Mainz II urinary diversion in low-resource settings: patient outcomes in women with irreparable fistula in Malawi

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BACKGROUND: Obstructed labor leading to a vesicovaginal fistula remains a devastating outcome of childbirth in low-resource countries. Women with an irreparable vesicovaginal fistula may be candidates for a urinary diversion, such as the Mainz II modified ureterosigmoidostomy procedure. Previous reviews state that the procedure should be considered in low-resource countries. However, given the limited duration of postoperative follow-up, these studies do not adequately represent the long-term morbidity and mortality that is likely associated with this procedure. We present data that strongly support avoiding the procedure in low-resource countries.

OBJECTIVE: This study aimed to evaluate the postoperative status of the patient (dead, alive, lost to follow-up) and time to death following the Mainz II procedure.

STUDY DESIGN: This is a case series including 21 patients who underwent a Mainz II urinary diversion from April 2013 to June 2015 for management of irreparable vesicovaginal fistula at the Fistula Care Centre in Lilongwe, Malawi. Patients were seen postoperatively at 3, 6, 9, and 12 months, followed by every 6 to 12 months thereafter. Descriptive statistics were performed to summarize the data.

RESULTS: During the postoperative period, 8 (38.1%; 8/21) patients died, 5 (23.8%; 5/21) were lost to follow-up, and 8 (38.1%; 8/21) are currently alive and followed up at the Fistula Care Centre. We strongly suspect that 7 of the 8 deaths were related to the procedure given that the patients had illnesses that exacerbated the metabolic consequences of the procedure. The eighth patient died after being attacked by robbers. Unfortunately, the exact cause of death could not be determined for these patients. Given that most of the suspected illnesses would be treatable in an otherwise healthy patient, even in this low-resource setting, we surmised that the metabolic compromise from the Mainz II procedure likely contributed to their untimely death. The average time from procedure to death was 58 months, with the earliest death at 10 months and the most recent at 7 years after the procedure.

CONCLUSION: The Mainz II procedure is an option for patients with irreparable fistula. However, it should likely not be performed in low-resource countries given the long-term complications that often cannot be adequately addressed in these settings, leading to significant morbidity and mortality.

Key words: global women's health, low-resource countries, obstetrical fistula, obstetrics and gynecology, obstructed labor, surgical outcomes, urogynecology, vesicovaginal fistula

Introduction

Obstetrical fistula (OF) remains a vexing problem in low-resource countries (LRCs), where 2 to 4 million women live with the condition.[1] In Malawi, the estimated prevalence is 1.6 per 1000 women.[2] Surgery is the only cure for OF. However, 2% to 5% of patients remain incurable after surgery.[3,4] For such patients, a urinary diversion is the only option to regain continence.

Multiple urinary diversion options exist. A continent urinary reservoir (such as a Miami pouch) is associated with a high risk of postoperative complications and is more difficult to perform than other urinary diversions.[5] The ileal conduit is a more straightforward procedure but may not be an option because of cost and availability of ostomy appliances in LRCs. In addition, the presence of a stoma and ostomy bag can lead to stigmatization of patients.[3,6] In the Mainz II procedure,

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AJOG MFM at a Glance

Why was this study conducted?

The Mainz II urinary diversion procedure is commonly performed for irreparable fistulas associated with obstructed labor. However, no studies to date have evaluated the long-term outcomes associated with the procedure.

Key findings

Of the 21 patients, 8 (38.1%) died, 5 (23.8%) were lost to follow-up, and 8 (38.1%) are currently alive. Average time from procedure to death was 58 months, with the earliest death at 10 months and the most recent at 7 years after the procedure. Even many years after the procedure, patients still experience negative consequences of a Mainz II urinary diversion.

What does this add to what is known?

The Mainz II procedure is an option for patients with irreparable fistula. However, extreme caution in low-resource countries is warranted given the long-term complications that often cannot be adequately addressed, leading to significant morbidity and mortality.

the ureters are implanted into a surgically created low-pressure pouch of sigmoid colon, allowing simultaneous urination and defecation.[6] This creates a functionally and socially acceptable solution for the patient and prevents the stigma often associated with an ostomy. Because of this, the Mainz II procedure has become the preferred option for incurable patients in LRCs.

