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Clinical, Sonographic and Biochemical Profiles of Patients with a Mainz II Pouch Urine Diversion in Rural Uganda. A Case Series

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Background: Mainz II pouch urinary diversion is an alternative surgery for patients with an incurable vesicovaginal fistula (VVF). We report six (6) cases of patients who had incurable VVF and were offered Mainz II pouch surgery at Soroti Regional Referral Hospital, between 2009 and 2018 and followed up in 2023.

Methods: A retrospective review of charts of 6 patients who were offered Mainz II pouch procedure and a cross-sectional assessment of their biochemical, sonographic and clinical profiles five (5) or more years after the procedure at Soroti Regional Referral Hospital were done. All case notes of patients who underwent the Mainz II procedure between 2009 and 2018 were retrieved from the registry and each patient profiled using a standard data abstraction tool.

Results: The ages of the six participants ranged between 16 and 65 years at the time of the procedure. Four of the 6 participants had lived with the fistula for less than 10 years. Four participants had only one delivery and the other 2 had five and six deliveries. All the participants had lived with the Mainz II pouch urine diversion for at least five years (5–14 years). One participant (1/6) had hypertension (BP=161/101). Most participants reported nocturnal incontinence. Sonographic findings revealed one-sided mild vesicoureteral reflux with loss of corticomedullary differentiation in two participants (2/6). One of six (1/6) patients had severe vesicoureteral reflux grade 4. The commonest metabolic disorders were compensated metabolic acidosis (4/6).

Conclusion: The Mainz II pouch procedure remains a viable option for managing incurable obstetric fistulas. However, the prevalence of metabolic complications, including acidosis and renal impairment, underscores the need for routine biochemical and sonographic monitoring to ensure optimal long-term patient outcomes.

Keywords: Mainz II pouch, vesicovaginal fistula, urinary diversion, acidosis

Introduction

Vesicovaginal fistula (VVF) is the commonest form of urogenital fistula, an abnormal tract between the vault of the vagina and the urinary system.[1] They may arise from trauma, surgery, infection, radiation therapy or as a complication of obstructed labor[2,3] There is a sharp contrast in the range of etiological factors between the developed and the developing countries. In the developed countries, the leading cause is iatrogenic (following surgery), accounting for 81–91%, while in the developing countries, 97% of the cases can be attributed to prolonged or obstructed labor.[4] However, recent trends indicate an increase in iatrogenic fistula in developing countries.[5]

The World Health Organization estimates that 50,000–100,000 women develop obstetric fistula every year.[6] In Asia and Sub-Saharan Africa, approximately 2,000,000 women live with untreated fistula as a result of birth complications,[6] 140,000 of these in Uganda.[7] These women continuously suffer incontinence, shame, social segregation and an array of health problems.[8]

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Although obstetric fistulas are curable in many cases, millions of women and girls suffer without any hope of intervention.[3] In addition, several cases (about 15%) of fistula are deemed incurable or refractory as success rates of the VVF repair are reported at an average of 85%.[9] Incurable fistula encompass a history of multiple failed surgeries and inability to close the fistula and restore the patient to continence, following an intervention by the most competent surgeon in an enabling environment.[10] For these cases, the Mainz II operation is sometimes performed. It is a urinary diversion procedure that uses a de-tubularized sigmoid pouch.[11] Success rate for the procedure is generally high, with day time and night time continence reported at 97% and 95%, respectively.[12] However, there are varied reports on outcomes and quality of life resulting from the Mainz II operation.[13–16] Girgin et alcompared the Mainz II pouch with other forms of urinary diversion and observed that the Mainz II pouch was the preferred procedure in patients who desired to maintain continence.[17]

The profiles of patients with fistula deemed incurable or refractory are also poorly documented and yet likely to be a critical determinant to the outcome of the intervention. Mainz II procedure has not been performed extensively in rural settings like Soroti in Eastern Uganda that had the first such operation in 2009. The outcome of these patients remains poorly scrutinized and yet this information can inform future interventions.

The aim of this study therefore was to determine the biochemical, sonographic and clinical profiles of patients with urogenital fistula deemed incurable as well as the outcomes of the intervention.

Methods

Study Design

Mixed methods study which involved retrospective review of charts of 20 patients who were provided with Mainz II pouch procedure in Soroti regional referral hospital between 2009 and 2018. We then conducted a cross-sectional clinical, biochemical and sonographic assessment of the six (6) patients who were successfully traced to determine their profiles and establish any abnormalities.

