

Experience with a low-pressure colonic pouch (Mainz II) urinary diversion for irreparable vesicovaginal fistula and bladder extrophy in East Africa

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Abstract

Introduction and hypothesis We report our experience with a low-pressure colonic pouch for urinary diversion in women with irreparable vesicovaginal fistulas and bladder extrophy.

Methods This is a case series of 35 women with irreparable vesicovaginal fistula who underwent urinary diversion and two cases performed for bladder extrophy.

Results Partial or complete loss of the urethra was present in over 90% of fistula cases. Fifty-five percent had prior vaginal repairs. The median length of stay was 21 days. Median follow-up for 29 (78%) patients was 18 months. Nighttime urinary incontinence occurred in 31%. Twenty-

one (91%) of 23 patients had a serum creatinine <1.5 although all patients had evidence of acidosis. Two patients died 4 years after surgery from sepsis and renal failure. **Conclusions** Urinary diversion using the Mainz pouch II can be performed in the developing world with low perioperative morbidity and mortality. Acidosis and nighttime incontinence are the most common complications.

Keywords Vesicovaginal fistula · Urinary diversion · Obstetrical fistula · Developing country

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Introduction

Vesicovaginal fistula as a result of obstetric trauma is a significant problem in the developing world, especially in sub-Saharan Africa and Southeast Asia. It is estimated that there are over two million women worldwide living with vesicovaginal fistula and in Africa alone, there are estimated 60,000–100,000 new cases of fistula each year [1].

Vaginal repair of small midvaginal fistulas has been consistently reported to be successful in over 80% of cases [2]. However, more complicated fistulas involving the bladder neck, urethra, and severe scarring have a much lower primary success rate and even when repaired are often associated with significant residual stress incontinence [3]. This residual incontinence is usually different from typical stress incontinence seen in developed countries and is particularly resistant to standard surgical techniques used for this condition, including suburethral slings [4, 5].

In 2003, the United Nations Population Fund (UNFPA) launched a “Global Campaign to End Fistula” which is aimed at increasing awareness of the problem, determining

needs, and implementing strategies to prevent and treat obstetric fistula. This program has rightly focused on training surgeons to treat the 80–90% of women who have fistulas amenable to relatively straightforward vaginal repair. However, any surgical team treating this condition is frustrated by 10–20% of patients who have such extensive damage and scarring that reconstruction of a continent functional bladder is not possible. For these patients, urinary diversion seems to be the only option to a life of misery and social isolation. There is limited information on the use of these techniques in the developing world and in 2007, Arrowsmith [6] reviewed considerations regarding the feasibility, safety, and follow-up for urinary diversion in women with vesicovaginal fistulas and made a call for more data.

The Stanford University Fistula Project was initiated in 2002 at the request of the National Ministry of Health of Eritrea to address the issue of obstetric fistula, one of the biggest public health problems afflicting women in that country. A long war of liberation has been costly and Eritrea is attempting to meet the needs of its citizens with extremely limited resources. Despite this, the country has made great strides in addressing pressing health needs such as malaria control and vaccination. However, in rural areas, new obstetric fistulas continue to occur and there was a backlog of cases which could not be treated during the years of war. This is especially true of many complex cases, some of which have such severe injury and scarring that vaginal repair is not possible. In order to avoid external appliances and to minimize surgical time and equipment, urinary diversion was performed using a detubularized sigmoid colon pouch [7] during nine surgical missions. This low-pressure pouch decreases colonic contractility and therefore allows a larger capacity, less ureteral reflux, and potentially less pyelonephritis and renal damage than standard ureterosigmoidostomy. Our experience with this method of diversion is reported.

Materials and methods

Subjects

Nine surgical missions (February 2004 through June 2008) were undertaken by a team of American gynecologic oncologists and urogynecologists as part of the Stanford University Eritrean Women's Project under the

auspices of the Ministry of Health of Eritrea and supported by the United Nations Population Fund. The entire project, including the collection of data, was approved by the Ministry of Health of Eritrea and the Stanford University Institutional Review Board. Eritrean doctors assisted in all operations and supervised preoperative preparation and postoperative care for all patients. Vaginal repairs continued to be performed by the Eritrean doctor in between visits by the American team. Because of language difficulties, consent and final decisions about whether to proceed were made by the Eritrean medical staff. Preoperative and postoperative counseling was also provided with an experienced nurse, midwife, and trained counselors.

The decision to perform urinary diversion was made in conjunction with the Eritrean doctors and was always agreed upon by at least two visiting American doctors. There were no specific criteria for diversion. At least three surgeons agreed that, based on their experience, the fistula could not be closed or continence obtained. This was most commonly due to severe scarring and absence of urethra. Although a prior attempt at vaginal repair was not required, 16/35 (55%) of patients had previous vaginal procedures. Characteristics of these patients were tabulated to see if the subjective indications conformed to suggested indications in the literature.

