The Safety of Epidural Analgesia for Open Hepatectomy-will Epidural Hematoma Occur? A Retrospective Study

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Objective: *To study the safety of the epidural analgesia technique among patients undergoing open hepatectomy.*
Material and Method: *A retrospective review of all medical records of patients who had undergone open liver surgery was done, using ICD-9-CM procedure code numbers to search from January 2010 to December 2015. The patient demographic data, preoperative and postoperative liver enzymes and coagulation function, size and weight of portion of the liver were collected and analyzed.*
Results: *From 2010 to 2015, 1,047 medical records were consecutively recruited. After following the exclusion criteria, 632 patients undergoing major hepatectomy for liver diseases per se and who were administered continuous epidural analgesia were eligible for analysis. According to the records, no epidural hematoma occurred [0/632 = 0%, 95% confidence interval 0 to 0.6%], even when the postoperative liver functions were abnormal. High prothrombin time (PT), high activated partial thromboplast in time (aPTT), low albumin level, high aspartate aminotransferase level, high alanine aminotransferase level, and thrombocytopenia were found in 90.5%, 46.2%, 86.8%, 86.3%, 92.4%, and 28.3% of laboratory-requested cases, respectively. A fair degree of relationship between either the portion of the liver size or weight and the PT abnormality was found, but there was little or no relationship with a PTT abnormality.*
Conclusion: *Major hepatectomy can cause abnormal liver function, especially coagulopathy, which may be associated with epidural hematoma after epidural catheter manipulation. However, the present study showed that epidural hematoma did not occur among those patients with epidural analgesia who developed coagulopathy after liver resection. The authors concluded that epidural analgesia may be safe for patients undergoing major hepatectomy who had normal, or even slightly abnormal, preoperative coagulogram.*

Keywords: *Epidural analgesia, Epidural hematoma, Hepatectomy, Coagulopathy*

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Partial hepatic resection, or hepatectomy, is a major procedure to treat primary liver mass or hepatic metastases. For patients who develop liver cancers, hepatectomy is considered for those with non-cirrhotic or Child-Turcotte-Pugh class A cirrhosis with preserved liver function and no portal hypertension[1]. Procedure-related morbidity and mortality has dropped significantly, partly due to the overall advances in surgical and anesthetic techniques. After hepatectomy, liver function tests may change and vary with the postoperative time interval, and they relate to the extent of hepatic resection[2,3].

Open hepatectomy is a major surgery that may cause severe postoperative pain. There are several postoperative analgesia measures to relieve patients' suffering, such as continuous or intermittent epidural analgesia, intrathecal analgesia, continuous intravenous infusion, intermittent intravenous injection or patient-controlled analgesia (PCA)[1,4,5]. An epidural analgesia is one of the most effective techniques to treat pain, but there are some issues about the safety of this technique, especially regarding epidural hematoma. This is because the coagulation profile may worsen after hepatectomy, and epidural hematoma could happen after epidural catheter manipulation[3,6,7]. Therefore, the issue of the safety of the epidural analgesia technique for patients undergoing hepatectomy is still controversial[4,8-10]. Some institutes prefer to avoid epidural analgesia in all such cases. At Siriraj Hospital, an epidural analgesia was used in most of the cases that had no, or minor, initial coagulopathy, or that had thrombocytopenia, because this technique provides effective pain control and enhances recovery[1,11-14].

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The primary objective of the present study is to evaluate the safety of epidural analgesia in patients undergoing major hepatectomy.

Material and Method

After approval by Siriraj Institutional Review Board (Si 180/2015), the authors conducted a retrospective study to search the medical records, using ICD-9-CM procedure code numbers, for all types of open liver surgeries at Siriraj Hospital, Mahidol University. The inclusion criteria were patients of any age and any ASA physical status classification, who had undergone open liver surgery. The exclusion criterion was any record which lacked important data. The authors started a recruitment of records consecutively from December 31, 2015 back to January 2010.

The authors found a total of 1,047 records during the six-year period. No record lacked important data. All medical records were then reviewed in detail, and it was found that some records were not relevant, i.e., the primary diagnoses were not related to liver diseases, and some were just a minor procedure. Then, more exclusion criteria were added later, including surgeries other than open major hepatectomy (ICD-9-CM codes 50.22 for partial hepatectomy, and 50.3 for liver lobectomy), and diagnoses for surgery that were other than liver mass, hepatocellular carcinoma and hepatic metastases.

