods of transection (n=25), other method of resection (n=21), trauma (n=3), or intraoperative death (n = 2; both from cardiac causes). There were 51 resections performed with crush/ clamp, 66 with stapler, and 24 with dissecting sealer. The mean age of the cohort was 57 + 14 years. The cohort was comprised of 52% males and 74% of hepatic resections were for malignant disease. No patients with Child-Pugh class B or C cirrhosis underwent a resection. Between the three groups, there were no statistically significant differences in preoperative patient demographics which are summarized in Table I. For the comparisons of means and proportions, power was adequate (≥ 0.80 at the 0.05 alpha level) to detect moderate effects (about 0.5 SD or 25 percentage points) between the stapler and crush/clamp and large effects (about 0.7 SD or 30 percentage points) between the dissecting sealer and crush/clamp groups. Power was ≥ 0.80 to detect a moderate overall effect of the multivariate model (analogous to R = 0.30).

Operative and postoperative variables are summarized in Table II. There were no statistically significant

Table I. Patient demographics.

Variable	Crush/clamp	Stapler	Dissecting sealer	<i>P</i> -value
N	51	66	24	
Age	56 ± 15	57 ± 13	60 ± 14	0.51
Male (%)	51%	55%	46%	0.76
Malignant (%)	69%	79%	71%	0.44
Creatinine	0.8 ± 0.2	0.9 ± 0.2	0.9 ± 0.3	0.29
T Bili	1.0 ± 2.5	0.5 ± 0.4	0.5 ± 0.3	0.21
ALP	135 ± 121	135 ± 99	123 ± 74	0.90
ALT	40 ± 32	36 ± 24	30 ± 20	0.35
AST	45 ± 44	37 ± 28	32 ± 28	0.33
INR	1 ± 0.1	1 ± 0.1	1 ± 0.1	0.14

Note: T Bili, total bilirubin; ALP, alkaline phosphatase; ALT, serum alanine transferase; AST, serum aspirate transferase; INR, international normalized ratio. Data are presented as mean \pm standard deviation or percentages.

differences in mean blood loss (p = 0.19), operative blood transfusion requirement (p = 0.47), length of ICU stay (p = 0.22), length of hospitalization (p =0.60), or in-hospital/30-day mortality (p = 0.85) between the three transection types. There were, however, significant differences in the proportions of major hepatic operations (p < 0.01), other major simultaneous operations (p=0.01), utilization of portal inflow occlusion (p < 0.01), and the proportions of patients who lost at least 1000 mL of blood (p=0.03). An overall difference existed in the mean operative time (p < 0.01). Post hoc comparisons revealed the stapler was quicker than both crush/ clamp (p = 0.01) and dissecting sealer (p = 0.02). The other major simultaneous operations that were performed are outlined in Table III.

Bile leaks occurred in two patients who underwent the crush/clamp technique, one patient who underwent stapler hepatectomy, and 0 patient who underwent transection with the dissecting sealer. The difference in the proportions of bile leaks between the three groups was not statistically significant (p=0.23).

The results of the logistic regression model (model p < 0.01) testing the association between blood loss ≥ 1000 mL and transection method, portal inflow occlusion, extent of hepatic resection, and synchro-

nous other major operations are summarized in Table IV. Hepatic resections performed with the dissecting sealer device were found to have an increased association with operative blood loss ≥ 1000 mL (OR = 3.09; 95% CI = 1.03–9.24; p = 0.04). There was no difference between the crush/ clamp and stapler techniques (p = 0.18). The need for portal inflow occlusion was associated with major blood loss (OR = 3.53; 95% CI = 1.55–8.06; p = 0.03). Major hepatic resections (p = 0.21) and other major synchronous operations (p = 0.30) were not associated with an increased association with blood loss ≥ 1000 mL.

The mean surgical margin for patients undergoing hepatic resection for malignant disease was 1.1 ± 1.1 cm. The difference in margin status between the three transection methods (crush/clamp 1.0 ± 1.0 cm; stapler 1.2 ± 1.2 cm; dissecting sealer 1.0 ± 1.2 cm) was not statistically significant (p = 0.90).

