



Clinical urologic and urodynamic outcomes in patients with anorectal malformation and absent vagina after vaginal replacement

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ABSTRACT

Introduction and objectives: Anorectal malformations (ARMs) represent a complex spectrum of anorectal and genitourinary anomalies and a paucity of evidence is available on long-term urologic outcomes in all ARM subtypes. It was our subjective bias from being a referral center for ARM patients that the subtype of rectovestibular fistula and absent vagina had higher risk of renal and bladder abnormalities than typical rectovestibular fistula patients. Therefore, to confirm or refute our clinical suspicions, the purpose of this study was to review this specific cohort of ARM patients and describe both the clinical urological and urodynamic outcomes.

Methods: A retrospective cohort study was performed for 120 patients who were treated for ARM and vaginal replacement at our institution between 1991 and 2017. Fifteen patients with rectovestibular fistula and absent vagina were included in our review. Demographic and clinical data were abstracted from their medical records, including urodynamic findings, need for clean intermittent catheterization (CIC), urinary continence, and renal function.

Results: Vaginal replacement surgery was undertaken concomitantly with ARM repair in 10 of the 15 patients (67%). One patient was lost to follow up, and mean follow up postoperatively was 39 months. In all but one patient, rectum or colon was used as the substrate for vaginal replacement. Of the 15 patients, 13 had continence data available. A total of 10 patients (77%) were able to achieve social continence. Overall six patients used CIC to manage their bladder and 40% of continent patients used CIC. Urinary continence outcomes in patients who had partial vaginal replacement compared to those with total vaginal replacement did not reveal a clinically significant difference. Continence was achieved in 3/4 patients (75%) with a history of tethered cord compared to 7/9 patients (78%) without a history of tethered cord release. Urodynamics were performed postoperatively in 7 of the 15 patients (47%). Uninhibited detrusor contractions (UDCs) were present in 3 out of 7 patients, and a cystometric capacity greater than expected was noted in 4 patients. Additionally, 2 patients had end filling detrusor pressure greater than 40 cm H₂O. GFR data were available for 13 of the 15 patients and (85%) were classified as chronic kidney disease (CKD) stage I or not having any significant loss of renal function.

Conclusions: In this cohort of rectovestibular fistula and absent vagina, 77% reported achieving urinary continence. However CIC was employed in 40% of the patients which is higher than prior published noncloaca female ARM patient population. Urodynamic abnormalities were noted when performed and led to change in bladder management. Renal function measured with GFR was normal in 85%. Patients with rectovestibular fistula and absent vagina benefit from urologic screening given higher rates of lower urinary tract dysfunction that can require CIC to protect the upper urinary tract and achieve urinary continence.

Type of study: Case series.

Level of evidence: Level IV.

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Anorectal malformations (ARMs) represent a wide spectrum of congenital anomalies with a broad range of phenotypic subtypes. One

association commonly seen with ARM is malformation of the genitourinary tract. Various studies have reported the incidence of genitourinary anomalies in patients with ARM to be as high as 50% [1]. It is also known that urologic outcomes vary with ARM type and may be influenced by concomitant spinal cord anomalies [2] [3]. Among females,

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rectovestibular fistula is the most common anorectal malformation, often coexisting with other gynecological defects [4]. It has been previously reported that with early recognition and appropriate treatment patients with gynecological abnormalities can have an excellent functional prognosis [5].

One unique malformation occurs in the subset of patients with rectovestibular fistula and concomitant absent vagina [4]. It was our subjective bias owing to practice in a referral center for ARM patients that this group had higher renal and bladder abnormalities than typical rectovestibular fistula ARM patients. Therefore, to confirm or refute our clinical suspicions, the purpose of this study was to review this specific subset of ARM patients and describe both the clinical urological and urodynamic outcomes. To our knowledge, such a detailed urologic examination has not previously been undertaken in this particular ARM subtype.

