Original Research

Randomized clinical trial of ligasure™ versus conventional splenectomy for injured spleen in blunt abdominal trauma

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Highlights

- This is a safe and fast technique of surgery for splenectomy in trauma patients.
- In this method, volume of bleeding decreased significantly.
- The operation time is decreased without any additional risk for patients.

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Abstract

Background: Spleen is the most common organ damaged in cases of blunt abdominal trauma and splenectomy and splenorrhaphy are the main surgical procedures that are used in surgical treatment of such cases. In routine open splenectomy cases, after laparotomy, application of sutures in splenic vasculature is the most widely used procedure to cease the bleeding. This clinical trial evaluates the role and benefits of the Ligasure™ system in traumatic splenectomy without using any suture materials and compares the result with conventional method of splenectomy.

Methods: After making decision for splenectomy secondary to a blunt abdominal trauma, patients in control group (39) underwent splenectomy using conventional method with silk suture ligation of splenic vasculature. In the interventional group (41) a Ligasure™ vascular sealing system was used for ligating of the splenic vein and artery. The results of operation time, volume of intra-operation bleeding and post-operative complications were compared in both groups.

Results: The mean operation times in control and interventional group were 21 and 12 min respectively (p < 0.05). The average volume of bleeding in control group during open splenectomy was 280 cc, but in the interventional group decreased significantly to 80 ml (p < 0.05) using the Ligasure system. Post-operative complications such as bleeding were non-existent in both groups.

Conclusion: The application of Ligasure™ in blunt abdominal trauma for splenectomy not only can decrease the operation time but also can decrease the volume of bleeding during operation without any additional increase in post-operative complications. This method is recommendable in traumatic splenic injuries that require splenectomy in order to control the bleeding as opposed to use of traditional silk sutures.

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1. Introduction

In developed and developing countries, trauma continues to be one of the leading causes of death [1]. Blunt abdominal trauma is frequently seen in almost all cases of multiple trauma patients [2], and splenic injury is a commonly seen phenomenon in such patients [3,4]. Motor vehicle accident and falls are the most common mechanisms for splenic injury in blunt abdominal trauma [5,6].

Therapeutic options for splenic injury consist of: Operative interventions (splenorrhaphy and splenectomy) and non-operative management. In recent years, current trends are towards non-operative management especially in patients with stable hemodynamic condition. However, in cases such as patients who are hemodynamically unstable, exploratory laparotomy is inevitable.
and splenectomy is indicated in about 30% of patients with blunt splenic injury \[8,9\]. It has been shown that in this group of patients, splenectomy can decrease morbidity and mortality and can result in a decrease in ICU stay time \[2\].

The most concerning issues in surgical treatment of traumatic splenic injury are the operation time and the volume of bleeding. Recently, application of Ligasure™ has improved the results of certain specific types of surgeries \[14\] as bleeding and operation time has been shown to be decreased using this vessel sealing system \[14,15,16\]. This investigation evaluates the role of Ligasure™ in operation time and volume of bleeding during splenectomy in comparison with conventional splenectomy using silk sutures.

2. Patients and methods

This is a randomized (with balanced block randomization \[1:1\]) single-blind, parallel-group clinical trial conducted in Iran and has been assigned the Iranian registry of clinical trials registration number: IRCT20111214375N2.

Sample size was calculated based on a study by Franklin et al. \[30\] with use of following formula:

\[
n = \left[ \left( \frac{Z_\alpha/2 + Z_\beta}{\delta} \right)^2 \times \left\{ \frac{2(\bar{y}^2)}{\mu_1 - \mu_2} \right\} \right] / \left( \mu_1 - \mu_2 \right)^2
\]

As the mean difference of operation time was 5 (SD: 7.4). So, the number of people in each group was obtained 35 that with a drop out of 10% sample size in each group was considered about 40.

Eligible participants were all adults aged 18–50 with blunt abdominal trauma and splenic injury who met the eligibility criteria for splenectomy according to the American Association for the Surgery of Trauma grading system \[17,18\]. These patients had BMI<30 and were in unstable hemodynamic status. After obtaining the signed consent form, (A number of trauma patients were mentally healthy enough to sign the consent form and for the ones who were not mentally healthy enough, it was the first legally-accepted decision maker who signed the consent form) all of the patients were divided into two groups. Control group (39 patients) was considered as the patients which splenectomy using conventional method, but the interventional group (41 patients) underwent splenectomy using the Ligasure™ system (Medtronic-Covedian, Saint-Laurent, Canada). Data was collected using a questionnaire which had been designed based on the objectives of the study including: demographic data, type of splenectomy, length of surgery (minutes), amount of intra-operative bleeding based on the blood collected in suction container and bloody gauze (each gauze = 10 cc and each laparotomy pad = 60 cc) and post-operative bleeding (blood collected in drain container). The study was done at general surgery ward of Imam Reza hospital affiliated with Birjand University of Medical Sciences, south Khorasan, Iran during 2012, which is a primary referral center for trauma in the eastern part of Iran and normally has 3 major and about 20–30 minor trauma patients every day.

