Complications Related to Linear Staplers

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Abbreviations

DVC	Dorsal venous complex
FDA	Food and Drug Administration
GIA	Gastrointestinal anastomosis
IVC	Inferior vena cava
MAUDE	Manufacturer and User Facility Device Experience
MIBC	Muscle-invasive bladder cancer
RALRC	Robotic-assisted laparoscopic radical cystectomy
RALRN	Robotic-assisted laparoscopic radical nephrectomy
RALRP	Robotic-assisted laparoscopic radical prostatectomy
RRP	Radical retropubic prostatectomy

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General

The incidence of complications related to linear staplers is difficult to ascertain, as they may not be routinely reported and mechanisms to document them are not standardized. Additionally, minor complications that are easily salvaged are less likely to be reported, and thus the scope of complications from these devices is likely underestimated. Often the exact etiology of a complication related to a linear stapler is difficult to pinpoint and theoretically could be due to a flaw in the device itself, user error, or patient factors. Adding to the complexity in understanding these problems is the fact that stapling devices are manufactured by different companies and their technologies continue to evolve and are released to surgeons without clinical studies to document their relative efficacy, equivalence, or superiority. Among surgical stapler users, urologic robotic surgeons are unique in their common use of these devices to control large blood vessels where a device malfunction could lead to immediate disaster. This is in contrast to malfunction during open surgery or during operations not centered around the control of large blood vessels where salvage of a complication may be easier and the complication presentation may not be as acute or severe.

In terms of reported complications, stapler misfires associated with incomplete staple formation

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or the inability to safely release the tissue from the device jaws appear to be most commonly mentioned. The US Food and Drug Administration (FDA) maintains a Manufacturer and User Facility Device Experience (MAUDE) database that collects hundreds of thousands of reports related to deaths, injuries, and malfunctions associated with medical devices [1]. Several groups have studied malfunctions and injuries attributed to linear staplers.

Brown et al. [2] looked at all surgical stapler-related adverse events in the MAUDE database irrespective of surgery type or approach. In a 10-year period, they identified 112 deaths that were related to surgical staplers. The majority of the cases were in gastrointestinal surgery, and approximately half of the cases resulted from staples not forming or other device failure/malfunction at the time of firing. They also analyzed FDA recalls from 1983 to 2003 and showed that 22 staplers were recalled, several of which were due to manufacturing issues relating to incomplete staple formation. Deng et al. [3] reviewed an institutional database of 460 laparoscopic urologic cases and found the rate of stapler-related complications to be about 1%. All of these complications occurred during radical nephrectomy or nephroureterectomy. Among these cases, 60% required open conversion, and 40% resulted in significant blood loss and transfusion.

Although stapler malfunctions causing injury are a rare event, the majority of laparoscopic surgeons feel that they have experienced at least one malfunction, and one third of surgeons have experienced three or more [4]. It is important to note that not all stapler-related malfunctions are primary device failures and can be the result of improper use and technique. This may be particularly true in cases of multiple failures during the same operation or recurrent failures for specific operators. The following section will address appropriate technique to prevent device failure.

Nephrectomy

Due to the proximity of the renal vessels to the aorta and inferior vena cava (IVC), RALRN represents the highest-risk operation for linear stapling within robotic urologic surgery. Stapler malfunctions can quickly lead to uncontrolled bleeding putting patients at risk for open conversion, blood transfusion, or death if not quickly controlled.