All patients received general anesthesia with endotracheal intubation, with or without an epidural block. They received standard monitoring and large intravenous access. Some patients had a central venous line placed for better intravenous access, and some had a radial arterial catheter placed for intraoperative hemodynamic monitoring. For those who underwent an epidural block, a thoracic epidural block was performed before induction of the anesthesia, with or without mild sedation during the block. A Tuohy needle 16G was used, and an epidural catheter 19G or 16G (depending on availability) was inserted by staff anesthesiologists or residents (depending on daily assignments). The initial "test dose" of 2% lidocaine with epinephrine 1: 200,000 3 mL was given to exclude intravascular injection. Not all anesthesiologists checked the analgesic level before commencing the induction of the general anesthesia and intubation. When vital signs were stable intraoperatively, the epidural analgesia was started with titration to effect. The epidural morphine administration and the concentration of the epidural solutions for infusion were varied at the discretion of the attending anesthesiologist.

If any patients complained of pain after the operation, the epidural analgesia was tested. If it was found that the epidural block had not worked, the epidural catheter was removed and changed to another proper technique for each patient (for example, intravenous patient-controlled analgesia (IV-PCA), continuous intravenous analgesia, or intermittent intravenous analgesic as needed (IV-PRN) with multimodal analgesia, and there was considered to be a primary failure of the epidural analgesia if it occurred within 12 hours postoperation. If the epidural block worked well, continuous epidural analgesia would be delivered using 0.0625% bupivacaine combined with morphine 0.02 mg/mL until pain was resolved, usually within 3 days, and then the epidural catheter was removed by the Acute Pain Service (APS). Patients were taken care of daily by the APS team. Any complications from the epidural catheter were observed. As the epidural block was a major relevant factor, patients not receiving a thoracic epidural block for postoperative analgesia, or who had primary failure of the thoracic epidural analgesia (defined as epidural catheter removal within 12 hours, postoperatively) were then also excluded.

As the safety concern of epidural analgesia is epidural hematoma, and it is known that epidural hematoma after an epidural block rarely occurs[15], the authors considered that the sample size calculation was not feasible and decided to use a consecutive recruitment of cases over a six-year period. Demographic data (age, gender, body weight, height, ASA physical status, portion of liver removed, anesthesia time, operative time) and perioperative data (estimated blood loss, intraoperative blood/blood component and fluid management, the size and weight of the resected portion and the number of the postoperative day on which the epidural catheter was removed); preoperative and postoperative liver function tests (serum albumin [Alb], serum aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) and coagulation function tests (prothrombin time [PT] and activated partial thromboplast in time [aPTT]); blood component replacement on the ward; and the incidence of epidural hematoma (clinically) were collected. The authors collected preoperative liver and coagulation function tests available within seven days before surgery, and $\pm$3 days from the day that the epidural catheters were removed. In the case of patients receiving platelet concentration or fresh frozen plasma

(FFP) transfusion intraoperatively or postoperatively, the platelet count or PT and aPTT were not collected because they might have interfered with the data analysis.

Statistical analysis

Patients' data were recorded in a Microsoft Excel spreadsheet and analyzed using PASW Statistics for Windows, 18.0 Chicago: SPSS Inc. All results are presented as percentages for categorical variables, mean ± standard deviation (SD), and median [min, max] for continuous variables. The authors used the Wilson score interval to calculate the confidence interval (CI) for proportions to estimate in a statistical sample and to allow for sampling error[16]. To analyze the relationship between either the liver resection size or weight and the PT and aPTT abnormality, the authors used Spearman's correlation[17]. All tests were two-tailed, and results with a *p*-value of <0.05 were considered to be statistically significant.

Results

At Siriraj Hospital during the six-year period, an epidural block was performed on 683 out of 898 patients (76.1%) undergoing open major hepatectomy. There were many reasons for not doing the epidural block. The most frequent one was preexisting coagulopathy. Primary failure of thoracic block occurred in 51 out of 683 patients (7.5%).

A total of 632 patients were eligible for analysis. The demographic and perioperative data are shown at Table 1.

Two-thirds of the cases (65.2%) underwent a partial hepatectomy, with an average operative time and anesthesia time (mean ± SD) of 3.2±1.5 hours and 4.2±1.5 hours, respectively. Most of the patients (66.5%) were ASA physical status 2. The estimated blood loss was 867.4±943.2 mL. Intraoperatively, 23.9%, 5.5% and 1.3% of patients required packed red cells, FFP and platelet concentrate transfusion, respectively. The average liver resection weight (mean ± SD) [min, max] was 350.0±411.3 [0.4 to 3,120] g.