There are limited studies on the Mainz II in LRCs. Authors in Nigeria found that of the 23 women who underwent a Mainz II procedure, 2 died of uncertain causes. The mean duration of follow-up was not noted.[3] A review in Eritrea examined 35 Mainz II patients. Median follow-up was 18 months. Two women died 4 years after surgery: one of sepsis and the other of renal failure. Eight women were lost to follow-up.[7]

In a retrospective review of 109 patients in Nigeria, 2 Mainz II patients died during the immediate postoperative period. The mean duration of follow-up was unclear.[8] All authors in these studies acknowledged lack of follow-up as a major concern.

Mortality from the Mainz II is uncommon in the first year after surgery. Long-term complications include hyperchloremic acidosis, ureteral stenosis, renal insufficiency, hydronephrosis, and recurrent kidney infections, all of which can lead to death.[4,6] Although patients in most high-resource countries have timely access to health care, this is not the case in LRCs. Delays in timely access to health care for otherwise routine illnesses such as diarrhea or malaria can be fatal in a Mainz II patient.

The objective of this study is to evaluate mortality from Mainz II urinary diversion performed in 21 otherwise incurable OF patients between 2013 and 2015 in Malawi. This study follows patients for up to a decade after surgery.

Materials and Methods

This study is a case series of 21 patients who had a Mainz II urinary diversion at the Fistula Care Centre (FCC) in Lilongwe, Malawi from April 2013 to June 2015 for management of irreparable vesicovaginal fistula. This is part of a larger, ongoing study on the outcomes of OF repair at our center, which has been approved by the Malawian National Health Science Research Committee and the Baylor College of Medicine Institutional Review Board.

Each patient was assessed before surgery using a standardized protocol. A patient was considered to have an irreparable vesicovaginal fistula after consensus of 2 expert fistula surgeons. There are no standardized criteria for "irreparable" fistula. However, some characteristics of irreparable fistula include the following: (1) dense, unresectable scar in the vagina with absent normal vaginal tissue, (2) absent or very short (<1 cm) urethra, (3) very small volume, scarred bladder, and (4) multiple previous failed attempts at repair. Before the Mainz II urinary diversion, extensive counseling was provided in the patient's native language. Counseling included indications for the procedure, risks and benefits, functional and anatomic changes after the procedure, the importance of scheduled follow-up, and the need to return to the FCC with any illnesses or complications. Written and verbal informed consent was obtained. Preoperative assessment of hemoglobin, creatinine levels, HIV serostatus, and pregnancy status were obtained. Anal sphincter competence was confirmed with a retention enema of 250 mL. All patients received prophylactic intravenous ceftriaxone and metronidazole.

Postoperatively, ureteral stents and a rectal tube were maintained for 21 days. Patients were placed on a liquid diet on postoperative day 1, and then transitioned to a regular diet within a few days. Patients continued their inpatient stay at the FCC for 36 days on average, and were seen by a physician daily until discharge. Patients at the FCC receive extensive education and have access to social reintegration programs, including financial literacy and small business opportunities.

Before discharge, patients were provided a mobile phone, airtime credit, and instructions on obtaining more credit from the FCC as needed. Follow-up was planned at 1, 3, 6, and 12 months after discharge. During postoperative follow-up, creatinine and sodium bicarbonate levels were routinely obtained, and a renal ultrasound was performed. Routine follow-up every 6 months thereafter was planned and modified as needed. All patients lived within a 100-km radius of the FCC at time of surgery and had a relative who could be contacted or had instructions to contact the FCC should a problem arise. The FCC has 2 ambulances; whenever possible, if a Mainz II patient contacted the center, she was transported via ambulance.

Results

Twenty-one Mainz II urinary diversions were performed from April 2013 to June 2015. Patient demographics are listed in Table 1. The mean (range) age was 30.4 (16−62) years. Most patients were from Malawi (95.2%) and lived in a rural setting (95.2%). Many live in homes with a grass roof or no roof at all (18; 85.7%), which can serve as a proxy for low socioeconomic status. Most were subsistence farmers (16; 76.1%). Two (9.5%) of the patients were HIV seroreactive. Of the 2 patients, 1 had a negative preoperative HIV test, but was diagnosed postoperatively as part of a workup for persistent fever. The patient who was HIV seroreactive was receiving antiretroviral medications with a normal CD4 count before surgery.

