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Evaluation of Surgical Staples for Ligation of the Renal Pedicle During Nephrectomy*

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Summary. A mechanical stapling instrument was evaluated for ligation of the renal pedicle during nephrectomy in nine healthy sheep. Two forms of disposable loading unit, from which stainless steel surgical staples could be dispensed in double or triple staggered row configuration, were assessed for their proper function when applied across the renal pedicle singularly or in series. The response of the sheep to surgery was assessed by physical, hematological, and serum chemistry evaluations. Tissue healing was determined by gross and histopathological examinations. Ligation and transection of the pedicle took 2 to 4 minutes. The vessels of the pedicle ranged in diameter from 3 to 12 mm. In two sheep, overzealous stripping of perivascular tissue from the renal pedicle prior to placement of a triple staggered row of staples resulted in mild hemorrhage from the renal stump. This was controlled by placing a second triple staggered row of staples proximal to the first. It was concluded that ligation of the renal pedicle could be performed rapidly, effectively, and safely in healthy sheep using the correctly applied mechanical stapler. It is inferred that a similar technique would be applicable to other species including man.

Key words: Nephrectomy – Renal pedicle – Hermostasis – Vascular staples

Introduction

In order to expedite the human nephrectomy surgical stapling instruments are being used with increasing frequency to ligate the renal pedicle prior its transection [8]. However, a lack of pertinent literature to support the technique, unfamiliarity with the equipment, and a concern for the intraoperative and postoperative complications associated with its use have prevented wide acceptance of stapling devices for this purpose.

The concept of using surgical stapling instruments for nephrectomy in humans is not entirely new. Reports in the literature, however, are few in number. Flye [2], in a letter to the editor, reported the successful use of the linear anastomosis stapler (GIA, United States Surgical Corporation, Norwalk, CT) for transection of the aorta proximal and distal to the renal arteries when performing en-bloc resection of cadaveric kidneys for implantation in a human recipient. Only two other reports could be found. In the first, Khalid [4] related his experience with the Russian UKL-60, a device similar to but somewhat larger than the mechanical stapling device used in our study, when performing 104 partial nephrectomies in humans. While the incidence of postoperative complications was reduced to 3.8% with the surgical stapler from 15.6% when using manual suturing techniques, the application of the surgical stapler for partial nephrectomy is significantly different from that when performing a complete nephrectomy. A somewhat more pertinent study was reported by Aivazian [1] who used Russian ULK40 and UKL50 surgical staplers to ligate and transect the renal stump during complete nephrectomy in 182 human patients. Unfortunately, while he implied that his results were good, he did not detail them quantitatively or outline any postoperative complications.

The study reported here was undertaken as a preliminary investigation of the use of a currently available surgical stapling instrument for simplified pedicle ligation during complete nephrectomy. The mechanical suture instrument (TA 30^{TM}, United States Surgical Corporation, Norwalk, CT) was used for ligation of the left renal pedicle in 9 sheep, chosen as models for the human patient. Two different designs of a disposable loading unit, from which the vascular staples were dispensed, were assessed for their reliability and ease of application when applied across the renal pedicle. The staples were compared for their hemostatic capabilities when used in three different ligation configurations. The response of the animals to surgery was assessed by means of physical, hematological, and serum chemistry

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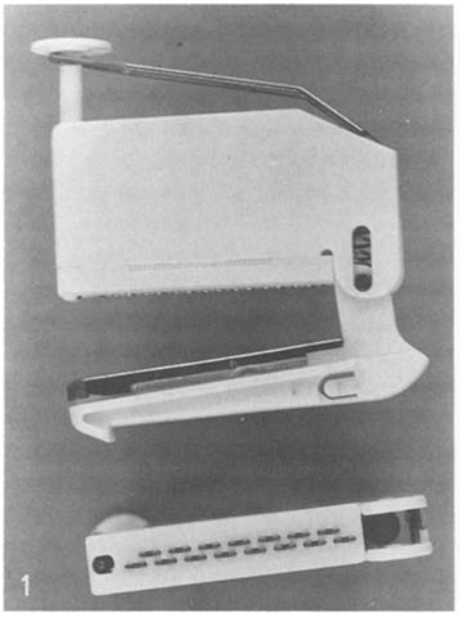