Initially for both groups, laparotomy was performed through a midline incision followed by insertion of at least four laparotomy pads in the left upper quadrant (LUQ) over the injured spleen as a pack for initial control of hemorrhage. Then, all of the blood in the abdominal cavity was entirely suctioned, washed out and then laparotomy pads were inserted around the spleen. For interventional group, after releasing anatomic splenic adhesions, the surgeon’s assistant pulled spleen toward the abdominal wall for better exposure of splenic hilum. Then a 10 mm Ligasure™ system was used for ligation and cutting of the splenic vasculatures (artery and vein). In the control group, bleeding in the splenic hilum was controlled with clamps and was transfixed by silk sutures. In the both groups, after splenectomy, the bed of spleen was observed carefully for bleeding. At the end of the operation a close-suction drain was inserted in LUQ for checking the post-operative bleeding.

Accumulated blood in LUQ during splenectomy was considered as intra-operative hemorrhage. Operation time has been considered from beginning of splenectomy in both group and was ended after removing of spleen. Accumulated blood in LUQ drain container was considered as post-operative bleeding.

All of the patients who were referred to our center and met the inclusion criteria, which consisted of 80 patients, were selected as our study population. Corresponding surgeon was able to choose either new or conventional method of surgery according to a computer generated randomization list. Randomization sequence was created using balanced block randomization with a 1:1 allocation using random block sizes of 4. Determination of whether a patient would be operated by conventional splenectomy or by Ligasure™ was made based on random numbers drawn up by corresponding surgeon. After assignment of a patient to one of the splenectomy procedures, operating room nurse recorded operation time and bleeding volume in a questionnaire. In this study, concealment and blinding was not essential for each patient because we were not evaluating the consequences of a specific method of therapy and the main variables were time and volume of bleeding. Between our two groups there was no similarity of interventions found.

Data were analyzed using SPSS version 15. Continuous variables were compared using the independent t-test and were calculated assuming normal distribution (age, BMI, blood loss). A Mann–Whitney U test was used for non-normal distribution variables (operating time) and chi-square test was used for categorical variables.

3. Theory

Recent developments in surgical innovation provide facilities which can change surgical techniques from time wasting and risky condition to a better and safer situation for patients and surgeons. Ligasure theoretically has decreased the suturing time and promote easier ligation of the vessel in poorly exposure areas especially in abdominal surgeries. We think this technique can give us better result in an emergent trauma splenectomy.

4. Results

Flow diagram of Ligasure™ splenectomy compared with conventional splenectomy for injured spleen after blunt abdominal trauma is shown in flow diagram (Fig. 1). Before randomization and after assessment for eligibility, we excluded 15 patients from the study. Of these patients, 4 declined to participate and 11 patients did not fit the inclusion criteria and were excluded from the investigation. Eligible participants were recruited from September 2012 to March 2013. All trauma patients were transferred by emergency medical services (EMS) to the emergency department of our center. Baseline data of our patients are outlined in (Table 1). Of total 80 patients, 39 and 41 patients assigned to control and interventional group respectively. Our results indicate that intra-operative hemorrhage has significantly decreased from 280 to 80 ml (p-value<0.001) in investigational group. Operation time shows significant change in investigational group by 12 min (P-value<0.001) compared to that of the control group: 21 min (Table 2). Related to the surgical technique in both group, no complications were seen.

