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The Use and Safety of Vascular Occlusion Techniques: A Survey of Practicing Surgeons

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A Thesis Submitted to the

Yale University School of Medicine

in Partial Fulfillment of the Requirements for the

Degree of Doctor of Medicine

by

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2007

ABSTRACT

THE USE AND SAFETY OF VASCULAR OCCLUSION TECHNIQUES: A SURVEY OF PRACTICING SURGEONS.

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Vascular occlusion techniques can be divided into two categories – transfixion and non-transfixion. Transfixion techniques are defined by the passage of suture material or staples through the vascular tissue. Non-transfixion techniques are defined as suture, metal, or polymer material placed solely around the vascular tissue.

The purpose of this study was to survey surgeons in various specialties to determine which vascular control technique they believe is safest and most appropriate to manage medium-sized arteries 6-10mm in diameter.

A survey was distributed to surgeons in the following specialties: general surgery, urology, thoracic surgery, vascular surgery, obstetrics and gynecology, and colon and rectal surgery. Survey recipients were all members of the American College of Surgeons practicing in New York and New England. The survey asked questions focused on the use, perceived safety, and technical failure of vascular occlusion techniques applied to the renal, splenic, and cystic arteries. The smaller cystic artery was included as a control.

506 surgeons completed the survey. The survey found that more surgeons chose transfixion techniques vs. non-transfixion techniques to occlude the renal artery in both open and laparoscopic operations (open = 72% vs. 28%, $p<0.0001$; laparoscopic = 55% vs. 45%, $p<0.01$). More surgeons chose transfixion techniques vs. non-transfixion

techniques to occlude the splenic artery (open = 68% vs. 32%, $p<0.0001$; laparoscopic = 60% vs. 40%, $p<0.0001$). In contrast, fewer surgeons chose transfixion techniques vs. non-transfixion techniques to occlude the cystic artery (open = 15% vs. 85%, $p<0.0001$; laparoscopic = 4% vs. 96%, $p<0.0001$).

Respondents were asked to rate the safety of vascular occlusion techniques on a 5-point Likert scale ranging from 1 “unsafe” to 5 “extremely safe”. Transfixion techniques were considered safer than non-transfixion techniques to occlude the renal artery (mean safety rating: 3.9 ± 0.5 vs. 2.6 ± 0.7). Transfixion techniques were considered safer than non-transfixion techniques to occlude the splenic artery (mean safety rating: 3.9 ± 0.4 vs. 2.6 ± 0.6). Transfixion and non-transfixion techniques were considered equally safe to occlude the cystic artery (mean safety rating: 3.9 ± 0.5 vs. 3.8 ± 0.5).

Respondents reported more cases of technical failure and severe hemorrhage associated with non-transfixion techniques than transfixion techniques for all three arteries. Renal artery: 44 cases (89% non-transfixion, 11% transfixion; $p<0.0001$); splenic artery: 50 cases (74% non-transfixion, 26% transfixion; $p<0.0001$); cystic artery: 68 cases (96% non-transfixion, 4% transfixion; $p<0.0001$).

In conclusion, to occlude blood vessels 6-10mm in diameter, surgeons chose transfixion techniques more frequently than non-transfixion techniques for both open and laparoscopic operations, considered transfixion techniques safer than non-transfixion techniques, and reported fewer cases of technical failure and severe hemorrhage associated with transfixion techniques than non-transfixion techniques.

ACKNOWLEDGEMENTS

First and foremost, I would like to thank my advisor Dr. Amy L. Friedman. Over the past four years, Dr. Friedman guided me through every step of the research process – designing the survey instrument, obtaining HIC approval, printing and distributing the survey, analyzing the results, writing and revising, etc. Dr. Friedman was extremely supportive throughout the entire process. Working with such a capable advisor and mentor was a valuable learning experience. Dr. Friedman's ability to balance the responsibilities of surgeon, professor, research scientist, spouse and parent is inspiring.

I thank Ms. Cynthia Bartley for all of her administrative assistance and encouragement along the way.

I thank the American College of Surgeons for providing us with a mailing list and I thank those members who took the time to complete and return the survey.

I thank my father, Leonard J. Kelly, for his guidance and assistance with the statistical analysis of the data.

I thank both of my parents, Leonard and Patricia Kelly, and my sister, Kristin Kelly Porter, for their love and support throughout my years in medical school.

Above all, I would like to thank my wife, Michelle Kelly. Thank you for reading my thesis and providing valuable feedback. Thank you for allowing me to take over the study with surveys, rough drafts, articles, and other piles of papers related to this project. Thank you for allowing me to commandeer your lap-top for the past two months. In short, I couldn't have completed this project or survived medical school without you. I love you.

This research project was supported in part by a Yale Medical Student Research Training Fellowship from the Yale Medical School Office of Student Research (6/1/04-8/31/04).

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I. INTRODUCTION

On the morning of June 25, 1990 the first laparoscopic nephrectomy was performed. For the first time, a tumor-bearing kidney was completely excised from an 85-year-old woman using the laparoscopic approach. The development of a nylon extraction bag and a tissue morcellator device made it possible to deliver the 190 gram kidney through an 11mm incision. The tissue morcellator device was an instrument that essentially cut the kidney tissue into pieces small enough to extract through the incision. The operation was a success. The patient was discharged home on post-operative day six. She resumed normal pre-operative activities by post-operative day ten. (1)

The authors described the control of the renal vasculature during the procedure as follows, “Due to the proximity of the dissection to the medial border of the kidney the vascular structures were smaller in size but multiple in number. Each of five segmental renal arteries was subsequently dissected and secured with ligature clips: 2 clips on the renal side and 2 or 3 on the vascular stump. The secured vessels were transected with a 5mm hook scissors.” The authors did not describe how the renal vein was managed, but it is assumed that clips were employed on the renal vein, as well. Surgical clips are small pieces of metal or polymer that are squeezed around a blood vessel to stop blood flow, see Figure 1 page 25. The authors state that the development of rapid load metal clip appliers contributed significantly to the success of the laparoscopic operation. “Rapid load metal clip appliers have been of great benefit… [They] allow for rapid and secure occlusion of vascular structures. This precludes the necessity of passing suture and tying surgical knots through the laparoscope, which is difficult and tedious." (1)

On February 8, 1995 the first laparoscopic live *donor* nephrectomy was performed. J.G., a 40-year-old man, agreed to donate his left kidney to his sister J.S., a 41-year-old woman with end-stage renal disease secondary to glomerulonephritis. The operation was a success. No intra-operative complications occurred. Blood loss was minimal. Adequate lengths of renal artery, vein, and ureter were obtained. The donor was discharged home on post-operative day one. The recipient was discharged home on post-operative day nine with a creatine level of 0.6 mg/dl (normal range 0.6-1.2 mg/dl). Based on this successful initial operation, the authors concluded that laparoscopic live-donor nephrectomy could be performed without detriment to either the donor or recipient. (2)

The vascular control of the renal pedicle during the first laparoscopic *donor* nephrectomy was described as follows, "The renal artery was occluded proximally with two 9-mm vascular clips and divided. The renal vein was transected anterior to the aorta utilizing an endovascular-gastrointestinal anastomosis (endo-GIA) stapler." Compared with the first laparoscopic nephrectomy, a difference in vascular control technique is already observed – an endo-GIA stapler was used to manage the renal vein instead of clips. In one motion, an endo-GIA stapler applies six rows of staples to a vessel and transects the vessel in between leaving three rows of staples on either side, see Figure 1 page 25. In other words, the endo-GIA stapler simultaneously ligates and transects the vessel. The authors do not indicate why they chose to manage the renal vein with an endo-GIA stapler as opposed to clips, but a later publication by different authors describe that the longer jaws of the stapler seemed more appropriate than clips for use on the wider renal vein. (3)

In February 1999, the same group who pioneered the laparoscopic live *donor* nephrectomy published an article updating their work. First, the authors performed a retrospective review of 70 laparoscopic live donor nephrectomies performed at their institution with 20 open donor nephrectomies performed at their institution *prior* to the introduction of the laparoscopic operation. The authors do not comment on how the 20 historic controls were selected. Nor do they comment on the patient selection criteria for the laparoscopic operation vs. the open operation. In addition, it is not specified whether the 70 laparoscopic operations were performed consecutively. However, with this relatively small sample size and a comparison to historic controls, the authors showed that patients who underwent *laparoscopic* donor nephrectomy demonstrated a statistically significant benefit in terms of estimated blood loss, analgesic requirement, hospital stay, resumption of oral intake, return to full activity, and return to work. (4)

The authors also conducted a retrospective review of laparoscopic vs. open donor nephrectomy using *contemporary* controls. They compared 25 laparoscopic donor nephrectomies with 35 contemporaneous open donor nephrectomies. All operations were performed between January 12, 1995 and December 1, 1996. All open donor nephrectomies were performed at Johns Hopkins Hospital. Laparoscopic donor nephrectomies were performed at both Johns Hopkins Bayview Medical Center and Johns Hopkins Hospital. There were no significant differences between the two donor groups in terms of age, gender, or race. The retrospective review with contemporary controls, albeit a small sample size in both groups, again demonstrated a statistical benefit in terms of hospital stay, analgesic requirement after discharge, return to work, time to resume driving, time to resume exercising, and time to resume household chores. (4, 5)

In papers published after the initial laparoscopic donor nephrectomy, the same group at Johns Hopkins described ligating and dividing *both* the renal artery *and* renal vein with an endo-GIA stapler. After thorough dissection, the endo-GIA stapler was used to ligate and divide the renal vein and renal artery sequentially, not simultaneously. (6, 7) Recall that in the initial laparoscopic donor nephrectomy, the renal artery was ligated using surgical clips and the renal vein was ligated with the endo-GIA stapler. While the authors did not account for the change in technique, a later article published by the same group described that using the endo-GIA stapler on both the renal artery and renal vein eliminated the need to introduce scissors into the operative field during a critical part of the operation when inadvertent vascular injury could occur. (8)

In March 2000, Chan et al. published an article describing endo-GIA stapler malfunctions during laparoscopic nephrectomy. From July 1, 1993 to September 30, 1999, 565 patients underwent laparoscopic nephrectomy at the authors' institution – 335 for benign and malignant diseases and 230 for renal donation. Failure of the endo-GIA device was identified in ten cases (1.7%). It was determined that *primary failure* of the endo-GIA device was the cause in only three cases – absence of the proximal row of staples (1 case), deployment of staples but failure to ligate the vessel (2 cases). Seven of the malfunctions were from *preventable causes* – deploying the device over a previously placed clip (5 cases), entrapment of venacaval tissue in the sliding device mechanism (1 case), and incomplete transection of the vessel because the GIA was not positioned properly (1 case). The authors concluded that, despite these malfunctions, use of the GIA device for vascular control was safe. They emphasized that "most GIA device failures were due to preventable causes, which could have been avoided with vigilant application of the device, and most malfunctions could be managed without conversion to an open procedure." (9)

Using a large sample size (565 patients) the authors clearly demonstrated a relatively low incidence of endo-GIA stapler failure (10 cases, 1.7%) during laparoscopic nephrectomy. In addition, only three cases (<1%) were determined to be the result of primary stapler failure. The authors focused only on the failures of the endo-GIA stapler and did not comment on whether other methods to occlude the renal vasculature during laparoscopic nephrectomy were in use at the time. As a result, a comparison to other techniques was not performed.

In April 2002, Deng et al. published a paper that also described failures of endo-GIA staplers. The authors conducted a retrospective review of 460 *laparoscopic* urologic operations conducted at two unspecified institutions. The procedures included simple nephrectomy for benign disease, radical nephrectomy and nephroureterectomy for suspected malignancy, adrenalectomy for both benign and malignant diseases, donor nephrectomy, prostatectomy, cystectomy, and bladder augmentation. It was not specified why these particular operations were chosen for the study, nor was it specified when these operations were conducted. In addition, it was not described how the endo-GIA stapler was used in each of these operations. However, in their retrospective review of these 460 operations, five cases (1%) involved GIA stapler malfunction. Three failures occurred during laparoscopic nephrectomy, one occurred during laparoscopic donor nephrectomy, and one occurred during nephroureterectomy. While the total number of operations was 460, the number of each type of operation performed was not reported. As a result, the incidence of stapler failure during laparoscopic nephrectomy or laparoscopic donor nephrectomy was not determined. Therefore, while the study reports a relatively low (1%) incidence of GIA stapler failure, the inclusion of eight different operations makes the study difficult to interpret. (10)

In the same paper, the authors also performed a search of the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database contains reports of adverse events involving medical devices since July 31, 1996. The adverse event information is voluntarily reported to the database by users, distributors, and manufacturers of the devices. The authors did not specify the time frame of their database search. They performed full-text searches of the database using the following terms: "nephrectomy", "stapler", and "laparoscopic". As a result, this part of their research focused on stapler malfunction during laparoscopic nephrectomy. Overall, the authors found 55 reports of endo-GIA failure in the database. 34 incidents occurred during laparoscopic nephrectomy and 21 incidents occurred during laparoscopic *donor* nephrectomy. Of the 34 incidents associated with laparoscopic nephrectomy, 5 required conversion to an open procedure, 4 required blood transfusion, and 2 resulted in death. Of the 21 incidents associated with laparoscopic donor nephrectomy, 7 required conversion to an open procedure, 2 required blood transfusion, and no deaths were reported. (10) There are two major drawbacks to this study which make interpretation of the results difficult. First, the MAUDE database is comprised of voluntary reports of adverse events related to device failures. The voluntary nature of the database may under represent the true number of device failures. Second, the MAUDE database does not report a device's frequency of use. Therefore, there is no "denominator" with which to calculate the device's true incidence of failure.