Based on the 632 records, no incidence of epidural hematoma occurred [0/632 = 0%, 95% CI 0 to 0.6%]. The average postoperative day (POD) of epidural catheter removal was 2.5±0.8. A platelet concentrate transfusion was required postoperatively by two patients (0.3%). Fresh frozen plasma was transfused

Table 1. Demographic and perioperative data of patients

Characteristics	Values (n = 632)	Missing
Age (years)	57.1±13.7	0
Gender (male:female)	390:242 (61.7:38.3)	0
Body mass index (kg/m^2)	23.5±3.8	1 (0.2)
ASA physical status I:II:III	70:420:142 (11.1:66.4:22.5)	0
Liver lobectomy:partial hepatectomy	220:412 (34.8:65.2)	0
Anesthesia time (hours)	4.2±1.5	0
Operative time (hours)	3.2±1.5	0
Intraoperative		
Estimated blood loss (mL)	867.4±943.2	1 (0.2)
PRC transfusion (n; mL)	151 (23.9); 0 [0, 3,029]	1 (0.2)
FFP transfusion (n; mL)	35 (5.5); 0 [0, 2,636]	1 (0.2)
Platelet concentrate transfusion (n; mL)	8 (1.3); 0 [0, 480]	1 (0.2)
Colloid infusion (n; mL)	269 (42.6); 0 [0, 3,000]	1 (0.2)
Crystalloid infusion (mL)	2553.3±1465.7	1 (0.2)
Postoperative FFP transfusion (n)	19 (3.0)	0
FFP transfusion before epidural catheter removal (n)	2 (0.3)	0
Postoperative platelet concentrate transfusion (n)	2 (0.3)	0
Liver resection size estimated (cm^3)	770.3±988.7	3 (0.5)
Liver resection weight (g)	350.0±411.3	46 (7.3)
Day of epidural catheter removal (POD)	2.5±0.8	2 (0.3)

Values are mean ± SD; number (%) or median [min, max]
ASA = American Society of Anesthesiologists; PRC = packed red cells; FFP = fresh frozen plasma; POD = postoperative day

postoperatively in the case of 19 patients (3.0%); two of these (0.3%) received the transfusion before the removal of the epidural catheter because of ongoing coagulopathy. The PT values of the first and the second ones were 20.4 sec and 26.3 sec, respectively (normal values: 10 to 13 sec), whereas the aPTT values were 37.9 sec and 38.1 sec, respectively (normal values: 23 to 30 sec).

The laboratory parameters are summarized at Table 2. In the preoperative period, 35.8% of patients had some degree of anemia (hematocrit <37%), 16% had thrombocytopenia (platelet count <150x10^3/mcL), 9.9% had low albumin level (<3.5 g/dL), 34.4% had high AST level (>37 U/L), 24.5% had high ALT level (>40 U/L), 27.8% had prolonged PT (>13 sec), and 11.4% had prolonged aPTT (>30 sec). These patients had just slightly abnormal laboratory values as the mean ± SD of the preoperative laboratory results were within normal limits.

The postoperative laboratory tests were not investigated routinely, but only when there were clinical indications. During the postoperative period, 81.7% of those who were investigated had anemia, 28.3% had thrombocytopenia, 86.8% had decreased albumin level, 86.3% had increased AST level, 92.4% had increased ALT level, 90.5% had prolonged PT, and 46.2% had prolonged aPTT. The authors calculated the PT and aPTT abnormalities using the absolute difference between the postoperative and preoperative values of each patient. The PT and aPTT differences were 4.7±3.9

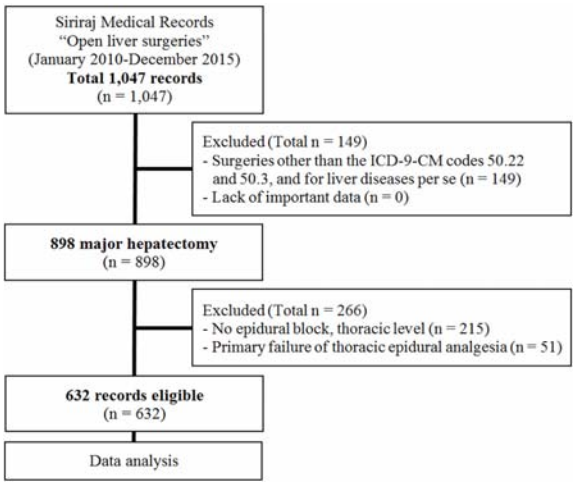

Fig. 1 CONSORT flow diagram.