Discussion

There have been only a handful of prospective, randomized comparisons of methods of hepatic transection and the results have varied. In a prospective randomized trial comparing four transection methods, Lesurtel and colleagues found the crush/

Variable	Crush/clamp	Stapler	Dissecting sealer	P-value
Major liver resections	39%	89%	58%	< 0.01
Other major operation	47%	24%	21%	0.01
Portal inflow occlusion	29%	61%	42%	< 0.01
Operative time (min)	$259 \pm 122^{\rm a}$	$204 \pm 113^{\rm b}$	$264\pm76^{\circ}$	0.01*
Blood loss (mL)	840 ± 1261	901 ± 1192	1413 ± 1656	0.19
Blood loss $\geq 1000 \text{ mL}$	28%	26%	55%	0.03
Blood transfusions	29%	20%	25%	0.47
ICU days	1 ± 2	2 ± 7	1 ± 1	0.22
Hospital days	6+5	7 + 7	5+2	0.60

Table II. Operative and postoperative variables.

Note: ICU, intensive care unit. Data are presented as mean \pm standard deviation or percentages. *Post hoc comparisons were statistically significant (p < 0.05) for a vs. b and b vs. c, but not a vs. c.

Table III. Other major simultaneous operations performed during the liver resections.

Operation	Ν
Roux-en-Y hepaticojejunostomy	13
Common bile duct exploration/resection	11
Nephrectomy	10
Major lymphadenctomy	9
Hemicolectomy	8
Diaphragmatic resection/herniorraphy	7
Abdominal/chest wall resection	5
Adrenalectomy	3
Enterectomy	3
Hysterectomy	2
Inferior vena cava thrombectomy	2
Retroperitoneal mass resection	2
Splenectomy	2
Choledochoduodenostomy	1
Distal pancreatectomy	1
Enterocutaneous fistula takedown	1
Pulmonary resection	1
Ureteroureterostomy	1
None	97

Note: The total of these operations were performed in 44 patients.

clamp technique was faster, had less blood loss, and lower postoperative blood transfusions than either ultrasonic dissection, hydrojet, or the dissecting sealer [12]. However, in this study, the crush/clamp technique was always performed under portal inflow occlusion whereas the other techniques were not thus potentially biasing the blood loss and transfusion outcome measures. There were no differences in the postoperative morbidity between groups, including bilomas requiring external drainage. This same study found that the crush/clamp technique was the least expensive. Our study concurs with this study in two ways. First, we found that hepatic resections performed with the dissecting sealer were more likely to have blood loss ≥ 1000 mL than those performed with the crush/clamp technique. Second, our study found no difference in postoperative bile leaks between the crush/clamp and dissecting sealer techniques.

Another study, performed by Takayama and colleagues, found no difference in blood loss or transec-

Table IV. Logistic regression testing the association between blood loss \geq 1000 mL and method of hepatic transection.

Variable	Odds ratio	95% CI	P-value
Resection method			0.01
SP vs. CC	0.51	0.19-1.37	0.18
DS vs. CC	3.09	1.03-9.24	0.04
Major resection	1.89	0.70-5.10	0.21
Other major operation	1.62	0.65-4.01	0.30
Portal inflow occlusion	3.53	1.55-8.06	0.03

Note: CI, confidence interval; SP, stapler; CC, crush/clamp; DS, dissecting sealer.

tion speed between the crush/clamp technique and ultrasonic dissection [14]. This same study also demonstrated that the crush/clamp technique resulted in increased precision and improved quality of hepatectomy according to a grading system considering such factors as positive surgical margins, appearance of landmark hepatic veins on the cut hepatic surface, and postoperative morbidity. Koo and colleagues also demonstrated that no difference existed with blood loss, transfusion requirements, speed of resection, or total operative time between crush/clamp and the ultrasonic dissector [11]. Radiofrequency-assisted hepatic transection has also been studied in a randomized, controlled fashion. The results of this study indicated that postoperative morbidity, including abscesses and biliary complications, was significantly higher with the use of radiofrequency-assisted resection compared to crush/clamp [15].

In a retrospective review, Fan and colleagues determined that ultrasonic dissection resulted in less blood loss and transfusion requirement, in-hospital morbidity and mortality, and improved tumor free margin when compared to the crush/clamp technique [16]. Another retrospective study found that the crush/clamp technique was associated with the least amount of bile leaks and shorter hospital stays when compared to ultrasonic dissection or microwave tissue coagulation [17]. In another retrospective review the crush/clamp technique, although faster, was associated with more blood loss, bile leaks, and intraabdominal fluid collections than the ultrasonic dissector [18].