Preoperatively, the patients were evaluated by history and physical exam. Staging was by the method of Waaldijk [8] (Table 1). If there was uncertainty about the best approach, then an examination under anesthesia (spinal) was performed. There were no facilities available for intravenous urogram, cystogram, or renal ultrasound. Routine laboratory studies (except hematocrit) were not available preoperatively. All patients underwent a 2-day bowel prep consisting of clear liquids, laxatives, and enemas. Patients were expected to retain an enema of 200–300 mL water for 2–3 h. All diversions were performed with spinal anesthesia and deep sedation or mask anesthesia, without intubation.

Postoperatively, all patients received 3 L of intravenous fluids each day until tolerating adequate liquids orally (usually 3–4 days). If there was abdominal distension or vomiting, a nasogastric tube was placed. The patients were advanced to a regular diet after tolerating liquids (usually 4–5 days), including one egg every day. A rectal tube attached to ureteral catheters was removed on postoperative day 10 unless the patient passed it spontaneously with a

Table 1 Classification of vesicovaginal fistulas

Type I: Not involving closing mechanism	A. Without urethral involvement
Type II: Involving closing mechanism	B. With urethral involvement
Type III: Miscellaneous: ureter and other exceptional	a. Not circumferential
	b. Circumferential

Adapted from Waaldijk [8]

bowel movement earlier. Broad spectrum antibiotics were continued for 7–10 days postoperatively.

Of the 35 patients with urinary fistulas, preoperative staging information was available for 29 (83%). Six charts with preoperative information were lost during transfer of the program to different hospitals. These patients all had persistent fistulas and severe scarring, but details of their lesions were not available. The primary indication (21/29, 72%) for surgery was for a fistula involving the closing mechanism with circumferential loss of the urethra (Waldijk type IIBb). These were usually associated with severe scarring. Of those 21, five had a cloaca (large rectovaginal fistula and absence of the anterior vaginal wall) and required extensive posterior reconstruction prior to diversion. Six patients had less than circumferential loss of the urethra (IIBa) and severe scarring and one patient (type IA) had a midvaginal fistula, severe scarring, and a capacity of <50 cc. Another patient had severe scarring, limited capacity (<50 cc), and a short fibrotic urethra. She underwent simple urodynamic testing and cystoscopy confirming the diagnosis. Twelve patients (41%) had prior rectovaginal fistula and/or anal sphincter repair. Characteristics of patients with and without prior vaginal repairs are listed in Table 2.

Surgical technique

The surgical procedures were performed and/or supervised by a gynecologic oncologist (MAM, AH) in all patients. A rectal tube was placed prior to surgery. Patients were given ampicillin, gentamycin, and metronidazole or a broad spectrum cephalosporin intravenously prior to incision and antibiotics were continued for 7–10 days postoperatively. A vertical suprapubic incision below the umbilicus was made and any adhesions were lysed and the ureters were identified and dissected free of the pelvic peritoneum from the level of the cervix to the pelvic brim. The ureters were ligated with silk ties near the cervix and cut. The peritoneal incision on the right side was extended superiorly above the sacral promontory and the left ureter was brought through the

sigmoid mesentery to the right side. A 20–25-cm segment of sigmoid colon was folded on itself in an inverted U configuration. Several interrupted silk sutures were placed connecting both sides of the U and forming the second layer of the posterior wall of the sigmoid pouch. The bowel was then opened along the tinea libera of the anterior surface and the posterior pouch wall was formed by anastomosing the two sides with a running stitch of delayed absorbable suture. In 15 cases, absorbable staples were used to create the anastomosis, a 5–7-cm inverted U incision was made on the anterior wall tinea and a Poly GIA 75® (Auto Suture) was used. Absorbable staplers were used when available and patients were not selected for use. The ureters were implanted in the superior part of the pouch with a short (2 cm) submucosal tunnel. Single J ureteral stents or pediatric feeding tubes were placed in the ureters and sutured to the rectal tube. The anterior wall of the pouch was closed in two layers: the first, a running stitch of delayed absorbable suture and the second, interrupted sutures of 3–0 silk.