Table 2 presents the clinical characteristics of the patients. All 21 patients were considered to have an irreparable vesicovaginal fistula. Goh classifications ranged from 1cii to 4ciii, with most patients having severe (Goh stage III) scar tissue. Twenty of the patients (95.2%) had at least 1 previous fistula repair, and 33.3% had at least 2 previous repairs. Preoperative creatinine and electrolytes were obtained and followed postoperatively for each patient. The average preoperative creatinine was 0.73 mg/dL and ranged from 0.5 to 1.5 mg/dL. Average operative time was 168 minutes, with an average blood loss of 173 mL. There were no perioperative deaths. No patient required an intraoperative blood transfusion. One patient (E.S.) had an inadvertent enterotomy of the proximal ileum at the time of surgery, which was recognized and repaired intraoperatively. One patient (E.M.) returned to the operating room 9 days after the Mainz II procedure for drainage of an ovarian abscess. The primary postoperative complication was fever, which occurred in 7 (33.3%) of the patients. Additional postoperative complications were anemia requiring a blood transfusion (1; 4.8%), pyelonephritis (1; 4.8%), and wound infection (1; 4.8%). Average length of stay was 36 days (ranging from 21 to 63 days). If patients were readmitted to the FCC, the most common reasons were for management of pyelonephritis, urosepsis, and malaria. Of the 21 patients, 4 (19%) required a Mainz II revision

TABLE 1
Patient demographics (n=21)

Variables	Types	Years	Number of patients	Percentage
Age[a]		30.4 (11.7)		
Country of origin	Malawi		20	95.2%
	Mozambique		1	4.8%
Residence	Rural		20	95.2%
	Urban		1	4.8%
Marital status	Single/never married		1	4.8%
	Married		9	42.8%
	Divorced		6	28.5%
	Separated		3	14.3%
	Widowed		1	4.8%
	Unknown		1	4.8%
HIV status	Nonreactive		19	90.5%
	Reactive		2	9.5%
Education level	None		5	23.8%
	S1−S8		16	76.2%
Roof type	Grass/none		18	85.7%
	Metal/wood/cement		3	14.3%
Occupation	Subsistence farmer		16	76.1%
	Small business owner		3	14.3%
	Housewife		1	4.8%
	Casual laborer		1	4.8%

[a] Mean (SD).

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TABLE 2
Patient clinical characteristics (n=21)

Variables	Types	Clinical markers	Number of patients	Percentage
Fistula per Goh classification				
	Proximity to the urethra			
	Type 1		1	4.8%
	Type 2		6	28.6%
	Type 3		4	19.0%
	Type 4		7	33.3%
	N/A		3	14.3%
	Size			
	A		7	33.3%
	B		6	28.6%
	C		5	23.8%
	N/A		3	14.3%
	Scar tissue			
	I		1	4.8%
	II		1	4.8%
	III		16	76.1%
	N/A		3	14.3%
Number of previous procedures				
	0		1	4.8%
	1		4	19.0%
	2		7	33.3%
	3		3	14.3%
	≥4		6	28.6%
Preoperative creatinine, mg/dL[a]		0.73 (0.26)		
Operative time, min[a]		168 (47.6)		
Estimated blood loss, mL[a]		173 (204.8)		
Postoperative complications				
	Fever of unknown origin		7	33.3%
	Anemia requiring blood transfusion		1	4.8%
	Pyelonephritis		1	4.8%
	Wound infection		1	4.8%
Hospital stay in d[a]		36.3 (21–63)		

N/A, not applicable.

[a] Mean (SD).