One retrospective study showed a postoperative bile leak rate of 8% when the stapler was employed [19]. In another study, the surgical stapler was also associated with a high rate of bile leak at 13% [6]. Thus the stapling technique may have an increased association with postoperative bile leaks. However, in our study, this was not the case. Our rate of bile leaks after parenchymal transection with staplers in patients not undergoing biliary enteric reconstruction was 1.6%.

Two small, descriptive studies of the dissecting sealer during hepatic resection both showed there to be a relatively minor amount of blood loss (100–150 mL) with no postoperative bile leaks [20,21]. Our results are similar to these studies with the lack of bile leaks; however, we experienced a much greater mean blood loss in our series. Of the 19 combined patients in the series mentioned above, only six underwent major hepatic resections. In our series, 10 of the 24 resections using the dissecting sealer were performed during major hepatic resections. In addition, five of the 24 patients underwent other major simultaneous operations.

There are limitations with this study. There are several potential confounding variables such as when other major simultaneous procedures are performed that could bias the data. We attempted to neutralize

these by adjusting for these variables with our statistical methods. Transection speed between the three groups cannot be directly assessed. However, there were statistically significant differences between the groups in mean total operative time that appeared to favor hepatectomies performed with staplers, which is only a surrogate for transection speed. There was no information available in the medical chart noting the actual time of hepatic transection so adjusting for the area of hepatic resection was not possible. Additionally, there may be a selection bias in the method of transection performed based on tumor size, location, and its proximity to major blood vessels and/or biliary structures with individual cases and with surgeon preference. Unfortunately, the information available in the medical chart with regards to the usage, type, and/or completion of chemotherapy in patients with malignant disease was incomplete, thus potentially biasing the data if one of the methods was performed more frequently in patients with this preoperative factor. This lack of information can make it quite difficult to ascertain if the groups being compared are truly comparable. Finally, not all patients had closed suction drains placed at the time of operation. This could bias the results leading to an underestimation of our bile leak rate; however, these would likely be small, clinically insignificant bile leaks.

Another potential limitation of this retrospective study is that of our group sample sizes were determined on the basis of the number of available cases in each transection group, which necessitated that power be calculated post hoc. For the between groups comparisons of means and proportions, power was adequate (≥ 0.80) to detect moderate effects for the stapler versus crush/clamp comparisons and large effects for the dissecting sealer versus crush/clamp techniques. In the multivariate regression model a moderate overall effect could be detected. However, it is important to note that in the multivariate model we found that patients who underwent a hepatectomy with the dissecting sealer (the smallest group) had significantly higher major blood loss in comparison to the crush clamp group.

Another potential confounding variable is that of technicians, not technique. None of the five main surgeons stayed exclusive to any one technique. Furthermore, individual surgeons were compared (data not shown) and there were no major statistical differences when comparing surgeons by technique.

In conclusion, we found there to be no differences in the proportions of patients having postoperative bile leaks between the three transection methods. We did find the dissecting sealer transection method to be associated with a higher likelihood of having blood loss ≥ 1000 mL than the crush/clamp method. There are many effective operative techniques available for surgeons to perform hepatic transections, each with specific advantages and/or disadvantages. Ultimately, the choice of resection technique is operator dependent, depends on patient circumstance, and subject to the resources available at individual institutions. However, we agree with Lesurtel et al. [12], it is likely that the crush/clamp under inflow occlusion technique offers similar or improved blood loss and results in similar postoperative bile leaks as the other more technologically advanced methods. Furthermore, the crush/clamp technique requires only basic surgical instrumentation and is likely the most costeffective. Therefore this technique should be familiar to all surgeons performing hepatic resections. However, we identified that surgical staplers were associated with less total operative time. Only a prospective, randomized trial in which hepatic transection time is addressed would be able to determine if staplers truly are faster than the crush/clamp technique and at what number of stapler loads would the potential time saved in the operating room curb any cost benefits.

Acknowledgements and disclosures

This project was supported in part by an educational grant from Novartis Pharmaceuticals, Inc.

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