

# Review of Urinary Diversion (Mainz II) for Women with Irreparable Vesico-Vaginal Fistula (VVF) In Eritrea, 2022: A Retrospective Study

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## ABSTRACT

**Introduction:** Mainz II urinary diversion procedures are increasingly being performed in the developing world for irreparable obstetric fistulas. Our goal was to review the long-term complications of continent urinary diversion and to evaluate the feasibility of the recommended follow-up protocols in a country with limited resources.

**Methods:** The medical records of patients who underwent urinary diversion or who are under follow-up for irreparable vesico-vaginal fistula (VVF) at National Fistula center (NFC) in Mendefera, Eritrea, between February 2004 and December 2021, were reviewed. Descriptive statistics was used to depict the complications and surgical outcomes.

**Results:** Urinary diversions were performed in 47 patients. The average duration of stay after surgery was 18 days. Metabolic panel and arterial blood gases (ABG) were found only in 26 of the records which showed hyperchloremic acidosis in 22 (84.7%) and decreased kidney function in 8 (30.7%) of the women. Night time incontinence was found in 24 (51.1%) of the cases with 9 (19.1%) experiencing symptomatic renal infections which required admission. Three of the patients developed pouch stones and two patients developed hydronephrosis. Five patients were able to conceive after diversion. Eleven (23.4 %) of the women were lost to follow-up and 10 (21.3 %) died, with majority (70%) of them with unknown cause of death.

**Conclusion:** On top of the long-term complications following diversion, there was substantial loss to follow-up and death after urinary diversion. Therefore, innovative approaches and continuous financial support to ensure patient return or local follow-up in residential regions need to be developed to overcome barriers to guarantee continuity of care and to decrease the morbidity and mortality of these women.

**Keywords:** Mainz II, Vesico-Vaginal Fistula, Urinary Diversion, Eritrea

## Introduction

Obstetric fistula is a devastating complication of childbirth affecting millions of women globally and especially in the developing world. The World Health Organization (WHO) defines obstetric fistula (OF) as an abnormal connection between the vagina, rectum and/or bladder which may develop after prolonged and obstructed labor and lead to continuous urinary or fecal incontinence [1].

The introduction of safe and widely available obstetric care has made the prevalence of obstetric fistula a rare event in the developed world. When fistulas arise, they are usually due to a congenital anomaly, surgical complication, malignancy, or radiation damage. On the other hand, in developing countries the overwhelming cause of vesicovaginal fistula (VVF) and rectovaginal fistula (RVF) is prolonged and obstructed labor [2]. According to the WHO, there are over two million women

worldwide living with VVF and there are estimated 60,000-100,000 new cases of fistula each year, in Africa alone [3].

Primary closure rate of small uncomplicated fistulas has been reported to be rewarding with over 80% of cases being successful [4]. However, more complicated fistulas with complete loss of urethra or fistulas with multiple repair attempts and severe scarring have a much lower success rate. And when these complicated fistulas are closed, they frequently have residual stress incontinence which is different from the typical stress incontinence and is resistant to standard surgical treatment [5-7]. For those women who have extensive damage and scarring where reconstruction is not possible, urinary diversion seems to be the only viable option to return to normal life. But for those women who refuse or who have contraindications for urinary diversion, provision of pads and barrier zinc-oxide cream is of great importance, along with continuous social and financial support [8].

There are two broad types of urinary diversion procedures—conduit diversions and continent diversions. One example

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of continent urinary diversions is the Mainz II pouch, which is commonly used in low-resource setting because of the relatively easier surgical approach and no requirement for appliances or bags. In this procedure, the ureters are implanted into a low-pressure pouch created using the sigmoid colon. Hence, both urine and feces are collected in a rectal pouch and eliminated concurrently via the rectum. Ileal conduit utilizes water-tight stoma appliances which are not readily available in the developing world. Therefore, continent urinary diversion by Mainz II pouch appears to be the best option for our VVF patients with incurable fistulae. This was shown in a study done in Rwanda which intended to identify the preferences and opinions regarding urinary diversion surgeries among women with inoperable VVFs- it was identified that almost all (93%) women would go for urinary diversion if the procedure was available, and the majority preferred ureterosigmoidostomy to avoid an ostomy bag [9].

