Complete Ileal Neobladder Intracorporeal Construction With Standard Sutured Technique and Novel Technology

Evren Durak, Gregory W. Hruby, Zhamshid Okhunov, Preston Sprenkle, Gabriella Mirabile, Franzo Marruffo and Jaime Landman*

From the Department of Urology, Columbia University Medical Center, New York, New York

Purpose: We compared the surgical efficacy and efficiency of a completely suture based procedure with a novel entero-urethral anastomosis device and an EndoGIA™ stapler to create an ileal neobladder.

Materials and Methods: Two groups of 7 pigs each were survived for 8 weeks. In group 1 the neobladder was constructed using a U-shaped segment of ileum sealed with the stapler. The entero-urethral anastomosis was created with a novel sutureless anastomosis device. All other procedures were completed with standard intracorporeal suturing techniques. In group 2 animals completely intracorporeal sutured technique was used. Total procedure, and enteroenteric, ileal neobladder, uretero-enteric and entero-urethral anastomosis times were recorded. Cystograms done immediately postoperatively, at 2 weeks and at sacrifice to evaluate the newly constructed system were rated from 0—no leakage to 3—severe leakage.

Results: In group 1 vs 2 the overall procedure, and enteroenteric, ileal neobladder, uretero-enteric and entero-urethral anastomoses were completed in 285.3, 32.3, 58.8, 54.2 and 5.5 vs 350.1, 29.9, 139.1, 58.0 and 46.3 minutes, respectively. In groups 1 and 2 the average postoperative cystogram rating was 0.83 and 1.6, respectively ($p = 0.63$). At 2 weeks and at sacrifice cystograms showed no extravasation in either group. The overall surgical procedure, pouch creation and entero-urethral anastomosis were statistically briefer in group 1 ($p = 0.036$, 0.01 and 0.039, respectively). Average survival in groups 1 and 2 was 30 (range 4 to 56) and 41 days (range 1 to 56), respectively ($p = 0.36$). All animals had voiding complications within 1 week after ureteral and urethral catheters were removed. One neobladder ruptured in group 1.

Conclusions: Combining stapled ileal neobladder construction and the entero-urethral anastomosis device significantly decreases operative time, pouch creation and urethral anastomoses.

Key Words: urinary bladder; anastomosis, surgical; urinary diversion; swine; equipment and supplies

Abbreviations and Acronyms

IVP = excretory urography

RC = radical cystectomy

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* Correspondence: 161 Fort Washington Ave., Room 1112, New York, New York 10032 (telephone: 212-305-5630; FAX: 212-305-6813; e-mail: landman.jaime@gmail.com).

Radical cystectomy is the treatment of choice for muscle invasive bladder cancer[1] but the procedure is associated with significant morbidity and is reserved for a select patient population.[2] To minimize the morbidity associated with RC minimally invasive options have been explored.

Minimally invasive techniques have transformed some aspects of urological surgery by decreasing surgical trauma, hospital stay and costs. There has been some initial success with minimally invasive RC done with laparoscopic and robotic assisted laparoscopic approaches.[2] The extreme technical challenges and limited success of laparoscopic RC have significantly limited the penetration of this procedure. Even with the advances in minimally invasive surgery in the last 10 years it has some technical limitations in orthotopic neobladder construction.[3]

The extirpative component of laparoscopic or robotic assisted laparoscopic RC is unremarkable and can commonly be achieved with success. The reconstructive components of laparoscopic or robot assisted laparoscopic RC procedures, including the delicate ureteral and urethral anastomoses, are challenging.[4] Also, neobladder creation from ileum presents unique hurdles to overcome in the laparoscopic environment. Intracorporeal reconstruction during this advanced operation is skill intensive and associated with extensive laparoscopic suturing.[3–5] To date entirely laparoscopic orthotopic neobladder construction and robotic assisted laparoscopic cystectomy have been reported from few centers.[4,5] The endurance and extreme technical skills required for the laparoscopic approach limit this technique to the elite laparoscopist.

