To knot or not to knot? Sutureless haemostasis compared to the surgeon's knot

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ABSTRACT

INTRODUCTION The aim of this study was to carry out an independent evaluation of the efficacy and security of a number of vessel ligation devices and ligatures.

MATERIALS AND METHODS A vascular ligation model was devised using fresh, ex vivo porcine internal carotid arteries of varying external diameters. Coloured normal saline was infused via a pressure/monitor device through the artery. The end lumen was occluded by five different techniques: (i) braided suture in a surgeon's knot; (ii) a monofilament suture in a granny knot; (iii) a metallic clip (Ligaclip, Johnson and Johnson); (iv) a bipolar diathermy system (Ligasure, ValleyLab); and (v) an ultrasonically activated scalpel (Harmonic Scalpel, Johnson and Johnson). The vessels were subjected to supraphysiological pressures. Loss of haemostasis was evident by leakage of coloured perfusion fluid.

RESULTS Secure haemostasis was obtained with all the techniques in all vessels below 5 mm in diameter. In vessels over 5 mm, secure haemostasis was obtained with all modalities except harmonic scalpel. With the harmonic scalpel, leaks occurred in 3/27 (11%) vessels between 5–6 mm and 3/5 (60%) vessels over 6 mm, confirming the manufacturer's instructions.

CONCLUSIONS In this first, independent, randomised study comparing vessel ligation devices and ligatures, the manufacturer's claims for each of the haemostatic methods were accurate. We find that all the modalities tested perform as well as the traditional surgeon's knot in vessels of 5 mm and below.

KEYWORDS

Knots – Ligatures – Suture – Harmonic scalpel – Diathermy

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It was believed, traditionally, that wounds healed more rapidly when they were bound together with a square (reef) knot. There has always been a growing concern that the knot construction employed by many surgeons is not optimal and that they use faulty technique in tying knots, which is the weakest link in a tied surgical suture. When a knotted suture fails to perform its functions, the consequences may be disastrous resulting in massive bleeding, wound dehiscence or incisional hernia. These concerns have caused surgical haemostatic techniques to be questioned constantly and modulated accordingly. A surgeon's knot has been held in the past, and is still taught in basic surgical skills courses, as the most secure method and the standard in achieving vascular haemostasis during a surgical procedure. However, advances in technology have delivered new devices capable of achieving secure and faster haemostasis. The application of these devices has, at least in part, led to the global expansion of

laparoscopic approaches in performing major surgical procedures for both benign and malignant disease. It is also claimed by enthusiasts that the use of these devices confers improved haemostasis, decreasing the average blood loss and, therefore, a decrease in blood transfusion requirement. So, individual surgeons must be able to rely on their haemostatic techniques, particularly in the laparoscopic setting. It is also important to verify efficacy from a financial point of view, particularly when expensive disposable instruments are needed.

There is, however, a paucity of independent evidence to support the effectiveness and security of new haemostatic tools. We were struck by the absence of independent data to confirm the claims of any of the manufacturers of haemostatic devices. Most surgeons appear to try new haemostatic techniques once or twice before deciding whether to use them or not. We have heard some anecdotal evidence as to whether various techniques are reliable or not; however, in

the continuously variable and uncontrolled setting of a surgical operation, it is difficult to be objective. Put bluntly, this situation seems analogous to a pharmaceutical company developing a drug, testing it in house and then giving it out to doctors to use if they liked its effect on one or two patients!

We, therefore, set out to assess and compare, independently, newer vessel sealing and ligation devices against conventional ligatures tied both as a reef and granny knot under standardised conditions.

Materials and Methods

Vascular ligation model

The ligation model devised employed fresh *ex vivo* porcine internal carotid arteries. This vessel has no branches in the pig. The artery was ligated using one of the haemostatic techniques below. Coloured saline was then infused through the artery using a pneumatic pressure device.

Haemostatic techniques

The following haemostatic methods were used (Fig. 1):

1. Braided suture/surgeon's knot.
2. Monofilament suture/granny knot.
3. Ligaclip (Johnson and Johnson).
4. Ligasure (electrothermal bipolar vessel sealer, EBVS, ValleyLab) vessel sealing system.
5. The harmonic scalpel (Ultracision, Johnson and Johnson).

A brief description of the above techniques is given below. When a knot is constructed by an initial double-wrap throw followed by a single throw, it is called a surgeon's (friction) knot. Granny knot is also called the 'lubber's knot'. It resembles a reef knot superficially but it is inferior. As the two half knots are tied in the same direction and not opposite as in the reef knot, it tends either to slip or to jam, or both. It is said to be a square knot done by a 'granny' or 'landlubber'.

Metallic clips, usually titanium clips deployed either from an automatic loading or free-hand loading device come in various forms and serve various purposes (*e.g.* intestinal anastomosis, skin stapling, *etc.*), in addition to vascular anastomosis and haemostasis. Their inertness in causing minimal bodily reaction has made their use widespread in almost all surgical procedures.