The authors concluded that their study justified concerns regarding the use of the endo-GIA stapler during laparoscopic donor nephrectomies. Given the limitations of the study as discussed above, it is questionable whether such a conclusion is valid. The authors stated that they no longer used the end-GIA stapler during laparoscopic donor nephrectomies and instead chose to employ a Hem-o-lok clip on the renal artery and an endo-TA stapler on the renal vein. A Hem-o-lok clip has a locking mechanism and raised ridges where the two sides of the clip meet; both features are intended to prevent dislodgment, see Figure 1 page 25. An endo-TA stapler applies three rows of staggered staples to ligate the vessel, but does not cut the vessel, see Figure 1 page 25. The authors offered no data to support their decision to use these devices other than the fact that no reports of Hem-o-lok malfunction were found in the MAUDE database and their use was "merely personal preference that developed from our familiarity with the devices." (10)

In May 2002, Hsu et al. published a study that reviewed the laparoscopic donor nephrectomy experience at the Johns Hopkins Medical Institutions with respect to renovascular complications and their management. From February 1995 to July 2001, 353 patients (144 men and 209 women) underwent laparoscopic donor nephrectomy for living-related renal transplantation at the Johns Hopkins Medical Institutions. A retrospective chart review was performed to identify and evaluate renovascular complications associated with these cases. Eight cases (2.3%) involved renovascular complications. (11)

The renovascular complications included: endovascular-GIA stapling failure (2 cases), surgical clip dislodgment (2 cases), vessel laceration during dissection (3 cases), and stapling across an atherosclerotic plaque (1 case). There was no mortality and no allograft loss at 3 months in any case. With regards to clip dislodgment, in both cases two 10mm clips were dislodged from the renal artery. One case occurred intra-operatively and one case occurred post-operatively, which required emergent re-operation with open repair. The two cases of clip dislodgment prompted the authors' to hypothesize that "the placement of three surgical clips rather than two as in our cases, with adequate stump length may help minimize the risk of clip dislodgment. Furthermore, new laparoscopic surgical clips such as the [Hem-o-lok] clip may help with the problem of clip dislodgment." The authors' suggestion that three clips instead of two might help mitigate dislodgement seems to operate on nothing more than the assumption that if less is not enough, perhaps more is better. The authors fail to consider the possibility that something inherent to the clip may contribute to its failure independent of the number applied. And while they suggest the use of Hem-o-lok clips may prove superior to non-locking clips, they cite no evidence to support this suggestion. In addition, while it is interesting that surgical clips and the endo-GIA stapler accounted for the same number of failures (2 cases each) to control the renal artery, the authors do not specify the two devices' frequency of use. In other words, they do not delineate how many cases employed surgical clips vs. the endo-GIA stapler. As a result, the authors could not report the incidence of failure for each device. They were only able to conclude that, in general, there is a relatively low incidence of renovascular complications (2.3%) in laparoscopic donor nephrectomy. (11)

In August 2002, Meng et al. published a new technique the authors employed in 97 laparoscopic donor nephrectomies to optimize vascular control. They ligated the renal artery using a single Hem-o-lok clip and a straight titanium clip placed more proximally to the aorta. The renal artery was cut distal to both clips. An endo-TA stapler was placed on the renal vein as close to the vena cava as possible, and the vein was cut distally with laparoscopic scissors. The graft-side vessels were not secured and only minimal back-bleeding (5 ml or less) was encountered. In contrast to the endo-GIA stapler, with the endo-TA stapler there was no need to trim staples (approx. 5 mm) from the graft vessels before anastomosis. As a result, “excellent vessel length” was achieved in all cases. They reported no donor complications using this technique and 99% of recipients had long-term graft survival (mean follow-up was 45 weeks). The authors conceded that previous use of the endo-GIA stapler resulted in vessel lengths that were adequate for recipient anastomoses and graft function, but they wanted to “optimize vascular length.” In addition, they believed that separating the steps of ligation and division, which occur simultaneously using the endo-GIA stapler, would increase safety. They cited that one cause of endo-GIA stapler failure was deployment of staples across a previously placed clip, which disrupts the staple line. With the technique described by the authors, the vessels were cut only after successful placement of the clips and TA staple line was confirmed. (3)

In March 2004, Joseph et al. published a comparison of the ability of 6 different vascular occlusion devices to withstand high pressure. They tested the Ti-Knot TK5 (LSI Solutions), Hem-o-lok MLK clip (Weck Closure Systems), Ligaclip 5-mm titanium clip (Ethicon), Endopath vascular staples (35 mm long, 12.3 mm wide) (Ethicon), and standard hand ties. Renal artery segments from 5 to 6 mm in diameter were harvested from fresh porcine kidneys. One end of the artery was attached to a saline infusion pump and pressure transducer and the other was occluded with one of the test devices. Each device was tested eight times. All Ti-knot devices, Hem-o-lok clips, titanium metal clips, and standard hand ties tolerated pressures >800 mm Hg with no leakage for 45 seconds, but 4 of the 8 vascular staple lines leaked before this maximum pump pressure was reached. For the 4 staple lines that leaked, the mean leak pressure was 273 mm Hg (range 237-322 mm Hg). Therefore, all devices tested were capable of occluding renal arteries under physiologic pressures *in vitro*, but staples had a higher likelihood of leakage under *supra*-physiologic pressures *in vitro*. (12) While it is informative to know that all of these devices withstood supra-physiologic pressures for 45 seconds, the fact that the studies were performed *in vitro* using porcine arteries and were tested for such a short duration of time makes the translation to the clinical situation difficult. A device's ability to secure the renal artery over an *extended period of time* is an essential characteristic of a vascular occlusion device. These devices are applied with the intention that they will permanently occlude the renal artery in the *in vivo* environment, where they will experience variable blood pressures, contact with other vessels and organs, etc. Joseph et al.'s experiment did not account for such conditions.

In April 2005, Elliott et al. published results from similar pressure tests with results very similar to those reported by Joseph et al. They tested fewer devices, but investigated whether the number of clips or the length of vascular cuff affected the strength of the ligation. One end of an adult porcine artery (3-7 mm in 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. The pulsatile infusion pump, which more closely approximates physiologic pressure generation, was an improvement over Joseph et al.'s pump which applied only constant pressure. Leak/failure pressures were measured using a digital barometer. Each device group was evaluated five times. All permutations of both non-locking and locking clips (one vs. two, no cuff vs. cuff) withstood mean supra-physiologic pressures of 1270 mm Hg or higher, suggesting that safety is not increased with additional clips or a longer cuff. Similar to results reported by Joseph et al, vessels closed with the stapler leaked at a mean pressure of 262 mm Hg, which is still supra-physiologic. (13) It is interesting that the number of clips and length of vessel cuff left beyond the clip did not seem to alter the pressure the clips withstood. But, again, this is an *in vitro* experimental set-up that does not closely approximate the *in vivo* application of these devices. The authors again did not compare these devices in terms of their ability to maintain occlusion of the artery over an extended period of time. Even if they had tested this parameter using their isolated, *in vitro* experimental design, the results of such a study would be difficult to translate to the actual clinical situation in which these devices must perform.

In June 2004, Eswar et al. published the use of Hem-o-lok clips to occlude both the renal artery *and* vein. They performed 50 hand-assisted simple or radical nephrectomies in which Hem-o-lok polymer clips were utilized for the ligation of both the renal artery and renal vein. Two clips were placed on the patient side and one distally on the specimen side before the vessels were divided. All 50 cases were completed with no major or minor complications. Mean operative time was 3 hours, with a mean estimated blood loss of 250mL. The authors concluded that the Hem-o-lok polymer ligating clip was safe, easy to use, and reliable in the control of the renal pedicle. (14) The relatively small sample size of the study (50 cases) makes it difficult to compare the efficacy and safety of clips vs. the endo-GIA stapler for control of the renal pedicle. The authors explain that recent studies revealed “complications” and “malfunctions” with use of the endo-GIA stapler. They cited the paper by Deng et al., which had reported a 1% failure rate of the endo-GIA stapler when used in 460 laparoscopic urologic cases. (10) While the authors concluded that the use of Hem-o-lok clips were safe and effective in their 50 cases, more operations using this technique were needed before a valid comparison with the endo-GIA stapler could be made.

In February 2006, Baumert et al. also advocated the use of Hem-o-lok clips to occlude both the renal artery and renal vein during laparoscopic nephrectomy. Unlike Eswar et al., Baumert et al. used the technique during both laparoscopic nephrectomy and laparoscopic *donor* nephrectomy. One 10-mm Hem-o-lok clip was applied to the renal artery. The renal vein was then lightly grasped by closing the jaws of a 5-mm laparoscopic Babcock behind it and gently pulled so that the diameter of the vein was reduced sufficiently to allow two 10-mm Hem-o-lok clips to be applied with the free hand. A third, lateral clip (not used during live donor nephrectomy) was placed distally to avoid back bleeding after vein transection. Once the vein had been divided, it was easier to further dissect the renal artery and place one or two *additional* Hem-o-lok clips on the artery before dividing it. (15)

Baumert et al. used this technique successfully for 130 consecutive laparoscopic nephrectomies (10 simple, 47 radical, 7 nephroureterectomies, and 66 live donor nephrectomies) between June 2002 and July 2005. No perioperative complications were reported. There was no increase in the kidney's warm ischemia time. The median warm ischemia time was four minutes. All transplanted kidneys recovered normal renal function quickly, and no renal vein thrombosis occurred. Of the 66 live kidney donations, 55 were left-sided and 11 were right-sided. Similar to Eswar et al., Baumert et al. concluded that using Hem-o-lok clips to occlude the renal pedicle was easy, safe, rapid and offered cost savings when compared to the endo-GIA stapler. They recommended the use of Hem-o-lok clips during both laparoscopic nephrectomy and laparoscopic donor nephrectomy.

In January 2006, Friedman et al. published the findings of a survey administered to all 893 surgeon-members of the American Society of Transplant Surgeons (ASTS). The survey was designed and distributed in October 2003 after the authors were made aware of two previously unreported laparoscopic donor deaths due to the failure of non-locking surgical clips applied to the donor renal artery. Dr. Friedman and colleagues recognized that laparoscopic kidney donors represented a special patient population, i.e. healthy volunteers undergoing a major surgical operation for the sole benefit of another. As such, any threats to the safety of donors needed to be investigated. 213 transplant surgeons participated in the study. (16)

Dr. Friedman and colleagues divided vascular occlusion techniques into two categories: transfixion and non-transfixion. Transfixion techniques were vascular control techniques in which suture material or staples were passed through the vascular tissue (e.g. oversew, suture ligature, GIA surgical stapler and the TA surgical stapler), see Figure 1 page 25. Non-transfixion techniques, on the other hand, were vascular control techniques in which suture, metal, or polymer material was placed solely around the vascular tissue (e.g. ties and surgical clips), see Figure 1 page 25.

Respondents were asked to describe which technique they would use to occlude the renal artery in both open and laparoscopic donor nephrectomy. Surgeons indicated the use of suture ligature plus simple tie (40% of respondents) and oversew (24% of respondents) as the techniques of choice to occlude the renal artery in *open* donor nephrectomy. Surgeons indicated the use of the endo-GIA stapler (30% of respondents) and multiple locking clips (18% of respondents) as the techniques of choice to occlude the renal artery in *laparoscopic* nephrectomy.

Respondents were asked to rate the *safety* of techniques used to occlude the renal artery stump in open and laparoscopic donor nephrectomies. The median safety ratings for techniques used to occlude the renal artery in *open* donor nephrectomy were as follows: "extremely safe" (oversew, suture ligature plus simple ties); "very safe" (suture ligature, GIA stapler, TA stapler); "safe" (multiple simple ties, multiple locking clips); "unsafe" (multiple non-locking clips, single locking clip, single simple tie, single non-locking clip). The median safety ratings for techniques used to occlude the renal artery in *laparoscopic* donor nephrectomy were as follows: "very safe" (oversew, multiple locking clips, GIA stapler, TA stapler); "safe" (suture ligature, suture ligature plus simple ties); "unsafe" (multiple non-locking clips, single locking clip, multiple simple ties, single simple tie, single non-locking clip). In other words, *all* of the transfixion techniques listed were considered "safe" to manage the renal artery in both open and laparoscopic live donor nephrectomies. The only non-transfixion techniques considered "safe" to occlude the renal artery in *open* donor nephrectomy were multiple simple ties and multiple locking clips. The only non-transfixion technique considered “safe” to occlude the renal artery in *laparoscopic* donor nephrectomy was multiple locking clips.

In addition, transfixion techniques were associated with fewer cases of severe renal artery hemorrhage compared to non-transfixion techniques (45 cases vs. 21 cases). When technical failure and hemorrhage occurred, “non-transfixion techniques were associated with more severe outcomes compared with transfixion techniques (p=0.01). When compared with all other techniques, clips were statistically significantly associated with worse complications of all hemorrhagic events, with non-locking clips most likely to be associated with [life-threatening complications including two deaths].” The results of the survey led Dr. Friedman and her colleagues to draw the following conclusions:

> 1) Surgical mishap and life-threatening hemorrhage appear to be associated more frequently with surgical clips than with other methods of arterial and venous control; 2) the perception that suture or staple transfixion of the renal artery is the safest and most appropriate way to manage the living kidney donor renal vasculature is agreed upon by the majority; and 3) post-operative pain control to prevent severe hypertension in the immediate postoperative period is an important adjunct to control delayed hemorrhage. Applying such principles to the living kidney donor may reduce the already low risk to life-endangering hemorrhage for these patients who offer a living gift to their recipients. (16)

Like the MAUDE database, Friedman et al. solicited voluntary reports of technical failure from kidney transplant surgeons. Voluntary reports of technical failure and adverse outcomes are always subject to under reporting. Unlike the MAUDE database, however, Friedman et al. obtained data that describe the techniques surgeons prefer to use to occlude the renal artery. The total number of cases in which the techniques were employed, however, was not obtained and, therefore, the actual frequency of technique failure could not be determined. One could hypothesize that by virtue of being a preferred technique it probably is used more often, but this might not be the case without the data to support it. As a result, the authors' could not conclude that surgical mishaps and hemorrhage were associated more frequently with surgical clips, but that surgical mishap and hemorrhage "appear" to be associated more frequently with surgical clips than other methods of arterial or venous control.

In December 2006, Dr. Maxwell Meng published a review of the MAUDE database for adverse events associated with Hem-o-lok clips. Dr. Meng found that between January 1996 and July 2005, a total of 27 adverse events involving Hem-o-lok clips were reported to the MAUDE database. Nearly all (96%) occurred during laparoscopic procedures. Twelve of the events (44%) occurred during laparoscopic nephrectomy. Nine involved renal artery bleeding. In only one case of renal artery bleeding was the situation salvaged laparoscopically by the placement of titanium clips on the arterial stump proximal to the two Hem-o-lok clips. During the other eight cases, immediate open conversion (N=1), delayed surgical exploration (N=5), and death (N=2) resulted. In all cases more than one Hem-o-lok clip was used and, at the time of open inspection and management, the clips were not on the renal artery. (17)

Problems with the Hem-o-lok clip typically were *not* noted during the operation; clips were apparently placed without issue but subsequently did not maintain control of the vessel. Thus, the presentation of these cases was of unexpected bleeding during the early post-operative period. Sudden loss of control of the renal artery can be a catastrophic event and, as noted above, led to death in two cases of laparoscopic donor nephrectomy.