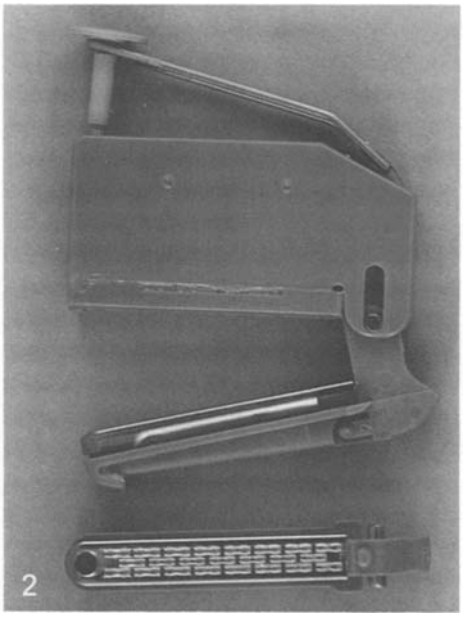

Fig. 1. The type 1 (TA 30 Premium^{TM}-V, United States Surgical Corporation) disposable loading unit. Above: side view showing the staple cartridge and anvil as a hinged unit. Below: end-on view of the staple cartridge revealing the double staggered row staple configuration

Fig. 2. The type 2 (TA 30 Premium^{TM}-V3, United States Surgical Corporation) disposable loading unit. Above: side view showing the staple cartridge and anvil as a hinged unit. Below: end-on view of the staple anvil revealing the triple staggered row staple configuration

Table 1. Summary of the sheep identification number, weight and stapling technique employed during complete left nephrectomy

Group	Sheep	Weight (kg)	Stapling technique: no. of Stapling cassettes x no. of Staggered rows	Remarks
A	1	46	2 x 2	Adhesion between parietal peritoneum and rumen
	2	55	2 x 2	
	3	64	2 x 2	Upper respiratory tract infection 11 days post surgery
B	4	50	1 x 3	
	5	50	1 x 3	
	6	64	1 x 3	
C	7	64	2 x 3	Fever 12 days post surgery. Mild hemorrhage from staple line of first cassette
	8	57	2 x 3	Mild hemorrhage from staple line of first cassette
	9	80	2 x 3	

evaluations. Healing of the renal stump was evaluated both by gross pathological and histopathological examination at the time of necropsy.

Materials and Methods

Nine healthy adult female sheep of mixed breed, between 4 and 5 years of age, and weighing from 46 to 80 kg, were randomly assigned a number and placed in one of three groups (Groups A, B and C) corresponding to the ligation technique employed. Two forms of disposable loading unit were under test. The first (Type 1, TA 30 Premium^{TM}-V, United States Surgical Corporation, Norwalk, CT) held 15 staples arranged in a double staggered row 31 mm long (Fig. 1). The second (Type 2, TA 30 Premium^{TM}-V3, United States Surgical Corporation, Norwalk, CT) held 23 staples in a triple staggered row 31 mm in length (Fig. 2). Both were dispensed from a mechanical suture instrument (TA 30^{TM}- United States Surgical Corporation, Norwalk, CT) for which they were specifically designed. Ligation was carried out in group A (sheep 1, 2, and 3) using staples dispensed from two Type 1 loading units; in Group B (sheep 4, 5 and 6) staples dispensed from one Type 2 loading unit; and in Group C (sheep 7, 8 and 9) staples dispensed from two Type 2 loading units (Table 1). The staples were manufactured from 0.21 mm diameter stainless steel wire, had a preclosure leg length of 2.5 mm, and a closed staple height of approximately 1.0 mm (Fig. 3).

Each sheep was housed in a 2 x 1.5 m pen and was offered a maintenance ration of hay and free water for the duration of the study. A complete physical examination was made on a daily basis prior to and following surgery. Blood samples were collected from the jugular vein for serum chemistries and for a hemogram prior to surgery. Serum urea nitrogen, creatinine, and hematological evaluations were repeated one, three, and five days post surgically and were assessed statistically using analysis of variance. Twenty-four h prior to surgery the sheep were administered 1 ml of tetanus toxoid, 1,500 IU tetanus antitoxin and 22,000 IU/kg of procaine penicillin intramuscularly (IM). Penicillin administration was continued at the same dosage twice daily for a further 5 days. Food was withheld for 24 h, and water for 12 h prior to surgery. Xylazine (0.05 mg/kg) and atropine (0.2 mg/kg) were administered IM as preanesthetic agents. Anesthetic induction was achieved using 13.2 mg/kg of 5% thiamylal sodium intravenously (IV). The sheep were intubated and maintained using halothane and oxygen in a semiclosed circle system.

