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REVIEW ARTICLE

Techniques to Secure Renal Hilum in Laparoscopic Donor Nephrectomy

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ABSTRACT

Laparoscopic donor nephrectomy is the standard of care in donor kidney procurement for renal transplantation. Use of nonabsorbing polymer locking clips for securing the renal artery in this procedure is widely practiced. The US FDA has given instructions contraindicating the use of Hem-o-lok clips in securing renal artery in donor nephrectomy. This article reviews the modalities for securing renal artery in laparoscopic nephrectomy published in the last decade.

Keywords: Laparoscopy, Donor nephrectomy, Renal artery, Hem-o-lok, Clips, Staples.

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INTRODUCTION

Laparoscopic donor nephrectomy is the standard of care for live renal procurement in transplantations. Generally, clips were used to secure renal artery, but at least five deaths from catastrophic postoperative hemorrhage following laparoscopic donor nephrectomy were reported since 2005 attributable to insecure ligation of their renal artery by a locking clip. US FDA issued a safety information on 5/6/2011 that Hem-o-lok clips are contraindicated in ligating renal artery in laparoscopic donor nephrectomy.[1] The alternatives are suture ligature, oversewing or stapling. Techniques that use transfixion are difficult to perform, time-consuming and challenging. This article reviews the modalities used to secure renal hilum in laparoscopic nephrectomy.

MATERIALS AND METHODS

An extensive electronic search of the medical literature published in the last decade using the keywords laparoscopy, hand-assisted laparoscopic donor nephrectomy (HALDN), Hem-o-lok clips, staples for renal artery. Included the articles mentioning securing of renal artery in laparoscopic nephrectomy for other indications. Excluded articles on the mass ligation of renal pedicle.

RESULTS

FDA issues safety alert to healthcare providers that Weck Hem-o-lok ligating clips should not be used for the ligation of the renal artery during a laparoscopic living-donor nephrectomy because of serious risks to the donor.[1] The clips may become dislodged, which can lead to uncontrolled bleeding, additional surgery or death of the donor. In 2006, the manufacturer added this contraindication to the 'Instructions for Use' after receiving 15 reports of 12 injuries and three deaths which occurred between 2001 and 2005. Since, the contraindication issued in 2006, there have been three more kidney donor deaths, all associated with the contraindicated use.

I searched online in the FDA MAUDE database (Manufacturer And User Facility Device Experience) from 1/1/2001 to 6/30/2011, found two cases of death following use of Hem-o-lok clips in donor nephrectomy.[2] One of the patient undergone laparoscopic donor nephrectomy in 2008 and died on the following day. The incident was reported as approximately 8 hours postoperative, a male donor nephrectomy developed difficulty in breathing and became unresponsive. He was returned to surgery where an exploratory laparotomy was performed and intraperitoneal bleeding was encountered and evacuated from the abdominal cavity. It was noted the clip that had been placed on the renal artery stump during the nephrectomy was not visible. A 1.5 cm tear was noted at the aorta, which was clamped and repaired. The renal artery appeared thin and friable. The patient developed DIC and expired.

The other report stated that a donor died a few hours after a live, donor nephrectomy. The event occurred at the national university hospital. No details were available. The manufacturer (Weck, Teleflex Medical Research Triangle Park NC) examined the batch of Hem-o-lok clips and reported: Pulsatile pump testing was performed which simulates the environment, the clips are subjected to during surgery with respect to closure. The blood pressure that the clips are subjected to is approximately twice the normal blood pressure in humans. The clips were tested for 24 hours and had an acceptance criteria of no clip slippage off the vessels and no failure to the locking mechanism of the clips. At the end of the 24 hours period, no solution was observed from the distal end of the clips. The results of the pulsatile pump testing show the product performed satisfactory. Based on review of the information provided and testing of like product, the device could have been functioning as intended, and we cannot conclude that the reported incident was caused by a failure of the Hem-o-lock clip.

There were concerns about the safety of the nonabsorbable polymer locking clips since 2004 to 2006 and FDA had temporarily banned it in 2006. With reintroduction late in 2006, transplant surgeons, urologists and minimally invasive surgeons were using the polymer locking clips extensively for securing the renal artery in donor nephrectomies as it was clear that the reported clip malfunctions were not frequent. Even though it is infrequent, it is catastrophic and we should respect the privilege of kidney donor.