We evaluated the application and feasibility of a novel sutureless vesicourethral anastomosis device (American Medical Systems, Minnetonka, Minnesota) and standard stapling technology at orthotopic neobladder construction in a porcine model to facilitate entero-urethral anastomosis and neobladder reconstruction (part *A* of figure). We compared the surgical efficacy and efficiency of a completely suture based procedure with a novel entero-urethral anastomosis device combined with the stapler to create a completely stapled ileal neobladder.

MATERIALS AND METHODS

Our institutional animal care and use committee approved the investigation. A total of 14 female swine weighing 35 to 40 kg were included in the study. The animals were divided into 2 groups of 7 each. Group 1 underwent entirely laparoscopic neobladder construction using a U-shaped ileal segment with sealing by an EndoGIA stapler. The entero-urethral anastomosis was completed with the novel sutureless device. Group 2 underwent laparoscopic neobladder construction and entero-urethral anastomosis using a sutured technique.

Upon arrival the animals were allowed to acclimatize for at least 2 days preoperatively. Each pig was initially anesthetized with 5 to 10 mg/kg ketamine and then intubated. It was brought to the surgical suite and anesthesia was maintained with 2% to 5% isoflurane. The pig was placed supine. The pelvis and abdomen were prepared with povidone-iodine scrub and draped. Cystoscopy was done and an 18Fr Council tip Foley catheter was placed to facilitate bladder access. Transperitoneal access was achieved using 3, 10 mm and 2, 5 mm trocars (part *B* of figure). Surgeons with at least 5 years of advanced laparoscopic surgical experience created the laparoscopic neobladder creation and performed the anastomoses.

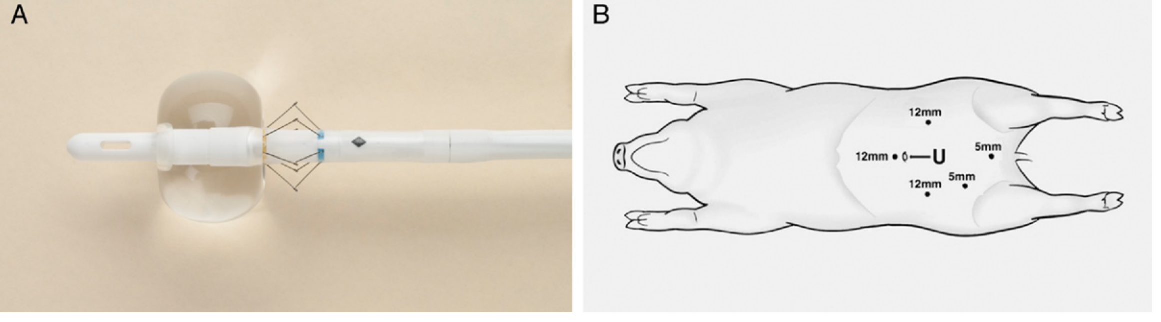
Surgical Procedure

In each group RC dissection was begun just inferior to the iliac vessels with a harmonic scalpel and extended down to the bladder. The urethra was dissected distal to the ureteral orifices. A 1.5 cm Hem-o-lok™ clip was applied just distal to the ureteral orifices. The bladder was divided from the urethra on the caudal side of the clip. The plane between the bladder and the vagina was developed bluntly. Dissection proceeded retrograde along the anterior vaginal surface. The ureters were clipped with 2, 1.0 cm clips and the ureter was divided between the 2 clips. A clip was left on the ureter to facilitate ureteral dilation. The bladder was placed in a 10 mm EndoCatch™ entrapment sack and placed aside for later removal. The ureters were reflected laterally to expose adequate length for the uretero-enteric anastomosis. The left ureter was mobilized to the right side of the pelvis through the sigmoid colon mesentery.

Distal ileum (40 to 50 cm) was measured with a premeasured length of suture and harvested with the stapler. Bowel continuity was reestablished intracorporeally by side-by-side anastomosis using the stapler and a running 2-zero suture was used to seal the remaining opening. The harvested segment was molded into an asymmetrical loop. To anchor the loop the distal end was fixed to the pubic arch with a stay stitch of 2-zero polyglactin to aid in laparoscopic manipulation, and cutting and suturing during orthotopic bladder construction.

