Complications Associated with the Use of Clips

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Introduction

With the widespread adoption of minimally invasive surgery that has occurred over the past couple decades, surgical clips have become a valuable tool in the hands of the laparoscopic surgeon. Knowing how they are used properly and having a solid understanding of common pitfalls can be helpful in anticipating and avoiding complications.

General Considerations: Surgical Clips in Urologic Surgery

Surgical clips are frequently used in minimally invasive urologic surgery. They may be used for control of bleeding and prior to ligation of minor and major blood vessels and other anatomic structures. While the cumbersome nature of laparoscopic suturing and knot-tying increased the applications for surgical clips, they are still used frequently in robotic surgery where suturing and knot-tying are less challenging. Other techniques for vessel ligation with overlapping applications

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include suture ligation, stapling, and instruments that use electrical, ultrasonic, or other energy sources such as the LigaSure®, Harmonic Scalpel®, Gyrus®, and others.

The two general categories of clips are nonlocking and locking. Both are nondegradable and the former are made of metal while the latter are made of nonmetallic polymers. The Weck Hemo-lok® (Teleflex, Research Park Triangle, NC) is a nondegradable locking clip for use on tissue and suture. Another locking clip, the LAPRA-TY® clip (Ethicon, Cincinnati, OH) is absorbable and is used only on suture where it provides a secure anchor for the suture that eliminates the need for tying. Non-locking clips are V-shaped, and when the two arms are compressed, they maintain their closed configuration due to the inherent properties of the metal. Locking clips are also V-shaped prior to application, and when compressed they maintain their closed configuration via a latching mechanism of the two arms. A distinct click can be felt or heard as the arms lock into place properly. Clips used in robotic surgery are most commonly applied using laparoscopic instruments via the assistant port; however a robotic locking clip applier is also available. Non-locking clips may be removed by pulling on the vertex of the closed clip, whereas locking clips must either be cut or a special instrument used to unlock them atraumatically.

Clips, both locking and non-locking, are used on structures of varying size and type. In urologic

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An additional use of surgical clips is for placement on sutures to anchor closures without the need for knot-tying. LAPRA-TY® clips or Hemo-lok® clips may both be used for this purpose, but if using Hem-o-lok® clips, the suture should be placed in the middle of the clip rather than at either of the edges for a better grip on the suture. A common application of this sliding-clip technique is for the renorrhaphy during a laparoscopic or robotic partial nephrectomy [1]. With this technique one or more clips are placed on the suture after it is passed through the tissue and are then slid down until flush with the tissue to maintain the tension on the closure.

General Considerations: Complications

Complications associated with the use of clips are generally apparent at the time of ligation but also may become known in the postoperative period. Clips may provide inadequate vascular occlusion or become displaced from the ligated vessel leading to hemorrhage. Locking clips in theory may become unlocked and displaced from the compressed structure; however welldocumented clinical occurrences of clips becoming unlocked are lacking. Clips may also be placed on an unintended structure such as bowel or the ureter and lead to occlusion or ischemia if not removed in a timely manner.

Clip migration can occur in a delayed fashion and may be of no significance or occasionally become clinically apparent. In the urologic literature, clip migration with apparent clinical manifestations has been reported following laparoscopic and robotic radical prostatectomy. In these reports, clips were found intravesically associated with calculi and at the vesicourethral anastomosis associated with bladder neck contracture [2, 3]. In these instances where the clip is likely contributing to the clinical problem, it is advisable to remove it, either with endoscopic or open surgical techniques.

Special Consideration: Use of Hem-olok Clips for Donor Nephrectomy

One important consideration and the topic of much debate with the use of surgical clips is their use during living donor nephrectomy. Unique to donor nephrectomy is the goal of preserving as much arterial length as possible, thus leaving a shorter stump for application of ligating clips and the need to control tributary arteries or veins. Prompted by a published survey by the American College of Transplant Surgeons on complications during donor nephrectomy [4], in 2006 the Hemo-lok® manufacturer issued a warning stating that use during donor nephrectomy was contraindicated. This survey identified 66 cases of arterial hemorrhage, of which 12 cases used locking clips on the renal artery. In comparison a stapler was used in 13, ties in 16, and non-locking clips in 13 of the hemorrhagic complications. The two deaths from arterial hemorrhage were secondary to failure of multiple non-locking clips. Later that year following the manufacturer contraindication, Meng published an analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database compiling information on the 27 reported cases of adverse events involving Hem-o-lok® clips [5]. Urologic laparoscopic surgery accounted for 13 of the cases, with 9 cases of renal arterial bleeding and 2 of these resulted in death. No clear etiology was identified for these occurrences; however in the cases with detailed information on the re-exploration, it was noted that clips were not present on the renal artery. In one case at autopsy, the question of a ruptured aneurysm proximal to the renal artery clip was raised but not definitively answered.