However, any kind of diversion procedure carries significant risks and complications. These have been reported to include hyperchloremic metabolic acidosis, renal failure, altered sensorium, urosepsis, pouch stones, cancer, and osteomalacia [10,11].

Therefore, women who underwent diversion need close follow up and monitoring, as the possibility for the development of long-term complications is significant. It is recommended for every woman to receive continuous care, routine monitoring of electrolytes and renal function, and screening for colon cancer when required. This is a challenge to the fistula center in Eritrea because visiting surgeons leave shortly after the operations without giving the patients adequate postoperative care. In addition, most fistula centers may receive financial support for fistula surgery but not for lifetime care which includes psychological, social and nutritional support as well as maintaining capable laboratory and diagnostic facilities [12].

The rationale of this study is to analyze the data collected from February 2004 to December 2021 and to assess the long-term complications and outcomes of Mainz II urinary diversion. Even though there was a previous study done by Morgan et al. in 2009 on a subset of the operated patients, this study focuses mainly on the long-term complications and outcomes of patients who underwent urinary diversion. In addition, the feasibility of the recommended comprehensive follow-up programs in a country with limited resources was evaluated.

## Methodology

### Study Setting

Eritrea is a country located along the coast of the Red Sea and is bordered by Djibouti, Ethiopia, and the Republic of Sudan. Although any population census has never been carried out in Eritrea, the estimated population of Eritrea for the year 2020 was 3.5 million based on a report by the Ministry of National development (MND) [13]. The National Fistula Center (NFC) is located in Mendefera Zonal Referral Hospital in Mendefera, which is found 54 kilometers south of the capital Asmara. The center is run by an Eritrean obstetrics and gynecology surgeon and fistula expert along with physician visitors from United States of whom a fistula surgeon manages all the study participants included in this analysis. The NFC includes a preoperative and postoperative ward. It also includes a 40-bed Fistula Rehabilitation center.

## Objective

The objective of this study is to determine the long term complications of urinary diversion procedures for inoperable VVF and to evaluate the current follow-up status of the operated fistula patients.

## Source and Study Population

Information of all the mothers who underwent low-pressure colonic pouch (Mainz II) urinary diversion for irreparable VVF in the NFC from February 2004 to December 2021 was retrieved and included in the study. There were a total of 54 patients who underwent the Mainz II procedure from February 2004 up until December 2022. However, 5 clinical cards were missing and two cases were excluded because the surgery was done for bladder exstrophy.

## Data Collection Tool and Approach

Data was collected from four sources, i.e. patient's card, the admission (log book), discharge form, and death registers.

## Data Analysis Plan

Data entry was performed using SPSS statistical package version 26 for windows (SPSS) for analysis. Descriptive statistics was used to describe frequency and percentage of surgical complications and outcomes.

## Ethical Consideration

Ethical approval was obtained from Zonal Ministry of Health (MOH) ethical clearance committee, the MOH research ethics and protocol review committee and also from the NFC of Mendefera Regional Hospital.

## Results

Analysis of demographic characteristics as shown in Table 1 indicates that the median maternal age at the time of diversion was 27 (Min.=16, Max.=68). The majority (40.4%) of the participants resided in Debub region. More than half (59.6%) were Muslim followers. The majority (40.4%) were from Tigre ethnic group followed by Tigrigna group (29.8%). Mothers had lived, on average, for 6 years with fistula before surgery.