The ligasure system is a computer-based, temperature-controlled bipolar electrocoagulation system (otherwise known as the electrothermal bipolar vessel sealer, EBVS; ValleyLab, Boulder, CO, USA) and is claimed to seal vessels up to 7 mm in diameter by denaturing collagen and elastin within the vessel wall and surrounding connective tissue (Fig. 2). The ligasure system determines adequate tissue sealing by sensing the resistive index monitored by the device. This then notifies the surgeon when the tissue is safe to be cut and the surgeon controls the knife cut of the tissue.

Figure 1 Haemostatic instruments used.

Using an energy source to excite piezo-electric crystals in the hand piece, the harmonic scalpel employs mechanical energy transmitted and amplified to very high frequency such that at the tip of the blade longitudinal motion frequency reaches 55,500 cycles/s. This rapid movement creates temperatures that denature proteins creating an area of coagulation and allowing concurrent cutting. This cutting and coagulation occurs without causing a significant rise in temperature at the tissue level, with less smoke formation, no muscular stimulation and without the transmission of energy through the patient. Its safety has been tested extensively in animal experiments and there is now ample evidence to suggest that it produces less thermal damage *in vitro* than electrosurgery and lasers. Using multifunctional hand pieces and adjusting power levels means that different balances between coagulation and cutting effects are possible. The manufacturers claim efficient and safe haemostasis in vessels < 3 mm using current hand pieces.

Burst pressure study

For each test experiment, a vessel was picked up randomly from a bag with eyes closed and the haemostatic source randomly selected and applied prior to vessel inflation (the

Figure 2 Microscopic features of a vessel sealed using the ligasure system.

Table 1 Haemostatic methods and burst pressure study results

Haemostatic method	Number of leaks at 190 mmHg	Number of leaks at 300 mmHg	Mean diameter of vessels (mm)
Braided suture in a surgeon's knot	0/50	0/50	5.34
Monofilament suture in a granny knot	0/50	0/50	5.31
Metallic clip (Ligacclip)	0/50	0/50	5.32
Ligasure	0/50	0/50	5.28
Harmonic scalpel (Ultracision)	5/50	1/50	5.18

dilated measurement could not be predicted from the measurement of the vessel while empty). The vessel was then infused and a baseline measurement of the diameter of the vessels was made using callipers at 120 mmHg intraluminal pressure. The intraluminal pressure was increased to 190 mmHg and held for 5 min using the pressure monitor device. Loss of haemostasis was evident by leakage of coloured perfusion fluid. The pressure was then increased further to 300 mmHg, held for 5 min and assessed for leak once again. This process was repeated 50 times with each modality.

Results

As outlined in Tables 1 and 2, with vessel diameters of 5 mm or less, all methods of haemostasis achieved good success, with no evidence of leakage either at 190 mmHg or at 300 mmHg. When vessel diameter, however, was measured at over 5 mm, six instances of leakage were seen where the harmonic scalpel (Ultracision) had been used. In contrast, all the other modalities maintained secure haemostasis however large the vessel and however high the infusion pressure.

Discussion

There can be little doubt that enthusiasm for alternative modalities to the knotted ligature in securing haemostasis is becoming wide-spread; indeed, one could say that the use of metallic clips in both open and minimal access surgery is now the 'norm'. Furthermore, it is likely that newer techniques can quicken a procedure, an important issue in attempting to achieve maximal efficiency in an operating unit.

Each of the haemostatic modalities used in this study has its own particular attributes in terms of usefulness in the surgical environment, beyond simply comparing how big a vessel at how high a pressure can be securely 'sealed'. Other important attributes include, ease of use, other effective applications (*e.g.* tissue dissection, heat generation and

distant heat transmission) and, of course, the cost of any generator and disposables.

The methods of achieving haemostasis used in this study represent the more commonly used modalities in modern surgery and each has both supporters and critics.

It has been shown that occlusion with titanium clips was ineffective in vessels with a diameter of > 7 mm, whereas in vessels of diameter < 7 mm occlusion with titanium clips was efficient and atraumatic.¹ Furthermore, Papaioannou *et al.*² tested the security of laparoscopically applied clips with respect to dislodgement and leakage, through two commercially available clip applicators – the Endo ClipII (US Surgical) and the Ligacclip (Ethicon). Leakage tests were performed under pulsatile blood circulation at mean pressure of about 800 mmHg. The dislodgement test showed that the Endo Clip II exhibits superior performance compared to the Ligacclip, based on the fact that it requires more force for transverse and semi-axial dislodgement. In the leakage test, both clip applicators performed equivalently and showed no leakage.²