Dr. Meng noted that the MAUDE database contained a significantly larger number of documented problems associated with linear cutting staplers, but this was likely related to the popularity and greater use of the staplers. The MAUDE database only reports problems associated with medical devices, it does not report their frequency of use. As a result, the incidence of device failure cannot be determined from the MAUDE database. While the incidence of clip failure vs. stapler failure could not be determined; it was the type of failure that occurred with clips vs. staplers that was particularly worrisome. Dr. Meng emphasized that failures associated with the GIA or TA stapler were almost always recognized during the application, firing, or removal of the device, which allowed the opportunity to correct the situation immediately, albeit usually after open conversion. In contrast, failures associated with clips tended to occur in a delayed and unpredictable manner during the early post-operative period, which resulted in significant morbidity (i.e., emergent open surgical exploration, excessive blood loss requiring transfusion, and even death in two cases). Despite these observations, Dr. Meng did not advocate the use of one method of ligation over another. He felt the choice of device depended largely on surgeon preference and comfort. He did, however, offer the following conclusion:

> Conceptually, the advantage of any stapler is that it transfixes the tissue, with the individual staples penetrating and securing through the vessel wall. The traditional ligation of the renal vessels using a proximal tie and a distal suture ligature is based on this same principle, with at least one suture passed through the vessel wall to prevent complete dislodgment. All externally applied clips, whether titanium or Hem-o-lok, are merely occlusive and can slip or pop off, as no transfixation is present. (17)

In April 2006, Teleflex Medical, the parent company of WECK Closure Systems, issued the following announcement regarding Hem-o-lok clips:

> Teleflex Medical has been made aware of rare incidents in which Hem-o-lok clips (sizes L and XL) were reported to have become dislodged following ligation of the renal artery after laparoscopic donor nephrectomy. Our preliminary assessment is that none of the incidents appears to have involved any defect in or malfunction of the Hem-o-lok

> ligating clips. We are aware, however, that laparoscopic donor nephrectomies pose special surgical challenges, including the surgeon's desire to maximize the length of the renal artery removed from the donor in order to facilitate the arterial anastomosis of the transplanted kidney. In rare instances, misapplication of the Hem-o-lok clips during such laparoscopic procedures may not immediately be apparent, but can have serious even life-threatening consequences post-operatively. Because of the nature of this risk and the surgical challenges posed by ligation of the renal artery during laparoscopic donor nephrectomies, we are contraindicating the use of Hem-o-lok clips to ligate the renal artery during laparoscopic nephrectomies in living donor patients. We also recommend that more than one clip be used to ligate the renal artery in procedures other than laparoscopic donor nephrectomy. (Daphne D. Maurer, Vice-president Regulatory Affairs)

In this correspondence, Teleflex Medical did not cite the source or number of reports in which Hem-o-lok clips became dislodged following ligation of the renal artery. And such reports remain publicly unavailable. In addition, the correspondence recognized the kidney transplant surgeon's need to maximize the length of the renal artery, but offered no evidence or discussion as to why the need to maximize renal artery length would affect the performance of the Hem-o-lok clip. One assumes it relates to the length of vessel cuff beyond the clip, but no evidence was cited that correlates cuff length with clip performance. Similarly, the recommendation that more than one clip be used to ligate the renal artery in procedures other than laparoscopic donor nephrectomy was not supported by evidence that more clips improves safety. The possibility that Hem-o-lok clip failure may be related to a property intrinsic to the clip or the clip's design, rather than the cuff length or the number of clips applied, was not discussed.

Teleflex Medical's decision to contraindicate the Hem-o-lok clip for use during live donor nephrectomy prompted a flurry of commentary that both supported and questioned the company's decision. Dr. Peter Steinberg from Dartmouth Hitchcock Medical Center wrote, "On the basis of our experience, reports to the FDA, and Weck's contraindication of the Hem-o-lok clip in laparoscopic donor nephrectomy, we do not recommend the Hem-o-lok clip for control of renal hilar vessels during laparoscopic nephrectomy. For the safety of patients undergoing laparoscopic nephrectomy, whether for kidney donation or otherwise, we strongly advocate controlling the renal hilar vessels with an endovascular stapler in the hands of an experienced surgeon." (18)

Dr. Herve Baumert replied, "The ideal device to control the renal pedicle does not exist, and major bleeding has been reported with either clips or the endo-GIA… We believe that the Hem-o-lok clips (equivalent to hand ties to occlude a renal artery, and better than vascular staple lines (12)) can be applied safely on the renal artery and vein with greater efficacy than conventional techniques." (19) As discussed previously, the study Dr. Baumert cites supporting the equivalency and superiority of Hem-o-lok clips to hand ties and staple lines was conducted in an *in vitro* environment using isolated porcine renal arteries. In addition, the vascular control techniques were tested under pressure for a mere 45 seconds.

Dr. Maxwell Meng commented, "The bottom line is that no single method is entirely safe and appropriate in all situations… Moreover, there is no logical, inherent reason why the [Hem-o-lok] clip should be specifically contraindicated for the renal artery during laparoscopic donor nephrectomy, as now stated by the manufacturer. This type of restriction seems to ignore the fundamental question: Are the Hem-o-lok clips reliable or not? Is this device safe on other structures or during open application?" (20)

While the information and publications discussed above are presented in chronological order for clarity, the progressive and relatively rapid evolution of techniques used to control the renal vasculature in laparoscopic operations often occurred simultaneously and at multiple institutions. In addition, the length of time it takes a submitted manuscript to reach publication varies from journal to journal. Therefore, while information was often presented in chronological order according to publication date, the research itself may not have occurred along that timeline and, where possible, the actual dates of the research were provided. Nevertheless, the literature clearly reflects the debate and lack of consensus regarding which techniques should be used to control the renal vasculature.

In the midst of the rapidly evolving discussion and debate regarding the use and evaluation of methods of vascular control, it was decided that a follow-up study, similar to the one Friedman et al. distributed to members of the American Society of Transplant Surgeons in October 2003 (16), would be appropriate and useful. A survey distributed to a larger number of surgeons in many different specialties would allow a comparison of vascular control techniques across specialties and operations. In other words, the results of the ASTS survey, which were specific to renal vasculature control in donor nephrectomy, could be compared and contrasted with vascular control techniques utilized in other operations. The survey would broaden the investigation into the use and safety of transfixion techniques vs. non-transfixion techniques. And the collection and dissemination of such information might ultimately help guide a surgeon's choice of vascular occlusion technique.

II. HYPOTHESIS AND SPECIFIC AIMS

Hypothesis: Surgical techniques of blood vessel occlusion that incorporate tissue transfixion are more secure and are associated with better patient safety, fewer complications and less severe complications than techniques that do not incorporate tissue transfixion, particularly when applied to blood vessels 6-10mm in diameter.

Specific Aim #1: To determine and compare the relative frequencies with which blood vessel occlusion techniques that incorporate tissue transfixion vs. non-transfixion are utilized for blood vessels 6-10mm in diameter.

Specific Aim #2: To determine and compare the perceptions of safety of blood vessel occlusion techniques that incorporate tissue transfixion vs. non-transfixion for blood vessels 6-10mm in diameter.

Specific Aim #3: To determine the actual safety of blood vessel occlusion techniques that incorporate tissue transfixion vs. non-transfixion on blood vessels 6-10mm in diameter by collecting primary reports of technical failure and severe hemorrhage.

III. METHODS

A survey instrument was designed based on the survey instrument previously distributed to ASTS members. (16) The survey instrument was modified for the intended study population. The ASTS survey targeted only transplant surgeons; while this study was expanded to include surgeons in other specialties who conduct operations that routinely require medium-sized blood vessel control. Therefore, the following surgical specialties were included: general surgery, urology, thoracic surgery, vascular surgery, obstetrics and gynecology, and colon and rectal surgery. Contact information for surgeons was obtained from the American College of Surgeons (ACS). The ACS membership department agreed to provide mailing addresses for members in the specialties listed above. To access a large population, while remaining within budgetary constraints, mailing information for members located in Connecticut (CT), Rhode Island (RI), Massachusetts (MA), New Hampshire (NH), Vermont (VT), Maine (ME), and New York (NY) was collected. The ACS provided 4265 mailing addresses for surgeons in the states and specialties specified. The ACS declined to release e-mail addresses. The survey was printed and distributed via postal mail. The significant cost associated with printing and postage precluded the ability to send follow-up reminders or a second mailing to increase study participation.

The survey was designed in five sections, see Appendix. Section I consisted of general information questions: surgical specialty, subspecialty, laparoscopic experience, and years of experience. Sections II, III, and IV addressed the control of three specific arteries – the renal, splenic, and cystic arteries, respectively. The renal artery was chosen to obtain data regarding the management of a major, medium-sized artery. Including the renal artery also afforded the opportunity to compare results with those obtained by the ASTS survey. Of course, only a subset of surgeons surveyed would have experience controlling the renal artery, so a second major, medium-sized artery that a larger proportion of respondents would have experience controlling, the splenic artery, was selected. The splenic artery is comparable to the renal artery in terms of size and mean blood pressure The cystic artery was included because, once again, a large proportion of respondents would have experience managing it. Including the cystic artery also provided the opportunity to compare and contrast the management of two larger arteries (approximately 6-10mm in diameter) with the management of a smaller artery (approximately 2mm in diameter). In addition to being performed in high volume, most surgeons conduct nephrectomies, splenectomies and cholecystectomies in a fairly uniform fashion with reproducible, fundamental steps of arterial control.

Each artery-specific section consisted of three parts.

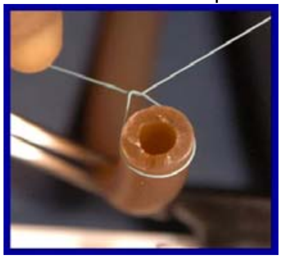
Part one asked which technique the surgeon would hypothetically use to occlude the artery specified. The survey provided a list of twelve techniques from which the respondent could choose: single simple tie, multiple simple ties, suture ligature, suture ligature plus simple tie(s), oversew, single non-locking clip, multiple non-locking clips, single locking clip, multiple locking clips, GIA stapler, TA stapler, and Ligasure™. Respondents could also write-in a technique not listed.

As described in the introduction, all of these techniques can be classified as either a transfixion technique or a non-transfixion technique. Transfixion techniques are defined by the passage of suture material or staples through the vascular tissue. Non-transfixion techniques are defined by suture, metal, or polymer material placed solely around the vascular tissue. Figure 1 page 25 defines each technique and categorizes each technique as transfixion or non-transfixion.

FIGURE 1

Vascular Occlusion Techniques Discussed in Survey

Non-Transfixion Techniques #1-4, Transfixion Techniques #5-8

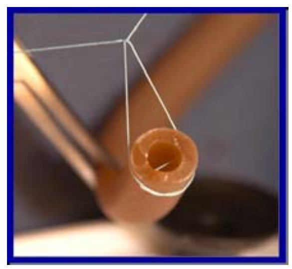


1. Simple Tie: Suture material is tied tightly around the blood vessel to occlude blood flow.

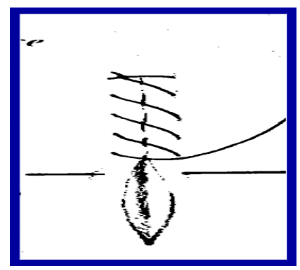
2. Non-Locking clip: Clip is squeezed around the blood vessel using a clip applier.

3. Locking clip: Clip is squeezed around blood vessel using applier until locking mechanism is engaged.

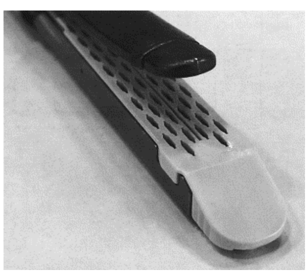
4. Ligasure[TM]: Instrument transmits thermal energy, which fuses the vessel's collagen and elastin forming a seal.



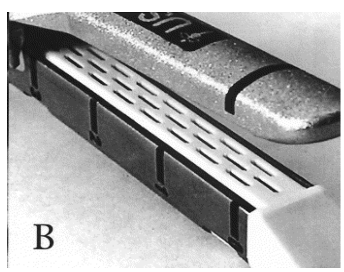
5. Suture ligature: Suture material is placed through the vessel wall and then tied tightly around the vessel.



6. Oversew: Suture material is passed through the edges of the vessel mutiple times in a continuous fashion.



7. GIA surgical stapler: Applies six rows of staggered staple lines through vessel and then cuts in between.



8. TA surgical stapler: Applies three rows of staggered staple lines through vessel. Does not cut.

To investigate techniques used to occlude the renal artery, surgeons were asked to identify which technique(s) they would use to occlude the renal artery during both an open and a laparoscopic nephrectomy, assuming the renal artery was 7mm in diameter. To investigate techniques used to occlude the splenic artery, surgeons were asked to identify which technique(s) they would use to occlude the splenic artery during both an open and a laparoscopic splenectomy, assuming the splenic artery was 10mm in diameter. Finally, to investigate techniques used to occlude the cystic artery, surgeons were asked to identify which technique(s) they would use to occlude the cystic artery during both an open and a laparoscopic cholecystectomy, assuming the cystic artery was 2mm in diameter.

Part two asked the surgeon, based on his/her opinion, to rate the safety of techniques used to occlude the artery. Surgeons were asked to rate the safety of various techniques that could potentially be used to occlude each artery – renal, splenic, and cystic; irrespective of whether the approach was open or laparoscopic. Each technique was rated on a Likert scale of 1 “unsafe” to 5 “extremely safe.” The mid-point, 3, was labeled “safe.” The same twelve techniques described above were listed, but respondents had the option to write-in and evaluate a technique not listed.

Part three asked the surgeon to report actual cases in which a vascular control technique failed to securely occlude the artery resulting in severe hemorrhage. Input was only solicited from surgeons with actual experience occluding the artery in question. If a surgeon indicated a technical failure with severe hemorrhage, he/she was asked to answer 6 additional questions. 1) What technique failed? 2) Did the patient require a blood transfusion? 3) Did the hemorrhage occur intra-operatively or post-operatively? 4) If the hemorrhage occurred post-operatively was re-operation needed? 5) What other serious consequences occurred (e.g. acute renal failure)? 6) Did the patient live or die?

Finally, section V asked the surgeon to provide any final comments.

It was clear that surgeons might be reluctant to answer questions regarding adverse surgical outcomes and complications because of potential legal risk, stigma, or emotional distress. For effective research, however, it was imperative that surgeons be willing to report instances of technical failure and hemorrhage. To this end, two levels of protection were added for respondents. First, respondents were permitted to return the survey anonymously. Though the offer of anonymity was a simple solution, experience from the ASTS survey showed that sometimes access to surgeons' contact information was extremely helpful, either to obtain more details about a specific case or to clarify a response. To address these issues, a second level of protection for respondents was added by obtaining a Certificate of Confidentiality (COC) from the National Institutes of Health (NIH). A COC prevents researchers from having to involuntarily disclose names or other identifying information about any individual who participates as a research subject. The certificate gave surgeons the opportunity to describe surgical complications and adverse outcomes without the possibility of their names or identifying information being subsequently released.

Approval from the Yale Human Investigations Committee (HIC) was sought and granted (HIC #27456). The eight page surveys were printed, bound and mailed by Yale Reprographic and Imaging Services (RIS) to 4265 recipients. A self-addressed, postage-paid return envelope was included in the mailing to simplify and encourage participation. The large initial investment in survey printing and postage, however, precluded any follow-up reminders or follow-up requests to participate. Similarly, the option to respond anonymously negated any ability to individually track responses or mail reminders only to those who had not participated.

