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Comparison of the Ti-knot Device and Hem-o-lok Clips with Other Devices Commonly Used for Laparoscopic Renal-Artery Ligation

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ABSTRACT

***Background and Purpose*: New devices such as the Ti-knot and Hem-o-lok clips have been developed for laparoscopic surgical applications. We compared the effectiveness of Ti-knot TK5 (LSI Solutions), Hem-o-lok MLK clips (Weck Closure), Ligaclip 5-mm titanium clips (Ethicon), and Endopath vascular staples (35 mm long, 12.3 mm wide) (Ethicon).**

***Materials and Methods*: Renal artery segments from 5 to 6 mm in diameter were harvested from fresh porcine kidneys. One end of the vessel was intubated with a 25-gauge ball-tipped needle and fastened with two silk ties. The other end was occluded with one of the test devices. Saline was infused into each arterial segment at 3 mL/min with the maximum pump pressure at 800 mm Hg. The maximum pressure with leakage was recorded. Each of the five test devices was tested eight times on a rotating basis. Saline infusion was stopped when the maximum pump pressure was reached or when leakage was observed.**

***Results*: All Ti-knot devices, Hem-o-lok clips, titanium metal clips, and standard hand ties tolerated pressures >800 mm Hg with no leakage, but 4 of the 8 vascular staple lines (50%) leaked before this maximum pump pressure was reached. For those that leaked, the mean leak pressure was 273 mm Hg (range 237–322 mm Hg).**

***Conclusions*: All devices tested are capable of occluding renal arteries under physiologic conditions. Ti-knot devices and Hem-o-lok clips occluded renal arteries to pressures that exceeded 800 mm Hg. They are equivalent to hand ties under supraphysiologic conditions.**

INTRODUCTION

LAPAROSCOPIC NEPHRECTOMY is now the procedure of choice for small renal tumors at many centers. Many techniques have been used in the past for renal vascular ligation during laparoscopic renal surgery. The most popular devices are metal clips and vascular staples, which were evaluated by Kerbl and associates in 1993.[1] New devices such as the Ti-knot TK5 (LSI Solutions, Victor, NY) and the Hem-o-lok MLK clips (Weck Closure Systems, Research Triangle Park, NC) have since been developed for laparoscopic surgical applications. They appear to be good alternatives to established devices for vascular ligation. In this paper, using an *ex vivo* cadaver porcine kidney model, we compared the effectiveness of Ti-knot TK5 devices, Hem-o-lok MLK clips, Ligaclip 5-mm titanium clips (Ethicon Endo-Surgery, Inc., Cincinnati, OH), Endopath vascular staples (35 mm long, 12.3 mm wide) (Ethicon Endo-Surgery), and hand-tied 2-0 silk ties in renal-artery ligations.

MATERIALS AND METHODS

Fresh cadaver pig kidneys were obtained from local butcher shops and promptly refrigerated by placing them on ice. Prior to the experiment, the kidneys were warmed to room temperature. The specimens were sprayed with saline to avoid overdrying. Segments of renal arteries from 5 to 6 mm in diameter were harvested and placed in normal saline solution. An arterial pressure transducer was connected to a computer-controlled ana-

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log-to-digital sampling board (National Instruments Corporation, Austin, Texas). The system was then calibrated so that the maximum pressure that could be transduced was 800 mm Hg. One end of the vessel segment was intubated with a 25-gauge ball-tipped needle and fastened with two 2-0 silk ties. The other end was occluded with one of the test devices. Using a stepping motor-controlled syringe pump, saline was infused into each arterial segment at 3 mL/min with the maximum pump pressure at 800 mm Hg. Pressures were digitally sampled from a range of 0 to 800 mm Hg, and the maximum pressure with leakage was recorded. The test devices used were the Ti-knot TK5, Hem-o-lok clips, Ligaclip 5-mm titanium clips, and Endopath 35-mm vascular staples. All devices had been provided courtesy of their respective manufacturers.

RESULTS

All arterial segments were inspected for integrity after dissection. Segments that appeared to be defective with visible holes or defects were discarded. The results from two arterial segments had to be discarded because leakage was noted to come from a small patent arterial branch on the vessel wall. All segments were inspected after deployment of the test devices to ensure that the proper application of the devices had been achieved. All staple lines appeared to be intact with no missing or misaligned staples.

Each of the five test devices was tested eight times on a rotating basis. A total of 40 arterial segments and 40 test devices were used. Saline infusion was stopped when the maximum pump pressure was reached and maintained for at least 30 seconds or when leakage was observed.

All Ti-knot devices, Hem-o-lok clips, titanium metal clips, and standard hand ties tolerated pressures >800 mm Hg. No leak was observed even when the maximum pump pressure was reached. As shown in Figure 1, the pressure inside each arterial segment increased rapidly until a plateau of 800 mm Hg was reached. All vessel segments showed maximal distention without leakage.