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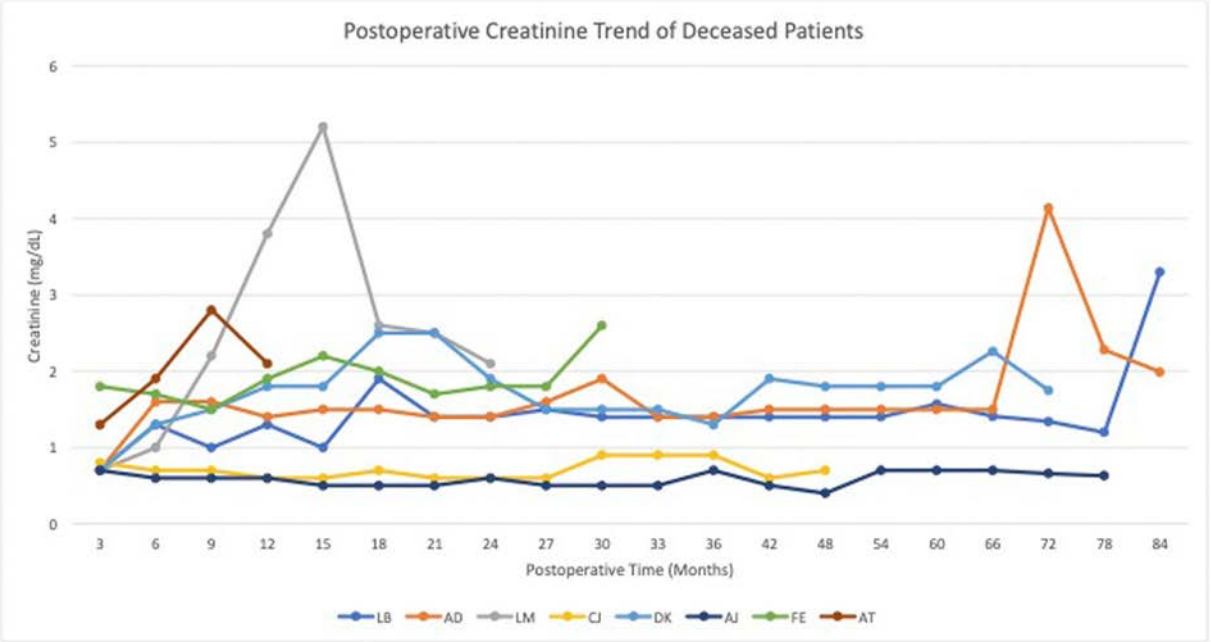
secondary to bilateral ureteral obstruction within 7 to 13 months from the initial procedure, diagnosed by ultrasound and elevated creatinine levels. All 4 had declined an ileal conduit.

When patients presented for follow-up, a complete blood count, creatinine, CO_2, and chloride level were obtained. Figures 1 to 3 depict the postoperative creatinine trend for patients who are confirmed dead, known to be living, and lost to follow-up, respectively.

Of the 21 patients, to date, there have been 8 (38.1%) confirmed deaths. Average time from procedure to death was

FIGURE 1
Postoperative creatinine trend of deceased patients



The legend consists of patient initials used to represent each patient. Each patient is represented in a different color, which corresponds to the creatinine trend (y-axis) over time (in months, x-axis).

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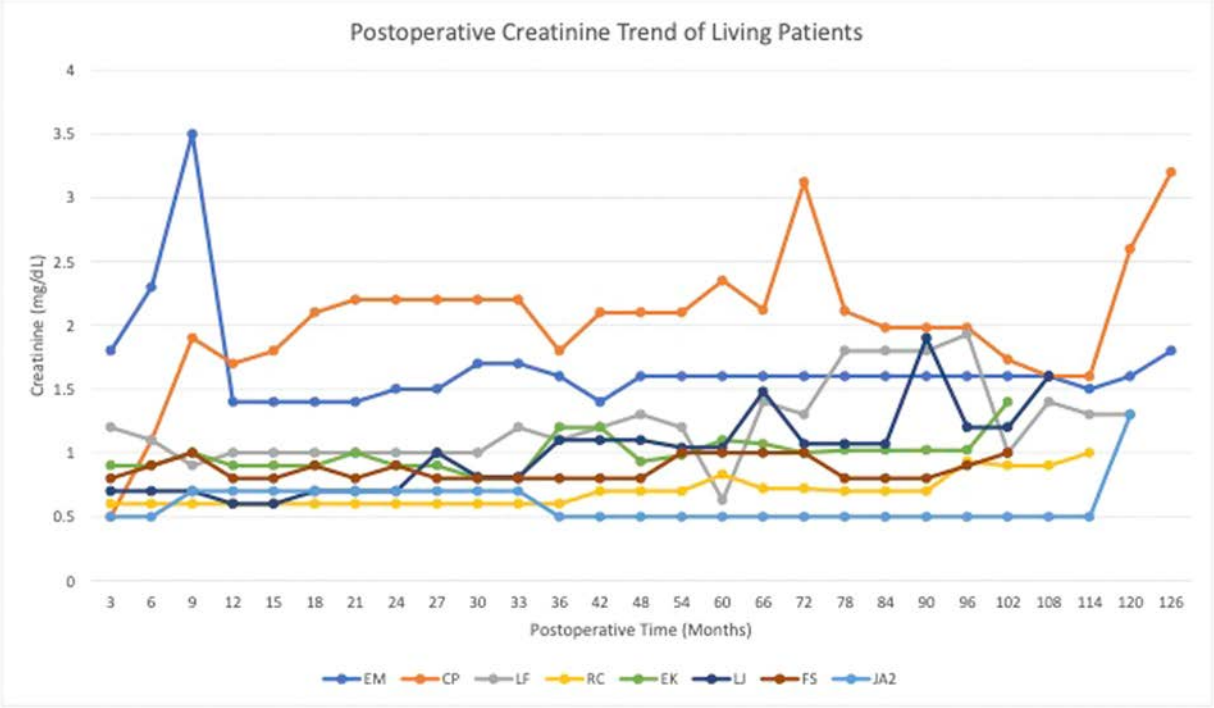
FIGURE 2
Postoperative creatinine trend of living patients