The mailing was timed such that surveys were expected to arrive at their intended destinations approximately 2-3 weeks before the response deadline of October 16, 2006.

Descriptive analysis was performed on the general information sections. To analyze the artery-specific vascular control data descriptive analysis was employed and, where appropriate, the Chi-Square test and the Z test for differences in two proportions were utilized. Descriptive analyses were performed using Microsoft Excel (Version 10.0, Microsoft Corporation, Redmond, WA). Chi-Square tests were performed using the Microsoft Excel statistical add-in program StatTools (Palisade Corporation, Newfield, NY). Z tests were performed using the Microsoft Excel statistical add-in program PHStat (Prentice-Hall, Inc., Upper Saddle River, NJ).

IV. RESULTS

A. General Information

4265 surveys were mailed to surgeons in NY, CT, RI, MA, NH, VT, and ME who practice the following surgical specialties: general surgery, urology, thoracic surgery, vascular surgery, OB/GYN, and colon and rectal surgery. 559 surveys were returned for a total response rate of 13.1%. 53 of those surveys, however, were returned without responses because the surgeon indicated that the questions did not fall within the scope of his/her practice (n=20) or the respondent was retired (n=33) and did not feel his/her answers would represent current practice. Therefore, 506 completed surveys were returned (Table 1) and were fully analyzed.

TABLE 1

Survey Response

	n (%)
Surveys mailed	4265
Surveys returned (total)	559 (13.1)
Surveys returned with data	506 (11.9)
Surveys returned without data*	53 (1.2)

*Surveys were returned without data either because the respondent felt the survey questions were not applicable to his/her practice OR the respondent was retired and did not feel his/her answers would represent current practice/opinion.

The majority of respondents were general surgeons (65%) followed by urologists (14%), thoracic surgeons (8%), vascular surgeons (7%), obstetricians and gynecologists (3%) and colon and rectal surgeons (3%). See Table 2. Note: the number of surgical specialties does not equal 506, because some surgeons did not list their specialty and some surgeons listed more than one specialty.

TABLE 2

Surgical Specialties Represented	
Surgical Specialty	**n (%)**
General Surgery	333 (65)
Urology	72 (14)
Thoracic Surgery	40 (8)
Vascular Surgery	38 (7)
OB/GYN	15 (3)
Colon and Rectal Surgery	13 (3)
Total:	511

Slightly less than half of the respondents (47%) indicated the practice of a sub-specialty with vascular surgery, trauma surgery, and surgical critical care comprising the top three. Once again, the total does not add to 506, because some surgeons listed more than one sub-specialty (Table 3).

TABLE 3

Surgical Sub-Specialties Represented	
Sub-Specialty	**n (%)**
No subspecialty	277 (53)
Vascular	61 (12)
Trauma	36 (7)
Surgical Critical Care	34 (7)
Surgical Oncology	23 (4)
Gynecologic Oncology	14 (3)
Transplant	14 (3)
Breast	11 (2)
Laparoscopic/MIS*	11 (2)
Pediatric	9 (2)
Bariatric	8 (2)
Endocrine	7 (1)
Hepato-Biliary	7 (1)
Gastro-Intestinal	6 (1)
Head and Neck	2 (<1)
Total:	520

*Minimally Invasive Surgery

Almost three-quarters of survey respondents indicated the performance of minimally invasive procedures, i.e. laparoscopic or thoracoscopic procedures (Table 4).

TABLE 4

Number of Respondents Who Perform Minimally Invasive Procedures	
	n (%)
Yes	358 (71)
No	133 (26)
Not specified	15 (3)

The vast majority of survey respondents (78%) had between 10 and 39 years of surgical experience (Table 5 and Figure 2). Table 5 and Figure 2 demonstrate a normal distribution of survey respondents according to years of experience (mean = 23.5 years of surgical experience). A normal distribution is reassuring that the respondent population was not biased towards those with very little experience or those with many years of experience.

TABLE 5

Respondents' Years of Surgical Experience	
Years of Surgical Experience Beyond Residency	**n (%)**
4-9	41 (8)
10-19	141 (28)
20-29	146 (29)
30-39	107 (21)
40-49	46 (9)
50-55	5 (1)
Not specified	20 (4)

FIGURE 2

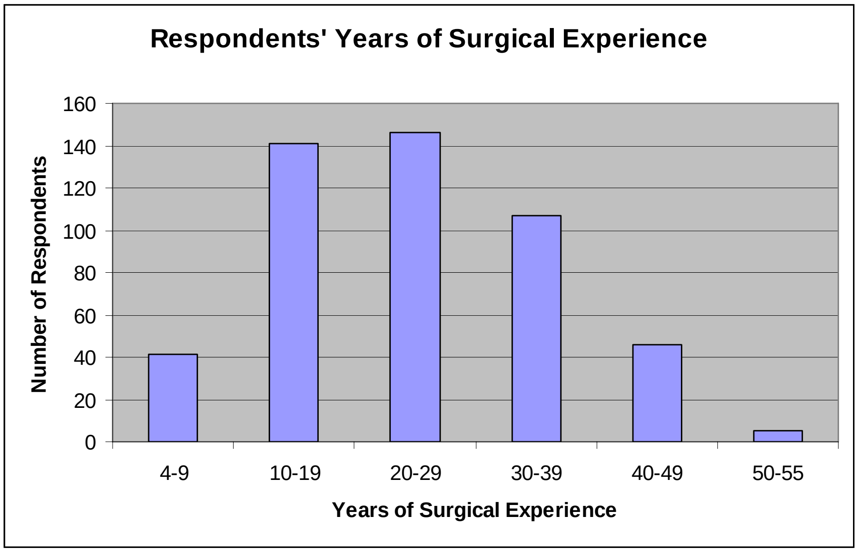


Table 6 is a compilation of the data presented in Table 2, Table 4, and Table 5. Table 6 offers a complete picture of the respondents in terms of surgical specialty, years of experience, and whether or not the surgeon performs laparoscopic procedures. Of interest, the vast majority of respondents in general surgery, thoracic surgery, OB/GYN, and colon and rectal surgery perform laparoscopic procedures; while less than half of respondents who practice urology and vascular surgery report performing laparoscopic procedures.

TABLE 6

A Closer Look at the Characteristics of Survey Respondents

Years of Surgical Experience

Surgical Specialty	4-9	10-19	20-29	30-39	40-49	50-55	Totals*:	Performs Laparoscopic or Thoracoscopic Procedures
General	29	83	88	62	14	2	278 (86%)	Yes
	0	6	13	11	15	1	46 (14%)	No
Urology	4	14	6	4	1	0	29 (41%)	Yes
	1	8	6	15	9	2	41 (59%)	No
Thoracic	2	7	9	6	4	0	28 (78%)	Yes
	0	3	3	1	1	0	8 (22%)	No
Vascular	0	2	2	1	0	0	5 (14%)	Yes
	4	9	14	3	1	0	31 (86%)	No
OB/GYN	2	4	4	2	1	0	13 (87%)	Yes
	0	1	1	0	0	0	2 (13%)	No
Colon and Rectal	2	3	3	1	0	1	10 (83%)	Yes
	0	1	1	0	0	0	2 (17%)	No
Totals*:	44	141	150	106	46	6		

*Note: Totals may differ slightly from those presented in other tables, because only respondents who included all three pieces of information are included in this table.

B. Choice of Vascular Occlusion Technique

Note: For each artery, fewer respondents commented on how the arteries should be occluded laparoscopically because, as shown in Table 4, 26% of respondents indicated they do not perform laparoscopic procedures.

1. Renal Artery Technique

483 respondents indicated which technique they would use to occlude the renal artery in *open* nephrectomy (Table 7). More than 483 responses are listed in Table 7, because respondents were able to choose multiple techniques. It should be noted that in instances where multiple techniques were chosen, it was not possible to determine whether the respondent intended those techniques to be used in combination or that each technique indicated would be solely sufficient. Therefore, each technique the surgeon chose was counted individually.

TABLE 7

Technique of Renal Artery Stump Closure 483 Respondents Would Use In OPEN Nephrectomy

Technique		n* (%)
Transfixion		
Suture ligature and simple tie(s)		277 (43)
Suture ligature		86 (13)
Oversew		57 (9)
GIA surgical stapler		22 (4)
TA surgical stapler		17 (3)
	Sub-total	459 (72)
Non-Transfixion		
Multiple simple ties		108 (17)
Single simple tie		27 (4)
Single hemostatic clip (non-locking)		13 (2)
Multiple locking hemostatic clips		11 (2)
Multiple hemostatic clips (non-locking)		11 (2)
Ligasure		6 (<1)
Single locking hemostatic clip		4 (<1)
	Sub-total	180 (28)

*Respondents were not limited to a single choice and some provided multiple responses.

In *open* nephrectomy, suture ligature plus simple tie(s) was the technique of choice (n=277, 43%) followed by multiple simple ties (n=108, 17%). Transfixion techniques were indicated significantly more often than non-transfixion techniques (n=459, 72% vs. n=180, 28%; $p<0.0001$). See Table 13 for statistical analysis. 39 surgeons (6%) chose surgical clips of all types as the technique to occlude the renal artery in *open* nephrectomy.

311 respondents indicated which technique they would use to occlude the renal artery in *laparoscopic* nephrectomy (Table 8).

TABLE 8

Technique of Renal Artery Stump Closure 311 Respondents Would Use In LAPAROSCOPIC Nephrectomy		
Technique		**n* (%)**
Transfixion		
GIA surgical stapler		161 (41)
TA surgical stapler		31 (8)
Suture ligature and simple tie(s)		14 (4)
Suture ligature		6 (2)
Oversew		3 (<1)
	Sub-total	215 (55)
Non-Transfixion		
Multiple locking hemostatic clips		69 (18)
Multiple hemostatic clips (non-locking)		56 (14)
Ligasure		20 (5)
Single locking hemostatic clip		13 (3)
Single simple tie		12 (3)
Multiple simple ties		5 (1)
Single hemostatic clip (non-locking)		4 (1)
	Sub-total	179 (45)

*Respondents were not limited to a single choice and some provided multiple responses.

In *laparoscopic* nephrectomy, the GIA surgical stapler was clearly the technique of choice (n=161, 41%). Again, transfixion techniques were indicated significantly more often than non-transfixion techniques (n=215, 55% vs. n=179, 45%; p<0.01). See Table 13 for statistical analysis. 142 surgeons (36%) chose surgical clips of all types as a technique to occlude the renal artery in *laparoscopic* nephrectomy.

2. Splenic Artery Technique

470 respondents indicated which technique they would use to occlude the splenic artery in *open* splenectomy (Table 9).

TABLE 9

Technique of Splenic Artery Stump Closure 470 Respondents Would Use In OPEN Splenectomy		
Technique		**n* (%)**
Transfixion		
Suture ligature and simple tie(s)		284 (39)
Suture ligature		86 (12)
Oversew		52 (7)
GIA surgical stapler		48 (7)
TA surgical stapler		20 (3)
	Sub-total	490 (68)
Non-Transfixion		
Multiple simple ties		157 (22)
Single simple tie		30 (4)
Multiple locking hemostatic clips		18 (2)
Multiple hemostatic clips (non-locking)		12 (2)
Single hemostatic clip (non-locking)		8 (1)
Ligasure		5 (<1)
Single locking hemostatic clip		2 (<1)
	Sub-total	232 (32)

*Respondents were not limited to a single choice and some provided multiple responses.

In *open* splenectomy, suture ligature plus simple tie(s) was the technique of choice (n=284, 39%) followed by multiple simple ties (n=157, 22%). Again, transfixion techniques were indicated significantly more often than non-transfixion techniques (n=490, 68% vs. n=232, 32%; $p<0.0001$). See Table 14 for statistical analysis. 40 surgeons (6%) chose surgical clips of all types as a technique to occlude the splenic artery in *open* splenectomy.

Interestingly, and perhaps not surprisingly, the rank order of techniques indicated for occluding the splenic artery during *open* splenectomy (Table 9) is almost identical to the rank order of techniques indicated for occluding the renal artery during *open* nephrectomy (Table 7).

322 respondents indicated which technique they would use to occlude the splenic artery in *laparoscopic* splenectomy (Table 10).

TABLE 10

Technique of Splenic Artery Stump Closure 322 Respondents Would Use In LAPAROSCOPIC Splenectomy

Technique		n* (%)
Transfixion		
GIA surgical stapler		195 (45)
TA surgical stapler		39 (9)
Suture ligature and simple tie(s)		12 (3)
Suture ligature		7 (2)
Oversew		4 (<1)
	Sub-total	257 (60)
Non-Transfixion		
Multiple locking hemostatic clips		76 (18)
Multiple hemostatic clips (non-locking)		46 (11)
Ligasure		17 (4)
Single simple tie		11 (3)
Multiple simple ties		10 (2)
Single locking hemostatic clip		9 (2)
Single hemostatic clip (non-locking)		4 (<1)
	Sub-total	173 (40)

*Respondents were not limited to a single choice and some provided multiple responses.

In *laparoscopic* splenectomy, the GIA surgical stapler was clearly the technique of choice (n=195, 45%). Again, transfixion techniques were indicated significantly more often than non-transfixion techniques (n=257, 60% vs. n=173, 40%; $p<0.0001$). See Table 14 for statistical analysis. 135 surgeons (31%) chose surgical clips of all types as a technique to occlude the splenic artery in *laparoscopic* splenectomy.

Once again, the rank order of techniques indicated for occluding the splenic artery during *laparoscopic* splenectomy (Table 10) is almost identical to the rank order of techniques indicated for occluding the renal artery during *laparoscopic* nephrectomy (Table 8).

3. Cystic Artery Technique

444 respondents indicated which technique they would use to occlude the cystic artery in *open* cholecystectomy (Table 11).

TABLE 11

Technique of Cystic Artery Stump Closure 444 Respondents Would Use In OPEN Cholecystectomy

Technique		**n* (%)**
Transfixion		
Suture ligature and simple tie(s)		55 (7)
Suture ligature		48 (6)
Oversew		11 (1)
GIA surgical stapler		4 (<1)
TA surgical stapler		3 (<1)
	Sub-total	121 (15)
Non-Transfixion		
Single simple tie		255 (31)
Multiple hemostatic clips (non-locking)		171 (21)
Multiple simple ties		143 (17)
Single hemostatic clip (non-locking)		54 (7)
Multiple locking hemostatic clips		34 (4)
Single locking hemostatic clip		24 (3)
Ligasure		17 (2)
	Sub-total	698 (85)

*Respondents were not limited to a single choice and some provided multiple responses.