Table 2. Preoperative and postoperative laboratory parameter data

Characteristics	Values (n = 632)	No. of patients having abnormal values	Missing
Pre-operative			
Hematocrit (%)	38.4±5.1	226/631 (35.8)	1 (0.2)
Platelet count (x10^3/mcL)	244.4±102.2	101/631 (16.0)	1 (0.2)
Albumin (g/dL)	4.05±0.44	62/628 (9.9)	4 (0.6)
Serum aspartate aminotransferase (AST) (U/L)	38.4±28.1	216/628 (34.4)	4 (0.6)
Serum alanine aminotransferase (ALT) (U/L)	34.3±29.8	154/628 (24.5)	4 (0.6)
Prothrombin time (PT) (sec)	12.6±1.2	171/615 (27.8)	17 (2.7)
Activated partial thromboplastin time (aPTT) (sec)	27.0±2.8	70/614 (11.4)	18 (2.8)
Postoperative*			
Hematocrit (%)	31.6±5.5	125/153 (81.7)	
Platelet count (x10^3/mcL)	214.0±109.8	71/251 (28.3)	
Albumin (g/dL)	2.9±0.5	190/219 (86.8)	
Serum aspartate aminotransferase (AST) (U/L)	170.5±230.0	182/211 (86.3)	
Serum alanine aminotransferase (ALT) (U/L)	204.1±208.4	195/211 (92.4)	
Prothrombin time (PT) (sec)	17.5±4.2	134/148 (90.5)	
Activated partial thromboplastin time (aPTT) (sec)	30.2±6.3	66/143 (46.2)	
Difference (Postoperative – Preoperative values)			
PT difference (sec)	4.7±3.9		484 (77)
aPTT difference (sec)	2.8±6.1		484 (77)

* Excluded patients who had received perioperative transfusion of each lab-related blood component, values are mean ± SD, number/total number (%) or number (%)

Table 3. Correlation coefficients between liver resection amount and PT or aPTT differences (postoperative-preoperative)

	Correlation coefficient	
	Liver resection size	Liver resection weight
PT difference	0.41	0.43
aPTT difference	0.14	0.08

>0.25 to 0.5 = fair degree of linear relationship; >0.5 to 0.75 = moderately strong linear relationship; >0.75 = very strong linear relationship; 1.00 = perfect linear relationship/deterministic relationship

sec, and 2.8±6.1 sec, respectively.

The authors examined the correlations between the liver resection size, the liver resection weight and the coagulation function abnormality. A fair degree of relationship between either the liver resection size or weight and the PT abnormality was found, but little or no relationship with aPTT abnormality. The data are shown at Table 3 and Fig. 2. No patients received perioperative heparin or anticoagulants for venous thromboembolism (VTE) prophylaxis.

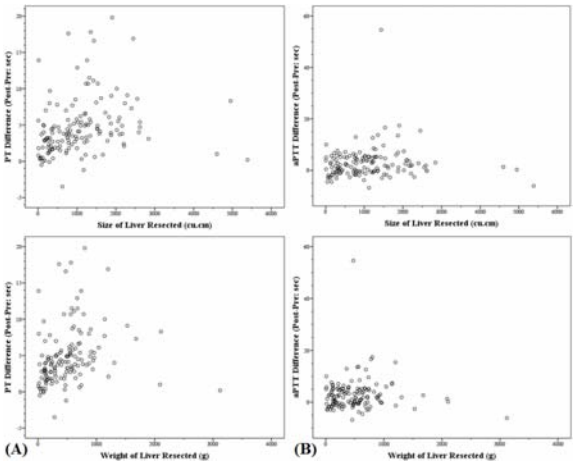

Fig. 2 Graphs show correlations between size and weight of liver tissue removal and PT difference (A), and aPTT difference (B).

Discussion

The authors found that the incidence of epidural hematoma from this study was zero, with a 95% CI of 0 to 0.6%. The upper limit of 0.6% means that it could occur in six out of 1,000 cases, and the higher the number of cases recruited, the lower the upper limit would be.

