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Sealing of Vessels Larger Than 7 Millimeters Using Enseal in Porcine Aorta

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ABSTRACT

Background: The Enseal (Ethicon Endo-Surgery, Blue Ash, Ohio) tissue-sealing device has proven efficacy for ligation of vessels <7 mm in diameter, even with significant supraphysiologic bursting pressures. We aimed to evaluate the safety of Enseal in porcine vessels >7 mm.

Materials and Methods: The lumbar aortas of pigs that were euthanized for unrelated procedures were harvested. A 5- to 6-cm segment of aorta was sealed using the Enseal device. The opposite end was attached to a pressure-testing device to measure pressures at leak or bursting. The bivariate Pearson correlation was used to determine the relationship between diameter and bursting pressure. One-way analysis of variance was used to determine differences between the groups of vessels on the basis of their diameter.

Results: Ninety samples of 5-cm aorta segments were used to assess bursting pressure. The median diameter was 14 mm (range, 7–18) and bursting pressure was 85 mm Hg (range, 24–650). The Pearson test showed a negative correlation between vessel diameter and bursting pressure ($P = .25$). One-way analysis of variance did not show any significant difference between vessel diameters grouped by size ($P = .517$), and neither did the Scheffe post hoc test when comparing diameter with bursting pressure; 31% of specimens failed to seal.

Conclusions: Bursting pressures are low and inconsistent after tissue sealing with the Enseal device in porcine vessels >7 mm. These vessels also demonstrated a higher rate of failure to seal. The histologic results of the aorta segments (ie, a low collagen-elastin ratio) may be the cause of the low bursting pressures.

Key Words: Enseal, Vessels, Porcine aorta, Bursting pressure, Collagen, Elastin.

INTRODUCTION

Rapid advances in the field of laparoscopic surgery have called for newer instruments that will safely replicate and, where possible, improve the techniques used in open surgery. Safe resection of tissues while maintaining hemostasis in laparoscopic colorectal surgery depends on good control of mesenteric vessels.

Currently, the US Food and Drug Administration has approved the Enseal tissue-sealing device (Ethicon Endo-Surgery, Blue Ash, Ohio) for vessels up to 7 mm in diameter. This is greater than or equal to the vessel diameter limit in other vessel-sealing systems that are widely used, such as Ligasure (Covidien, Boulder, Colorado) and the Harmonic Scalpel (Ethicon Endo-Surgery). Anecdotal evidence suggests that the Enseal device can safely seal vessels >7 mm. At our institution, we have gravitated toward the Enseal device for all colorectal procedures; we find it to be effective and reliable. Its versatility is evidenced by its use as a grasper, dissector, scissors, and vessel and soft-tissue sealer.

We investigated the utility of the Enseal device in porcine vessels >7 mm. If found to be effective, use of the device would further reduce tissue handling, operative time, and blood loss and thus hasten postoperative recovery.

MATERIALS AND METHODS

On the basis of previously published data, we determined an adequate sample size to be 50 cases. The institutional review board approved the study. Ninety specimens were harvested from pigs euthanized for other purposes, such as for training residents and fellows. The pig aortas were harvested from the infrarenal position to the bifurcation of

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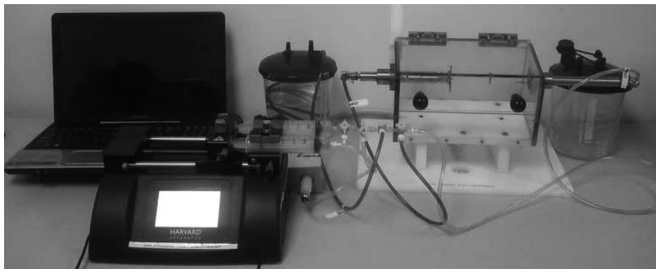

Figure 1. Harvard apparatus (Syringe pump).

Table 1.
General Characteristics

Data for Total Aortas (N = 90)	
Size of each vessel, cm	5
Number failed to seal, n (%)	29 (31%)
Median diameter, mL (range)	14 (7–18)
Median bursting pressure, mm Hg (range)	85 (24–650)

the iliac vessels via laparotomy. They were immediately transferred to the laboratory in moist and cold containers. The side branches of the aorta were dissected and ligated using silk ties. The aorta was then transected into 5-cm segments. One end of the segment was sealed using the Enseal device. The opposite end was attached to the pressure measurement system, Harvard apparatus (Syringe pump) (**Figure 1**). The device measures pressure continuously as it infuses the segment with normal saline at a constant rate (50 mL/h). Bursting pressure was the maximum pressure at which the sealed vessel leaked or burst open. A failure to seal was defined as a leak at pressure <50 mm Hg.