**Table 1: Demographic characteristics of the study participants (n=47)**

Variables	Frequency	%
<b>Zonal Address</b>		
Debub	19	40.4
Gash Barka	11	23.4
Northern Red Sea	9	19.1
Anseba	8	17
<b>Religion</b>		
Muslim	28	59.6
Christian	19	40.4
<b>Ethnicity</b>		
Tigre	19	40.4
Tigrigna	14	29.8
Saho	10	21.3
Others	4	8.4

When looking at the obstetric history of the respondents, the majority were pregnant for the first time with a median of 1 (IQR=1). The participants, at most, were pregnant for five times and nearly everyone (97.9%) of the pregnancy ended up in still birth. Delivery was attended at home for most (63.8%) of the study respondents. The majority (72.3%) gave birth via spontaneous vaginal delivery and only 4.3% were assisted with either vacuum or forceps. Less than a quarter (19.1%) underwent cesarean section due to obstructed labor.

The respondents' clinical cards were reviewed in regards to indications and outcomes of surgery as depicted in Table 2. The most common indications for diversion were failed prior fistula repair and absence of urethra. However, in majority of the cases it was due to a combination of two or more factors. Thirty-five (74.5%) of the patients had previous fistula repair procedures which included surgery for VVF (38.3%) followed by surgery for both VVF and RVF (27.7%) fistula. A little above third (38.3%) reported to have history of other surgeries (hysterectomy, colostomy and rectal repair). The average duration of hospital stay after surgery was 18 days (IQR=15) with one woman staying for 149 days. Five women achieved pregnancies afterwards. Latest records of the patients also show that 10 women died at unspecified duration after the surgery.

**Table 2: Indications and outcomes of surgery**

Surgery indications and outcomes	Num	%
Indications for urinary diversion	22	46.8
Failed fistula repair	16	34
Complete absence of urethra	4	8.5
Severe scarring	3	6.4
Minimal bladder capacity	2	4.3
Absence of anterior vaginal wall		
Prior history of surgery for fistula		
Surgery for VVF	18	38.3
Surgery for RVF	4	8.5
Both VVF and RVF	13	27.7

### Complications and Outcomes After Surgery

Out of the 47 study participants, night time incontinence was found in 24 (51.1%) of the cases. Post-operative metabolic panel and arterial blood gas results were found only in 26 of the records. These showed hyperchloremic acidosis in 22 (84.7%) of the cases and decreased kidney function in 8 (30.7%) patients. Hydronephrosis was noted in 2 of these patients. Symptomatic renal infection which required admission was found in 9 (19.1%) of the total 47 patients. Three patients developed pouch stones and fourteen (29.8%) participants developed anemia.

Although there was no perioperative mortality, 10 (21.3%) of these patients died with mean duration of 5 years. The cause of death in seven of the patients was unknown but two patients died because of renal failure and one patient died because of sepsis. Eleven (23.4%) women were lost on follow-up during the study period.

### Discussion

Eritrea joined the global campaign to end fistula in 2003, and since then approximately 1764 patients with VVF were

admitted. From these all, 54 (3%) underwent surgeries for urinary diversion. Continuous clinical follow-up of these women remains a challenge because most of them return to their habitually remote rural villages, making it difficult to contact them to assess long-term surgical outcomes.

However, using the deficient follow-up data available at the National Fistula Center (NFC), we attempted to draw conclusions on the surgical outcomes and feasibility of Mainz II urinary diversion in Eritrea. The decision to go through and perform urinary diversion on the study participants was decided by the consensual agreement of at least three surgeons. Based on their experience, there were no specific criteria for diversion. Therefore, there is a need to develop a standardized protocol for indications to perform diversion procedures.

High-quality information on long-term complications of diversion in obstetric fistula patients is sparse. In this study, we attempted to look into some of the complications that these patients experienced during the follow-up period.

### Complications

#### Incontinence

In women with obstetric trauma to the pelvic floor, some degree of anorectal dysfunction is expected. In this study, night time incontinence was found in 24 (51.1%) of the cases- consistent with a study done by Ahmadi et al. where 54.7% had nocturnal leakage [14].