Hsi et al. [5] analyzed the MAUDE database from 1992 to 2006 and identified 111 stapler-related malfunctions during radical nephrectomy. The most common complications were incomplete staple line formation (47%) and difficulty releasing from tissue (30%). Chan et al. [6] analyzed the stapler use in laparoscopic nephrectomy from 1993 to 1999 at two institutions and assessed malfunctions primary to the device (e.g., missing staples, ligation failure) compared to secondary preventable causes (e.g., deployment over surgical clip, poor positioning). This group found a malfunction rate of 1.7% out of 565 cases and showed that 70% of the malfunctions were preventable with proper technique. Proper stapling techniques include ensuring appropriate position of the staple jaws completely across the vessel to be ligated. In addition, it is important that no additional tissue be interposed between the device that could cause incomplete staple formation. Appropriate loading and reloading of the device is required for effective use, and any signs that the device may be loaded incorrectly should prompt investigation and testing prior to its use on tissue. It is important to note that surgical stapler placement across clips is a common cause of device failure in radical nephrectomy. When placing clips for control of non-hilar vessels, care should be taken to avoid placing clips near the hilum where the stapler will be deployed. In patients with heavily calcified vessels, the operator should avoid areas of heavy vascular calcification while stapling which can lead to unpredictable results. Adherence to these basic techniques can significantly decrease the rate of stapler-related complications. In a current review of the MAUDE database for the last 10 years, there were two deaths and six serious injuries reported to the FDA-related to stapler-related complications after laparoscopic nephrectomy. Both deaths and 4/6 injuries were related to stapler misfire where the full staple line did not fire or did not seal a portion of the artery or vein. The additional two injuries were related to the stapler

not releasing from tissue after firing. In these reports there was no way to assess for user error compared to primary device failure [1]. In general, stapling of the renal hilum is safe with a low complication rate, but when complications do occur, they are usually significant requiring quick action. If a stapling misfire is suspected, the jaws should not be released from the vessel and more proximal control should be obtained before removing the device. If this is unable to be performed safely robotically, then open conversion may be necessary to gain vascular control.

En bloc hilar stapling is advocated by some surgeons and institutions as a way to simplify the operation and decrease blood loss. Several studies have reported this technique to be safe and lead to decreased blood loss and operative time without an increase in immediate postoperative complications. Resorlu et al. [7] analyzed 60 patients who underwent laparoscopic radical nephrectomy and compared those who had separate ligation vs en bloc ligation with linear staplers. This group showed that both groups had similar blood loss and length of stay but that the en bloc stapling group had approximately 20 min shorter operative course. They further showed that there were no stapler-related complications in either of the groups and concluded that en bloc stapling is a safe technique. However, it is also important to note that by taking both the renal artery and vein with one staple line, there is a theoretical risk of increased arteriovenous (AV) fistula formation. A prospective randomized trial studied the presence of AV fistula after en bloc stapling vs separate ligation in 60 patients and showed that with 12 months follow-up, no patients had developed an AV fistula in either group [8]. These data suggest that en bloc stapling is a safe technique with comparable complications to individual ligation. However, longer-term follow-up may be needed to definitively rule out an increased risk in AV fistula.

Although staplers are the most standard method for hilar control in RALRN, vascular Hem-o-lok clips (Weck Closure Systems, Research Triangle Park, NC) are also endorsed by some urologists, and it is important to discuss their related complications. Baumert et al. [9] described a technique where Hem-o-lok clips were used to ligate the renal artery and vein instead of an endovascular GIA stapler. In 130 cases, this group did not experience any complications related to bleeding or faulty clip placement. However, this was met with significant speculation as other groups have seen life-threatening complications. One case described clip dislodgement in the setting of a heavily calcified renal artery suggesting that clip placement was not safe in patients at high risk for significant atherosclerosis [10]. In addition, using large clips on small arteries can result in slippage and delayed bleeding from the renal hilum [10]. Finally, as previously discussed clip placement at or near the hilum may preclude safe stapler firing on the hilar vessels if needed. Ultimately, the FDA in 2006 released a report contraindicating the use of Hem-o-lok clips during laparoscopic donor nephrectomies due to the findings of 12 injuries and three deaths from 2001 to 2005 resulting from Hem-o-lok clips [11]. Due to the FDA's position, the authors do not advocate the use of these clips for renal hilar ligation. Finally, it is important to note that complications related to suture ligation of the renal hilum likely occur but are not well delineated in the modern literature.