Several studies have reported safety with clip usage on the renal hilum specifically during donor nephrectomy and are highlighted here. Ponsky et al. reported on over 1600 laparoscopic nephrectomies at 9 institutions using Hem-o-lok clips, including 486 donor nephrectomies, and reported zero instances of clip-related complications [6]. Ay et al. reported on 883 donor nephrectomies where Hem-o-lok clips were used on the hilum, with about half of patients having an additional Prolene transfixation suture placed between the ligating Hem-o-lok clips [7]. They also encountered no bleeding complications or problems with clip placements. Simforoosh et al. reported on over 1800 nephrectomies using clips on the hilum, with 962 being donor nephrectomies using 1 Hem-o-lok and 1 titanium clip on the renal artery and Hem-o-loks alone on the renal vein [8]. There were no cases of clip dislodgement or slippage during the operations, but there was one case of an aortic root aneurysm requiring reoperation. This was a case early in their institutional experience, and the authors felt that it may have been a result of placing the clip too close on the aorta and causing abrasion to the arterial wall. Baumert et al. included 66 donor nephrectomies in their report on a total 130 nephrectomies using only Hem-o-lok clips on the hilum and experienced no clip-related difficulties or bleeding complications [9]. Regardless of whether Hem-o-lok clips are used alone, or in combination with a titanium clip or suture ligature, these large studies support that they are a safe means for ligation of the renal hilum during donor nephrectomy.

Technique and Prevention of Complications

Several measures should be taken when using surgical clips to ensure their proper function and minimize the risks of complications. The authors agree that the vast majority of clip-related complications may be avoided with adherence to sound surgical techniques described below and summarized in Table 5.1 adapted from Ponsky et al. [6].

Proper surgical dissection of the structure to be ligated is paramount and is particularly important with larger arteries and veins. Entirely isolating the vascular structure from surrounding tissues (Fig. 5.1) ensures ligation only of the intended Table 5.1 Principles of Hem-o-lok clip placement

- 1. Complete circumferential dissection of the vessel (Fig. 5.1)
- Visualization of the tips of the clip around and beyond the vessel (Fig. 5.2)
- Confirmation of the tactile snap when the clip is engaged
- Maintenance of a visual stump below the most proximal clip for control or additional clips if needed (Fig. 5.3)
- 5. No cross-clipping
- 6. Handles squeezed only hard enough to snap closed (compared to metal clips which require tight squeezing
- Careful removal of the applier after placement of the clip (tips are sharp and could cause injury to adjacent structures)
- 8. During transection of vessels, only a partial division is performed initially to confirm hemostasis from the closure prior to complete transection (Fig. 5.4)
- Minimum of two clips placed on the patient side, with an additional 1–2 mm cuff distal to the last clip (Fig. 5.4)

Modified from Ponsky et al. [6] with permission from Elsevier



Fig. 5.1 Complete circumferential dissection of the vessel

structure, allows for visualization of the tips of the clip during closure (Fig. 5.2), and allows the clip to maintain an occlusive position without slipping. A vascular stump below the most proximal clip should be maintained (Fig. 5.3) in case additional clips are needed in case of hemorrhage. The vessel should initially be partially cut rather than fully transected (Fig. 5.4) to confirm hemostasis. This allows better control of the vessel in case



Fig. 5.2 Visualization of the tips of the clip around the vessel, unimpeded by additional tissue



Fig. 5.3 Maintenance of a visual stump proximal to the most proximal clip



Fig. 5.4 Minimum of two clips on the patient side or stay side of the hilar vessel and with a 1–2 mm cuff of tissue beyond the distal clip in case of slippage. Partial division of the vessel to confirm hemostasis while still maintaining control of the vessel before it is completely transected

additional clips or other hemostatic measures are required. Clips placed over staple lines or other clips are likely to have problems closing and should be avoided. Similarly, calcified, atherosclerotic arteries are also more likely to prohibit proper closure and require a low threshold for the use of additional clips or the addition of a suture ligature.

Both locking and non-locking clips come in a variety of sizes, and an appropriately sized clip should be selected for ligation. If the tips of a locking clip are not completely around a vessel, whether by improper positioning or by using an undersized clip, it should be noted that the vessel will be pierced when the clip is locked into place. For this reason, a larger clip or a non-locking clip that is less likely to pierce the vessel wall should be selected.

For smaller vessels and less-defined structures such as the prostate vascular pedicles, it is helpful to create windows in the adventitial tissue so that the clips can properly lock and the connected tips can be directly visualized. Locking clips will still function if there is some tissue within the latching portion provided that it is not overly thick, and in this situation the tactile feedback from a proper clip closure is key.

Elliott et al. described how closures failed in laboratory studies at supraphysiologic pressures [10]. Non-locking clips tended to fail by leaking through the clip as though the intraluminal pressure was able to pry open the arms. Locking clips maintained a closed configuration; however with proximal ballooning of the vessel, the cut edge would retract behind the clip and result in a bursting failure. Although these failures were well above physiologic blood pressure (>900 mm Hg), this description of the mechanism of failure is helpful in considering prevention. Indeed, in clinical accounts of failures, locking clips were noted to be slipped off of the bleeding vessel but remained locked [11, 12].