Each animal was placed in right lateral recumbency. Standard skin preparation and sterile draping was completed. A paracostal

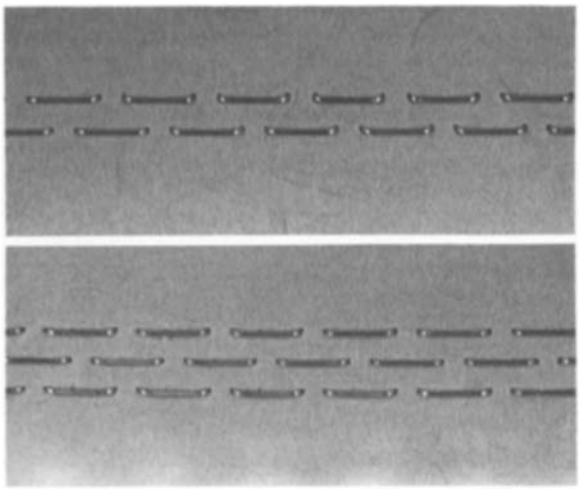

Fig. 3. The double (above) and triple (below) staggered row configuration of 0.21 mm diameter stainless steel wire staples used to ligate the left renal pedicle in a series of nine sheep. The base of each staple is 3 mm long

Fig. 4. The left kidney of sheep 3 retracted to reveal the disposable loading unit applied across the renal pedicle. The stainless steel arm of the surgical stapling instrument can be seen in the foreground. Abdominal contents are packed off using saline soaked towels and the incision edges are retracted using Balfour abdominal retractors

incision of the left flank, beginning 2 cm ventral to the lateral extremity of the transverse process of the second lumbar vertebra and 4 cm caudal to the last rib, was continued ventrally for 20 cm. Subcutaneous fat was reflected to reveal the abdominal wall musculature. This was incised with the underlying peritoneum, permitting access to the abdominal cavity and retroperitoneal space.

To facilitate access to the left kidney, intestine was reflected out of the surgical field using towels soaked in physiologic saline. The margins of the incision were carefully retracted using Balfour abdominal retractors. The left and right kidneys were palpated directly to assess their approximate dimensions and to determine the position of the renal vessels and ureters. Perirenal fat was reflected to expose the left kidney which was then elevated and exteriorized through the incision. Excessive perirenal adipose and connective tissue was removed to allow easy placement of the surgical stapling instrument, the jaws of which were secured across the renal pedicle 5 cm proximal to the kidney. The diameter of the renal vessels and ureter were measured and the staples were dispensed (Fig. 4). The stapling instrument was then released and removed from the surgical field.

In those animals where two loading units were used, the one more proximal on the renal pedicle was placed first. A second was then applied parallel and 1 cm distal to it. A Mixter hemostatic forceps was placed across the pedicle immediately adjacent to the kidney and a scalpel used for transection between the most distal staple line and the forceps. The staple line was checked for bleeding and the abdominal wound was closed in a routine fashion. A stent bandage was sutured over the incision. A non-steroidal anti-inflammatory drug, flunixin meglumine, was administered (1 mg/kg IM) following surgery to provide postoperative analgesia.

The sheep were sacrificed with a commercial euthanasia solution (T-61 Euthanasia Solution – American Hoechst Corporation, Somerville, NJ) 14 days after surgery, and a complete postmortem examination was undertaken. The diameters of the right and left renal arteries, veins and ureters were recorded. The left renal pedicle stump was removed intact and placed in 10% buffered formalin for histopathological evaluation.

Results

Prior to surgery all sheep were in good health on the basis of physical examination, a hemogram, and serum chemical evaluations. Sheep 3 developed an upper respiratory tract infection on the eleventh day following surgery and sheep 7 developed a fever of unknown origin (105 °F, 40.5 °C. Normal for this sheep: 102.5 °F, 39.2 °C.) on the twelfth postoperative day. Both improved clinically within 36 h without specific therapy. The remaining animals had an uncomplicated recovery after surgery. A statistically significant ($P < 0.01$) increase in total white blood cell count occurred following nephrectomy. The mean total white blood cell count increased from 7.56 (T ± 1.9 S.D.) x 10^3/mm^3 preoperatively to 9.44 (T ± 2.25 S.D.) x $10^3/mm^3$ twenty-four hours after surgery. A return to preoperative levels had occurred by the third postoperative day. The serum urea nitrogen and blood creatinine values did not show significant variations from preoperative values in response to nephrectomy.