Prostate

Traditionally in radical retropubic prostatectomy (RRP), the DVC is controlled using suture to provide hemostasis and is then divided. However, recently some urologists endorse using linear staplers as an alternative nonthermal mean to control the DVC particularly in robotic surgery. This technique was described in open RRP in 1996 and revealed that stapling of the DVC using an endovascular GIA was generally well tolerated with comparable blood loss and complications to suture ligation but with decreased operative time [12]. Since this description, several groups have compared linear stapler control of the DVC to traditional suture ligation. Muto et al. [13] showed that in open RRP, utilization of a linear stapler resulted in significantly decreased overall blood loss and fewer blood transfusions. However, they did show an increased rate of

anastomotic strictures in the stapling group. This finding suggests that the presence of metallic staples in proximity of the vesicourethral anastomosis may result in inflammation leading to increased stricture formation. However, this finding has not been validated in additional studies.

More recently, Nguyen et al. [14] compared suture ligation and stapler DVC control in laparoscopic prostatectomy and showed no difference in terms of EBL, operative time, and positive margin rate. Although they did not look at anastomotic stricture rate specifically, there was no significant difference between PSA recurrence, SHIM score, and continence rate. Wu et al. [15] specifically analyzed patients undergoing RALRP and showed that within a single institution, DVC control using a linear stapler was associated with faster operative times, decreased EBL, and lower apical positive surgical margin rates. Similarly, this group did not assess anastomotic stricture rate but did show similar rates of PSA recurrence, continence, and SHIM status.

Overall, the use of linear staplers for DVC control is a safe and effective method in RALRP. Recent studies suggest that it may be associated with decreased EBL and operative times and potentially a lower positive surgical margin rate. There is some evidence that the presence of staples near the anastomosis may lead to an increased stricture rate; however, this has not been validated in recent studies. Thus, it is critical to end the staple line short of the urethra to avoid staple erosion into the anastomosis or bladder and minimize inflammation. It is important to note that general stapler-related complications including misfires, incomplete staple formation, and inadequate stapler release can occur when controlling the DVC. However, this is less significant than in renal hilar control as additional bleeding is generally mild to moderate and can be controlled safely with additional suture ligation or pressure.

Bladder

In muscle-invasive bladder cancer (MIBC), RALRC has become an increasingly popular option among urologists. Most commonly this is associated with open urinary diversion; however, more institutions are beginning to perform intracorporeal urinary diversions. Linear staplers are utilized both in the extirpative portion of the operation for control of the vascular pedicles and during the reconstructive portion to perform the bowel resection and anastomosis.

Chang et al. [16] in 2003 compared 70 patients who had undergone radical cystectomy with either the use of linear staplers or traditional suture ligation for vascular pedicle control. Within the stapler group, there was decreased blood loss and fewer transfusions compared to suture ligation. Importantly, they did not experience any complications directly related to the use of a linear stapler and determined it safe to use for vascular pedicle control in radical cystectomy. This group later compared the linear stapler to the more modern Impact LigaSure (Covidien Surgical, Boulder, CO) device and showed no difference in blood loss or transfusion rate but did show significantly decreased cost with the LigaSure device without any complications attributable to either device [17]. These studies highlight that the use of a linear stapler for vascular control during radical cystectomy is generally well tolerated and provides excellent hemostasis. However, in these small series, although they do not reveal any stapler-specific complications, larger series would be needed to assess for rare mechanical failures.