1. Methods

A retrospective cohort study was performed of the medical records of 120 patients who were operated on for ARM with vaginal replacement at our institution between the years of 1991 and 2017. Institutional review board approval was obtained under IRB number 2002-0886. Only patients with rectovestibular fistula and absent vagina were included in the study group and all other ARMs (i.e. cloacal anomalies) were excluded. Vaginal replacement was either partial (native vaginal with Mullerian structure anastomosed to intestinal interposition substrate) or total (no Mullerian structure anastomosed to intestinal substrate). The absent vagina was surgically addressed either at the time of initial pull-through or during a separate surgical encounter. Demographic and clinical data were then abstracted from their medical records. Variables such as sacral ratio, presence of tethered cord, intraoperative operative details, urodynamic data, use of clean intermittent catheterization (CIC), reporting of urinary continence, the need for urinary diversion or continent reconstruction, and renal function were recorded. Continence was defined as the ability to store urine for 3 to 4 h during the daytime, and up to 8 h overnight without leakage in those patients that were more than the age of 5 years at last follow up. Among urodynamic variables we specifically reviewed patient data for the presence or absence of uninhibited detrusor contractions, bladder capacity as compared to expected bladder capacity calculated for age, and elevated end filling detrusor pressure defined as greater than 40 cm H₂O in absence of detrusor voiding contraction. An uninhibited detrusor contraction was defined as a contraction of 15 cm H₂O in amplitude or greater on urodynamic tracing. Age expected bladder capacity is estimated using the calculation: (Age in years + 2) × 30 = Bladder capacity expressed in mL.

Table 1
Surgical demographics.

Patient	Age at surgery (months)	Absent vagina recognized and addressed at time of ARM surgery?	Posterior sagittal approach alone to address absent vagina?	Substrate used in neovaginal replacement	Mullerian structures anastomosed to neovagina?	Sacral ratio	Tethered cord present?
1	22	Yes	Yes	Colon; Distal Rectal left in situ	No	0.54	No
2	235	Yes	Yes	Colon; Distal Rectal left in situ	No	0.57	No
3	52	Yes	Yes	Colon; Distal Rectal left in situ	No	0.77	No
4	56	No	Yes	Colon; Distal Rectal left in situ	No	0.45	No
5	9	No	No	Sigmoid Colon	Yes	0.5	Yes
6	14	Yes	Yes	Colon; Distal Rectal left in situ	No	0.67	No
7	228	No	No	Sigmoid Colon	Yes	0.92	No
8	22	Yes	Yes	Colon; Distal Rectal left in situ	No	0.47	Yes
9	74	Yes	Yes	Colon; Distal Rectal left in situ	No	0.52	Yes
10	102	No	No	Sigmoid Colon	Yes	0.77	No
11	13	Yes	Yes	Colon; Distal Rectal left in situ	No	0.25	Yes
12	12	Yes	Yes	Colon; Distal Rectal left in situ	No	1.0	Yes
13	41	Yes	No; Laparoscopy assisted	Colon; Distal Rectal left in situ	No	0.4	No
14	76	No	No; Laparotomy	Ileum	No	0.44	No
15	63	Yes	No; Laparotomy	Sigmoid Colon	No	0.79	No

Renal function was defined through glomerular filtration rate (GFR) calculation. GFR was estimated using the most recent Cystatin C value available or the bedside Schwarz equation. Patients were categorized as CKD stage I (normal) if GFR was determined to be >90 ml/min/1.73 m², stage II (mild CKD) if GFR was 60 to 89 ml/min/1.73 m², stage III (moderate CKD) for GFR between 30 and 59 ml/min/1.73 m², stage IV (severe CKD) if GFR was between 15 and 29 ml/min/1.73 m², and stage V (end-stage) if their GFR was below 15 ml/min/1.73 m².