Intraopeartive clip malfunction is not infrequent. Maartense S et al reported two cases of perioperative clip dislocation during laparoscopic donor nephrectomy and the techniques to tackle the situation.[3] In the first case, during left HLDN the clips placed on the renal artery dislodged, and the surgeon managed to control the bleeding by compressing the focus of the bleeding with his finger. A balloon occlusion catheter was inserted through a groin incision in the aorta and advanced to the origin of the renal artery. Due to control of the hemorrhage, it was possible to close the renal artery stump by laparoscopic suturing and a conversion was averted. In the second case, during right HLDN, the clips on the renal artery dislodged during stapling of the renal vein. The bleeding was controlled by finger compression and new clips were placed. The cuff of the artery was long enough to be clipped again. The use of a balloon occlusion catheter is an elegant way to avert conversion.

Elliott SP et al[4] from the University of California studied the bursting strength with various methods of renal artery ligation and potential mechanisms of failure. One end of an adult porcine artery (3-7 mm diameter) was occluded with a titanium clip, self-locking polymer clip or laparoscopic linear cutting stapler. Comparisons were made with one or two clips and with different distal cuff lengths (i. e. flush or 2 mm). The open end was secured to a pulsatile infusion pump. Leak/failure pressures were measured using a digital barometer. The mean bursting pressures for the clips were found above physiologic arterial pressures (1220-1500 mm Hg). However, the vessels closed with the stapler leaked at a lower mean pressure (262 mm Hg). Failure of titanium or self-locking polymer clips was the result of vessel retraction into and behind the clip, while staple-line leakage occurred between individual staples. Bursting pressures with the titanium and self-locking polymer clips were unaffected by the number of clips or length of vascular cuff. He concluded that all tested methods of vascular control performed well at physiologic pressures, suggesting that safety is not increased with traditional maneuvers such as additional clips or longer cuff length.

The efficacy of nonabsorbable polymer ligating (NPL) and titanium clips applied with and without a 1 mm vascular cuff at physiologic and supraphysiologic pressures *in vitro* equine-vessel model was compared by Jellison FC et al[5] in Loma Linda University Medical Center, CA. Ten millimeter NPL and standard Ti clips were applied to veins (10 mm) and arteries (10, 6 and 5 mm) with and without a 1 mm cuff and tested until they held a pressure of 300 mm Hg (veins) or 760 mm Hg (arteries) for 2 minutes or leaked. The NPL clip was noted statistically more secure on 10 mm veins with and without a cuff, 10 mm arteries with and without a cuff and 6 mm arteries with a cuff than was the Ti clip. Leaving a 1 mm cuff resulted in a statistically higher leak point in all vessels tested except the 6 mm arteries secured with the Ti clip. They concluded that the NPL clip was more secure than the Ti clip on larger arteries and veins. A 1 mm vascular cuff enhances the security of both NPL and Ti clips in vessels of all sizes. The NPL clip is secure and reliable in securing both arteries and veins.

Endolinear stapling devices with clips in hand-assisted laparoscopic donor nephrectomy were compared by Baldwin DD et al.[6] The stapling devices have a potential for misfire. Use of the NPL clip during laparoscopic donor nephrectomy provides increased graft vessel length compared with the stapling device, and the NPL clip has a locking mechanism which may increase security compared with standard titanium clips. The 50 consecutive HALDN patients in their series were conducted with two parallel NPL clips used to control both the renal artery and vein. They opined that the NPL clip was 100% safe and effective in controlling the renal artery and vein during HALDN, allowed for additional vessel length, and resulted in a disposable cost savings of US 362 dollars per patient.