In addition to vascular control, in RALRC the linear stapler is also utilized for bowel resection and anastomosis in intracorporeal urinary diversion. Although robotic cystectomy with intracorporeal diversion is still a relatively new technique, there have been several studies analyzing associated outcomes. It is well known that in general surgery, bowel anastomotic leak can occur at the staple line when performing stapled bowel anastomosis and lead to significant morbidity and mortality frequently requiring reoperation [18]. In a prospective study of 70 patients undergoing radical cystectomy with intracorporeal neobladder creation, approximately 6% of patients developed postoperative ileus, but there were no reported cases of bowel leakage from the stapled anastomosis [19]. A similar study analyzing 100 robotic-assisted intracorporeal ileal conduits showed a 22% rate of overall bowel complications

and specifically revealed one bowel fistula requiring reoperation [20]. These studies suggest that overall there is a low rate of bowel anastomotic leak for intracorporeal urinary diversion but that when it occurs it results in significant morbidity. Additionally, as this technique becomes more prevalent, larger studies are needed to clarify the overall rate of staple line leakage in comparison to open surgery.

Unique to urinary diversion, nonabsorbable foreign objects near the bladder or neobladder can predispose to stone formation. Shao et al. [21] studied patients undergoing intracorporeal ileal neobladder formation and compared those with a stapled reconstruction to those with traditional suturing. This study revealed a decreased operative time in the stapling group but with a 9% rate of stone formation from penetrated staples that required removal with cystoscopy.

Overall, the use of linear staplers in robotic radical cystectomy is well tolerated with a low risk of anastomotic leak at the stapled intestinal anastomosis. However, it is important to note the unique complication of stone formation when nonabsorbable staples penetrate into the lumen of the urinary diversion. These stones can be treated readily with cystoscopic removal of the stone and penetrated staple.

Additional Considerations

Robotic surgery is unique in that the main operator is not scrubbed at the bedside. It is important for robotic teams to be thoroughly educated on the use of surgical staplers. Critical to this effort are simulating situations where a stapler complication occurs and reviewing each team member's role. For example, should a stapler malfunction while ligating the renal artery, there is little time for everyone to react. Even when prepared for this scenario, the outcome may be poor, but preparation should hopefully minimize the adverse sequelae.

Depending on the case performed, having a surgical sponge ready to apply pressure in case of a bleeding vein or having a "rescue" vascular suture available are generally advised in case of complications. The robotic surgeon could apply pressure with the robotic arms on a bleeding staple line, but in order to further work safely or for controlled open conversion, the assistant must be able to replicate that pressure—this scenario is unique to robotic surgery, and thus preparation and prevention are both extremely important.

Conclusions

The use of linear staples has become commonplace in robotic urologic surgery for vascular control during major extirpative operations. Generally, linear staplers function well without issues and provide excellent hemostasis. However, there are several specific complications related to stapler malfunction that can lead to significant morbidity. Although the exact rate of stapler malfunctions is not clear due to variable reporting practices, most minimally invasive surgeons have experienced at least one complication attributable to a linear stapler. Across all operations, staplers can misfire leading to incomplete staple formation resulting in bleeding which can vary from mild to severe. In addition, staplers can fire appropriately but not release leading to a challenging situation where the stapler can remain stuck on important vascular structures.

Stapler malfunctions are most significant in radical nephrectomy where misfires or inadequate staple line formation when controlling the hilum can lead to significant blood loss and conversion to open surgery. Techniques to prevent malfunctions include ensuring that the additional tissue is not caught within the stapler and to reduce the number of clips near the hilum that can prevent appropriate staple line formation. If a staple misfire is suspected or the device becomes stuck on an important structure, it is important to leave the device closed if possible and obtain proximal control prior to attempted removal. In radical prostatectomy, staplers have become more common in DVC control but are prone to similar complications related to device malfunction. However, these complications are generally less serious as DVC control can be regained with additional suturing. Finally, robotic cystectomy is increasing in popularity, and linear staplers are utilized for intracorporeal diversion.

Early studies suggest a low rate of bowel anastomotic leakage but do show a low but significant prevalence of stone formation within the urinary diversion. Ultimately good judgment and knowledge on the use of surgical staplers is the key to minimizing complications and managing them with minimal morbidity.

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