The extent of hepatic resection could affect liver function tests[2,3], but the present study found that the size of the portion of the liver removed could not predict PT or aPTT abnormality after operation. Postoperative coagulopathy after liver resection is a phenomenon resulting from the combination of transient hepatic synthetic insufficiency, blood loss and coagulation factors consumption[18]. The typical changes after hepatectomy are transient prolonged PT and a decreased platelet count. Several studies have shown the same results[3,6,7,18-22]. Because of this phenomenon, the issue of the use of epidural anesthesia and analgesia in patients undergoing hepatectomy has been much debated in many countries, and may be a reason for avoiding placement of an epidural catheter by some institutes.

At Siriraj Hospital, the anesthesiologists would rather provide epidural analgesia for open major hepatectomy in those cases where the patients' preoperative laboratory results were within normal limits or slightly abnormal; this is because epidural analgesia can manage postoperative pain effectively, and patients can return to their normal daily life very quickly. Among those patients in this study whose laboratory tests were requested postoperatively, the incidence of abnormality included (1) high ALT level in 92.4% of patients, (2) prolonged PT in 90.5%, (3) low albumin level in 86.8%, (4) high AST level in 86.3%, (5) prolonged aPTT in 46.2%, and (6) thrombocytopenia in 28.3%. Although the PT and aPTT values were prolonged, most of the epidural catheters could be removed without any clinical signs suggestive of epidural hematoma. Nevertheless, other studies found that epidural catheter removal was delayed because of prolonged PT, so it increased the risk of catheter-related infection and the risk of infection from FFP transfusion[6,23].

Barton et al. concluded in their study that patients undergoing partial hepatectomy showed a short period of hypercoagulable state, followed by normal coagulation function monitored by thromboelastography (TEG), despite a prolonged PT

and INR. Hence, PT-INR should not be used to guide the decision to correct coagulopathy, whereas TEG better characterized functional coagulation among postoperative hepatectomy patients[24]. From their study, it may not be proper to use the PT value as a guide to whether to give an FFP transfusion before removal of the epidural catheter, or to make the decision whether it was safe to remove the epidural catheter or not, but TEG may be more useful. This needs further study.

In the present study, the authors found that the laboratory tests were usually requested according to the clinical findings, rather than done routinely. When ever any abnormalities occurred, they were corrected every time. Of the 19 patients who received an FFP transfusion, only two patients had an APS-requested coagulogram and FFP transfusion before removal of the epidural catheter because they were still receiving treatment for coagulopathy. Although many epidural catheters were removed on a day when no laboratory test was requested, no clinical hematoma occurred.

One limitation of this retrospective study was that there were many missing laboratory values because blood sampling was not done routinely after hepatectomy. Consequently, there was no serial laboratory parameter assessment available for study. The surgeons requested them only when clinical signs suggested the need. However, the authors considered this to be a practical and cost-effective practice.

How much the blood component transfusion affected the laboratory results is not known, as is whether it might have interfered with the data analysis; the authors therefore did not include in the analysis any of the laboratory data of those patients who received platelet concentrate or an FFP transfusion intraoperatively or postoperatively. This may be another limitation of the results. In any future study, a prospective controlled analysis of hepatectomy should be performed, and better laboratory results may require serial laboratory requests if changes of the liver function and platelets are to be seen. The use of TEG compared with PT to determine the safety of epidural catheter removal should also be studied.

Conclusion

Major hepatectomy-caused abnormality of liver function, especially coagulopathy, may be associated with epidural hematoma after insertion or removal of the epidural catheter. The present study showed that even in patients with abnormal coagulation function after liver resection, epidural hematoma did not occur. The epidural analgesia technique may be safe for those patients undergoing open hepatectomy for whom preoperative laboratory test results were within normal limits or only slightly abnormal.

What is already known on this topic?

Major hepatectomy can cause abnormal coagulogram which may be associated with epidural hematoma after insertion or removal of the epidural catheter. Many institutes consider that an epidural block is not safe for giving analgesia in hepatectomy cases.

What this study adds?

Epidural analgesia is safe for hepatectomy cases if preoperative laboratory results are within normal limits or slightly abnormal. Although most of the cases had postoperative abnormal liver function tests and coagulation function values, no clinical hematoma occurred in patients receiving epidural analgesia.

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Potential conflicts of interest

None.

