

Bladder Neck Contractures Related to the Use of Hem-O-Lok Clips in Robot-Assisted Laparoscopic Radical Prostatectomy

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OBJECTIVE	Recently, several large series of robot-assisted laparoscopic radical prostatectomy (RALP) have described a low incidence of bladder neck contractures (BNC). We have had a similar experience at our institution. Our objective is to describe our experience with BNC after RALP and a novel relationship to the use of Hem-o-lok Clips (HOLC).
METHODS	We reviewed a database of patients who underwent RALP at our institution from January 2004 to September 2007 and identified patients with BNC or complications related to the use of HOLC. We performed a retrospective chart review to attempt to determine the cause of each BNC. We also performed a PubMed search and review of the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database.
RESULTS	Of 524 patients undergoing RALP, 4 had a BNC develop, 2 of the BNCs were associated with HOLC migration and erosion into the vesicourethral anastomosis, and 1 was found to have HOLC migration within the bladder. A fifth patient had an anastomotic leak develop secondary to a HOLC that migrated into the bladder neck. Two similar cases of HOLC-related migration have been reported to MAUDE.
CONCLUSIONS	When early BNC or unexplained urinary retention occurs after RALP, one should have a high index of suspicion for migration of HOLC. Clip use should be minimized on tissue immediately adjacent to the anastomosis, and every effort should be made to retrieve loose clips after the procedure. UROLOGY xx: xxx, xxxx. © 2008 Elsevier Inc.

Bladder neck contracture (BNC) is a complication of prostate surgery that can be a devastating problem leading to urinary retention, incontinence, and multiple repeated invasive procedures. The estimated incidence after open radical prostatectomy ranges from 3% to 26%.¹⁻⁹ Risk factors may include previous surgery, radiation, postoperative bleeding, or anastomotic leakage. Robot-assisted laparoscopic radical prostatectomy (RALP) is becoming a more prevalent procedure with clear differences in postoperative complications when compared with open retropubic radical prostatectomy (RRP). Several RALP series have suggested that the incidence of BNC after RALP may be lower than in patients undergoing RRP, ranging from 0.6% to 3% after RALP versus 0.5% to 10% after RRP.¹⁰⁻¹⁵ The cause of this lower incidence is unclear. The purpose of this study was to evaluate our own experience with post-RALP

BNC, and document the relationship of BNC formation with the use of Hem-o-lok clips (HOLC; Teleflex Medical, Research Triangle Park, NC).

MATERIALS AND METHODS

The robotic program at our institution was initiated in January 2004. We have since maintained a prospective database of clinical, surgical, and pathologic parameters. For this study, we retrospectively reviewed our database of complications to identify all patients who had a BNC develop. We also performed a search of the United States Food and Drug Administration Manufacturer and User Facility Device Experience Database (MAUDE) to identify reported failures of HOLC between July 2005 and June 2007.

We perform the vesicourethral anastomosis after RALP by using the double-arm technique described by Van Velthoven *et al.*¹⁶ Two monocryl sutures, tied together at their ends, are used to perform a running closure. One arm is started at the 5:30 position and is run counter clockwise to the 12:00-o'clock position, and the second arm is started at the 6:30 position and run clockwise to the 12:00-o'clock position. The 2 arms are tied together at the 12:00-o'clock position with the knot in an extravascular location.

Originally, we ligated the vasa and seminal vesicle arteries along with the prostatic pedicles after placing large HOLC to

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secure the structures. We identified a relationship between migration of the HOLC and BNC formation at approximately case 415. Since then, we ligate the vasa and seminal vesicle arteries with cautery, specifically avoiding HOLC of these midline structures, limiting clip placement to the prostatic pedicle exclusively. We also meticulously remove all loose clips from the pelvis before closure.

RESULTS

Between January 2004 and September 2007, 524 consecutive patients underwent RALP at our institution by 2 surgeons (H.A.F., J.D.E.). The average follow-up time for the entire cohort was 10.78 months. We identified 4 patients with BNC within the cohort (0.76%), 2 of the BNCs were found to have HOLC migration into the urinary tract. A fifth person has been identified also with HOLC migrated into the bladder but no associated BNC.

Patients 1 and 2 had obstructive lower urinary tract symptoms with recalcitrant BNC develop that did not respond to dilation or transurethral incision. Both patients had early contracture and rapid recurrence develop. Patient 1 was found to have a HOLC clip within the BNC scar tissue during KTP laser vaporization of his contracture (Fig. 1). This patient currently performs self-catheterization twice a week to ensure patency and is continent. Patient 2 had a short BNC develop and a HOLC was noted within the BNC scar tissue during transurethral incision and steroid injection. Patient 2 also performs self-catheterization twice weekly and has 1 pad-per-day incontinence 9 months after surgery. For both of these patients, cystoscopic removal of the migrated clips abruptly stopped the cycle of quick BNC recurrence.

Patient 3 had a BNC develop that resolved after a single urethral dilation. No HOLC was found in the bladder neck.

Patient 4 had a significant pelvic bleed and recurrent clot retention develop. He was diagnosed with an unusual prostatic pedicle pseudoaneurysm that developed 24 to 36 hours after surgery that required embolization. Approximately 1 year after surgery he underwent cystoscopy for hematuria and pyuria. A minor BNC was found and multiple HOLCs were found within the bladder.

Patient 5 presented with urinary retention and subsequent anastomotic urine leak. Cystourethroscopy was performed after a cystogram revealed HOLC migration into the anastomosis that correlated with the anatomic location of the anastomotic leak. The anastomotic leak ceased after removal of the HOLC. This patient never had a BNC develop, and at a 6-month follow-up was continent and voiding freely.