In *open* cholecystectomy, a single simple tie was the technique of choice (n=255, 31%) followed by multiple non-locking clips (n=171, 21%) and multiple simple ties (n=143, 17%). Unlike techniques indicated for the renal and splenic arteries, non-transfixion techniques were indicated overwhelmingly more often than transfixion techniques for occluding the cystic artery during *open* operation (n=698, 85% vs. n=121, 15%; p<0.0001). See Table 15 for statistical analysis. 283 surgeons (35%) chose surgical clips of all types as a technique to occlude the cystic artery in *open* cholecystectomy.

381 respondents indicated which technique they would use to occlude the cystic artery in *laparoscopic* cholecystectomy (Table 12).

TABLE 12

Technique of Cystic Artery Stump Closure 381 Respondents Would Use In LAPAROSCOPIC Cholecystectomy

Technique		**n* (%)**
Transfixion		
GIA surgical stapler		8 (2)
Suture ligature		3 (<1)
Suture ligature and simple tie(s)		2 (<1)
Oversew		2 (<1)
TA surgical stapler		2 (<1)
	Sub-total	17 (4)
Non-Transfixion		
Multiple hemostatic clips (non-locking)		302 (63)
Multiple locking hemostatic clips		63 (13)
Single hemostatic clip (non-locking)		27 (6)
Single locking hemostatic clip		25 (5)
Ligasure		23 (5)
Single simple tie		15 (3)
Multiple simple ties		6 (1)
	Sub-total	461 (96)

*Respondents were not limited to a single choice and some provided multiple responses.

In *laparoscopic* cholecystectomy, multiple non-locking clips were clearly the technique of choice (n=302, 63%). Once again, unlike techniques indicated for the renal and splenic arteries, non-transfixion techniques were indicated overwhelmingly more often than transfixion techniques for occluding the cystic artery during *laparoscopic* operations (n=461, 96% vs. n=17, 4%; $p<0.0001$). See Table 15 for statistical analysis. 417 surgeons (87%) chose surgical clips of all types as a technique to occlude the cystic artery in *laparoscopic* cholecystectomy.

4. Summary and Statistical Analysis of Technical Choices

The following three tables are, in essence, a summary and statistical analysis of the data presented in Table 7 through Table 12.

a. Renal Artery Technique Summary

Table 13 demonstrates three statistically significant relationships. First, in *open* nephrectomy surgeons chose a significantly higher proportion of transfixion techniques vs. non-transfixion techniques (72% vs. 28% respectively, $p<0.0001$). Second, in *laparoscopic* nephrectomy surgeons again chose a significantly higher proportion of transfixion techniques vs. non-transfixion techniques (55% vs. 45%, $p<0.01$). Statistical significance was determined using the Z-test for differences in two proportions (one-tailed). The Z-test compares the calculated proportions to the null hypothesis. In this case, the null hypothesis states that if there was no technical preference, the proportion of transfixion techniques vs. non-transfixion techniques would be the same, i.e. 50%. In both open and laparoscopic nephrectomy, however, the proportions are clearly not the same. Therefore, the one-tailed Z-test demonstrates that the proportion of transfixion techniques chosen was statistically higher than non-transfixion techniques chosen for both open and laparoscopic nephrectomy (Table 13).

TABLE 13

Summary and Analysis of Techniques Surgeons Would Use to Control the Renal Artery in Nephrectomy

	Transfixion Techniques	Non-Transfixion Techniques	Totals	
Open Nephrectomy	459 (72%)	180 (28%)	639	Z-Test p<0.0001*
Laparoscopic Nephrectomy	215 (55%)	179 (45%)	394	Z-Test p<0.01*
Totals	674	359		Chi Sq. Test p<0.0001*

*See text for discussion of statistical analysis.

Third, the Chi-Square test for independence demonstrates a statistically significant relationship between the type of operation performed (open vs. laparoscopic) and the type of vessel occlusion technique chosen (transfixion vs. non-transfixion). In other words, the proportions of transfixion and non-transfixion techniques chosen for open surgery are statistically different from the proportions of transfixion and non-transfixion techniques chosen for laparoscopic surgery. A closer look at Table 13 demonstrates that, in fact, surgeons chose a larger proportion of non-transfixion techniques in *laparoscopic* nephrectomy vs. *open* nephrectomy (45% vs. 28% respectively, $p<0.0001$). Note: the Chi-Square test analyzes the data against the null hypothesis that if technique choice did not depend on operation type the proportions of transfixion vs. non-transfixion techniques would be the same in both open and laparoscopic operations.

b. Splenic Artery Technique Summary

Table 14 again demonstrates three statistically significant relationships. First, in *open* splenectomy surgeons chose a significantly higher proportion of transfixion techniques vs. non-transfixion techniques (68% vs. 32% respectively, p<0.0001). Second, in *laparoscopic* splenectomy surgeons again chose a significantly higher proportion of transfixion techniques vs. non-transfixion techniques (60% vs. 40%, p<0.0001). Third, the Chi-Square test demonstrates a statistically significant relationship between the type of operation performed and the type of vessel occlusion technique chosen. Table 14 demonstrates that, in fact, surgeons chose a larger proportion of non-transfixion techniques in *laparoscopic* splenectomy vs. *open* splenectomy (40% vs. 32% respectively, p<0.01).

TABLE 14

Summary and Analysis of Techniques Surgeons Would Use to Control the Splenic Artery in Splenectomy

	Transfixion Techniques	Non-Transfixion Techniques	Totals	
Open Splenectomy	490 (68%)	232 (32%)	722	Z-Test p<0.0001*
Laparoscopic Splenectomy	257 (60%)	173 (40%)	430	Z-Test p<0.0001*
Totals	747	405		Chi Sq. Test p<0.01*

*See text for discussion of statistical analysis.

c. Cystic Artery Technique Summary

Table 15 once again demonstrates three statistically significant relationships. Unlike the renal and splenic arteries, however, non-transfixion techniques were strongly favored for the cystic artery in both open and laparoscopic procedures. First, in *open* cholecystectomy surgeons chose a significantly higher proportion of non-transfixion techniques vs. transfixion techniques (85% vs. 15% respectively, p<0.0001).

Second, in *laparoscopic* cholecystectomy surgeons again chose a significantly higher proportion of non-transfixion techniques vs. transfixion techniques (96% vs. 4%, p<0.0001). Third, the Chi-Square test for independence demonstrates a statistically significant relationship between the type of operation performed and the type of vessel occlusion technique chosen. Table 15 demonstrates that, similar to the renal and splenic arteries, surgeons chose a larger proportion of non-transfixion techniques in *laparoscopic* cholecystectomy vs. *open* cholecystectomy (96% vs. 85% respectively, p<0.0001).

TABLE 15

Summary and Analysis of Techniques Surgeons Would Use to Control the Cystic Artery in Cholecystectomy

	Transfixion Techniques	Non-Transfixion Techniques	Totals	
Open Cholecystectomy	121 (15%)	698 (85%)	819	Z-Test p<0.0001*
Laparoscopic Cholecystectomy	17 (4%)	461 (96%)	478	Z-Test p<0.0001*
Totals	138	1159		Chi Sq. Test p<0.0001*

*See text for discussion of statistical analysis.

C. Safety Ratings for Vascular Occlusion Techniques

1. Renal Artery Safety Ratings

Table 16 summarizes survey respondents' safety ratings of techniques for renal artery stump closure in nephrectomy. Table 16 shows the median safety rating of all transfixion techniques to be 4(very safe) or 5(extremely safe). Suture ligature plus simple tie(s) and oversew were both considered 5(extremely safe) for renal artery stump closure. All *transfixion* techniques received higher median and mean safety ratings compared to *non-transfixion* techniques. Taken together, transfixion techniques had a mean safety rating of 3.9 ± 0.5. Taken together, non-transfixion techniques had a mean safety rating of 2.6 ± 0.7. Multiple simple ties, multiple locking clips, and Ligasure were the only *non-transfixion* techniques with a median safety rating of 3(safe) to occlude the renal artery stump. Note, however, that the Ligasure device had a *mean* safety rating of 2.7, which is below 3(safe).

TABLE 16

Survey Respondents' Ratings of Safety of Techniques for Renal Artery Stump Closure In Nephrectomy			
	Safety Ratings*		
Closure Technique	Median	Mean	Stdev
Transfixion			
Suture ligature and simple tie(s)	5	4.6	0.7
Oversew	5	4.2	1.0
Suture ligature	4	3.8	1.0
GIA surgical stapler	4	3.6	1.2
TA surgical stapler	4	3.5	1.2
Non-Transfixion			
Multiple simple ties	3	3.4	1.1
Multiple locking hemostatic clips	3	3.3	1.1
Ligasure	3	2.7	1.0
Multiple hemostatic clips (non-locking)	2	2.5	1.0
Single locking hemostatic clip	2	2.4	0.9
Single simple tie	2	2.0	1.0
Single hemostatic clip (non-locking)	1	1.6	0.8

* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."

2. Splenic Artery Safety Ratings

Table 17, which displays respondents' ratings of safety of techniques for splenic artery stump closure in splenectomy, is almost identical to renal artery safety ratings (Table 16) in both rank order and absolute values. Table 17, once again, shows the median safety rating of transfixion techniques to be 4(very safe) or 5(extremely safe). Suture ligature plus simple tie(s) was considered 5(extremely safe) for splenic artery stump closure. All *transfixion* techniques received higher median and mean safety ratings compared to *non-transfixion* techniques. Taken together, transfixion techniques had a mean safety rating of 3.9 ± 0.4. Taken together, non-transfixion techniques had a mean safety rating of 2.6 ± 0.6. Multiple simple ties, multiple locking clips, and Ligasure were the only non-transfixion techniques with a median safety rating of 3(safe) to occlude the splenic artery stump. Note, however, that the Ligasure device had a *mean* safety rating of 2.6, which is below 3(safe).

TABLE 17

Survey Respondents' Ratings of Safety of Techniques for Splenic Artery Stump Closure In Splenectomy

Closure Technique	Safety Ratings* Median	Mean	Stdev
Transfixion			
Suture ligature and simple tie(s)	5	4.6	0.7
Oversew	4	4.1	1.0
Suture ligature	4	3.7	1.0
GIA surgical stapler	4	3.7	1.2
TA surgical stapler	4	3.6	1.1
Non-Transfixion			
Multiple simple ties	3	3.4	1.2
Multiple locking hemostatic clips	3	3.3	1.1
Ligasure	3	2.6	1.1
Multiple hemostatic clips (non-locking)	2	2.5	1.0
Single locking hemostatic clip	2	2.4	0.9
Single simple tie	2	2.0	1.1
Single hemostatic clip (non-locking)	1	1.7	0.9

* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."

3. Cystic Artery Safety Ratings

Table 18 summarizes survey respondents' ratings of safety of techniques for cystic artery stump closure in cholecystectomy. Not surprisingly, for the much smaller cystic artery, every closure technique received a median rating of 3(safe) or higher (Table 18). Suture ligature plus simple ties, multiple simple ties, and multiple locking clips were all considered 5(extremely safe) for use on the cystic artery in cholecystectomy. Taken together, the mean safety rating of transfixion techniques was

3.9 ± 0.5, which was almost identical to the mean safety rating of non-transfixion techniques (3.8 ± 0.5) for use on the cystic artery.

TABLE 18

Survey Respondents' Ratings of Safety of Techniques for Cystic Artery Stump Closure In Cholecystectomy

Closure Technique	Safety Ratings* Median	Mean	Stdev
Transfixion			
Suture ligature and simple tie(s)	5	4.5	0.8
Suture ligature	4	4.2	0.9
Oversew	4	4.0	1.1
GIA surgical stapler	4	3.4	1.4
TA surgical stapler	4	3.4	1.4
Non-Transfixion			
Multiple simple ties	5	4.3	0.9
Multiple locking hemostatic clips	5	4.3	0.8
Multiple hemostatic clips (non-locking)	4	4.2	1.0
Ligasure	4	3.6	1.1
Single locking hemostatic clip	4	3.6	1.1
Single simple tie	4	3.6	1.2
Single hemostatic clip (non-locking)	3	3.0	1.1

* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."

4. Comprehensive Evaluation and Statistical Analysis of Safety Ratings

The next three tables display a more comprehensive analysis of how respondents rated the safety of each technique for each artery type.

a. Renal Artery Safety Ratings (A Closer Look)

Table 19 shows that for the renal artery 90% of all safety ratings for *transfixion* techniques were 3(safe) or *higher*. The most common safety rating given to transfixion techniques was a 5(extremely safe) (n=832, 40%). On the other hand, 79%

of all safety ratings for *non-transfixion* techniques were 3(safe) or *lower*. The most common safety rating given to non-transfixion techniques was a 2(not safe) (n=837, 29%). A Chi-square analysis of the data indicates that the safety profile was indeed dependent on the choice of technique (p<0.0001). Clearly, transfixion techniques were considered safer than non-transfixion techniques for renal artery stump closure.

TABLE 19

A Closer Look at Survey Respondents' Ratings of Safety of Techniques for Renal Artery Stump Closure In Nephrectomy

	Safety Ratings* (n)				
Closure Technique	**1**	**2**	**3**	**4**	**5**
Transfixion					
Suture ligature and simple tie(s)	2	1	34	92	324
Oversew	7	17	62	108	211
Suture ligature	10	28	115	174	111
GIA surgical stapler	25	49	98	128	103
TA surgical stapler	24	49	96	123	83
Sub-Totals	**68**	**144**	**405**	**625**	**832**
	3%	**7%**	**20%**	**30%**	**40%**
Non-Transfixion					
Multiple simple ties	18	77	145	109	100
Multiple locking hemostatic clips	28	61	136	113	65
Ligasure	55	91	125	63	10
Multiple hemostatic clips (non-locking)	76	159	128	48	16
Single locking hemostatic clip	68	161	123	39	8
Single simple tie	177	139	95	24	9
Single hemostatic clip (non-locking)	229	149	38	14	0
Sub-Totals	**651**	**837**	**790**	**410**	**208**
	23%	**29%**	**27%**	**14%**	**7%**
					Chi Sq. Test p<0.0001**

* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."
** See text for discussion of statistical analysis.

b. Splenic Artery Safety Ratings (A Closer Look)

Renal artery safety ratings (Table 19) and splenic artery safety ratings (Table 20) were almost identical. Table 20 shows that for the splenic artery 90% of all safety ratings for *transfixion* techniques were 3(safe) or *higher*. The most common safety rating given to transfixion techniques used to occlude the splenic artery was a 5(extremely safe) (n=798, 39%). On the other hand, 79% of all safety ratings for *non-transfixion* techniques were 3(safe) or *lower*. The most common safety rating given to non-transfixion techniques was a 2(not safe) (n=776, 28%). A Chi-square analysis of the data once again indicates that the safety profile is dependent on the choice of technique ($p<0.0001$). Clearly, transfixion techniques were considered safer than non-transfixion techniques for splenic artery stump closure.