2. Results

Of the 120 female ARM patients with some type of vaginal replacement reviewed, 15 (12.5%) were found to have the diagnosis of rectovestibular fistula with congenital absence of the vagina. Vaginal replacement surgery was undertaken concomitantly with ARM repair in 10 of the 15 patients (67%). In the remaining five patients who did not undergo vaginal replacement at the time of their ARM repair, four patients did not have the diagnosis of absent vagina documented until referral to our center whereas in the remaining patient there was intentional deferment of creation of the neovagina until the patient was older. Native upper vagina with its accompanying Mullerian structure was sutured to intestinal interposition substrate in three patients defined for the study as partial vaginal replacement. The substrate for neovagina creation was leaving the distal aspect of the rectum in situ and pulling through more proximal colon in 11 patients (Table 1). Sigmoid colon was used as neovagina in three patients and in one patient creation of her neovagina was with ileum owing to abnormal colonic vasculature. A posterior sagittal approach alone was utilized in addressing the creation of the neovagina in nine patients. One patient was lost to follow-up after surgery. Mean follow-up postoperatively in the remaining 14 patients was 39 months, with a median follow-up of 37 months (range 12–105 months).

2.1. Urinary continence and urology outcomes

With regard to urinary continence outcomes, 13 patients were more than the age of 5 years at the time of last follow up and continence data were available in all 13 patients. Three patients (23%) were incontinent at last follow up, while 10 (77%) were continent of urine (Table 2). The three patients who were incontinent occurred in patients with those performing CIC and in those solely voiding. One patient had urine leakage between CIC during the daytime and nocturnal enuresis. The remaining two incontinent patients were spontaneously voiding alone with one having diurnal incontinence and the other admitting to only nocturnal enuresis. Four patients (40%) who achieved urinary continence were on a CIC regimen while the remaining six were spontaneously voiding alone. In total, one patient underwent further surgery to achieve urinary continence consisting of bladder augmentation, bladder neck division,

Table 2
Clinical urologic outcomes in patients with rectovestibular fistula and absent vagina.

Patient	Continent?	Continent reconstruction performed?	Clean intermittent catheterization (CIC)	Route of catheterization
1	Age < 5yo	No	No	--
2	Yes	No	No	--
3	Yes	No	No	--
4	Yes	No	No	--
5	No	No	No	--
6	No	No	No	--
7	Yes	No	No	--
8	Age < 5yo	No	Yes	Native urethra
9	Yes	No	Yes	Native urethra
10	Yes	No	No	--
11	Yes	No	Yes	Native urethra
12	Yes	No	No	--
13	No	No	Yes	Native urethra
14	Yes	Yes	Yes	Mitrofanoff
15	Yes	No	Yes	Native urethra

and Mitrofanoff channel creation owing to incompetent bladder outlet and decreased bladder capacity for age and poorly compliant bladder. This patient is continent postoperatively. A total of six patients were on CIC at the time of last follow up, either via a catheterizable channel or native urethra, resulting in urinary continence in 5/6 (83%) of patients. Indication for initiation of CIC varied in these six patients, from worrisome urodynamic findings in three patients, incontinence in one, recurrent urinary tract infections in one, and both incontinence and recurrent urinary tract infection in one patient. The worrisome urodynamic findings present included elevated end filling detrusor pressures and dilated upper urinary tract on imaging in all three patients.

A tethered cord was identified in five (33%) patients with all undergoing tethered cord release before age 5. CIC was performed in a higher percentage of patients with a history of tethered cord (3/5, 60%) compared to those patients without (3/10, 30%). However, urinary continence was not much different between these two groups with continence achieved in 3/4 (75%) with a history of tethered cord compared to 7/9 (78%) without a history of tethered cord release. Six of the eight patients who were voiding spontaneously were continent, and only one of the incontinent voiding patients had history of tethered cord. The sacral ratio ranged from 0.25 to 1. We did not observe any correlation between sacral ratio and urinary continence either with CIC or spontaneous voiding. In a subgroup analysis of urinary continence outcomes in the three patients who had partial vaginal replacement compared to those with total vaginal replacement, we did not find a clinically significant difference (2/3 continent vs. 8/8 continent).

Table 3
Urodynamic findings at last follow-up in the seven patients with rectovestibular fistula and absent vagina.