Mean and standard deviation were used for continuous data. The Pearson correlation coefficient was used to determine the relationship between continuous variables such as diameter and bursting pressure. Vessels were divided into 3 groups on the basis of the diameter: 7–10 mm, 11–15 mm, and >16 mm. One-way analysis of variance was used to determine differences among these 3 groups. Further subgroup analysis was done using the Scheffe post hoc test. SPSS version 16 was used for the statistical analysis (SPSS 16.0, IBM Inc., Armonk, New York).

RESULTS

Ninety 5-cm segments of lumbar aorta were retrieved from pigs. The median vessel diameter was 14 mm (range, 7–18), and bursting pressure was 85 mm Hg (range, 24–650). Thirty-one percent (n = 29) of vessels failed to seal

Table 2.
Mean Bursting Pressures Among Groups Based on Diameter of Vessel

Group (diameter, mm)	N = 90	Mean Bursting Pressure, mm Hg (range)	*P* value
1 (7–10)	18	142 (0–650)	.421
2 (11–15)	46	102 (0–467)	.302
3 (<16)	26	100 (0–210)	.260

Table 3.
Failed Sealing per Group

Groups (diameter)	Failed (%)	*P* value
1 (7–10 mm)	15	.10
2 (11–15 mm)	45	
3 (>16 mm)	40	

(**Table 1**). The Pearson test showed a negative correlation between vessel size and bursting pressure ($P = .25$).

Vessels were divided into 3 groups based on diameter: group 1 (7–10 mm) had 18 vessels, group 2 (11–15 mm) had 46 vessels, and group 3 (>16 mm) had 26 vessels. Overall, there was no significant difference in the mean bursting pressures among the groups ($P = .517$). Intergroup analysis with the Scheffe post hoc test also did not show any statistically significant difference in bursting pressure; however, there was a trend toward a lower bursting pressure with increasing diameter (**Table 2**).

The rate of failure to seal in groups 1, 2, and 3 were 15%, 45%, and 40%, respectively ($P = .10$). Specimen failure was scattered throughout all groups ($P = .10$) (**Table 3**).

DISCUSSION

The US Food and Drug Administration has approved the Enseal bipolar sealing device for sealing vessels up to 7 mm in diameter. To our knowledge, there are no studies in the literature that have evaluated the efficacy of this device in vessels >7 mm. Our evaluation of the sealing ability of the Enseal bipolar energy device showed significantly inconsistent bursting pressures, with a wide range between 24 and 650 mm Hg. The larger vessels were found to have lower bursting pressures and higher failure-to-seal rates. The histologic nature of the vessels used in our study may have also contributed to the overall low bursting pressures and high failure rates. The higher the collagen to elastin ratio, the

higher the bursting pressure.[1,2] The aorta is histologically an elastic vessel with higher elastin content in the tunica media compared with nonelastic vessels and low collagen content mostly located in the tunica adventitia.[3] The resulting low collagen to elastin ratio may be the cause of the low bursting pressures in our study.

There are myriad new devices developed for the purpose of vessel sealing that have been found to be as effective as conventional methods such as clips and ties.[4–6]

The Enseal device is newer and gaining popularity. Studies have shown that it has much higher bursting pressures than other sealing systems (678 mm Hg for Enseal vs 489 mm Hg for Ligasure).[7] Other notable features of the Enseal device include less adventitial damage detected on histopathologic evaluation.[8] However, all of these studies have been done on vessels <7 mm in diameter.

To exclude the histologic factor, further studies are needed to evaluate the Enseal device in vessels >7 mm with a higher collagen to elastin ratio. Another variable to consider is the duration of energy expenditure each time the instrument is applied. These would improve our understanding on the determinants of the quality of seal and lateral thermal damage with the Enseal device.

CONCLUSION

Bursting pressures are low and inconsistent after tissue sealing with the Enseal device in porcine vessels >7 mm. These vessels also demonstrated a higher rate of failure to seal. The histologic results of the aorta segments (ie, low collagen to elastin ratio) may be responsible for the low bursting pressures. Clinical use of vessels >7 mm is therefore not recommended in light of the results of this study.

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