TABLE 20

A Closer Look at Survey Respondents' Ratings of Safety of Techniques for Splenic Artery Stump Closure In Splenectomy

	Safety Ratings* (n)				
Closure Technique	**1**	**2**	**3**	**4**	**5**
Transfixion					
Suture ligature and simple tie(s)	1	3	26	99	306
Oversew	6	22	67	116	186
Suture ligature	7	32	120	165	96
GIA surgical stapler	25	41	78	132	116
TA surgical stapler	18	46	85	127	94
Sub-Totals	**57**	**144**	**376**	**639**	**798**
	3%	**7%**	**19%**	**32%**	**39%**
Non-Transfixion					
Multiple simple ties	23	89	125	104	100
Multiple locking hemostatic clips	25	64	132	104	61
Ligasure	60	82	103	64	9
Multiple hemostatic clips (non-locking)	74	148	123	54	10
Single locking hemostatic clip	68	158	122	35	5
Single simple tie	191	107	88	27	11
Single hemostatic clip (non-locking)	215	128	49	15	2
Sub-Totals	**656**	**776**	**742**	**403**	**198**
	24%	**28%**	**27%**	**14%**	**7%**

Chi Sq. Test p<0.0001**

* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."
** See text for discussion of statistical analysis.

c. Cystic Artery Safety Ratings (A Closer Look)

For the much smaller cystic artery, the technical safety profile is much different than the safety profiles seen for the renal and splenic arteries. As seen previously in Table 18, *all* techniques used on the cystic artery were given a median safety rating of 3(safe) or higher. Indeed, Table 21 confirms that both transfixion and non-transfixion techniques were given favorable safety ratings when used to occlude the cystic artery. Specifically, 86% of the ratings were a 3(safe) or higher for both transfixion and non-transfixion techniques. The chi-square test again shows a statistical relationship between safety rating and choice of closure technique. The chi-square test demonstrates that even though transfixion and non-transfixion techniques both received *favorable* safety ratings, the safety rating profiles are sufficiently different to evoke a statistical difference. Interpreting the statistical difference in the safety profile between transfixion and non-transfixion techniques, however, is not straightforward since all techniques were given a favorable rating. On close examination, the most perceptible difference is that transfixion techniques received more ratings of 5(extremely safe) than non-transfixion techniques (46% vs. 35%).

TABLE 21

A Closer Look at Survey Respondents' Ratings of Safety of Techniques for Cystic Artery Stump Closure In Cholecystectomy

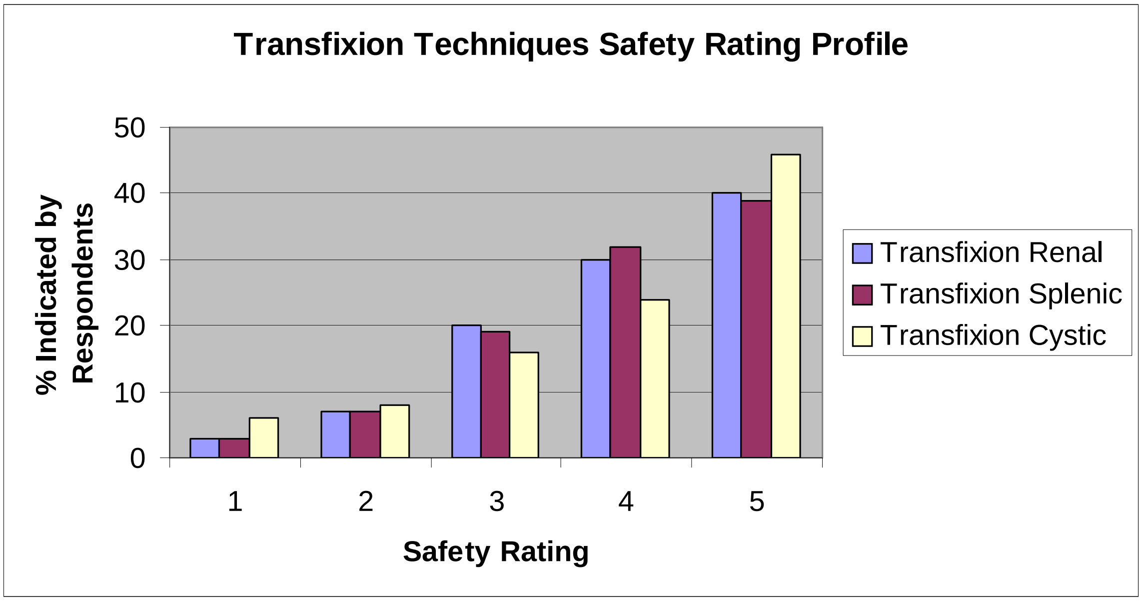
	Safety Ratings* (n)				
Closure Technique	**1**	**2**	**3**	**4**	**5**
Transfixion					
Suture ligature and simple tie(s)	3	8	40	80	255
Suture ligature	5	16	63	111	186
Oversew	13	23	70	81	153
GIA surgical stapler	44	37	50	69	86
TA surgical stapler	42	41	51	66	82
Sub-Totals	**107**	**125**	**274**	**407**	**762**
	6%	**8%**	**16%**	**24%**	**46%**
Non-Transfixion					
Multiple simple ties	5	11	59	108	234
Multiple locking hemostatic clips	2	7	50	112	190
Multiple hemostatic clips (non-locking)	6	22	58	130	187
Ligasure	17	35	70	100	73
Single locking hemostatic clip	12	47	108	114	80
Single simple tie	31	31	121	132	110
Single hemostatic clip (non-locking)	40	104	129	84	44
Sub-Totals	**113**	**257**	**595**	**780**	**918**
	4%	**10%**	**22%**	**29%**	**35%**
					Chi Sq. Test p<0.0001**

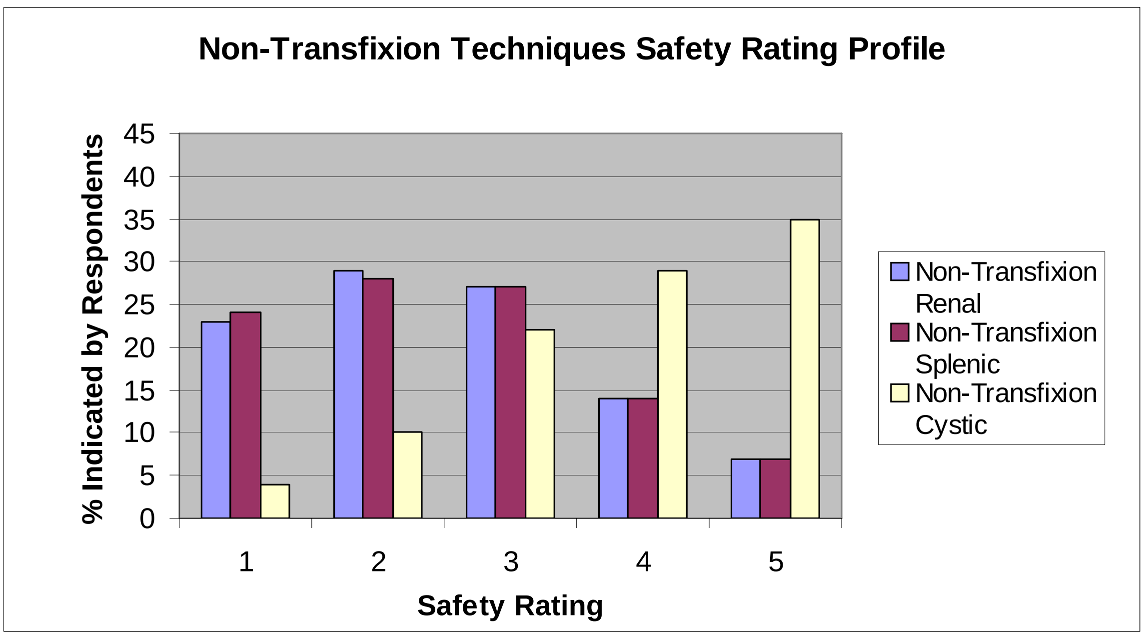
* Respondents were asked to rate techniques from 1 "unsafe" to 5 "extremely safe." Ratings of 3 or greater were considered "safe."
** See text for discussion of statistical analysis.

5. Safety Ratings Summary and Comparison

Figure 3 is a summary of the information presented in Table 19, Table 20, and Table 21. Figure 3 reiterates that the majority of safety ratings given to *transfixion* techniques for use on the renal, splenic, and cystic arteries were a 3 “safe” or higher. On the other hand, the majority of safety ratings given to *non-transfixion* techniques for use on the renal and splenic arteries were a 3 “safe” or lower, while non-transfixion techniques maintained a favorable rating profile for use on the cystic artery.

FIGURE 3


Transfixion Techniques Safety Rating Profile
% Indicated by Respondents
50
40
30
20
10
0
1
2
3
4
5
Safety Rating
Transfixion Renal
Transfixion Splenic
Transfixion Cystic


Non-Transfixion Techniques Safety Rating Profile
% Indicated by Respondents
45
40
35
30
25
20
15
10
5
0
1
2
3
4
5
Safety Rating
Non-Transfixion Renal
Non-Transfixion Splenic
Non-Transfixion Cystic

D. Reports of Technical Failure and Severe Hemorrhage

1. Renal Artery Technical Failures

290 surgeons (57% of total respondents) indicated actual experience occluding the renal artery irrespective of open vs. laparoscopic approach. 42 surgeons (14.5% of those with renal artery experience) reported 44 cases of technical failure with severe hemorrhage from the renal artery. The cases are summarized in Table 22 and Table 23. Table 22 summarizes the technical failure data according to specific technique. Table 23 provides a summary and analysis of the technical failure data in terms of transfixion techniques vs. non-transfixion techniques. It should be noted the date these technical failures occurred was not requested. Therefore, the exact technology in use at the time of the reported failure is not known. It is possible that the technology involved in a case of failure may have improved since the time of the failure. For example, one respondent reported a case in which multiple clips failed to occlude the cystic artery resulting in severe post-operative hemorrhage. But the respondent noted that the case occurred in the early 1990s with early generation laparoscopic clip appliers.

TABLE 22

Techniques of Renal Artery Stump Occlusion that Failed to Prevent Severe Hemorrhage in 44 Reported Cases

Technique	Number of Cases	Hemorrhage Intra-Op	Hemorrhage Post-Op	Required Transfusion	Re-Operation Required	Other Serious Consequences*	Death
Non-Transfixion							
Single simple tie	13	9	4	8	4	1	1
Multiple simple ties	8	3	5	6	5	2	1
Multiple hemostatic clips (non-locking)	5	4	1	2	1	1	0
Multiple locking hemostatic clips	4	2	2	3	2	3	0
Single simple tie and clip (unspecified)	2	1	1	1	1	0	1
Single hemostatic clip (non-locking)	2	2	0	2	0	1	0
Single simple tie and clip (non-locking)	1	0	1	1	1	0	0
Multiple simple ties and clip (unspecified)	1	0	1	1	0	0	0
Single clip (unspecified)	1	1	0	0	0	0	0
Multiple clips (unspecified)	1	1	0	0	0	0	0
Single locking hemostatic clip	1	1	0	0	0	0	0
Sub-Totals	**39**	**24**	**15**	**24**	**14**	**8**	**3**
Transfixion							
Suture ligature	2	2	0	2	0	0	0
Stapler (unspecified)	1	1	0	1	0	0	0
TA surgical stapler	1	1	0	0	0	1	0
GIA surgical stapler	1	1	0	0	0	0	0
Sub-Totals	**5**	**5**	**0**	**3**	**0**	**1**	**0**

* Serious consequences include ARF, ARDS, PE, DIC, stroke, etc. Consequences related to specific techniques are discussed in the text.

The technique associated with the most failures to prevent severe hemorrhage from the renal artery was a single simple tie (13 cases) followed by multiple simple ties (8 cases), multiple non-locking clips (5 cases), and multiple-locking clips (4 cases). 39 cases were attributed to *non-transfixion* techniques and 5 cases to *transfixion* techniques.

9 cases (8 non-transfixion, 1 transfixion) had serious consequences associated with the technical failure: 1. Single simple tie: pulmonary embolus (PE). 2. Multiple simple ties: multi-system organ failure (MSOF). 3. Multiple simple ties: adult respiratory distress syndrome (ARDS) and disseminated intravascular coagulation (DIC). 4. Multiple non-locking clips: reopened through hand-port to control bleeding. 5. Multiple locking clips: conversion from laparoscopic to open operation. 6. Multiple locking clips: conversion from laparoscopic to open operation. 7. Multiple locking clips: transient intra-operative cardiac arrest with no long-term sequelae. 8. Single non-locking clip: converted from laparoscopic to open operation. 9. TA stapler: converted from laparoscopic to open operation.

Three deaths occurred in association with technical failure and hemorrhage from the renal artery. The techniques associated with those three deaths were all non-transfixion techniques: single simple tie (1 case), multiple simple ties (1 case), and single simple tie plus clip (1 case).

a. Renal Artery Technical Failures (Statistical Analysis)

Technical failures that resulted in severe hemorrhage from the renal artery were associated with a significantly higher proportion of non-transfixion techniques than transfixion techniques (89% vs. 11%, $p<0.0001$), see Table 23. A higher proportion of hemorrhages occurred intra-operatively using transfixion techniques vs. non-transfixion techniques (100% vs. 62%, $p<0.05$). Conversely, a higher proportion of hemorrhages occurred post-operatively for non-transfixion techniques vs. transfixion techniques (38% vs. 0%, $p<0.05$). The small number of technical failures attributed to transfixion techniques made it difficult to demonstrate statistically significant differences for the other parameters – transfusion, re-operation, serious consequences, or death. It can be noted, however, that transfixion techniques were associated with a lower proportion of all these complications when compared to non-transfixion techniques. Notably, no re-operations and no deaths were attributed to transfixion techniques.

TABLE 23

Non-Transfixion vs. Transfixion Techniques in 44 Cases of Renal Artery Stump Hemorrhage

	Non-Transfixion		**Transfixion**		**p-value***
Number of Cases	39/44	(89%)	5/44	(11%)	<0.0001
Hemorrhage Intra-Op	24/39	(62%)	5/5	(100%)	<0.05
Hemorrhage Post-Op	15/39	(38%)	0/5	(0%)	<0.05
Required Transfusion	24/39	(62%)	3/5	(60%)	0.47
Re-Operation Required	14/39	(36%)	0/5	(0%)	0.05
Other Serious Consequences	8/39	(21%)	1/5	(20%)	0.49
Death	3/39	(8%)	0/5	(0%)	0.26

* Z-test for difference between two proportions.