Patient	Uninhibited detrusor contractions (UDC) ^a	Cystometric bladder capacity (mL)	Percentage of estimated bladder capacity for age (%) ^a	End filling detrusor pressure (Pdet) (cm H2O) ^b
4	Present	284	135.2	51
6	Absent	451	90.2	13
9	Absent	360	109.1	21
10	Absent	384	76.8	9
12	Present	197	109.4	67
13	Present	343	142.9	30
15	Absent	420	93.3	24

^a Age expected capacity is calculation based upon formula (patient age in years + 2) × 30 expressed in mL. The percentage of estimated bladder capacity is calculated value based upon formula cystometric capacity divided by age expected capacity. 80%–120% considered within normal limits.

^b End filling detrusor pressure is ideal when lower than 40 cm H2O to avoid long term upper tract injury from elevated detrusor pressures.

Table 4
Renal functional outcomes.

Patient	GFR ^a measured at last follow up (ml/min/1.73 m ²)	CKD stage
1	97.8	1
2	Unknown	Unknown
3	135	1
4	124	1
5	89.6	2
6	142	1
7	Unknown	Unknown
8	152	1
9	144.3	1
10	106	1
11	44.1	3
12	146	1
13	192.7	1
14	162.8	1
15	122	1

^a GFR calculated either by most recent Cystatin C value or estimated by bedside Schwartz Equation.

2.2. Urodynamic findings

Urodynamics were performed in 7 of the 15 patients (47%) and available for review. A total of 17 urodynamic studies were performed in these 7 patients postoperatively. One patient had preoperative urodynamic data available. Data from the most recent urodynamic studies found uninhibited detrusor contractions (UDCs) were present in 43% (43/7) of these patients (Table 3). Three patients were also found to have a cystometric capacity greater than their estimated capacity for age and two patients had end filling detrusor pressures greater than 40 cm H2O, both of whom also had UDC and increased cystometric capacities. No patient was on anticholinergic medication preoperatively, and three patients were started on anticholinergics postoperatively in conjunction with CIC. Of these three patients, one remained incontinent and continued to have uninhibited detrusor contractions on their most recent follow up urodynamics.

2.3. Renal functional outcomes

GFR data were available for 13 of the 15 patients, with 11 patients (85%) classified as CKD stage I. One patient had an estimated GFR of 89.6 ml/min/1.73 m² and was classified as CKD stage II, while the remaining patient had an estimated GFR of 44 ml/min/1.73 m², being classified as CKD stage III (Table 4). No patient has undergone renal replacement therapy or transplantation.

3. Discussion

While genitourinary anomalies are common in patients with ARM, rectovestibular ARM with absent vagina represents a very small subset of these patients. A review by Levitt et al. found only 8 such cases in a series of 1007 patients with anorectal malformations (0.8%) [6]. Among 272 patients with ARM and rectovestibular fistula, 26 patients were found to have either total or partial vaginal atresia [4]. The literature is limited largely to case reports and series with only occasional exploration of clinical outcomes and infrequently commenting on urologic outcomes. We present a cohort of 15 patients with the specific diagnosis of rectovestibular fistula with absent vagina, all of whom have undergone vaginal replacement surgery either at the time of their ARM repair or subsequently. All patients, with the exception of one, had vaginal replacement using colonic substrate, and in most cases rectum distal to the fistula was left in situ to act as neovagina. We specifically examined urinary continence and various urodynamic variables in these patients, along with the need for urinary tract reconstruction and presence of CKD. We noted, implementing a strict definition of urinary continence,