Four of eight of the 35-mm Endopath vascular staple lines (50%) also showed no leakage of fluid despite reaching the maximum pump pressure of 800 mm Hg (Fig. 2). Again, maximal distention of these arterial segments was noted without leakage. However, four of the vascular staple lines leaked before the maximum pump pressure was reached (Fig. 2). Leakage was noted to come from the staple line in all four cases. Further inspection of these segments showed intact staple lines, confirming the proper deployment of the stapling device. For the arterial segments that leaked, the mean leak pressure was 273 mm Hg (range 237–322 mm Hg).

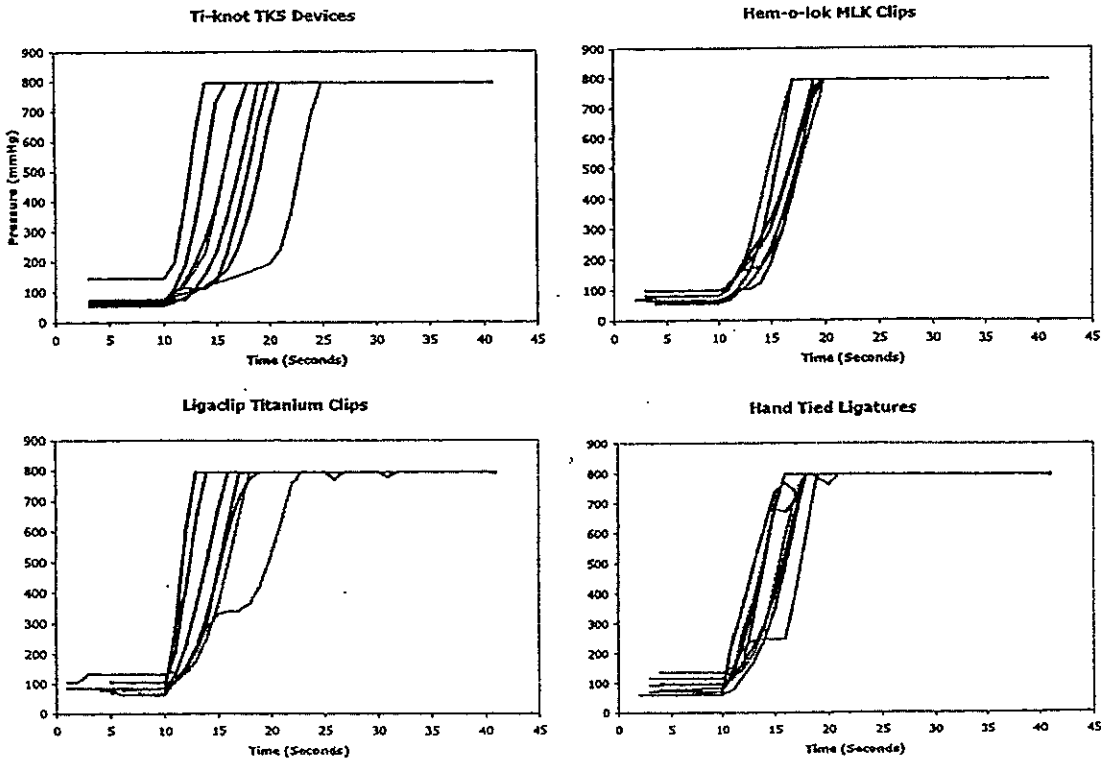

FIG. 1. Pressure profiles of Ti-knot devices, Hem-o-lok clips, titanium metal clips, and hand-tied ligatures when arterial segments are infused at 3 mL/hour. No leakage was noted for any device, even when maximum pump pressure of 800 mm Hg was reached.