Study Setting

Soroti Regional Referral Hospital (SRRH), Department of Surgery. SRRH is in Soroti city, approximately 321 km from Kampala-Uganda. It has a bed capacity of 250, serves a population of about 3 million people from 10 districts of Teso sub-region and one city. The coordinates of SRRH are 1°42'58.0"N, 33°36'47.0"E (Latitude: 1.716111; Longitude: 33.613056). The major economic activity of the population is mixed subsistence farming. The population is majorly young.[18]

Study Participants

In the period between 2009 and 2018, twenty patients were offered the Mainz II pouch procedure at SRRH. Patients diagnosed with vesicovaginal fistula deemed incurable and had undergone Mainz II pouch at SRRH in the stated period were the candidates for follow-up. Of the 20 patients with Mainz II pouch followed up, 4 were reported dead (details of which are provided in the result section), 9 could not be traced as they had relocated from their known addresses in their files and had no active phone numbers, one was successfully traced but was excluded as the indication for Mainz II procedure was different from VVF. We report on the six patients who were successfully traced, interviewed and examined for their progress and possible complications of the procedure.

Data Collection and Analysis

Between March and December 2023, all case notes of patients who underwent the Mainz II procedure between 2009 and 2018 were retrieved from the registry of SRRH for profiling using a standard data abstraction tool.

Using patient demographics, contact tracing was done for all patients. The 6 patients who were successfully traced and reached were facilitated to travel to SRRH for clinical evaluation. Informed consent was sought from the clients prior to clinical evaluation.

Clinical examination findings recorded in the questionnaires included: body mass index (BMI), level of pallor, Jaundice, edema, Blood Pressure, Pulse rate, Respiratory Rate, Central and Peripheral nervous system evaluation.

Ultrasound examination of the abdomen to look for evidence of upper urinary tract dilatation was done.

Five milliliters of peripheral venous blood (from the forearm/arm) was drawn for laboratory analysis, including a full hemogram, serum creatinine, blood urea and nitrogen (BUN), serum potassium, serum sodium, serum chloride, serum calcium, serum bicarbonate, serum magnesium, serum phosphate and blood gases.

Summary statistics were used to summarize and report the findings.

Ethical Approval

Ethical approval for this study was obtained from Mbale Regional Referral Hospital Research and Ethics Committee, MRRH-2023-260 and registered with the Uganda National Council of Science and Technology (UNCST). The study was conducted in compliance with the declaration of Helsinki. Informed written consent was obtained from the participants before interviewing them. Strict confidentiality was maintained when handling participant data by anonymizing the collected information. The participants provided consent to publish the information.

Results

Baseline Characteristics of Participants

The procedures were carried out between 2009 and 2018 and the ages of participants ranged between 16 and 65 years at the time of the procedure. Two of the 6 participants had stayed with the fistula for less than 5 years (1–2), while 2 participants had lived with the fistula for 6 and 9 years, one lived with it for 35 years and the other 45 years. Four participants had only one delivery and the other 2 had five and six deliveries. The indication for the Mainz II pouch procedure was an irreparable obstetric fistula for all the six participants (Table 1).

Clinical and Sonographic Characteristics

All the participants had lived with the Mainz II pouch urine diversion for more than five years (5–14), had normal body mass index (BMI), except one who had class I obesity. One participant had developed hypertension (BP=161/101), and the rest had normal blood pressure. Most participants reported night urine incontinence. Sonographic findings revealed one-sided mild vesicoureteral reflux with loss of corticomedullary differentiation. One patient had severe vesicoureteral reflux grade 4, with incidental left renal calculus (Table 2).

Biochemical Profiles of the Participants

The biochemical tests conducted included a panel of serum electrolytes (sodium, potassium, chloride, calcium, bicarbonates, phosphorous, anion gap and PH). Table 3 has been color coded to summarize key findings (red implies grossly abnormal, yellow implies slightly abnormal whereas green indicates the measurement was normal).

Table 1 Baseline Characteristics of Participants (at the Time of Procedure)

Participant No	Month and Year of Procedure	Age at Procedure/Years	Fistula Duration/years	Parity	Indication for Procedure (Diagnosis)
1	10/2014	29	2	P_{6+0}	Irreparable obstetric fistula, Type, Thimble bladder
2	05/2014	16	1	P_{1+0}	Irreparable Obstetric fistula, Type, Thimble bladder
3	09/2009	23	6	P_{1+0}	Irreparable Obstetric fistula, Type IIBa- Two failed repairs
4	09/2011	42	9	P_{5+0}	Irreparable Obstetric fistula, Type IIBb- Two failed repairs
5	06/2018	65	45	P_{1+0}	Irreparable Obstetric fistula, grade IIBb
6	08/2015	52	35	P_{1+0}	Irreparable Obstetric fistula, Type IIBb- Thimble bladder