Another report comparing the outcomes in left renal artery clipping *vs* stapling in HALDN by James et al[15] at the Medical College of Georgia. A 55 HALDN procedures were performed by one laparoscopy-trained urologist from 2003 to 2007. During the first 30 months, 27 consecutive HALDN patients underwent renal artery occlusion with two nonabsorbable polymer locking clips (group 1). The subsequent 18 months saw 28 consecutive HALDN patients receive three-row vascular stapling to occlude the renal artery (group 2). The preoperative patient factors were age, sex, body mass index, serum creatinine (Cr) and presence of supernumerary left renal artery. Intraoperative factors included estimated blood loss (EBL), operative time (OT) and warm ischemia time (WIT). Postoperative data were 24 hours Cr and hemoglobin concentration, transfusion requirement, hospitalization time and complications. Data are presented as mean ± standard deviation and analyzed

using parametric tests ($\alpha = 0.05$). They found no significant difference between groups with respect to preoperative factors, OT and EBL; however, WIT was shorter in group 2 (3.6 ± 0.2 *vs* 2.6 ± 0.3, $p = 0.048$). Within-group comparisons revealed longer WIT for patients with supernumerary renal artery compared with those with a single artery (group 1, $p = 0.044$; group 2, $p = 0.042$). Moreover, no major between-group variations were seen in postoperative donor outcomes. Left renal artery ligation during HALDN using a three-row vascular stapler is safe and yields donor outcomes comparable with dual polymer clips. In addition, left renal artery stapling may decrease WIT compared with dual clipping.

Casale P et al[7] reported their personal experience in 31 laparoscpic nephrectomies in which both the renal artery and the renal vein were secured using only NPL clips. No renal vessel injuries, cases of clip dislodgement or slippage, or bleeding were recorded. They also achieved meaningful reduction in the cost of procedure.

Lee Ponsky et al[8] reported a multiinstitutional review from nine institutions with laparoscopic trained urologists performed 1695 laparoscopic nephrectomies (radical nephrectomy, N = 899; simple nephrectomy, N = 112; nephroureterectomy, N = 198; donor nephrectomy, N = 486). Follow-up was a minimum of 6 months from the time of surgery. For each case, we used Hem-o-lock clips to control the renal artery. The renal vein was controlled with Hem-o-lok clips in 68 cases (radical nephrectomy, N = 54; simple nephrectomy, N = 3; nephroureterectomy, N = 5; donor nephrectomy, N = 6). Number of clips placed on the patient side of the renal artery was most often 2, occasionally 3. Number of clips placed on the patient side of the renal vein was most often 2 and rarely 3. All cases used the large (L-purple) clip on the artery, and most cases of renal vein used the extra-large (XL- gold) clip on the vein. No cases of clip failure such as intraoperative or postoperative clip dislodgement necessitating reoperation was recorded.

Izaki et al[9] reported 40 laparoscopic nephrectomies in which renal pedicle ligation was accomplished using extralarge (XL) Hem-o-lok clips on both the renal arteries and veins by placing two clips on the patient side and one clip on the specimen side. Vascular control using XL Hem-o-lok clips was successful in all 40 cases, without any slipping of clips or uncontrolled bleeding.

Yip SK et al[10] reported 46 nephrectomies (40 HALDN, 6 lap). Venous control was achieved solely by the Hem-o-lok clips where at least two clips were applied on the patient side. Arterial control was obtained by the Hem-o-lok clips either alone or in combination with the metal clips. Hem-o-lok was successful in all 46 cases without any slipping of clips or uncontrolled bleeding.

Controlled ligation and division of renal vessels is a critical step during any nephrectomy procedure. It has generally been presumed that titanium clip ligation of renal vessels is risky and insecure. In a report from Sir JJ Hospital and Grant Medical College, Mumbai, India,[11] they analyzed their experiences over 5 years with ligaclips 10 mm titanium clips for secure ligation of renal hilum during laparoscopic nephrectomy. Titanium clips of 10 mm were used to secure renal vessels in 86 patients. They managed to get across the entire width of renal vein with a 10 mm titanium clip by crimpling the vein with the help of the clip applicator before firing the clips. In all except two cases, ligaclips alone were enough to ensure secure occlusion of renal hilum. There was no incidence of slippage or dislodgement of clips applied on renal vessels. On cost analysis, it was found that the Hem-o-lok clip and gastrointestinal anastomosis stapling device were approximately 6-fold and 12-fold costlier than ligaclips.