2. Splenic Artery Technical Failures

396 surgeons (78% of total respondents) indicated actual experience occluding the splenic artery irrespective of open vs. laparoscopic approach. 50 surgeons (12.6% of those with splenic artery experience) reported 50 cases of technical failure with severe hemorrhage from the splenic artery. The cases are summarized in Table 24 and Table 25. Table 24 summarizes the technical failures according to specific technique. Table 25 provides a summary and analysis of the technical failures in terms of transfixion techniques vs. non-transfixion techniques.

TABLE 24

Techniques of Splenic Artery Stump Occlusion that Failed to Prevent Severe Hemorrhage in 50 Reported Cases

Technique	Number of Cases	Hemorrhage Intra-Op	Hemorrhage Post-Op	Required Transfusion	Re-Operation Required	Other Serious Consequences*	Death
Non-Transfixion							
Single simple tie	17	9	8	11	7	2	1
Multiple simple ties	10	3	7	7	5	1	2
Single hemostatic clip (non-locking)	3	2	1	2	1	0	0
Single simple tie and clip (unspecified)	2	1	1	1	0	0	0
Ligasure	2	2	0	0	0	0	0
Single clip (unspecified)	1	1	0	1	0	0	0
Multiple clips (unspecified)	1	1	0	1	0	0	0
Multiple hemostatic clips (non-locking)	1	1	0	1	0	0	0
Sub-Totals	**37**	**20**	**17**	**24**	**13**	**3**	**3**
Transfixion							
GIA surgical stapler	4	2	2	2	2	0	0
Suture ligature	2	1	1	2	1	0	0
Suture ligature and simple ties	2	1	1	2	1	0	0
Stapler (unspecified)	2	2	0	1	0	0	0
Endovascular stapler and Ligasure	1	1	0	1	0	0	0
GIA stapler and single simple tie	1	1	0	0	0	0	0
Suture ligature and simple tie	1	1	0	0	0	0	0
Sub-Totals	**13**	**9**	**4**	**8**	**4**	**0**	**0**

* Serious consequences include ARF, ARDS, PE, DIC, stroke, etc. Consequences related to specific techniques are discussed in the text.

The technique with the most failures to prevent severe hemorrhage from the splenic artery was a single simple tie (17 cases) followed by multiple simple ties (10 cases). Interestingly, these two techniques were associated with the highest incidence of failure and severe hemorrhage when used to occlude the renal artery, as well. 37 cases were attributed to *non-transfixion* techniques and 13 cases to *transfixion* techniques.

3 cases (all non-transfixion) had serious consequences associated with the technical failure: 1. Single simple tie: atelectasis and pneumonia. 2. Single simple tie: post-op infection. 3. Multiple simple ties: adult respiratory distress syndrome (ARDS) and disseminated intravascular coagulation (DIC).

Three deaths occurred in association with technical failure and hemorrhage from the splenic artery. The techniques associated with those three deaths were all non-transfixion techniques: single simple tie (1 case) and multiple simple ties (2 cases).

a. Splenic Artery Technical Failures (Statistical Analysis)

Technical failures that resulted in severe hemorrhage from the splenic artery were associated with a significantly higher proportion of non-transfixion techniques than transfixion techniques (74% vs. 26%, $p<0.0001$), see Table 25. No statistically significant differences were observed for the other parameters – post-operative hemorrhage, transfusion, re-operation, serious consequences, or death. It can be noted, however, that transfixion techniques were associated with a lower proportion of all these complications when compared to non-transfixion techniques. Notably, no serious consequences and no deaths were attributed to transfixion techniques.

TABLE 25

Non-Transfixion vs. Transfixion Techniques in 50 Cases of Splenic Artery Stump Hemorrhage					
	Non-Transfixion		Transfixion		p-value*
Number of Cases	37/50	(74%)	13/50	(26%)	<0.0001
Hemorrhage Intra-Op	20/37	(54%)	9/13	(69%)	0.17
Hemorrhage Post-Op	17/37	(46%)	4/13	(31%)	0.17
Required Transfusion	24/37	(65%)	8/13	(62%)	0.41
Re-Operation Required	13/37	(35%)	4/13	(31%)	0.39
Other Serious Consequences	3/37	(8%)	0/13	(0%)	0.14
Death	3/37	(8%)	0/13	(0%)	0.14

* Z-test for difference between two proportions.

3. Cystic Artery Technical Failures

Finally, 375 surgeons (74% of total respondents) indicated actual experience occluding the cystic artery. 65 surgeons (17.3% of those with cystic artery experience) reported 68 cases of technical failure with severe hemorrhage from the cystic artery. The cases are summarized in Table 26 and Table 27. Table 26 summarizes the technical failure data according to specific technique. Table 27 provides a summary and analysis of the technical failure data in terms of transfixion techniques vs. non-transfixion techniques.

TABLE 26

Techniques of Cystic Artery Stump Occlusion that Failed to Prevent Severe Hemorrhage in 68 Reported Cases

Technique	Number of Cases	Hemorrhage Intra-Op	Hemorrhage Post-Op	Required Transfusion	Re-Operation Required	Other Serious Consequences*	Death
Non-Transfixion							
Single hemostatic clip (non-locking)	13	8	5	2	5	0	0
Single simple tie	12	8	4	5	4	1	0
Multiple clips (unspecified)	11	5	6	5	4	3	1
Single clip (unspecified)	11	7	4	4	4	0	0
Multiple hemostatic clips (non-locking)	8	4	4	2	3	1	0
Multiple simple ties	6	3	3	4	2	0	0
Electrocoagulation	2	2	0	0	0	0	0
Single locking hemostatic clip	2	2	0	0	0	0	0
Sub-Totals	**65**	**39**	**26**	**22**	**22**	**5**	**1**
Transfixion							
Suture ligature	2	2	0	0	0	0	0
Oversew	1	1	0	0	0	0	0
Sub-Totals	**3**	**3**	**0**	**0**	**0**	**0**	**0**

* Serious consequences include ARF, ARDS, PE, DIC, stroke, etc. Consequences related to specific techniques are discussed in the text.

The techniques with the most failures to prevent severe hemorrhage from the cystic artery were a single non-locking clip (13 cases), single simple tie (12 cases), multiple unspecified clips (11 cases), and single unspecified clip (11 cases). 65 cases were attributed to *non-transfixion* techniques and 3 cases to *transfixion* techniques.

5 cases (all non-transfixion) had serious consequences associated with the technical failure: 1. Multiple unspecified clips: laparoscopic operation converted to open. 2. Multiple unspecified clips: bile leak. 3. Multiple unspecified clips: acute renal failure (ARF) and stroke. 4. Single simple tie: ARF, prolonged open abdomen and massive hernia. 5. Multiple non-locking clips: prolonged hospitalization.

One death occurred due to the failure of multiple non-locking clips to occlude the cystic artery.

a. Cystic Artery Technical Failures (Statistical Analysis)

Technical failures that resulted in severe hemorrhage from the cystic artery were associated with an overwhelmingly higher proportion of non-transfixion techniques than transfixion techniques (96% vs. 4%, $p<0.0001$), see Table 27. The small number of technical failures attributed to transfixion techniques made it difficult to demonstrate statistically significant differences for the other parameters – post-op hemorrhage, transfusion, re-operation, serious consequences, or death. It should be noted, however, that transfixion techniques were associated with *none* of these complications.

TABLE 27

Non-Transfixion vs. Transfixion Techniques in 68 Cases of Cystic Artery Stump Hemorrhage

	Non-Transfixion		**Transfixion**		**p-value***
Number of Cases	65/68	(96%)	3/68	(4%)	<0.0001
Hemorrhage Intra-Op	39/65	(60%)	3/3	(100%)	0.08
Hemorrhage Post-Op	26/65	(40%)	0/3	(0%)	0.08
Required Transfusion	22/65	(34%)	0/3	(0%)	0.11
Re-Operation Required	22/65	(34%)	0/3	(0%)	0.11
Other Serious Consequences	5/65	(8%)	0/3	(0%)	0.31
Death	1/65	(2%)	0/3	(0%)	0.41

* Z-test for difference between two proportions.

V. DISCUSSION

In October 2003, Friedman et al. distributed a survey to members of the American Society of Transplant Surgeons (ASTS) to assess the use and safety of vascular occlusion techniques utilized in open and laparoscopic nephrectomy. The results of the survey demonstrated that transplant surgeons prefer the use of transfixion techniques in both open and laparoscopic nephrectomy, transfixion techniques were considered safer than non-transfixion techniques, transfixion techniques accounted for fewer reports of severe arterial hemorrhage, and surgical clips, in particular, accounted for worse complications. The ASTS survey, however, focused on a very specific population (transplant surgeons) and a very specific operation (donor nephrectomy) with specific challenges (the need to maximize the length of vasculature on the donated organ to facilitate anastomosis in the recipient and the need to work quickly to preserve the viability of the organ). Consequently, the results of the ASTS survey were not necessarily generalizable. It was recognized, however, that the results of the ASTS survey may, in fact, be relevant to the management of other major, medium-sized arteries in contexts other than organ donation.

Based on the results of the ASTS survey, it was hypothesized that blood vessel occlusion techniques that incorporate tissue transfixion are more secure and are associated with better patient safety, fewer complications and less severe complications than techniques that do not incorporate tissue transfixion when applied to medium-sized arteries in the size range of 6-10mm. To test this hypothesis, a survey was designed to assess the use and safety of vascular control techniques utilized for two major medium-sized arteries – the renal and splenic arteries. Questions regarding the management of the smaller cystic artery were included as a control.

506 surgeons completed the survey. The respondents represented six different surgical specialties: general surgery, urology, thoracic surgery, vascular surgery, obstetrics and gynecology, and colon and rectal surgery. Clearly, the response rate of 13.1% was low. A brief review of the literature reveals few published surgical surveys with response rates below 30%. (16, 21-23) (Note: despite the ASTS survey's response rate of 24%, it was published in the top surgical journal because of its significance.) One reason why the response rate may have been so low is simply because surgeons are so busy. One respondent commented, "Don't let a low response rate discourage you. We're all too busy all the time…" The survey was estimated to require approximately 15 minutes to complete. Unfortunately, the 8-page, 5-section survey could appear daunting and time-consuming at first glance, but if the surgeon read carefully he/she would realize that sections II, III, and IV asked identical sets of questions and, in reality, could be completed rather quickly. In designing any survey, it is a balancing act between asking enough questions to gather meaningful and comprehensive data, and not asking too many questions such that the recipient is discouraged from participating. The busy life of a surgeon, the length of the survey (8 pages), and the fact that it was sent via postal mail with no follow-up reminders or email reminders likely all contributed to a low response rate. Nevertheless, few surveys have collected such detailed information from this many surgeons (n=506) and the respondent population was large enough to obtain statistically significant results.

A statistically significant proportion of respondents indicated that transfixion techniques should be used to occlude the renal and splenic arteries in both open and laparoscopic operations. The highest ranked choice to occlude the renal and splenic arteries in *open* operations was suture ligature plus simple ties. The next highest ranked choice was multiple simple ties, a non-transfixion technique. The highest ranked choice to occlude both the renal and splenic arteries in *laparoscopic* operations was the GIA surgical stapler. Once again, the next highest ranked choice was multiple locking clips, a non-transfixion technique. Therefore, while the majority of surgeons felt transfixion techniques should be used to occlude the renal and splenic arteries a clear consensus was not evident.

Respondents rated the *safety* of techniques used to occlude the renal and splenic arteries. All of the transfixion techniques were rated safer than non-transfixion techniques. Suture ligature plus simple ties, the highest-ranked choice to occlude the renal and splenic arteries in *open* operations was considered safer than multiple simple ties, the second-ranked choice. The GIA surgical stapler, the highest-ranked choice to occlude the renal and splenic arteries during *laparoscopic* operations was considered safer than multiple non-locking clips, the second-ranked choice. Therefore, the majority of surgeons are chose what is considered a safer technique, but surgeons are choosing techniques considered less safe. More alarming, a number of surgeons reported the use of techniques considered *unsafe* by the majority to occlude the renal and splenic arteries. Techniques considered *unsafe* to occlude the renal and splenic arteries included: multiple non-locking clips, single locking clip, single simple tie, and single non-locking clip.

Surgeons indicated they would use transfixion techniques more frequently than non-transfixion techniques to occlude the renal and splenic arteries in both open and laparoscopic operations. However, the proportion of non-transfixion techniques chosen for *laparoscopic* operations was higher than the proportion chosen for *open* operations. The tendency to use an increased proportion of non-transfixion techniques during laparoscopic operations is perhaps not surprising. It is very difficult, for example, to suture ligate or oversew a blood vessel using laparoscopic instruments. Even laparoscopic surgical staplers can be cumbersome at times. In contrast, it can be easier to quickly apply a few surgical clips. In spite of this, the GIA surgical stapler was still considered safer than surgical clips to occlude the renal and splenic arteries during laparoscopic operations. In other words, the tendency to use a higher proportion of non-transfixion techniques in laparoscopic operations was quite surprising given the fact that non-transfixion techniques were considered *less safe* than transfixion techniques.

The safety of a given technique can also be predicated on the patient's anatomy and the condition of the tissues being manipulated. One respondent commented, "The presence of acute inflammation, fibrosis, or calcified plaque may require alteration of technique. The above conditions render clips and stapling devices less likely to succeed in securing hemostasis." Another respondent commented, "The [vascular occlusion] techniques are fitted to the size of artery and quality of tissues." And yet another respondent argued, "You [did] not include what is most important - the primary adequate mobilization [of the vessels] before any closure is done." Another respondent agreed that adequate dissection of the vessel is often just as important as the choice of vessel occlusion technique -- "Not only is it important to ligate the vessel correctly, it is frequently just as important to clean the vessel such that the technique used, whatever it is, will properly and securely occlude the vessel without slipping. Too much tissue around the artery can cause post-op slipping of the ligature and subsequent bleeding."

Safety ratings, while informative, do not necessarily reflect actual safety. To investigate the *actual* safety of vascular control techniques, reports of technical failure were sought. Reports of technical failure alone can be misleading, but in the context of technical choice and safety rating, however, technical failure data can be informative.

For example, the use of a single simple tie to occlude the renal artery stump accounted for the highest number of reported technical failures and severe hemorrhage (13 cases, including one death). The use of a single simple tie to occlude the renal artery was considered "unsafe" and it was the 6th ranked technical choice for open nephrectomy and the 8th ranked choice for laparoscopic nephrectomy. In other words, even though many surgeons consider a single simple tie unsafe to use on the renal artery and few surgeons choose to occlude the renal artery with a single simple tie, there is a population of surgeons who use a single simple tie on the renal artery with sometimes disastrous results, as indicated by the high number of reported failures. The dissemination of such information to surgeons who currently elect to occlude the renal artery with a single simple tie might prove valuable and improve patient safety. This survey, at the very least, attempts to establish a consensus regarding which techniques are considered safe and are associated with the fewest failures vs. which techniques are considered unsafe and are associated with the most failures. Hopefully, this information will help guide surgeons' choices of vascular occlusion techniques.