Group 1

For neobladder construction and entero-urethral anastomosis the mirrored antimesenteric border of the ileal loop



A, anastomosis device active component, including balloon and 2 sets of opposing nitinol tines to create anastomosis. *B*, trocar placement.

was secured to itself with stay sutures every 5 cm. On the proximal end of the ileal loop 2, 5 mm slits were made. The stapler was introduced through the 2 openings in the ileal loop and fired, effectively securing and transecting the ileal loop into a single lumen. Five stapler deployments were needed to create the pouch. The remaining opening on the newly constructed pouch was closed with a 2-zero polyglactin running stitch. Two apertures were created on the longer leg of the ileal pouch to receive the ureters.

After dilating the ureter significantly the clips were removed from the ureters with cold scissors. The ureteral ends were spatulated and the ureters were catheterized with a 16 cm 6Fr Double-J® catheter via laparoscopic retrograde introduction of the ureteral catheter. The ureters were then sutured to the separate apertures using a 4-zero polyglactin suture on a CV-23 needle.

The stay stitch securing the distal section of the pouch was released and an additional 1 cm aperture was created on the distal end for the neobladder outlet. A guidewire was placed through the original Foley catheter and the catheter was then removed. The anastomosis device was placed over the guidewire, and inserted through the urethra into the abdominal cavity and then into the pouch through the created aperture. The device catheter balloon was inflated and the proximal device tines were deployed. The bladder neck was approximated to the urethral stump. The second set of nitinol tines was deployed to engage the urethral tissues, thereby securing the entero-urethral anastomosis.

Group 2

For neobladder construction and entero-urethral anastomosis the antimesenteric border of the ileal loop was transected with cold scissors. The medial sides of the 2 loops were secured to each other with a running 2-zero polyglactin suture. The suture was locked every fifth stitch to ensure a secure suture line. The 2 lateral borders of the loop were secured to each other in the same manner. Two apertures were created on the longer leg of the ileal pouch to receive the ureters.

After significant ureteral dilation the clips were removed from the ureters with cold scissors. The ureteral ends were spatulated and the ureters were catheterized with a 16 cm 6Fr Double-J catheter via laparoscopic retrograde introduction of the ureteral catheter. The ureters were sutured to the separate apertures using a 4-zero polyglactin running suture on a CV-23 needle.

The stay stitch securing the distal section of the pouch was released and an additional 1 cm aperture was created for the neobladder outlet. The original Foley balloon was deflated and then introduced into the distal aperture of the ileal pouch. The entero-urethral anastomosis was completed using the vanVethoven vesicourethral anastomosis.[4]

In each group overall operative time and time needed to complete each step were recorded. After completing the surgical procedure the newly constructed urinary system was infused with 200 ml sterile saline. Any noticeable extravasation defects were addressed with a 2-zero polyglactin figure-of-8 stitch. A Jackson-Pratt drain was placed in the pelvis and the entrapment sac containing the bladder was removed.

Followup and Sacrifice

All Foley catheters were secured to the underbelly with No. 1 nonabsorbable proline suture every 2 cm. All neobladders were evaluated for extravasation by cystography immediately postoperatively, at 2 weeks and at sacrifice. Cystograms were rated on a subjective rating scale from 0—no leakage to 3—severe extravasation. The Foley and ureteral catheters remained indwelling for 2 weeks, at which time cystoscopy was done to remove them.

All animals were sacrificed 8 weeks after surgery. IVP was done before sacrifice. Bladder capacity was measured, and gross and histopathological evaluations were done after sacrifice. After sacrifice en bloc dissection of the upper and lower urinary system with the neobladder was done. The classification used by Baldwin et al to evaluate ureterointestinal anastomotic quality was used.[3,4] The entero-ureteral anastomosis was calibrated by passage of a 0.038-inch guidewire and a 14 gauge angiocatheter. Pigs in which the guidewire could not be passed and no function was noted on IVP were considered obstructed. Pigs in which the guidewire passed but IVP revealed delayed opacification were considered to have a stricture. Pigs in which a 14 gauge angiocatheter passed easily and IVP showed prompt function at 5 minutes were considered to have a widely patent system.