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Table 2 Clinical and Sonographic Characteristics of Participants in 2023

Participant No	Current Age/ Years	Duration on Pouch/ Years	Clinical profile			Sonographic Profile
			BMI (Kg/m^2)	Blood Pressure (mmHg)	Urine Incontinence	
1	47	9	21.7	100/71	Night incontinence	Normal ultrasound findings
2	24	10	20.3	121/75	None	Mild reflux on the right with bilateral loss of Cortico-medullary differentiation
3	37	14	22.2	114/79	Night incontinence	Mild right Vesico-Ureteric reflux. Bilateral loss of cortical-medullary differentiation
4	54	12	21.5	115/80	Occasional night incontinence	Normal ultrasound findings Normal kidneys
5	70	5	31.5	133/69	Night incontinence	Severe right Vesico-Ureteric reflux grade four. Incidental left renal calculus
6	52	8	28.5	161/101	Night incontinence	Mild left hydronephrosis with grade 1 reflux on the left and simple renal cysts bilaterally.

Table 3 Biochemical Profiles of Participants

Item/Range	Normal Range	Patient No					
		1	2	3	4	5	6
Serum Electrolytes (mmol/L)							
Sodium (Na+)	135–150	136.8	133.7	135.5	121.7	139.1	142.3
Potassium (K+)	3.5–5.0	3.8	3.99	4.16	4.4	4.4	4.7
Chloride (Cl-)	98–109	98.6	96.5	102.3	86.5	104.6	104.9
Calcium (Ca)	2.2–2.7	1.3	2.3	2.2	2.1	2.2	2.3
PH	7.2–7.6	7.0	7.3	7.3	7.2	7.3	7.4
Bicarbonate	17–29	15.6	23.4	15.9	35.0	23.3	31.2
Anion Gap	8.0–16.0	22.6	13.8	17.3	0.2	11.2	6.2
Phosphorous mg/dL	2.4–4.6	6.5	6.2	4.4	3.7	4.2	4.3
Creatinine (Cr) µmol/L	35–97	63	64.6	60.2	94.2	168.7	98.0
Urea (µmol/L)	1.7–6.5	6.4	7.1	7.2	6.3	10.7	11.5
GFR (ML/Min/1.73m^2)	90–1500	118	142	141	74	30	66

Notes:

	Normal
	Mild deviation
	Severe deviation

Profiles of Patients Who Died After the Procedure

Patient 001

Died at the age of 17 years in 2015. She got VVF at age 15 and underwent a successful Mainz II pouch procedure 1 year afterwards. In 2015, she committed a crime over fistula associated stigma and was sentenced to civil prison for 1 year, but

shortly released for community service, where she fell ill with sepsis and recurrent constipation, underwent additional surgeries in Soroti regional referral hospital, but died in October 2015 after 2 months of hospitalization.

Patient 002

Died at 48 years in 2018. Had lived with VVF for 7 years before a urinary diversion procedure was done in 2013. Five years after the Mainz II pouch procedure, she fell ill, taken to Matany Hospital where she was diagnosed with cervical cancer, referred to radiotherapy but could not afford the cost of travel and treatment. Died one year after the diagnosis of cervical cancer.

Patient 003

Died at 38 years old, in 2018. Developed VVF in 2013 following prolonged obstructed labour, offered Mainz II pouch procedure in 2015. She improved but later developed Tuberculosis, started on treatment, but did not improve and died in November 2018.

Patient 004

Died at 17 years in 2018. Was diagnosed with bladder exstrophy at birth and had chronic urine leakages. Underwent 2 unsuccessful surgeries at early years and was later referred for urinary diversion at the age of 15 years which was done successfully in Soroti regional referral hospital. She resumed schooling, but one day, she developed severe headache and vomiting, delayed being taken to the hospital, died on the 3rd day of hospitalization.