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ความปลอดภัยของการระงับปวดด้วยวิธีใส่สายในช่องเหนือเยื่อดูราของไขสันหลังสำหรับการผ่าตัดเนื้อตับออกบางส่วนแบบเปิด จะมีลิ่มเลือดในช่องเหนือเยื่อดูราเกิดขึ้นหรือไม่: การศึกษาแบบย้อนหลัง

วิมลลักษณ์ สนั่นศิลป์, วิรชัช สนั่นศิลป์, สัจจพร อินทร์นิพัฒน์

วัตถุประสงค์: เพื่อศึกษาความปลอดภัยของการระงับปวดด้วยวิธีใส่สายในช่องเหนือเยื่อดูราของไขสันหลัง สำหรับการผ่าตัดเนื้อตับออกบางส่วนแบบเปิด

วัสดุและวิธีการ: ศึกษาย้อนหลังในสถาบันเดี่ยว โดยใช้ข้อมูลผู้ป่วยในโรงพยาบาลศิริราช ในปี พ.ศ. 2553 ถึง พ.ศ. 2558 มีผู้ป่วยได้รับการผ่าตัดเนื้อตับออกบางส่วนแบบเปิดและระงับปวดด้วยวิธีใส่สายในช่องเหนือเยื่อดูราของไขสันหลังจำนวน 632 ราย บันทึกและวิเคราะห์ข้อมูลพื้นฐานของผู้ป่วย ค่าการทำงานของตับและค่าการแข็งตัวของเลือดก่อนและหลังการผ่าตัด ขนาดและน้ำหนักของเนื้อตับที่ถูกตัดออก

ผลการศึกษา: จากการใช้รหัสผ่าตัด/หัตถการ ICD-9-CM สืบค้นข้อมูลผู้ป่วยในโรงพยาบาลศิริราชตั้งแต่ พ.ศ. 2553 ถึง พ.ศ. 2558 พบการผ่าตัดเนื้อตับออกบางส่วนทั้งหมด 1,047 ราย เป็นผู้ป่วยที่ได้รับการระงับปวดด้วยวิธีใส่สายในช่องเหนือเยื่อดูราของไขสันหลังร่วมด้วยจำนวน 632 ราย จากข้อมูล ถึงแม้ค่าการทำงานของตับมีความผิดปกติในช่วงหลังผ่าตัด แต่ก็ไม่พบการเกิดภาวะเลือดออกเหนือเยื่อดูรา [0/632 = 0%, ช่วงความเชื่อมั่น 95% 0 ถึง 0.6%] โดยพบผู้ป่วยที่มีค่า prothrombin time (PT) นาน ค่า activated partial thromboplastin time (aPTT) นาน ค่าอัลบูมินต่ำ ค่าเอนไซม์ของตับ AST สูง ค่าเอนไซม์ ALT สูง และค่าเกล็ดเลือดต่ำจำนวนร้อยละ 90.5, 46.2, 86.8, 86.3, 92.4 และ 28.3 ของผู้ป่วยที่มีการส่งตรวจตามลำดับ ผู้วิจัยพบความสัมพันธ์ระดับพอใช้ระหว่างขนาดหรือน้ำหนัก ของเนื้อตับที่ถูกตัดกับความผิดปกติของค่า PT แต่ไม่มีหรือมีความสัมพันธ์เพียงเล็กน้อยกับความผิดปกติของค่า aPTT

สรุป: ถึงแม้ว่าการผ่าตัดเนื้อตับออกบางส่วนส่งผลให้ค่าการทำงานของตับมีความผิดปกติ โดยเฉพาะการแข็งตัวของเลือด ซึ่งอาจสัมพันธ์กับภาวะเลือดออกเหนือเยื่อดูราจากการใส่หรือถอดสายที่คาในช่องดังกล่าว แต่ในการศึกษานี้ไม่พบภาวะเลือดออกในช่องเหนือเยื่อดูรา ผู้วิจัยเห็นว่าการระงับปวดโดยวิธีใส่สาย ในช่องเหนือเยื่อดูราของไขสันหลังน่าจะปลอดภัยในผู้ป่วยที่รับการผ่าตัดเนื้อตับออกบางส่วนแบบเปิด ซึ่งในช่วงก่อนผ่าตัดมีค่าการแข็งตัวของเลือดเป็นปกติ หรือผิดปกติเพียงเล็กน้อย