COMMENT

Long *et al.*¹⁷ reported on a metal clip migration causing vesicourethral stricture after radical prostatectomy after multiple episodes of urinary retention and several failed urethrotomies. To our knowledge, our series is the first



Figure 1. Cystoscopic evidence of clip erosion in patient 1 undergoing transurethral vaporization of BNC with KTP laser.

case report describing Weck HOLC migration into the vesicourethral anastomosis. Our experience brings to light questions regarding the use of foreign bodies in close proximity to the vesicourethral anastomosis during RALP.

Our review demonstrates several interesting points. The incidence of BNC in our cohort of 524 consecutive RALP patients is 0.76%. Although the majority of our practice is referral based, we routinely follow our RALP patients during the first postoperative year. Therefore, we are confident that our database of complications within the first postoperative year is relatively complete with regard to awareness of symptomatic BNCs. We have not seen this complication since we implemented a change in our technique and stopped using clips in the midline near the vesicourethral anastomosis (now more than 100 patients). Hu *et al.*¹⁵ reported a similar BNC rate in their RALP series. It is not obvious why the rate of BNC is significantly lower than that quoted in the open prostatectomy literature, but we believe that a running anastomosis approximates the mucosal edges more completely than with a simple interrupted anastomosis, thus leading to less urethral distraction and faster sealing of the anastomosis.

With the recent surge in minimally invasive surgery (robotic and laparoscopic assisted surgery) there has been an increasing interest in hemostatic alternatives to suturing. Several devices including automated suturing devices include the EndoStitch (AutoSuture, USSC, Norwalk, Conn), LapraTy clips (Ethicon, Endosurgery Inc, Piscataway, NJ), and Weck HOLC clips (Teleflex Medical). Before this review, we used HOLC clips for ligation of the vasa deferentia, seminal vesicle arteries, and prostatic pedicles to prevent excessive electrocautery and possible injury to the neurovascular bundles. However, several limitations, in addition to the concern for clip migration, have become apparent. Excessive clip usage in a narrow pelvis can limit visualization and mobility during a RALP. Another concern is the potential for an

inflammatory reaction near the neurovascular bundles, similar to what we have seen at the vesicourethral anastomosis. A major concern is for clip malfunctioning resulting in clip dislodgment and subsequent delayed bleeding. There have been several reports of HOLC clip dislodgement after ligation of the renal artery during laparoscopic donor nephrectomy. Friedman *et al.*¹⁸ surveyed members of The American Society of Transplant Surgeons (ASTS) and reported 8 cases of dislodgement of locking clips from the renal artery. Sixty-one percent of respondents believed that single-locking clips were "unsafe" for arterial closure. In April 2006, Teleflex Medical issued a statement strongly discouraging the use of HOLC to control the renal artery during laparoscopic living donor nephrectomy. Although the majority of reported complications with HOLC are related to hemorrhage, the consequences of clip migration in the RALP population should also be recognized as important.

We searched the MAUDE database for Weck HOLC clip malfunction and related complications. This database reports on the adverse events involving medical devices and is updated quarterly.¹⁹ Meng *et al.*²⁰ reported on 27 adverse events involving Hem-o-lock clips from 1999 to July 6, 2005. Complications occurred after 12 nephrectomies, 7 cholecystectomies, 6 unknown surgeries, 1 prostatectomy, and 1 colectomy. Of the nephrectomies, 10 of 12 involved bleeding vessels (9 renal arteries, and 1 gonadal artery).

Between July 6, 2005 to June 2007, there were 28 additional reported adverse events in the MAUDE database, including 2 after laparoscopic prostatectomy and 2 after RALP.¹⁴ Fourteen of these events involved HOLC applicator malfunction. There was 1 reported case of bile leakage at the clip site during a laparoscopic cholecystectomy and 3 episodes of shearing of a vessel. Eight cases of delayed hemorrhage after HOLC dislodgement were reported. Importantly, there were 2 reported cases of HOLC migration, postoperatively. One involved migration of 2 clips into the bladder after laparoscopic radical prostatectomy, and the other case involved migration of all 4 pedicle clips into the bladder after RALP.

There are several potential weaknesses of this review. As previously mentioned, much of our practice is referral based. Although we closely follow patients postoperatively within the first year, there may be some patients with BNC formation that were not captured in our database. The surgical modification was made relatively recently, approximately 10 months ago. Patients treated in this manner accounted for the shortest follow-up. However, 3 of the 4 patients who had a BNC develop did so within 4 to 8 weeks after surgery. Lastly, traditional risk factors known to cause BNC secondary to anastomotic disruption, such as pelvic hemorrhage or urine leak, occurred in 3 of the 5 patients described. These complications undoubtedly contributed to the formation of BNC in these patients. We believe that the relationship between HOLC migration into the anastomosis and

BNC formation is not coincidental, and postulate that the physical distraction of the anastomosis by the HOLC contributed to poor healing, and possibly an inflammatory reaction resulting directly from the HOLC.

CONCLUSIONS

On the basis of these findings, we recommend minimizing the use of HOLC on tissue immediately adjacent to the anastomosis during RALP, specifically the vasa and seminal vesicles, and every effort should be made to retrieve any loose clips after the procedure. These clips are prone to migration and may cause, or significantly contribute to, BNC formation after RALP. Migration of HOLC into the vesicourethral anastomosis should be considered in patients with symptoms consistent with BNC after RALP.

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