RESULTS

Of the animals 13 successfully underwent complete laparoscopic neobladder construction. Animal 1 in group 2 was converted to an open technique due to inability to catheterize the ureters. In group 1 vs 2 the overall procedure, and the enteroenteric, ileal neobladder, entero-ureteral and entero-urethral anastomoses were completed in 285.3, 32.3, 58.8, 54.2 vs 5.5 vs 350.1, 29.9, 139.1, 58.0 and 46.3 minutes, respectively (see table). The overall surgical procedure, pouch creation and entero-urethral anastomosis were statisti-

Anastomosis data

	Group 1	Group 2	p Value
Mean time (mins):			
Total operative	285	350	0.036
Enteroenteric	32	30	0.64
Ileal neobladder	59	139	0.01
Uretero-enteric	54	58	0.57
Urethro-enteric	6	46	0.039
Mean diameter (mm):			
Normal urethral	20.6	34.6	0.09
Anastomosis	16.3	31.0	0.042
Difference	4.3	3.6	0.83
Mean entero-urethral anastomosis:			
Fibrosis	2	3	0.078
Inflammation	1	1	0.88
Mean enteroenteroanastomosis:			
Fibrosis	1.6	3	0.19
Inflammation	0.83	1	0.60
Mean entero-ureteral anastomosis:			
Fibrosis	2	1.5	0.63
Inflammation	0.8	1	0.60

cally briefer in group 1 ($p = 0.036$, 0.01 and 0.039, respectively). In groups 1 and 2 the average cystogram rating at postoperative evaluation showed a mean leak rating of 0.83 and 1.6, respectively ($p = 0.63$) but 2-week and sacrifice cystograms revealed no extravasation. Final bladder volume in group 1 vs 2 was 433 vs 550 ml ($p = 0.57$).

Average survival time in groups 1 and 2 was 30 (range 4 to 56) and 41 days (range 1 to 56), respectively ($p = 0.36$). All animals had voiding complications within 1 week after the ureteral and urethral catheters were removed. Foley catheterization for the remaining survival period was initiated in all animals. Postmortem pathological examination showed anatomical hydroureteronephrosis in all pigs, which was associated with renal scarring. No obstruction was noted at the entero-urethral or uretero-enteric anastomoses. All entero-ureteral anastomoses in groups 1 and 2 allowed passage of the 0.038-inch guidewire and the 14 gauge angiocatheter but all animals showed delayed opacification on IVP. One neobladder in group 1 ruptured.

DISCUSSION

In 1992 Parra et al performed the initial laparoscopic simple cystectomy.[6] Despite advancements in laparoscopic surgical techniques and technologies in the last 2 decades the need for extensive intracorporeal suturing and other technical issues limit the implementation of entirely laparoscopic neobladder creation in current surgical practice. Several attempts to incorporate a minimally invasive approach into this operation showed some initial success. Sanchez de Badajoz et al combined a laparoscopic and an extracorporeal technique for ileal conduit urinary diversion.[7] Murphy et al reported the feasibility of robot assisted laparoscopic RC in 23 patients.[8] They also created an ileal conduit using extracorporeal technique with excellent intraoperative and postoperative outcomes.

Advancing this minimally invasive technique in the clinical setting necessitates extensive laboratory development. Kaouk et al created a laparoscopic orthotopic ileal neobladder with a Studer limb in 12 survival animals using intracorporeal technique.[9] They used a completely intracorporeal suturing technique and noted an average neobladder construction time of 180 minutes. We positioned and placed ports, harvested the ileal segment and used sutures to create the ileal pouch and ureteroileal anastomosis with laparoscopic freehand suturing in a fashion similar to that described by Kaouk et al and achieved similar results.

Until recently the RC urinary diversion phase was routinely done extracorporeally. Some groups preferred constructing a neobladder through small midline or Pfannenstiel incisions after entirely laparoscopic cystectomy.[2] Turk et al reported their successful human experience with a completely intracorporeal orthotopic ileal neobladder.[10] Although there has been certain progress in laparoscopic urological surgical techniques, this has been limited for entirely laparoscopic urinary diversion. Completely laparoscopic creation of an ileal pouch requires advanced laparoscopic skills for intracorporeal suturing. Although a surgeon may be capable of this laparoscopic suturing dexterity, considerable time is needed for neobladder construction and entero-urethral anastomosis.