Another report from Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India, (Kapoor R et al)[12] included 246 laparoscopic ablative nephrectomies (178 simple; 68 radical) were performed for benign and malignant conditions, underwent either standard transperitoneal (N = 204) or retroperitoneal (N = 42) nephrectomy. Venous and arterial control was obtained using Hem-o-lock clips. In cases where the clips could not be applied directly on the renal vein, various maneuvers were employed to secure the occlusion. The features compared were the number of clips used, safety, cost and requirement for blood transfusion. Conversion to an open procedure was required in 36 patients (28 in the transperitoneal group and 8 in the retroperitoneal group). In all cases, arterial and venous control was achieved by application of two Hem-o-lok clips on the patient side. Blood transfusion was required by 7.2% of the patients (right-side nephrectomy 4.6%; left-side nephrectomy 2.6%), but none was attributable to clip-related complication.

Ryan SA Hsi et al[13] reported a review to characterize the mechanisms of failure and patient outcomes during complications with the use of endoscopic stapling devices, nonlocking titanium clips, and locking polymer clips during laparoscopic donor nephrectomy. They identified 92 cases of complications due to device malfunctions. In the 92 complications identified, 59 (64%), 21 (23%), and 12 (13%) failures of endoscopic staplers, titanium clips and locking clips had occurred respectively. The most common mechanisms of stapler failure were missing/malformed staple lines (51%) and failure to release (25%). The most

common titanium clip failures resulted from scissoring or malformation (52%), jamming (19%) and dislodgement (14%). Clip dislodgement was most common with the locking clip, either postoperatively in seven (58%) or intraoperatively in three (25%). Intraoperative conversions were required for 21 (36%), one (5%) and two (17%) for staplers, titanium clips and locking clips respectively. The estimated overall failure rate was 3.0% for staplers, 4.9% for titanium clips and 1.7% for locking clips. They concluded that donor surgeons must be familiar with and anticipate the potential failures seen with each of the techniques used to secure the renal hilum. Knowledge of potential device failures, combined with prompt and appropriate corrective action, may limit donor morbidity when malfunction occurs. Finally, it is the responsibility of surgeons to act as donor advocate and continue to petition device manufacturers to improve the safety of existing devices. In a previous study by the same author of complications with hemostatic devices during laparoscopic nephrectomy, they observed a greater proportion of locking clip failures occurring during donor procedures compared with stapler and titanium clip failures (67 *vs* 24 and 19% respectively).[21]

Nasser Simforoosh et al[14] reported the use of a new modification of the technique for controlling the renal pedicle during laparoscopic donor nephrectomy (LDN) with Hem-o-lok clips. They did LDN in 241 candidates. At the end of procedure for renal-artery closure, one 10 mm Hem-o-lok clip was applied a few millimeters distal to the root from the aorta, and a medium-large titanium clip was applied distal to the Hem-o-lok clip using a nonautomatic firing applier to exert sufficient closing pressure to the titanium clip to ensure adequate tightness. Then the renal vein was doubly ligated with one 12 mm and one 10 mm Hem-o-lok clips. They reported that there were no intraoperative or perioperative bleeding complications, clip dislodgments or slippages. The conversion rate was zero, and the mean warm ischemia time was 7.50 ± 0.71 minutes (range, 3-17 minutes). Graft function was excellent, with a mean serum creatinine concentration of 1.42 ± 0.46 mg/dl after 12 months of follow-up and no renal-artery or vein thrombosis in any of the grafts. They concluded that with these techniques, there is more security on the arterial closure, and sufficient pedicle length can be obtained for anastomosis. The warm-ischemia time is within an acceptable range. Also, this approach is less expensive than the use of endovascular staplers.

Tmsit et al[16] reported the feasibility of a simple surgical artifice that aims to preserve the advantages of lockable clips with increased safety while respecting the manufacturer's legal recommendations. Since January 2009, a polyglactin-0 tie was placed on the renal artery in addition to the two usual Hem-o-lok clips in LLDN at our institution (n = 10) using a pretied loop suture (Endoloop ligature, Ethicon) placed on the artery stump, proximally to the aorta, after kidney removal. This artifice increased operating time of 65 seconds (range, 35 to 85 seconds) with no modification of warm ischemia time and led to visually decreased aortic pulsation transmitted to the clips. Without evidence of increased safety, they assume that this use may protect surgeons from prosecution in cases of clip displacement. It certainly decreases the risk of clip slippage and should be considered as a cheap, easy artifice to reduce the already low-risk of hemorrhage in LLDN.