The legend consists of patient initials used to represent each patient. Each patient is represented in a different color, which corresponds to the creatinine trend (y-axis) over time (in months, x-axis).

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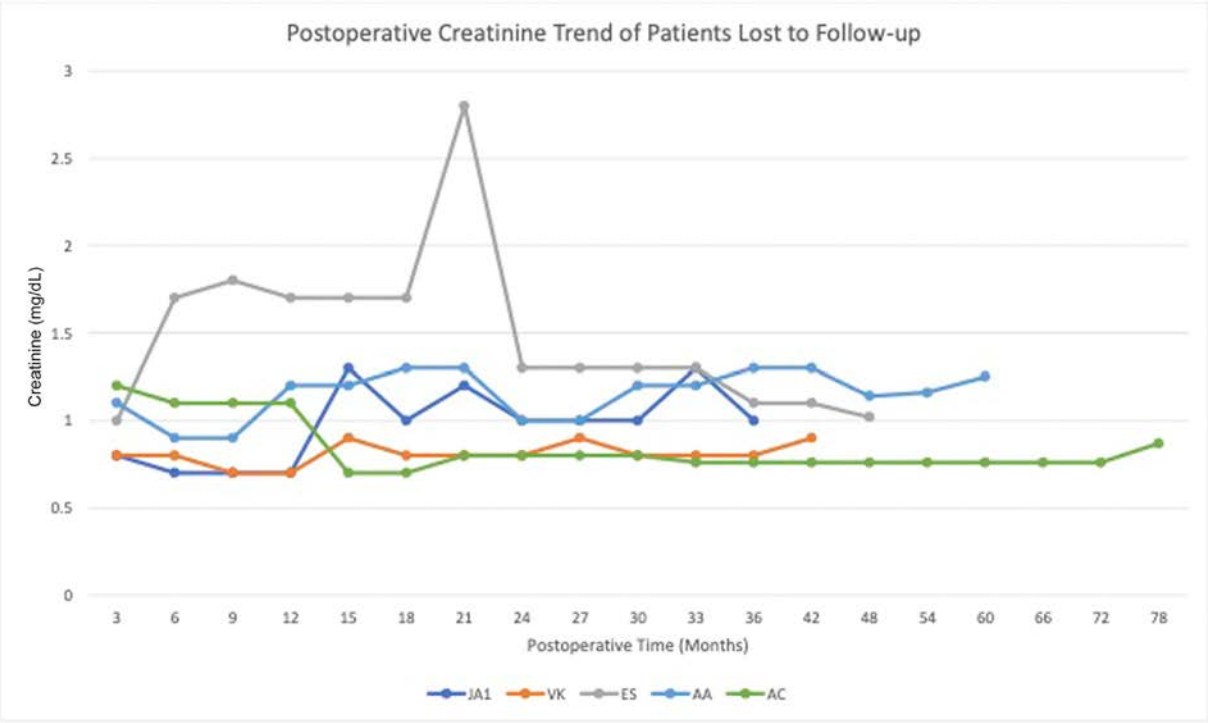
FIGURE 3
Postoperative creatinine trend of patients lost to follow-up



The legend consists of patient initials used to represent each patient. Each patient is represented in a different color, which corresponds to the creatinine trend (y-axis) over time (in months, x-axis).