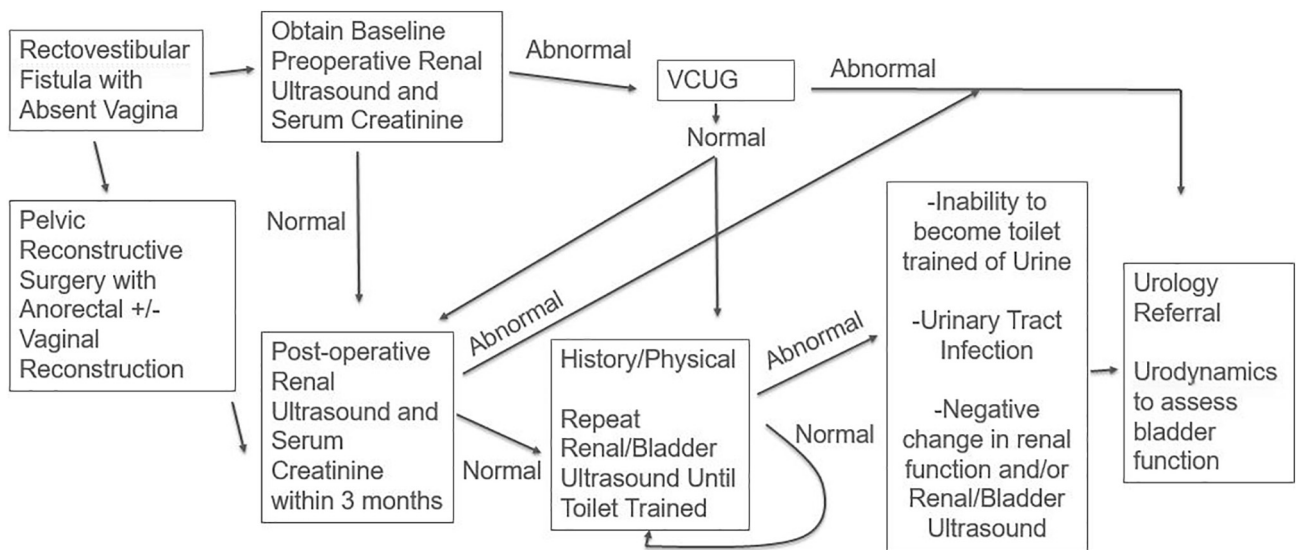


Fig. 1. Proposed algorithm for the urologic surveillance of anorectal malformation patient with rectovestibular fistula and absent vagina.

that 77% of the cohort was continent of urine with varying means of bladder management to achieve this.

The overall incidence of urinary incontinence in patients after repair of ARM varies in the literature, based on level of the ARM. Up to a third of ARM patients were reported to be incontinent of urine postoperatively prior to the use of posterior sagittal anorectoplasty (PSARP) [7]. In a series of 233 patients with high lesions repaired with (PSARP), Pena described a 10% incidence of urinary incontinence. [8] Rintala et al. examined 83 adult patients who underwent repair of low ARM and 11% of patients were found to have urinary incontinence. [9] Rintala et al. also examined urinary continence outcomes in 40 children with low ARM and found 27% reported some form of daytime or nighttime wetting; however, none had complete urinary incontinence or are described as using CIC for bladder management. [10] Versteegh et al. reported urinary continence outcomes on 11 females with rectovestibular fistula ARM and no vaginal abnormality repaired with posterior sagittal approach [11]. No rectovestibular fistula ARM patient was on CIC and 8/11 were continent with 3 patients (27%) classified as incontinent.

Other authors have described clinical outcomes in noncloaca ARM patients with absent vagina. Wester et al. reported a multicenter case series of seven female patients, six of which were rectovestibular ARM type, with vaginal agenesis or distal vaginal atresia [12]. All patients except one underwent simultaneous reconstruction of the anorectum and vagina during the first year of life. While urinary outcomes were not reported in all seven patients, the authors described one patient with a neurogenic bladder owing to sacral agenesis requiring CIC and needed ileocystoplasty later in life. The authors did not describe lower urinary tract dysfunction in the remaining 6 patients for a presumed spontaneous voiding rate of 86. Pandya et al. described 15 ARM patients with associated vaginal anomalies, of which 8 are described as rectovestibular ARM type. [13] Postoperative urinary continence was assessed in 7/15 patients, with only 4 out of 7 to be continent daytime and nighttime (57%), while the remaining respondents were incontinent (43%). Five patients were too young to assess urinary continence and three patients underwent a urinary diversion procedure. Data on CIC use were not reported in their series.