We compared the surgical efficacy and efficiency of a completely suture based procedure with those of a novel entero-urethral anastomosis device and the Endo-GIA stapler to create an ileal neobladder. Hruby et al previously reported the laparoscopic surgical efficacy of the anastomosis device.[11] They observed superior tissue healing at the vesicourethral anastomotic site during the acute healing phase using this device. To our knowledge the entero-urethral anastomosis has not been created using the anastomosis device after entirely laparoscopic neobladder construction to date. In our experience knot tying and needle orientation are the most challenging components of the entero-urethral anastomosis. Even with extensive laparoscopic experience passing the needle and tying knots may traumatize tissue. The novel anastomosis device decreased anastomosis time by a mean of 50 minutes with results comparable to those of standard anastomosis in regard to extravasation.

In our study 13 animals successfully underwent complete laparoscopic neobladder construction. In group 1 average operative time was 285 minutes and total operative time was 350 minutes in group 2. Neobladder creation with the stapler significantly decreased neobladder creation time compared to that needed for the hand sewn neobladders in group 2 (58.8 vs 139.1 minutes). Urethra-to-neobladder anastomoses required 5.5 and 58 minutes in groups 1 and 2, respectively. The stapler and the novel anastomosis device dramatically decreased our total operative time. Our reported operative time was also shorter than that of Kaouk et al, who constructed the neobladder with standard intracorporeal suturing technique.[9] The anastomosis device and the stapler also technically simplified total intracorporeal construction of the ileal neobladder.

Although our study subjects did well postoperatively, the challenges included distention, renal scarring, hydronephrosis and bladder rupture. Animals in each group showed voiding complications within 1 week after the ureteral and urethral catheters were removed. Foley catheterization was needed for the remaining survival period. One neobladder in group 1 ruptured, which we believe to have been the result of extensive dissection during the early phase of the procedure. We essentially produced a denervated organ that may have had peristaltic activity, as it does normally as ileum. However, even if there were some residual peristaltic activity, it is highly unlikely that it would generate enough force to overcome the healing entero-urethral anastomotic site, which may have caused the proximal neobladder dilatation. Also, neobladder position in the abdominal cavity creates another cause for concern. The neobladder was not secured to the pelvic wall and as a result was allowed to settle in the most ventral aspect of the abdominal cavity, that is below the urethra, preventing bladder drainage by gravity and at the same time promoting bladder dilatation by gravity.

Postmortem pathological examination revealed hydroureteronephrosis associated with renal scarring in all animals. Hydroureteronephrosis was attributed to a lack of trained voiding in this animal model and baseline ureteral tortuosity in pigs, as seen by Kaouk et al.[9] The porcine neobladder may require overflow incontinence since created neobladders may not have spontaneous voiding mechanisms.[4] Extensive dissection during the initial laparoscopic cystectomy phase may also be a leading factor in neobladder distention.

All except 1 neobladder were intact at sacrifice, and all entero-urethral and entero-ureteral anastomoses were intact and patent. Neobladders underwent significant dilation during the postoperative course and some attained a capacity of 1,500 ml. This was due to inability of the animal to void at regular intervals. No ureters were kinked at the transposition site from the left to the right side.

Stone formation risk is a concern when using nonabsorbable staples for urinary diversion.[12–14] Steven and Poulsen reported up to a 30% risk of stone formation 5 years after neobladder construction when titanium staples are used.[15] To date no such device has been available with absorbable tacks on the laparoscopic EndoGIA stapler. Nevertheless, we saw no evidence of bladder stone formation in this animal model.

This initial experience shows satisfactory equivalence of the efficacy of the vesicourethral anastomosis device to establish entero-urethral continuity. As expected, the device had extraordinary efficiency compared to a sutured anastomosis. The device was efficient for the urethra-to-neobladder anastomosis in this animal model and technically it was easy to use.

CONCLUSIONS

Application of the anastomosis device and the stapling technique significantly decreased the time needed to complete the entire neobladder procedure and the entero-urethral anastomosis. With continued refinement of these techniques laparoscopic continent diversion may become a more clinically viable option.

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