Discussion

In this study, we aimed to assess the biochemical, sonographic and clinical profile of patients with a Mainz II pouch in rural Uganda. Most of our patients (4/6) had lived with the obstetric fistula deemed incurable for more than 5 years, with multiple attempts to repair attempts. In addition, majority of participants (4/6) carried only one pregnancy. Patients with irreparable fistulas are characterized by living long with the fistula (more than 5 years), and having carried only one pregnancy by the time of getting the fistula.[19]

Our study is among the few which assessed the long-term profiles and complications of Mainz II pouch procedure as all our patients had lived for 5–14 years after the procedure. In our study, most of the patients (5/6) reported normal BMI and blood pressure (5/6), while the most common complaint was night incontinence (5/6). This is comparable with findings by Sleemi et al.[20]

Other studies which followed the patients for 5 or more years include one in China which reported mild incontinence and no severe complications.[21] Similarly, a study in Germany which followed patients for an average of 46 months reported very good day and night time continence rates of 97% and 95% respectively[12] and Tanzania where Mainz II procedure demonstrated good outcome in terms of continence, less complications resulting improved quality of life to patients.[22]

As reported by Girgin et al, the Mainz II pouch is a preferable choice for patients who desire continent urine diversion.[17] This is a clear indication that Mainz II procedure is a viable option for irreparable fistula which should be promoted alongside other preventive measures for VVF such as maternal education on the signs, risks and complication of obstructed labor and strengthening the capacity of the health facilities to promptly respond to obstetric emergencies.

Sonographic findings in our study were normal in 2/6 patients, mild reflux in 3/6, mild hydronephrosis in one patient and severe reflux in one patient (1/6). Renal reflux is a common complication of Mainz II pouch procedure as has been observed other studies. In Ukraine, among the 94 patients who were provided with Mainz II procedure for bladder cancer and followed for late complications, 19% reported with ureteral reflux,[23] while hydronephrosis, which results from poor urine drainage has been reported as a long term complication in 5% of 98 patients who were provided with Mainz II pouch procedure in Turkey and 6% in Serbia.[24,25] China reported 6/45 patients with mild hydronephrosis among the 45 patient cohorts followed up prospectively for 6 years on average.[21] Patients who receive Mainz II pouch urine diversion need to be followed closely for anatomical changes for early detection and management before advancing into severe renal impairment.

The commonest metabolic complication for our patients was metabolic acidosis (4/6) with one having fulminant renal failure. Metabolic acidosis in patients with Mainz II pouch results from the malabsorption of electrolytes.[26] Metabolic acidosis has been commonly reported in patients who have undergone Mainz II pouch procedures.[12,24,25] It is therefore important to conduct routine yearly clinical and biochemical assessments on patients who received Mainz II procedure for early detection and management of metabolic and other complications resulting from the procedure. The hyperchloremic metabolic acidosis is routinely managed by long-term oral alkalinising agents.[25]

Our study has some limitations. The success rate in tracing the patients operated was low (11/20). This could be due to the long follow-up period spanning for close to 20 years, whereas some of the patients had stopped routine visits to the facility due to long distances to their homes. The study was not able to explore the causes of death among the patients who were confirmed dead (4/11) during the follow-up period as only verbal autopsies were obtained. We had very few patients, and therefore the study was not powered enough to conduct statistical inferences to generate the factors contributing to the successes or failures of the procedures. Despite these limitations, our study had some strengths. It is one of the few studies which assessed the profiles of patients who have lived with the Mainz II pouch urine diversion for long (more than 5 years), in Sub-Saharan setting. Most studies assessing the long-term complications of Mainz II pouch procedure are old and mainly conducted in high-income countries. Besides, most of the studies on Mainz II pouch procedure are conducted for patients who had bladder cancer, our study is therefore among the few which highlights the benefits of this procedure in addressing irreparable VVF in Sub-Saharan Africa.

Conclusion

The Mainz II pouch procedure remains a viable option for managing incurable obstetric fistulas. However, the prevalence of metabolic complications, including acidosis and renal impairment, underscores the need for routine biochemical and sonographic monitoring to ensure optimal long-term patient outcomes.

There is a need for routine yearly medical evaluation of the beneficiaries of the procedure to ensure early detection and management of the complications. Patients who are receiving the procedure need to be properly mapped and regularly contacted to limit the lost to follow-up rates and enhance their clinical evaluations and research in the future term. There is a need to design a longitudinal study to ascertain the long-term survival and complications of Mainz II pouch procedures.

Consent for Publication

All the patients provided informed written consent for publication of this manuscript.

Definition of Terms

A vesicovaginal fistula (VVF) is an abnormal tract connecting the female genital system (vagina, cervix or Uterus) to the urinary system (ureter, urinary bladder and urethra).

Fistula deemed incurable is a vesicle vaginal fistula in which there is extensive tissue destruction of the urinary and genital system that makes restorative surgery impossible. There may be a history of multiple failed attempts of restorative surgery by the most competent person in an enabling environment.

Mainz II Pouch is a detubularized segment of sigmoid colon with ureters implanted into it.

Author Contributions

All authors made a significant contribution to the work reported, including the conception, study design, execution, acquisition of data, analysis and interpretation. They took part in drafting, revising, critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest in this work.

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