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approximately 58 months (4 years and 10 months). The earliest death was at 10 months; the most recent death was at 7 years after the procedure. All but 1 of the patients who died had a medical illness such as diarrhea or were admitted to the central hospital before passing away. We strongly suspect that the Mainz II procedure contributed to 7 patient deaths given that any illness can lead to significant, devasting metabolic changes. Unfortunately, we were unable to obtain an exact cause of death for each patient because of limited availability of resources preventing further investigation. This is not uncommon in LRCs. One patient was killed in an attack by robbers at her home (C.J.). Five (23.8%) patients were lost to follow-up despite substantial efforts to trace them. Currently, there are 8 (38.1%) patients known to be alive who present to FCC for follow-up. Two patients had a stable creatinine for 9.5 years after the procedure, and only recently presented with increasing creatinine levels (C.P. 2.0 to 3.2 mg/dL; and J.A.2 0.5 to 1.3 mg/dL).

Discussion

Principal findings

This study involves an extended period of follow-up and monitoring of patients after Mainz II procedures in an LRC. Previous reviews in LRCs followed patients for a maximum of 48 months, with shorter mean maximum follow-up. Mainz II patients from the FCC continue to follow up a decade after the last procedure.

Despite extensive and contextually uncommon perioperative planning to avoid this, we still had 5 patients lost to follow-up. Our patients are mostly subsistence farmers with inherent and often unpredictable challenges to timely follow-up. All 5 patients were lost to follow-up at ≥36 months postoperatively and had a normal creatinine level at their last visit. Given that all patients were adhering to the follow-up schedule well into their third postoperative year, and others died after illnesses with normal or slightly raised creatinine, it is plausible if not likely that the patients lost to follow-up also died.

Results

In September 2014, we held a symposium to examine the technical and ethical aspects of performing Mainz II urinary diversions in LRCs.[6] We concluded that there is known morbidity and mortality associated with the procedure. However, given the patients' incurable fistulas and the apparent immediate and short-term overall efficacy and safety of the procedure, the Mainz II urinary diversion procedure could be considered in select patients in LRCs with appropriate counseling and pre- and postoperative care.

We have examined the outcomes of our patients up to a decade after surgery and note a mortality of at least 38.1%, and likely higher. In addition, we have seen women with stable renal function for up to 10 years postoperatively return

with progressive renal failure and upper tract disease. On the basis of these findings, we conclude that our previously stated caution from the symposium was correct; however, our ultimate conclusions were incorrect. Although Mainz II urinary diversions can be performed safely and have excellent early results in LRCs, the long-term complications are devastating, and our previous enthusiasm should be reconsidered.

Clinical implications

For patients known to have died, the exact causes of death were often unknown. In most cases (5 patients; 62.5%), family members called to inform us that the patient died. It is highly likely that the procedure contributed to their deaths given that family members reported diarrhea or systemic illnesses that exacerbate the metabolic consequences of the procedure. Most patients with a Mainz II urinary diversion have some degree of metabolic acidosis, even with sodium bicarbonate supplementation, and thus cannot tolerate prolonged systemic metabolic changes that occur with systemic illnesses, even with normal renal function.

Creatinine serves as a fair proxy for renal function. For example, patient D. K. had a preoperative creatinine level of 0.6 mg/dL and underwent the Mainz II procedure in July 2013. As shown in Figure 1, her creatinine remained stable until 18 months postoperatively in January 2015, when she had renal obstruction and creatinine increased to 2.5 mg/dL. As she recovered, her creatinine stabilized but remained elevated between 1.3 mg/dL and 1.9 mg/dL. However, 62 months postoperatively, in September 2018, she had urosepsis and creatinine increased to 2.26 mg/dL. She recovered from urosepsis, but her creatinine remained elevated at 1.8 mg/dL. Unfortunately, D.K. died in 2019 of unknown causes. Given that she had urosepsis and increasing creatinine before her death, the diversion was the likely culprit. This scenario, where an abrupt increase in creatinine levels due to pyelonephritis, diarrhea, or another systemic illness leads to a significant decline in renal function and subsequent death, is similar for many other patients shown in Figure 1.

Patients who maintained a normal creatinine level (A.J. in Figure 1 and J. A.2 in Figure 3) still either died (A.J.) or were lost to follow-up (J.A.2). Although creatinine is an important marker and diagnostic tool after a Mainz II procedure, it is not the only component to follow. As mentioned in the Methods section, other laboratory tests and renal ultrasound were also used in follow-up.

C.P. is a patient with one of the longest follow-up periods at 10 years and 5 months (Supplemental Material). Her creatinine stabilized at approximately 2.0 mg/dL for 9 years; however, in May 2023, she was noted to have a creatinine level of 3.2 mg/dL. With almost 10 years of postoperative follow-up, the newly elevated creatinine and bilateral hydronephrosis raises concerns about worsening renal failure. She was counseled and will likely proceed with an ileal conduit procedure. She demonstrates that even after a decade, patients still experience negative consequences of a Mainz II urinary diversion and can require additional surgery to survive.