Results

From February 2004 through June 2008, 519 patients were evaluated and treated for obstetric urinary fistula as part of the fistula program. Thirty-five patients (7%) underwent urinary diversion. Sixteen patients (3%) underwent diversion as their primary procedure. Two other diversions were performed for bladder extrophy. The mean age was 29 years (18–62). Two cases took 3 h; one involved a complicated mesh ventral hernia repair and the other an extensive lysis of adhesions and salpingo-oophorectomy. All other cases took 2 h and 30 min or less surgical time. On average, cases in which absorbable staples were used were completed 15 min faster than the hand-sewn procedures. Seven cases were completed in less than 2 h. No patients required a blood transfusion and the estimated blood loss was less than 300 cc in all but one case. This patient had an estimated blood loss of 400 cc, most occurring during a

Table 2 Characteristics of patients with and without prior vaginal repair attempt

	Prior surgery (16)	No prior surgery (13)
Age (years), mean (range)	30.1 (18–60)	29.5 (19–62)
Waldijk stage		
IIBb	9	12
IIBa	5	1
IA	1	0
<50 cc capacity, no fistula	1	0
Prior RVF repair	6	6
Prior colostomy	1	3

RVF repair rectovaginal fistula and/or anal sphincter repair

cystectomy for bladder extrophy. One patient, found to have tapeworm at the time of surgery, was successfully treated with antibiotics.

There was no perioperative mortality. The average length of stay was 21 days (9–42). Eight patients (22%) had a fever $>38^{\circ}\text{C}$ requiring antibiotics for more than 10 days. One patient returned to surgery for a ureteral leak found at the time of laparotomy for abdominal distension and fever. The ureter was reimplanted and the patient was discharged on day 27 from the diversion.

Twenty-one of the first 23 patients (91%) have returned for follow-up from 6 to 48 months (median 24 months). Twenty-nine of the total 37 (78%) have returned for follow-up from 6 to 48 months (median 18 months). Two patients are known to have been readmitted for fever. One was attributed to malaria and the other patient was admitted several times for fever and presumed pyelonephritis. She responded to antibiotics each time, but was admitted for sepsis a final time 4 years from surgery and died at age 42. Another patient died of renal failure 4 years after surgery at age 44. She was found to have bilateral hydronephrosis at the time of diversion although both ureters were functioning (one side minimally) and were reimplanted. She was admitted a year before her death with an elevated creatinine that responded to intravenous hydration (see below).

Of the 29 patients who have been seen in follow-up, nine (31%) complain of nighttime urinary incontinence but still report being better off than before surgery. They have all returned to their families and function socially during the day. Nighttime incontinence was seen in four of 12 (33%) who had a prior rectal or anal sphincter repair and five of 17 (29%) who did not. One patient had an unsuspected small rectovaginal fistula that was repaired and another patient continues to have episodes of daytime incontinence due to an incompetent anal sphincter. Another patient, who had a complex rectovaginal fistula repair prior to diversion, developed another rectovaginal fistula which has subsequently been repaired. One patient is known to have become pregnant and delivered a live baby by Cesarean section due to a uterine rupture. One patient developed a large stone in the pouch which required a proctotomy to remove.

Blood tests were performed on 23 patients 6–48 months from surgery. At their most recent testing, 18 patients had a serum creatinine <1.0 mg/dL, three had a creatinine between 1 and 1.5 mg/dL, and two were between 1.5 and 2 mg/dL. The latter two patients were admitted with dehydration and a creatinine of 2.4 mg/dL, given intravenous hydration and the creatinine improved to less than 2 mg/dL. One of these patients subsequently died of renal failure. Blood gas testing was not available, but the mean CO_2 was 16.5 mmol/L at the most recent blood testing.

Discussion

The use of urinary diversion for “irreparable” vesicovaginal fistula in the developing world remains a controversial issue. Acceptance has been appropriately slow for several reasons: It is perceived to be costly and “high tech”, many countries do not have the medical and nursing infrastructure to allow adequate follow-up, many of the surgeons treating fistulas do not have experience or training in these techniques, high case fatality rates have been reported in early studies, and equipment for stoma management and catheterization is not readily available. However, as noted by Wall et al., there are times when even a vaginal approach to fistula repair can be costly and life-threatening [9].

In the developed world, urinary diversion has moved away from ureterosigmoidostomy. Either the incontinent ileal diversion or one of the many methods of continent diversion requiring catheterization has become standard. These techniques are not well suited to the developing world however because of the technical expertise required for construction and follow-up and the equipment required for urine collection or catheterization. The ureterosigmoidostomy, on the other hand, has a record of poor quality of urinary control, ureteral stenosis, and chronic pyelonephritis leading to long-term renal failure and an increased risk of secondary malignancy [10–12]. The high pressure reached in the sigmoid colon with defecation or mass movements is regarded as a major contributor to the continence problems and recurrent pyelonephritis with conventional ureterosigmoidostomy. Fisch and colleagues in Mainz, Germany developed a useful modification of the classic ureterosigmoidostomy by creating a low-pressure reservoir by simple detubularization and leaving the bowel in continuity (Mainz pouch II) [7]. There is now extensive experience with this procedure. It can be performed in about 2 h with a very low mortality and morbidity and high continence. Symptomatic renal infection is uncommon but ureteral stenosis may be seen in 5–10% of cases [13–15]. Hyperchloremic acidosis is frequent, but can usually be managed by oral administration alkalinizing agents, and there is evidence that electrolyte derangements associated with continent diversion improves spontaneously over time [16].