#### Metabolic Acidosis

Hyperchloremic metabolic acidosis is the hallmark metabolic abnormality in patients who underwent ureterosigmoidostomy, seen in 80% of the cases, but can occur in patients with virtually all types of urinary diversion. DeMarco and Koch found that 10% to 15% of ileal conduit diversions and 50% of continent catheterizable diversions were also complicated by metabolic acidosis. In our study, post-operative serum electrolytes and arterial blood gases were found only in 26 of the records and showed hyperchloremic acidosis in 22 (84.7%) cases [15]. Alkalinizing agents such as sodium bicarbonate and other locally available foods with alkalinizing properties could be recommended to reduce the degree of acidosis. This is an area of research that can be further explored in future studies.

#### Renal Damage

Renal insufficiency and hydronephrosis may result from the reflux of urine and stool. In this study, renal damage resulting in decreased kidney function was seen in 8 (30.7%) of the 26 women who had done renal function tests. This number is significantly higher than the study done by Shimko et al. in patients who underwent conduit urinary diversion where renal failure occurred in 19% [16]. Another study showed severely decreased renal function in 17% but remained unchanged in the majority 61% of the patients who underwent a ureterosigmoidostomy urinary diversion procedure [17].

Hydronephrosis occurs due to uretero-colic stenosis or due to functional obstruction, following a gradual rise in pouch pressure towards normal colonic pressure. In one study, stenosis of the ureter which might lead to hydronephrosis and renal failure, if undetected, was found in 13% of the patients who

underwent Mainz II surgeries. [17] In our study, hydronephrosis was noted in 2 patients. The reason for this small number might be attributed to the fact that not all patients were screened for hydronephrosis during their follow-up.

### Urinary Tract Infections (UTIs)

Infectious complications are reported as common after classical ureterosigmoidostomy when compared with Mainz pouch II and other modified techniques [18]. Symptomatic renal infection which required admission was seen in 9 (19.1%) of the patients in our study. This number might be an underestimated result given the poor reliability of testing, as any urine would be mixed with fecal material. In a cohort of 66 patients with orthotopic neobladder, Wood et al. reported bacteriuria in 78% of patients, and symptomatic urinary tract infection developed in half of these patients. Despite high incidence of bacteriuria, urosepsis is rare and occurs in the context of recurrent symptomatic infections [19,20].

### Pouch Stones

Patients with urinary diversion are at an increased risk of developing urinary stones. Three (6.4%) women in this study developed pouch stones, which were removed surgically. In a cohort of 445 consecutive patients with stapled orthotopic neobladder, the authors reported an incidence of stone formation at about 10% after a median follow-up of 41 months. However, the incidence of stone formation increased over time up to 25%, 7 years after surgery [21]. Appropriate hydration and treating metabolic and electrolyte disturbances as well as adequate reservoir emptying are the main preventive measures.

### Anemia

Although data on the nutritional status of the patients was not available, 14 (29.8%) of the study participants developed anemia. The mean corpuscular volume of the red blood cells showed that the anemia was microcytic, which was mostly due to iron deficiency. The anemia in ileal conduit type of diversion is usually megaloblastic anemia as the absorption of Vitamin B12 is compromised [11].

### Malignancy

In this study, the incidence of secondary malignancy could not be determined because facilities for performing proctosigmoidoscopy were nonexistent. According to a study by Austen & Kalblein in 2004, there were more than 200 cases of secondary malignancy reported with the risk increasing 477-fold in patients under the age of 30 when compared to patients between 55-60 who have only 8-fold increase [22].

Therefore, decisions to undertake urinary diversion procedures on these young group of patients might be complicated. Follow-up starting between 3 and 5 years postoperatively, with yearly endoscopy and ultrasonography examination, is recommended by most experts [23].