5. Discussion

Use of the Ligasure™ system in splenectomy in abdominal...
trauma patients reduced operating time and volume of bleeding by 57.1% and 28.5% respectively. This study shows that the new technique offers several advantages over the conventional method for splenectomy without any increase in complication rate. Technically, the use of the Ligasure™ system is simple, and quick to apply. Furthermore, use of the Ligasure™ system in radical gastric cancer surgery has been shown to reduce the operating time by 23.9% compared with the conventional method and intra-operative blood loss by 40.6% without any additional increase in complication rates. These data corroborate previous results of Ligasure™ use in hemorrhoidectomy and hepatectomy [19,20]. Lepner and Vaasna have reported significant decrease in operation time in thyroidectomy with Ligasure™ vs. conventional method [21]. In another investigation claimed, Ligasure™ vessel sealing instrument in laparoscopic heptectomy is applicable in cases of liver cancer. It was demonstrated that the use of this system could decrease the operation time, reduce the intra-operative blood loss and postoperative hospital stay with a good safety profile and minimal invasiveness. It is demonstrated that high-technology methods (such as the Ligasure™ system) increase reliability of homeostasis and can improve surgical factors such as intra-operative blood loss and duration of surgery [22]. In a study which had been done in Italy by Romano et al. [32] application of Ligasure in laparoscopic splenectomy using Ligasure, the average intraoperative bleeding was reported very low.

It is believed that intra-operative blood loss and the subsequent need for blood transfusion are considered significant risk factors for increased complication rates, poor postoperative outcome, and a shorter disease-free survival [23,24]. In trauma patients, blood transfusions have been shown to be an independent risk factor for death, peri-operative infection, post injury multiple organ failure and admission to the intensive care unit (ICU). Blood transfusion within 24 h of admission was a significant independent predictor of mortality, ICU admission, and ICU length of stay in the acute trauma setting [25]. Blood transfusions were infrequent in our series, with 17% (7 patients) of investigational group and 22% (9 patients) of control group were transfused intra-operatively, a lower rate than in major series reported in literature: DeMatteo et al. reported a large series in which 38% of patients received intra-operative transfusions, and Nuzzo et al. reported, reported a 41% rate of blood transfusion in surgical intervention of blunt splenic trauma [29].

Table 1
Baseline data.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ligature (n = 41)</th>
<th>Conventional (n = 39)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Number (percent)</td>
<td>Number (percent)</td>
<td>0.35</td>
</tr>
<tr>
<td>Male</td>
<td>34 (82.9)</td>
<td>29 (74.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7 (17.1)</td>
<td>10 (25.6)</td>
<td></td>
</tr>
<tr>
<td>Age (Mean ± SD)</td>
<td>32.07 ± 10.95</td>
<td>30.05 ± 9.74</td>
<td>0.39</td>
</tr>
<tr>
<td>BMI (Mean ± SD)</td>
<td>27.90 ± 1.66</td>
<td>28.28 ± 1.21</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Table 2
Comparison of outcomes in two groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ligasure (n = 41)</th>
<th>Conventional (n = 39)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated intra-operative blood loss (ml)</td>
<td>80.12 ± 59.94a</td>
<td>280.23 ± 99.27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>11.93 ± 3.45</td>
<td>21.41 ± 4.98</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

a Values are Mean ± SD.
Ligation of tissues and vessels with the Ligasure™ system in the bed of spleen and adjacent to the pancreas, requires no need for extensive tissue dissection and it is applicable with minimal invasions and tissue destruction. This can in turn lead to a decrease in bleeding and additional complications. But in conventional suture-based splenectomy for taking tissues and vessels with clamps, tissues must be dissected more for placement of knots, which can thereby increase the rate of adjacent organ injury. Additionally it is notable that the safety of the ligated vessels is 100% using the Ligasure™ system, but in some cases of conventional splenectomy knots become loosened or released and ongoing bleeding will happen. In a bloody surgical field finding the loosened knot can be time wasting and unwanted suturing of the adjacent organs is a possibility.

It is notable that the use of Ligasure™ system has been shown to not improve outcomes in certain other surgical interventions. One randomized controlled trial showed that while this vessel sealing system was safe, its use was not associated with any significant decrease of the operation time or blood loss during liver transaction as compared with that of the clamp crushing method [28]. There may be, however, a cost benefit association with this new technique. In a study by Shabahang et al. [31], they showed that the hemostasis during splenectomy using Ligasure is simply and easily achieved with little dissection.

Although the Ligasure™ system effectively reduced the operating time and volume of bleeding, it added minimal additional cost to the surgical procedure in our study. It is therefore our conclusion that the Ligasure™ system provides a safe and improved method in order to improve intra-operative factors and it is recommended to be used in surgical treatment of blunt splenic trauma as opposed to traditional use of silk sutures.

Ethical approval

This investigation has been approved by Birjand university of medical sciences ethical committee by the number 189728-bums.

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Author contribution

Vejdan sa, (main author) = methodology, technique of surgery, discussion.
Khosravi (Co-author) = data collection, data analysis.

Conflicts of interest

This investigation does not have any conflict of interest.

Guarantor

Naseh Ghodratollah M.D.

Trial registry number

IRCT201112148375N2.

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