Although this study lacks complete follow-up and the use of an objective quality-of-life measurement tool, it does demonstrate that the Mainz pouch II can be performed in the developing world with low perioperative mortality and morbidity. Many issues need to be resolved, however, before this approach should gain widespread acceptance. Long-term follow-up is necessary to determine whether infection or renal compromise increases with time and is manageable with limited resources. These factors were the cause of two deaths 4 years after diversion in this series. It

also must be demonstrated that metabolic effects of hyperchloremic acidosis can be ameliorated by better education regarding diet and compliance with alkaline supplementation. In desert regions of sub-Saharan Africa, inadequate fluid intake often complicates this problem.

An essential part of the Eritrean Fistula Project is to establish a system of centralized follow-up for complicated cases and accessibility to regional health centers. Implementation of such a system will be essential for any country providing urinary diversion as an alternative for women with irreparable fistulas. After three surgical missions (23 cases), our follow-up was 91% and this encouraged us to continue the project. Our overall current median follow-up of 18 months in 78% of patients hopefully will improve as the health system in Eritrea matures and more follow-up visits are performed. A portable electrolyte analyzer recently donated by the US Embassy is expected to allow more frequent monitoring and correction of electrolytes and acid–base abnormalities. Previously, these studies had to be sent to a central laboratory in another city.

Facilities should also be available for proctosigmoidoscopy and the incidence of secondary malignancy needs to be determined. The mean latency for the development of adenocarcinoma is about 25 years [12], with the earliest reported case occurring approximately 10 years after diversion [17]. Before performing a diversion to the colon, anal continence needs to be assured. This is important as up to 40% of patients with obstetric fistula also have some degree of fecal incontinence [4]. Currently, our preoperative evaluation is limited to retention of an enema and a digital exam. Our experience suggests that even with this evaluation, nighttime urinary incontinence may be experienced in approximately 30% of patients regardless of whether a recognizable rectal/sphincter injury had been present and repaired. It is not surprising that the two women who had urinary diversion for bladder extrophy had no problems with nighttime incontinence since their rectal sphincters were not damaged with childbirth. This is consistent with experience with this pouch when used for this indication in children in western countries [18].

Other important issues that need to be addressed include informed consent, alternative techniques, and the development of standardized criteria for diversion. Many classifications of fistula have been proposed, but none is universally accepted [19]. The Waaldijk classification system emphasizes the urethra and its' closing mechanism as it relates to prognosis. This system is particularly relevant because the inability to obtain continence, regardless of closure, is the primary reason for considering diversion. Even very large fistulas that do not involve the continence mechanism can be repaired with a high success rate [8]. When diversion is performed for a contracted bladder, it is important to perform at least simple

urodynamics and cystoscopy to insure that detrusor overactivity is not the real cause of incontinence. This condition may often be treated with medication or bladder training. Severe scarring, absence of urethra, and minimal bladder capacity after repair are often quoted as reasons for diversion [6, 9]. Although these features are not always requirements for diversion, in our patients selected for diversion, they were usually present. This study cannot provide better insight regarding whether these are the optimal ones. However, a 7% “diversion rate” is consistent with what is reported by most centers for irreparable fistulas and we feel that a 3% “diversion rate” without attempting a vaginal repair is reasonable [2, 4].

Language problems and cultural differences create special problems for developing a universal policy on informed consent [9]. It will be essential for national medical and lay personnel to have major input in this area, not just visiting surgeons. It is important to note that the Eritrean Fistula Project is a program developed and monitored by the Ministry of Health of Eritrea, with help from visiting surgeons, health professionals, and the UNFPA and is a work in progress. A counseling curriculum has been developed, tested, and is being utilized with trained social workers and nurses, but an improved infrastructure is needed in the country to deal with this and other ethical issues in medicine. Plans are in place to incorporate this area in the new medical school and residency program in obstetrics and gynecology.

Finally, we need long-term data on the life expectancy of patients who undergo diversion. This must be compared to the life expectancy of women living with unrepaired fistulas in the same population. Unfortunately, baseline life expectancy data for women with unrepaired fistulas is not available. However, it is likely less than the general population, especially in light of the fact that up to 50% of women with unrepaired fistulas have been found to be suicidal [20]. It is not clear how preoperative psychosocial profiles correlate with postoperative adjustment to urinary diversion, but this is an important area to study in the future.

Conclusion

Urinary diversion using a detubularized sigmoid pouch (Mainz pouch II) is a reasonable option for women with irreparable urinary fistulas in the developing world. Further work is necessary to determine the long-term effects of this procedure and the feasibility of a comprehensive follow-up program in countries with limited resources. Issues regarding criteria for diversion, psychological effects, alternative techniques, and informed consent need further study.

Conflicts of interest None.

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