Liu et al[17] had concerns about the stapler malfunction and satisfied clips. They had no vascular complications and no device failure during vascular control using polymer locking clips. They believe that polymer locking clips are safe, yielding greater vessel length during laparoscopic donor nephrectomy.

Geron et al[18] from South America described their experience with the use of nonabsorbable polymer ligaclip (NPL) to control the renal artery, vein, and ureter in hand-assisted laparoscopic donor nephrectomy (HALDN). They performed 85 procedures and reported the NPL was safe and cost-effective, not increasing morbidity of the procedure.

Edmund et al[19] reported a retrospective review of Mayo Clinic experience with 400 LDN from 1999 to 2007. The endovascular gastrointestinal anastomosis (GIA) stapler has been used for renal vascular control for their donors since the inception of their LDN program. Forty-one were on the right. There were no statistically significant differences between the donor groups or their respective recipients. There were four (1%) stapler malfunctions, all occurring on the left side; two of these procedures were converted to open to obtain hemostasis. There were nearly equal rates of vascular complications, 4.9 and 4.7%, in the right and left groups respectively. The overall immediate graft failure rate was 2.3%. Right and left recipient creatinine levels up to 24 months demonstrated no statistically significant differences. They proposed that the endovascular GIA stapler for left and right laparoscopic donor nephrectomy is safe for the donor. It standardizes the process, minimizes the need for additional maneuvers in securing the renal hilum, and produces similar outcomes for the recipient. The transplant team also plays an equally large role in favorable graft outcomes.

In contrast to vessel wall occlusion with metal clips, the Endo-TA stapler transfixes the vessel with three rows of

staples and has been shown to preserve vessel length compared with the Endo-GIA and Endopath devices.[20]

DISCUSSION

Laparoscopic donor nephrectomy is the preferred mode of renal procurement and it demands more surgical skill compared to conventional laparoscopic nephrectomy. The need for adequate length of renal artery on the left side force to reduce the renal artery stump. The need for securing gonadal, adrenal and lumbar veins make the situation difficult. The shorter right renal vein poses risk on the right-sided nephrectomy. Moreover, the surgeon is in a hurry during the clue time to reduce the warm ischemia time.

Nonlocking clips, locking polymer clips and staples and ligatures were used, all with safety, but none is 100% safe. Stapling devices poses potential for missing, malformed staple lines, and failure to release. In renal arteries with early branching, surgeons feel it challenging to get multiple renal arteries with graft rather than to get the proximal end with single stem. Stapler and NPL are costlier 12 and 6 times respectively when compared with titanium clips. NPL clips increase the graft length, locking mechanism increases security. Chances of dislocation are more with intraoperative conversion and postoperative exploration. Titanium clips poses the risks of scissoring, malformation, jamming and dislodgement.

Surgeon should be familiar to all the potential problems that arises with securing of the renal artery and should anticipate the device malfunctions. Reminding some of the precautions already known to all may be of use. Take precaution in all steps of vessel dissection, the vessel should be nicely dissected off all fatty tissue before applying the device. When using clips, a minimum number of two clips should be applied on the donor side, with adequate gap between them to form a perfect dumbbell. Apply the clip at right angles to the vessel. Obliquely applied clips are insecure. Clearly visualize all around the clip. There should be adequate vascular cuff beyond the clip (1-2 mm). Avoid electrocoagulation in the vicinity of clips to prevent conductive tissue necrosis and subsequent clip dislocation. When using NPL clips, other augmenting modalities like the use of pretied loop suture, and use of a titanium clip distal to the NPL clip can also be considered. Use of suture ligature with inracorporeal or extracorporeal knotting is always safe there in the hands of a laparoscopic surgeon.

CONCLUSION

The various securing devices for renal artery in laparoscopic donor nephrectomy are generally safe, but not exempt from infrequent malfunctions and complications which can be lethal and cannot be neglected. As the live kidney donation is a gift of life, it is our responsibility to ensure the donor safety.

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