In other laboratory studies, Jellison et al. showed that leaving a 1 mm cuff beyond the distal clip resulted in fewer failures than when the vessel was transected adjacent to the clip [13]. We and others advocate leaving at least a 1-2 mm cuff beyond the distal clip to prevent a

slipped clip from catastrophically falling off the vessel [12, 14].

In both Elliott's and Jellison's studies, using more than one clip performed better than a single clip only at supraphysiologic pressures which suggests the effectiveness of using a single clip in clinical use. However, by weighing the very minimal benefits of using a single clip against the potential for catastrophic failure, we and others advocate for leaving at least two clips on the patient side of larger vessels such as the renal artery and vein [4, 6, 8, 13].

Risk Factors

While lapses in the above techniques are the primary risk factor for clip-related complications, there may be anatomic variations that make their use and placement more difficult. Short vascular segments leave little room for clip placement and leaving cuffs and stumps. Large arteries or aneurysmal segments may be oversized for certain clips; however this shouldn't be an issue given the variety of available clip sizes. Hardened, calcified arteries may not be as amenable to using clips, and some authors advocate the use of a stapler in this scenario [15]. Similarly, fibrotic tissue such as with prior surgery or radiation may be more difficult for placing clips.

During minimally invasive surgery, difficult instrumentation angles and visualization may make precise clip placement difficult in some scenarios. Clips that are not placed perpendicular on the vessel or placed over other clips or staple lines may be less secure. While right-angle clip appliers are available for open surgery and can minimize this difficulty, they don't exist for endoscopic clip appliers due to the additional width of the instrument that would be required.

Controlling hypertension in the postoperative period can minimize the forceful arterial pulsations on a freshly ligated artery and reduce the risk of clip malfunction. Adequate pain control is a key component to preventing hypertensive episodes. Although the vast majority of clip failures in laboratory studies were seen well above physiologic pressures, providing adequate pain control and treating hypertensive episodes remain important clinical principles of post-operative care. [10, 13].

Identification and Treatment

As with most complications, a key component to minimizing the impact to the patient is prompt identification and treatment. Being able to anticipate how clip-related complications can occur is helpful in avoiding them altogether but also for their prompt recognition and safe management.

In the rare instance where a clip provides inadequate closure of the artery intraoperatively, there are some techniques to control the situation and avoid the rapid hemorrhage that could ensue. Once the clips are in place, the vessel should first be partially divided and only then completely transected once hemostasis is confirmed. This allows the surgeon to maintain traction on the artery in order to identify and control any source of bleeding. The most proximal clip on the renal artery or vein should not be placed at its initial takeoff due to the tapered nature of this portion. Leaving this small proximal stump allows the surgeon to grasp and temporarily control a hemorrhaging vessel, while also leaving a space to place additional clips or suture ligatures if needed.

Once major vessels have been taken with clips, there is often still a fair amount of maneuvering or surgical dissection in order to free up and extract the specimen. During these steps disturbing the ligated vessels and clips should be minimized. We advocate taking a "second look" at the vascular pedicles and surgical bed with the pneumoperitoneum down to 5 mmHg or less to ensure hemostasis and stable clip positioning prior to completion.

The removal of a clip may be necessary in a few situations such as after placement on an unintended structure or when a clip is in the path of a staple line. For non-locking clips the arms may be pried apart, whereas locking clips require some additional maneuvers. A laparoscopic clip remover is available from the manufacturer; however our experience is that not all operating rooms are equipped with this instrument. The clip remover requires the clip to be completely situated within the jaws of the instrument before applying firm pressure to open it. When this is not feasible due to angulation, availability, or other difficulty, a harmonic scalpel may be used to safely dissolve one arm of the clip which will allow it to unlock and be removed without thermal damage to the surrounding tissue [16].

In the postoperative period, patients are monitored closely for any changes in vital signs, urine output, abdominal exam, and laboratory results. Delayed hemorrhage, when it occurs, may result in a precipitous decline in the patient's condition in the case of arterial bleeding or may be more gradual in the case of venous bleeding. Diagnostic studies such as conventional or CT angiography may be useful in stable patients where bleeding is equivocal, but in the actively bleeding or unstable patient, these studies will unnecessarily delay management and should be omitted. Prompt recognition and resuscitation, with return to the operating room for exploration, are crucial but unfortunately in some cases may not be sufficient to prevent ischemic complications or death.

Conclusion

Surgical clips are a valuable addition to the toolbox of the laparoscopic and robotic urologic surgeon. They provide an excellent and safe means of controlling large vessels such as the renal hilum as well as smaller vessels and tissue and have an established role as a substitute for more cumbersome suture or staple ligatures. Many of the complications related to clips may be avoided with adherence to sound surgical principles and correct techniques when applying the clips. Nevertheless, no method for ligation is fail-safe, and having an understanding of these complications is important for appropriate management.

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