The mean surgery time was 60 min. Although the vessels of the renal pedicle ranged in diameter from 3 to 12 mm, the surgical stapling instument, the disposable loading units, and the staples all functioned well. Occasionally, narrowness of the renal pedicle resulted in some staples failing to engage soft tissue. Preoperatively the mean diameter of the left renal arteries of the sheep was 5.0 mm and the left renal veins 9.0 mm. Postoperatively the mean diameters had decreased slightly to 4.5 mm and 8.2 mm respectively. No supernumerary renal arteries or veins were identified supplying the left kidney of any sheep. Ligation of the pedicle took from 2 to 4 min.

Very mild hemorrhage developed along the staple line in sheep 7 and 8 following placement of the first triple staggered row of staples. However, this ceased after placement of the second triple staggered row proximal to the first.

Gross pathological examination revealed normal wound healing in all but sheep 1 where mild adhesions were found between the parietal peritoneum and dorsal abdominal wall. All staple lines were covered by fibrous scar and adipose tissue and generally the ligated renal stump could only be identified by tracing the left ureter proximal from the bladder.

Histopathologic examination revealed colonization of gram positive cocci bacteria and lymphocytic infiltration of the transected wall of the left renal artery in sheep 1. Mild proliferation of granulation tissue, focal mineralization, and lymphocytic infiltration was also present in the surrounding connective and adipose tissue. Local areas of lymphocytic infiltration were also noted in sheep 9 while sheep 2, 3, and 7 showed, on microscopic evaluation, evidence of focal, acute hemorrhage into the perivascular tissue.

Discussion

The primary concern of a surgeon performing a nephrectomy is to minimize the surgery time without risking increased intraoperative or postoperative complications. The 2 to 4 min required to secure the renal pedicle with the TA 30 stapling instrument is rapid and provides a reason to promote the technique as an acceptable alternative to hand ligation for individual renal vessels prior to their transection. Indeed, while no sheep in this series had supernumerary renal vessles, the TA 30 may be particularly expedient for ligating the pedicle in patients with more than one artery or vein per kidney. The stapler separates the vessels when the pedicle is compressed within its jaws at the time of closure, minimizing the likelihood of arteriovenous fistula formation, a postoperative complication that can occur when vessels are closely apposed following en mass manual ligation [3, 5].

Intraoperative and postoperative hemorrhage from the renal stump has been reported as a major complication of nephrectomy [6, 7]. Although unsupported by controlled data, concern for the hemostatic properties of staple closed vascular elements in particular has discouraged the use of surgical staples for ligation of the renal pedicle. While the total number of sheep in this study does not allow for good statistical comparison of the hemostatic capabilities of the three stapling techniques employed, significant hemorrhage was not a complication with any of them. Even though mild seepage of blood was noted intraoperatively from the staple line in sheep 7 and 8, the authors believe that this was caused by overzealous stripping of the perivascular adipose and connective tissue from the pedicle prior to placement of the occluding staples. The relatively isolated renal vessels and ureter which remained failed to provide sufficient tissue for the staples, which are non-strangulating and non-necrosing, to achieve adequate compression of the vessel lumen. Should this occur, our results indicate that use of a Type 2 loading unit is no more likely to guarantee hemostasis than use of a Type 1 loading unit, Indeed, on both occasions that hemorrhage from the staple line was noted, a Type 2 loading unit had been employed. It is important, therefore, that care be taken to strip only sufficient perivascular tissue to place the jaws of the instrument. Hemorrhage from the staple line will then be unlikely to occur. If it should, placement of a second loading unit proximal to the first may halt the bleeding as it did in our study, supporting the unpublished contention of some surgeons that two loading units provide greater security against hemorrhage then the use of one alone.

The histopathologic identification of some focal hemorrhage within the perivascular tissue of the renal pedicles of sheep 2, 3 and 7 should be expected given the fact that the staple wires perforate the vessel walls immediately prior to being bent into their final "letter B" configuration. It is not an indication of failure of the staple line to achieve adequate hemostasis.

The use of double or triple staggered rows of staples may be particularly appropriate in patients with inflammatory reactions or excessive fat in the region of the pedicle since hand-tied ligatures are prone to slip under these circumstances [9]. In comparison, the TA 30 provides a two to three layered ligation effected by stainless steel staples which simultaneously transfix the tissue through which they are inserted.

The mechanical stapler can also be expected to provide for rapid ligation and transection of the great vessels when performing en bloc resection of cadaveric kidneys for transplantation and other purposes.

While the results of this preliminary study indicate that ligation and transection of the renal pedicle in healthy sheep can be performed rapidly, effectively, and safely using the TA 30 mechanical suture instrument, studies of larger numbers of subjects remain desirable. The technique would appear to have considerable potential for continued application in humans and in other animal species.

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