### Outcomes

#### Pregnancy After Diversion

There are no long-term studies that have evaluated the birth rates of women after repair of fistulas but it has been reported, from experiences in multiple sites, that patients with repaired fistulas can get pregnant and deliver healthy infants, although the rates

are assumed to be markedly lower as a result of pelvic adhesions [24, 25]. Five women in this study have achieved pregnancy after diversion and delivered by cesarean section. This shows that pregnancy after diversion is possible and helps in the re-integration of the patients to the society as having children is of great concern, not only to the patient but to also to her family.

### Death

Although there was no reported perioperative mortality, 10 (21.3%) of these patients died upon review of each patient's record. The cause of death in seven of the patients was unknown but two patients died because of renal failure and one patient died because of sepsis.

### Lost to follow-up

Adequate follow-up is a critical aspect of care for any woman considering a urinary diversion. The patients must be capable of, and committed to, close follow-up, and they must have access to imaging, blood laboratory work, and even endoscopic surveillance.

Substantial loss to follow-up after diversion remains a big challenge in our setting with 11 (23.4%) women lost during the study period. Therefore, new approaches to ensure patient return or local follow-up in or around their residence must be developed to overcome barriers for continuity of care. Integrating care of fistula patients with the existing health systems and training of health care workers are some of strategies that can help reduce the number of lost patients.

There was no guideline for follow-up after diversion in our setting. In the future, a guide should be drafted which will make it easier for healthcare professional anywhere to provide the required services.

### Ethical Consideration

Finally, we suggest that treatment options should be selected on the basis of the realistic likelihoods that the procedure will benefit the patient. This is particularly a difficult decision to make for patients with low education level and awareness. Therefore, patients should be extensively informed about the follow-up requirements and long-term risks; after which they can then make their decision. Physicians, family members and the community should be included in the process of decision making.

### Conclusion

Mainz II is the urinary diversion preferred in low economic settings. However, it has significant shortcomings- long term complications, patients get lost to follow-up and death after the diversion surgery. Therefore, innovative approaches and continuous financial support must be developed to ensure patient return. Local follow-up in residential regions need to be available to overcome barriers to guarantee continuity of care and to decrease the morbidity and mortality of these women.

### Recommendations

Since the surgeries are done by foreign surgeons who leave the country after performing the surgeries, the patients do not get the proper postoperative care nor do they get the necessary long term follow-up. Hence, there should be empowerment of the local capabilities of the center to have its own fistula experts and surgeons who do the diversion along with the proper follow-up

and intervene accordingly. Moreover, the fistula centers where the diversion patients stay postoperatively and visit for follow-up have no adequate setup to perform different investigations. Thus, the presence of necessary investigative modalities and their continuous maintenance is of paramount importance. A significant percentage of the patients get lost to follow-up despite the high prevalence of the long-term complications in those who undergo diversion. As one of the main reasons that the patients are lost to follow-up is the remoteness of their residence, decentralizing the urinary diversion follow-up care is crucial. Nearby hospitals should be able to provide proper follow up and care for urinary diversion patients. Finally, as there are no clear criteria for performing diversion up to this date, drawing up the possible indications is suggested. Moreover, a national guideline on appropriate follow-up and management of patients who underwent surgical urinary diversion is of a high need.

### Limitations of the Study

Given the insufficient diagnostic equipment for conducting proctosigmoidoscopy, the incidence of colorectal malignancy could not be determined properly. For the same reason, monitoring and correction of electrolytes, acid base abnormalities and renal function tests was challenging because of the frequent shortcomings in the laboratory and machine malfunctioning. Moreover, there were no specific criteria for diversion and patients were not offered other alternative treatments, for example, ileal conduit. Furthermore, life expectancy of the women who had diversion could not be compared to the life expectancy of women living with unrepaired fistulas in the same population because baseline life expectancy data for women with unrepaired fistulas is not available.

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