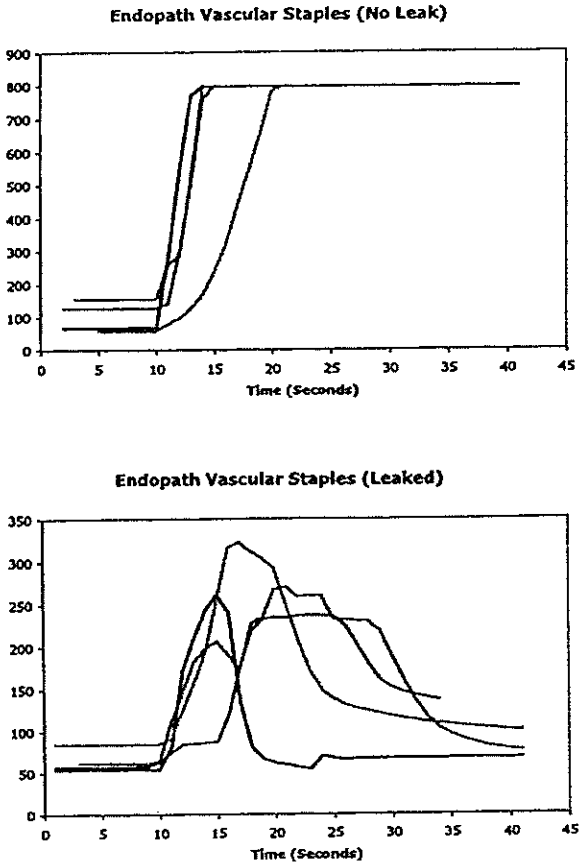

FIG. 2. Pressure profiles of 35-mm Endopath vascular staples. Four of eight stapled vessels showed no leak despite reaching maximum pump pressure of 800 mm Hg. Remaining four showed leakage when pressure reached mean of 273 mm Hg (range 237–322 mm Hg).

DISCUSSION

Our study confirmed the safety and security of the Ti-knot TK5 devices and the Weck Hem-o-lok clips compared with the traditional occlusion devices such as titanium metal clips and hand-tied ligatures. These devices have been gaining popularity in the laparoscopic urologic community. Vascular staples also appear to be effective under physiologic conditions: they leak only if a supraphysiologic pressure of >237 mm Hg is reached. These conditions will likely occur only if a surgical patient has poorly managed systolic hypertension.

Kerbl and associates performed a similar study on *in situ* and *in vivo* pig kidneys, comparing the effectiveness of staples, clips, and sutures in renal-artery ligation.[1] They found that three consecutive 9-mm titanium clips are as secure as 2-0 or 0 silk ties in occluding renal arteries. They also showed that vascular staples can be problematic because of leakage around the triple-staggered staple lines at supraphysiologic arterial pressures. Our experiments confirmed their findings. We found that metal clips (in our case, a single 5-mm clip) are as effective as 2-0 silk ties in renal-artery occlusion. However, 50% of the vascular staples failed when the arterial pressure reached a mean of 273 mm Hg (range 237–322 mm Hg). This suggests that vascular staples may be effective in low-pressure occlusions such as in renal-vein ligations but may have a higher likelihood of failure and leakage in arterial occlusions under supra physiologic pressures. This theoretical risk of leakage after renal-artery clipping can occur in a hypertensive surgical patient with a mean arterial pressure of 200 mm Hg or more.

Lurie and colleagues[2] used a triple-staggered line vascular stapling device on canine inferior vena cava with a mean diameter of 1.9 cm. In their *in situ* preparation, bursting pressures that ranged from 150 to 300 mmHg were noted. We have found a similar range of bursting pressures (237 to 322 mm Hg) in four of eight of our arterial segments occluded with a stapling device. Chan and coworkers[3] reported that GIA staple failures occurred in 10 of 565 of their laparoscopic nephrectomies. Seven of those failures were related to improper device applications, but three were the result of device failure. In one case, there was absence of a staple line on one end of the ligated vessel. In another case, there were staples, but the vessel remained open. In the last case, continued bleeding was noted at a renal-artery ligation necessitating urgent conversion to open laparotomy. Further inspection during laparotomy revealed an intact staple line. However, continued pulsatile bleeding was noted between the apposed vessel edges. Although they did not document the patient's arterial pressure when this failure occurred, their description is similar to what we observed during our experiment when leakage across the staple lines occurred. This suggests again that vascular staples are not as secure as the traditional hand ties or clips in ligations with higher than normal arterial pressures.

With the increased popularity of laparoscopic urologic procedures, new vascular occlusion technologies have been developed. These include the Harmonic Scalpel[4,5] and bipolar vacular sealing devices.[6,7] Comparisons of these devices have been done on cystic ducts by Matthews et al.[8] Although not recommended for large vessel occlusions, these new devices will need to be evaluated on vessels of different sizes using a similar experimental set-up to document the pressures at which vessels of various sizes can withstand use of these newer technologies.

In our study, arterial pressure was generated using a nonpulsatile generator. Pressure was increased by infusing saline at 3 mL/min until leakage occurred or until maximum pump pressure was reached. This experimental set-up approximates a condition in which the mean arterial pressure is gradually increased. However, to better approximate the *in vivo* condition, a preparation using a pulsatile pressure-generating device such as a perfusion pump may be more appropriate. In addition, the rate at which the pressure is generated may affect the final arterial bursting pressure.

CONCLUSIONS

All devices tested are capable of occluding renal arteries under physiologic conditions. Ti-knot devices and Hem-o-lok clips occluded renal arteries to pressures that exceeded 800 mm Hg. They are equivalent to hand ties under supraphysiologic conditions. Vascular staples have a lower pressure tolerance (mean leak pressure 273 mm Hg). However, they ap-

pear to remain secure unless a supraphysiologic pressure is reached.

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