As another example, suture ligature plus simple ties was the highest-ranked choice to occlude the renal and splenic arteries in open operations. Suture ligature plus simple ties was considered "extremely safe." Two cases of technical failure and severe hemorrhage associated with suture ligature plus simple ties were reported; both involving the splenic artery. Multiple simple ties were the next highest-ranked technique to occlude the renal and splenic arteries in open operations. Multiple simple ties were considered "safe." Eighteen cases of technical failure and severe hemorrhage were attributed to multiple simple ties, including three deaths. In other words, the highest-ranked choice (suture ligature plus simple ties) accounted for only two failures, while the second-ranked choice (multiple simple ties) accounted for eighteen failures. Surgeons who have previously employed multiple simple ties to occlude the renal artery during open nephrectomy may be prudent to consider the use of a transfixion technique like suture ligature plus simple ties instead.

Questions regarding the cystic artery were included in the study to compare the management of a smaller artery with larger arteries like the renal and splenic. It was hypothesized that transfixion techniques would show superiority over non-transfixion techniques when used on larger blood vessels, 6-10mm in diameter. In other words, in order to achieve secure occlusion of vessels 6-10mm in diameter the suture material or staples need to pass through the vascular tissue to prevent dislodgment. On the other hand, for vessels the size of the cystic artery it was felt the added security of transfixion is unnecessary and technically difficult to achieve. For the cystic artery, respondents agreed that non-transfixion techniques were just as safe as transfixion techniques and, in fact, non-transfixion techniques were chosen to a much higher degree than transfixion techniques to occlude the cystic artery. For *open* cholecystectomy, the highest-ranked choice to occlude the cystic artery was a single simple tie. The next highest ranked choices were multiple non-locking clips and multiple simple ties. For *laparoscopic* cholecystectomy, the highest-ranked choice was multiple non-locking clips.

The reports of technical failure and hemorrhage from the cystic artery are more difficult to interpret compared with the renal and splenic artery. With the renal and splenic arteries, surgeons chose a higher proportion of transfixion techniques, considered transfixion techniques safer, and transfixion techniques were associated with fewer failures. For the cystic artery, on the other hand, transfixion techniques were again associated with fewer failures, but transfixion techniques were not the technique of choice for cystic artery management. The proportion of technical failures for non-transfixion vs. transfixion techniques is roughly equal to the proportion of non-transfixion vs. transfixion techniques chosen to occlude the cystic artery. As a result, neither technique can be deemed safer than the other to occlude the cystic artery. The conclusion that neither transfixion or non-transfixion techniques are shown to be superior for occluding the cystic artery is actually in agreement with the hypothesis, which stated that transfixion techniques would demonstrate superiority only in larger vessels 6-10mm in diameter.

In conclusion, our research study demonstrates that for blood vessels 6-10mm in diameter, like the renal and splenic arteries, vascular occlusion techniques that incorporate tissue transfixion are chosen more frequently in both open and laparoscopic operations, are considered safer than non-transfixion techniques, and are associated with fewer technical failures and severe hemorrhage.

Collection of data on six preventable deaths linked to the use of non-transfixion techniques on medium-sized arteries substantiates the importance of reviewing outcomes for the purpose of improving patient safety. One would hope that sharing these data, together with the clear consensus that non-transfixion techniques are less safe than transfixion techniques may effectively induce a change in practice.

VI. APPENDIX

Yale Medical Student Research Survey: Vascular Control in Surgery

As part of a Yale medical student research project, I am assessing the techniques used to control blood vessels during surgical operations. My advisor, Amy L. Friedman M.D., F.A.C.S. and her colleagues became directly aware of several recent perioperative deaths and catastrophic hemorrhage in live kidney donors as a result of failed arterial or venous control. By surveying American transplant surgeons, they obtained data that appear to statistically correlate certain methods of vascular control with a greater risk of hemorrhagic complications. We want to expand this vascular control study to include more surgeons and more surgical specialties. Please take a few moments to complete the following survey. Your answers will be considered strictly confidential.

Please note the following: This survey contains questions regarding adverse surgical outcomes and complications. We recognize that surgeons may be hesitant to report adverse outcomes because of potential legal risk or stigma. THEREFORE, we obtained a Certificate of Confidentiality (COC) from the NIH. A COC prevents researchers from having to involuntarily disclose, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, names and other identifying information about any individual who participates as a research subject. This protection is afforded by the Public Health Service Act §301(d), 42 U.S.C. §241(d). ADDITIONALLY, this survey can be returned anonymously. If you do choose to provide identifiable information it will be kept confidential and separate from data and results. Identifiable information will not be released to any external agency and is protected under the COC.

This survey instrument received Yale School of Medicine IRB approval (HIC #27456). Study participation is voluntary and survey return will indicate consent. Thank you in advance for your participation.

Please return the completed survey in the postage-paid envelope provided or fax to 203-785-7162.

Please respond before ***10/16/2006***.

We sincerely appreciate your participation!!!

Ryan Kelly YSM 2007 and Amy L. Friedman M.D., F.A.C.S.

Section I: General Information

1. What is your surgical specialty? (circle)
    a. Colon and Rectal Surgery
    b. Obstetrics and Gynecology
    c. General Surgery
    d. Thoracic Surgery
    e. Urology
    f. Other: (please specify) ____________________

2. Do you have a surgical subspecialty? (circle)
    a. Gynecologic Oncology
    b. Surgical Critical Care
    c. Trauma surgery
    d. Vascular Surgery
    e. Transplant Surgery
    f. Other: (please specify) ____________________

3. Briefly describe the types of surgeries you perform:
____
____
____
____

4. Do you perform laparoscopic or thoracoscopic procedures? (circle)
    a. Yes
    b. No

5. How many years of surgical experience do you have? ____________

Section II: Renal Artery Control

Imagine that you are removing a kidney. Use the following questions to describe for us how you would occlude the renal artery stump while removing the kidney. Assume the renal artery is 7mm in diameter.

1. During open surgery, which technique would you use to occlude the renal artery stump? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Open surgery
a. Single simple tie	_______
b. Multiple simple ties	_______
c. Suture ligature	_______
d. Suture ligature and simple tie(s)	_______
e. Oversew	_______
f. Single hemostatic clip (non-locking)	_______
g. Multiple hemostatic clips (non-locking)	_______
h. Single locking hemostatic clip	_______
i. Multiple locking hemostatic clips	_______
j. GIA surgical stapler	_______
k. TA surgical stapler	_______
l. Ligasure™	_______
m. Other: ______________________	_______

2. During laparoscopic surgery, which technique would you use to occlude the renal artery stump? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Laparoscopic surgery
a. Single simple tie	_______
b. Multiple simple ties	_______
c. Suture ligature	_______
d. Suture ligature and simple tie(s)	_______
e. Oversew	_______
f. Single hemostatic clip (non-locking)	_______
g. Multiple hemostatic clips (non-locking)	_______
h. Single locking hemostatic clip	_______
i. Multiple locking hemostatic clips	_______
j. GIA surgical stapler	_______
k. TA surgical stapler	_______
l. Ligasure™	_______
m. Other: ______________________	_______

3. How do you rate the safety of the following techniques to occlude the renal artery stump?

	Unsafe		Safe		Extremely safe
Single simple tie:	1	2	3	4	5
Multiple simple ties:	1	2	3	4	5
Suture ligature:	1	2	3	4	5
Suture ligature and simple tie(s):	1	2	3	4	5
Oversew:	1	2	3	4	5
Single hemostatic clip (non-locking):	1	2	3	4	5
Multiple hemostatic clips (non-locking):	1	2	3	4	5
Single locking hemostatic clip:	1	2	3	4	5
Multiple locking hemostatic clips:	1	2	3	4	5
GIA surgical stapler:	1	2	3	4	5
TA surgical stapler:	1	2	3	4	5
Ligasure™	1	2	3	4	5
Other (specify) ____________________:	1	2	3	4	5

Section II: Renal Artery Control

If you have actual experience occluding the renal artery stump, please answer the following questions. If not, please proceed to Section III.

4. Have any of the above techniques ever failed to prevent severe hemorrhage from the renal artery stump in your cases? (circle)
   a. Yes. Which technique? ___________________________
   b. No

If yes,
5. Did the patient require a blood transfusion? (circle)
   a. Yes
   b. No

6. Did the hemorrhage occur intra-operatively or post-operatively? (circle)
   a. intra-operatively
   b. post-operatively

6a. If the hemorrhage occurred post-operatively, was re-operation needed? (circle)
   a. Yes
   b. No

7. What other serious consequences occurred? (e.g. acute renal failure)
____
____
____

8. Did the patient live or die? (circle)
   a. Lived
   b. Died

9. Additional comments about the case or outcome:
____
____
____
____

Section III: Splenic Artery Control

Now imagine that you are removing a spleen. Use the following questions to describe for us how you would occlude the splenic artery while removing the spleen. Assume the splenic artery is 10mm in diameter.

1. During open surgery, which technique would you use to occlude the splenic artery? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Open surgery
a. Single simple tie	_______
b. Multiple simple ties	_______
c. Suture ligature	_______
d. Suture ligature and simple tie(s)	_______
e. Oversew	_______
f. Single hemostatic clip (non-locking)	_______
g. Multiple hemostatic clips (non-locking)	_______
h. Single locking hemostatic clip	_______
i. Multiple locking hemostatic clips	_______
j. GIA surgical stapler	_______
k. TA surgical stapler	_______
l. Ligasure™	_______
m. Other: ______________________	_______

2. During laparoscopic surgery, which technique would you use to occlude the splenic artery? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Laparoscopic surgery
a. Single simple tie	_______
b. Multiple simple ties	_______
c. Suture ligature	_______
d. Suture ligature and simple tie(s)	_______
e. Oversew	_______
f. Single hemostatic clip (non-locking)	_______
g. Multiple hemostatic clips (non-locking)	_______
h. Single locking hemostatic clip	_______
i. Multiple locking hemostatic clips	_______
j. GIA surgical stapler	_______
k. TA surgical stapler	_______
l. Ligasure™	_______
m. Other: ______________________	_______

3. How do you rate the safety of the following techniques to occlude the splenic artery?

	Unsafe		Safe		Extremely safe
Single simple tie:	1	2	3	4	5
Multiple simple ties:	1	2	3	4	5
Suture ligature:	1	2	3	4	5
Suture ligature and simple tie(s):	1	2	3	4	5
Oversew:	1	2	3	4	5
Single hemostatic clip (non-locking):	1	2	3	4	5
Multiple hemostatic clips (non-locking):	1	2	3	4	5
Single locking hemostatic clip:	1	2	3	4	5
Multiple locking hemostatic clips:	1	2	3	4	5
GIA surgical stapler:	1	2	3	4	5
TA surgical stapler:	1	2	3	4	5
Ligasure™	1	2	3	4	5
Other (specify) ___________________:	1	2	3	4	5

Section III: Splenic Artery Control

If you have actual experience occluding the splenic artery please answer the following questions. If not, please proceed to Section IV.

4. Have any of the above techniques ever failed to prevent severe hemorrhage from the splenic artery in your cases? (circle)

a. Yes. Which technique? __________________________
b. No

If yes,

5. Did the patient require a blood transfusion? (circle)

a. Yes
b. No

6. Did the hemorrhage occur intra-operatively or post-operatively? (circle)

a. intra-operatively
b. post-operatively

6a. If the hemorrhage occurred post-operatively, was re-operation needed? (circle)

a. Yes
b. No

7. What other serious consequences occurred? (e.g. acute renal failure)

____
____
____

8. Did the patient live or die? (circle)

a. Lived
b. Died

9. Additional comments about the case or outcome:

____
____
____
____

Section IV: Cystic Artery Control

Finally, imagine that you are removing a gallbladder. Use the following questions to describe for us how you would occlude the cystic artery while removing the gallbladder. Assume the cystic artery is 2mm in diameter.

1. During open surgery, which technique would you use to occlude the cystic artery? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Open surgery
a. Single simple tie	______
b. Multiple simple ties	______
c. Suture ligature	______
d. Suture ligature and simple tie(s)	______
e. Oversew	______
f. Single hemostatic clip (non-locking)	______
g. Multiple hemostatic clips (non-locking)	______
h. Single locking hemostatic clip	______
i. Multiple locking hemostatic clips	______
j. GIA surgical stapler	______
k. TA surgical stapler	______
l. Ligasure™	______
m. Other: ____________________	______

2. During laparoscopic surgery, which technique would you use to occlude the cystic artery? (Place a check next to the technique you would use. If you would combine techniques, check both.)

	Laparoscopic surgery
a. Single simple tie	______
b. Multiple simple ties	______
c. Suture ligature	______
d. Suture ligature and simple tie(s)	______
e. Oversew	______
f. Single hemostatic clip (non-locking)	______
g. Multiple hemostatic clips (non-locking)	______
h. Single locking hemostatic clip	______
i. Multiple locking hemostatic clips	______
j. GIA surgical stapler	______
k. TA surgical stapler	______
l. Ligasure™	______
m. Other: ____________________	______

3. How do you rate the safety of the following techniques to occlude the cystic artery?

	Unsafe		Safe		Extremely safe
Single simple tie:	1	2	3	4	5
Multiple simple ties:	1	2	3	4	5
Suture ligature:	1	2	3	4	5
Suture ligature and simple tie(s):	1	2	3	4	5
Oversew:	1	2	3	4	5
Single hemostatic clip (non-locking):	1	2	3	4	5
Multiple hemostatic clips (non-locking):	1	2	3	4	5
Single locking hemostatic clip:	1	2	3	4	5
Multiple locking hemostatic clips:	1	2	3	4	5
GIA surgical stapler:	1	2	3	4	5
TA surgical stapler:	1	2	3	4	5
Ligasure^{TM}	1	2	3	4	5
Other (specify) ____________________:	1	2	3	4	5

Section IV: Cystic Artery Control

If you have actual experience occluding the cystic artery please answer the following questions. If not, please proceed to Section V.

4. Have any of the above techniques ever failed to prevent severe hemorrhage from the cystic artery in your cases? (circle)
   a. Yes. Which technique? ___________________________
   b. No

If yes,
5. Did the patient require a blood transfusion? (circle)
   a. Yes
   b. No

6. Did the hemorrhage occur intra-operatively or post-operatively? (circle)
   a. intra-operatively
   b. post-operatively

6a. If the hemorrhage occurred post-operatively, was re-operation needed? (circle)
   a. Yes
   b. No

7. What other serious consequences occurred? (e.g. acute renal failure)

____
____
____

8. Did the patient live or die? (circle)
   a. Lived
   b. Died

9. Additional comments about the case or outcome:

Section V: Final Comments

May we contact you for further information if needed?
If the answer is yes, please fill in your name, e-mail address and/or phone number:

THANK YOU VERY MUCH!!!

Ryan Kelly YSM 2007 and Amy L. Friedman M.D., F.A.C.S.

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