Additionally, there is controversy over whether bladder dysfunction in patients with ARM is congenital or the consequence of surgical repair or associated with spinal cord abnormalities. Goossens et al. reported that postoperative bladder dysfunction is encountered in as many as 52% of ARM patients with this level being associated with the level of

ARM [14] Boemers et al. examined 27 patients with urodynamics pre- and postoperatively after undergoing PSARP for correction of their ARM. They were able to demonstrate detrusor failure consistent with autonomic denervation of the bladder after surgical correction in three boys, but no females [15]. **A combined transabdominal and posterior sagittal approach was needed in all of these male patients to correct the ARM.** While this represents only a small fraction of patients, these findings highlight the fact that any patient undergoing significant retrovesical dissection as part of their ARM repair should be assessed and monitored postoperatively for bladder dysfunction to ensure continued safety of their bladder and upper urinary tracts. In our series of the six patients who did not undergo a solely posterior sagittal approach, two (33%) are incontinent postoperatively compared to 1/9 (11%) utilizing only a posterior sagittal approach.

Therefore our urinary incontinence rate of 23% is within the range of prior reported rates patients with rectovestibular ARM and no vaginal abnormality [9–13]. A unique observation of our study is that the utilization of CIC (6/15 patients) is much higher than these previous reports. The incidence of CIC utilization in our series is more comparable to that seen in cloacal malformation patients (42%) in a recent systematic review [16]. Indications for CIC in our cohort were clinically based owing to symptoms such as incontinence and/or urinary tract infection as well as guided by urodynamic findings. The higher rate of CIC could be that a combined transperitoneal approach as well as a posterior sagittal approach was needed to address the complex pelvic malformation. CIC use was seen in 50% of patients who required more than isolated posterior sagittal approach (3/6) compared to 33% of patients utilizing a posterior sagittal approach alone (3/9). We speculate there may be an unrecognized factor for altered bladder function that is unique to the rectovestibular fistula and absent vagina warranting close urologic investigations. We propose a postoperative algorithm for urologic surveillance after reconstructive surgery in patients with rectovestibular fistula and absent vagina (Fig. 1).

One of the primary goals in urological management of patients with ARM is preservation of renal function. The incidence of CKD and ESRD in patients with ARM was low at 5.7% and 0.8%, respectively, in one series [17]. A separate analysis conducted by Bischoff et al. found that between 0.7% and 2% of patients born with ARM progress to ESRD requiring renal transplantation [18]. Several factors have been attributed to the deterioration in renal function seen in ARM patients including those present at birth, those acquired by infection and/or neurogenic bladder, and a combination of the two [19]. In the present series, no patient had

progressed to ESRD at the time of their most recent follow up and the majority (87%) were noted to have a GFR of 90 ml/min/1.73 m² or greater at last follow-up.

We believe this is the largest rectovestibular fistula with absent vagina study reported to date, but is subject to several limitations in interpreting its observations. Our study population is a small sample size, although rectovestibular fistula and absent vagina are exceedingly rare conditions. The study's retrospective design and inherent bias, accompanied by single institution experience with its referral bias are limitations as well. We acknowledge that reliance upon prior published urologic outcomes in rectovestibular ARM patients is a less than ideal comparison method. The lack of a control group for comparison of the clinical urologic and urodynamic outcomes severely limits study interpretation. A lack of standardized postoperative urodynamic protocol is another limitation of this study. While our data do not discern whether incontinence data retrieved from the medical record was furnished by the patient, parent, or through physician obtained history and physical exam, it has been previously established that discordance does exist between these sources [20]. Therefore we acknowledge that the source of incontinence data may also have had an impact on our results. Finally, there was room for bias relative to the definition of urinary continence, but we believe our definition provides more clarity for classifying outcomes.

4. Conclusions

We present the largest review to date of the urinary and urodynamic findings in patients with rectovestibular fistula and absent vagina. In our cohort 77% reported achieving urinary continence; however, CIC was employed in 40% of the cohort which is higher than prior published rectovestibular fistula patient series. Urodynamic abnormalities were noted when performed which led to change in bladder management. Indications for CIC were clinical owing to incontinence and infections as well as urodynamic based. Renal function measured with GFR was normal in 85% of the patients **and** only two patients have CKD stage ≥ 2 . Patients with rectovestibular fistula and absent vagina benefit from urologic screening given higher rates of lower urinary tract dysfunction that can require CIC to protect the upper urinary tract and achieve urinary continence.

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