Surgeons in LRCs continue to perform Mainz II urinary diversions, often lacking information about their patients' long-term outcomes. The relatively low immediate and short-term mortality from the Mainz II procedure inspires a false sense of security. Patients with irreparable OF are desperate for a cure. The temptation to offer a hopeless patient a means to a cure with a procedure that has relatively good short-term safety is very powerful. This may outweigh a surgeon's concerns for the patient's long-term health and well-being. However, on the basis of our case series, we do not recommend the Mainz II urinary diversion in LRCs.

Research implications

Our case series demonstrates that the Mainz II urinary diversion can have devastating consequences, and it contributes to the evaluation of long-term patient outcomes. As Wall et al[9] discuss in their article, long-term follow-up is limited by the ability of the patient to present to a hospital, the capacity of a facility to treat a sick patient, and the ability to obtain appropriate laboratory or imaging studies. Our follow-up was unpredictable even when planned with atypical attention to detail. In many LRCs, lack of diagnostic and treatment resources, and delays in timely diagnosis and treatment for women who become ill are the norm rather than the exception. However, additional long-term follow-up of patients from other LRCs that perform the procedure is recommended to truly capture the long-term outcomes and allow for a comparison of findings. In the interim, the Mainz II urinary diversion should be abandoned or only be performed in LRCs under a research protocol that ensures an even higher level of postoperative follow-up than we were able to provide.

Strengths and limitations

Study limitations include the small number of patients with a 23.8% loss to follow-up rate, and lack of complete data on other relevant markers of renal injury besides creatinine. We followed our patients in a very intentional and structured manner with substantial dedicated resources. Despite this, 5 patients were lost to follow-up. Over time we concluded that creatinine was the most reliable measure of declining renal function. Upper tract dilation detected by ultrasound in the absence of rising creatinine did not prompt us to pursue a Mainz II revision or conversion to an ileal conduit. In retrospect, this may have been a mistake, and either option could have been considered earlier. The strengths include the frequent and long-term nature of the follow-up. The follow-up of patients undergoing Mainz II urinary diversions in this study is extensive and may represent a best-case real-world scenario for postoperative surveillance in this setting.

Conclusions

Our initial enthusiasm has been dampened by the harsh reality that women can die many years after surgery of conditions likely exacerbated or caused by the Mainz II procedure. The safety of

the surgical procedure and the potential for fewer long-term metabolic and renal consequences make the ileal conduit the safest option among the many diversion options. Walker et al[10] found that 82.3% of women in Bangladesh who had an ileal conduit urinary diversion felt they were cured. However, the ethical, social, and practical implications of an ileal conduit must be examined closely in each setting. If an ileal conduit is performed and the patient does not have a lifetime supply of ostomy appliances, her incontinence is moved from the vagina to her abdomen, which can have severe social implications. In addition, in some settings, there is as much or greater stigma associated with a stoma as there is with a vesicovaginal fistula.[6,11] At the FCC in Malawi, we have created an endowed fund for urinary ostomy appliances for ileal conduit patients. We have an exploratory group to examine the long-term feasibility of this plan and will ensure that it is carried forward sustainably.

Unfortunately, there is no clear solution for women with incurable fistula in LRCs. On the basis of our long-term follow-up findings, we do not recommend that the Mainz II urinary diversion procedure be offered to patients in LRCs. Surgeons capable of performing a Mainz II urinary diversion should reconsider whether they should do so in light of our findings. This also emphasizes the need for high-quality, safe obstetrical care for all women globally to prevent OF and obviate the need to confront this ethical dilemma in surgical practice. ■

CRediT authorship contribution statement

Tulsi D. Patel: Writing – review & editing, Writing – original draft, Validation, Formal analysis, Data curation, Conceptualization. **Ennet B. Chipungu:** Writing – review & editing, Investigation, Data curation. **Jennifer M. Draganchuk:** Writing – review & editing, Data curation. **Chisomo Chalamanda:** Writing – review & editing, Data curation. **Jeffrey P. Wilkinson:** Writing – review & editing, Supervision, Project administration, Methodology, Data curation, Conceptualization.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.xagr.2024.100350.

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