In a similar study to that described here, Joseph *et al.*⁵ compared the effectiveness of Ti-knot TK5 (LSI Solutions), Hem-o-lok MLK clips (Weck Closure), Ligacclip 5-mm titanium clips (Ethicon), and Endopath vascular staples (35 mm long, 12.3 mm wide; Ethicon), using fresh porcine renal artery segments from 5–6 mm in diameter. They found that all devices tested were capable of occluding renal arteries under physiological conditions and all except vascular staples occluded renal arteries to pressures that exceeded 800 mmHg. They were equivalent to hand ties under supraphysiological condi-

Table 2 The 'failures' of the harmonic scalpel (*n* = 6)

Average diameter of leaking vessel	6.1 mm
Vessel diameter < 5 mm	0% leak (0/18)
Vessel diameter 5–6 mm	11% leak (3/27)
Vessel diameter > 6 mm	60% leak (3/5)

tions. In their study, 50% of vascular staple lines leaked before the maximum pressure of 800 mmHg was reached with a mean leak pressure of 275 mmHg (range, 237–322 mmHg). In our study also, the maximum diameter of the vessel in which the Ligaclip was used was 6.2 mm and, both at physiological and supraphysiological pressures, secure haemostasis was maintained; however, we did not use pressures of 800 mmHg.

Kennedy *et al.*⁴ had in the past demonstrated that the prototype bipolar sealing device failed to seal arteries with a diameter of 5.1–7.0 mm, while Chandler⁵ reported that the bursting pressures for the ligasure vessel sealing device, clips and sutures were similar and above the physiological range.

Landman *et al.*⁶ assessed the usefulness of the ligasure vessel sealing system for vascular control during laparoscopic surgery and compared it with other available haemostatic modalities. The 5-mm laparoscopic vessel sealing system sealed arteries up to 6 mm and veins up to 12 mm in diameter at supraphysiological bursting pressure. They evaluated 13 arteries with a diameter of 6 mm or less at a mean bursting pressure of 662 mmHg (range, 363–1985 mmHg) and 11 veins with a diameter of 12 mm or less with a mean bursting pressure of 233 mmHg (range, 65–440 mmHg). They concluded that the ligasure system sealed arteries up to 6 mm and veins up to 12 mm in diameter at supraphysiological bursting pressure and can be viable option for management of haemostasis laparoscopically. However, the ligasure device was inferior to clip and staple technology but superior to standard bipolar energy. They also demonstrated that the harmonic scalpel did not reliably seal vessels larger than 3 mm but resulted in the least amount of acute collateral tissue injury and staples were found to be the most expensive occlusive modality.⁶ Other studies have observed decreased blood loss and significant reduction in operative time with ligasure.⁷

In a similar study, Harold *et al.*⁸ compared the bursting pressure of arteries sealed with ultrasonic coagulating shears, electrothermal bipolar vessel sealer (EBVS), titanium laparoscopic clips, and plastic laparoscopic clips. They demonstrated that plastic laparoscopic clips and titanium laparoscopic clips secured all vessel sizes to well above physiological levels. The EBVS can be used confidently in vessels up to 7 mm. The burst pressures of ultrasonic coagulating shears and EBVS were not significantly different at a vessel size of 2–3 mm. For greater vessel sizes, EBVS had higher burst pressures compared to ultrasonic coagulating shears; at 4 or 5 mm this was 601 versus 205 mmHg and at 6 or 7 mm this was 442 versus 175 mmHg.⁸ So, in a laparoscopic setting, one of the important practical aspects evident from these studies is that it is bleeding from smaller vessels that can be controlled by the ligasure or harmonic scalpel and larger vessels are usually controlled by mechanical methods namely staplers, endo-loops and various clips.

The results of our study are similar to the results of the studies above, although our study was performed more in line with an open surgery setting and may not have similar applicability

in laparoscopic settings. However, one important aspect of our study is that it is an independent evaluation of the haemostatic modalities, albeit conducted in a small laboratory setting. It seems reasonable to conclude that one can safely rely on these methods of achieving haemostasis for vessel sizes as claimed by the manufacturing companies. The possible advantages of the new energy delivering devices over metallic clips in not leaving a foreign body within the patient are self-evident; however, in comparing the harmonic scalpel and the ligasure vessel sealing system, issues other than shear efficiency of achieving haemostasis may be important. Whilst the ligasure system would appear to achieve excellent and reliable haemostasis even in larger diameter vessels at supraphysiological pressures, the harmonic scalpel is much more multipurpose and can be used by the surgeon to fulfil a number of roles, including tissue grasping, tissue dissection, tissue cutting and, of course, vascular haemostasis.

Furthermore, this study would also indicate that surgical dictat relating to the much maligned granny knot in the tying of a ligature, may not be based on sound evidence, even if there are theoretical reasons to worry about slippage of knots. The results would indicate that even when a monofilament ligature is tied in a granny knot, reliable and secure haemostasis is achieved in large vessels and at supraphysiological pressures. This would suggest that the most important aspect of knot tying is that the knot should be tied well, what ever kind of knot that may be.

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