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**Genital fistula among Ugandan women: Risk Factors,
Treatment Outcomes and Experiences of Patients & Spouses**

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MAKERERE UNIVERSITY



Kampala and Stockholm 2015

Cover photo: A patient with urogenital fistula in alone and isolated as she waited for surgery at Mulago Hospital fistula ward (by Justus 2013).

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Published by Karolinska Institutet and Makerere University.

Printed by AJ E-PRINT AB, Oxtorgsgatan 9, 11157 Stockholm

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ISBN: 978-91-7549-969-7

Dedicated to family and friends for the support, encouragement and understanding during this academic journey.

“Only a life lived for others is a life worthwhile”. Albert Einstein.

Genital Fistula Among Ugandan Women: Risk Factors, Treatment Outcomes, and Experiences of Patients & Spouses

THESIS FOR DOCTORAL DEGREE (PhD) AT KAROLINSKA INSTITUTET AND
MAKERERE UNIVERSITY

This thesis will be defended in public at Inghe Hall, Floor 2, Widerströmska Huset,
Tomtebodavägen 18A, Solna Campus, Stockholm
At 9.00 am on Friday 30 October 2015

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ABSTRACT

Background: An estimated 2-3 million women globally and majorly in sub-Saharan Africa and Asia, suffer from genital fistula with an annual incidence of 50,000-100,000 women. Uganda like other low-income countries is not an exception and has an estimated fistula prevalence of 2%, with western Uganda having the highest prevalence of 4% among females aged 15-49 years. The main cause is prolonged and neglected obstructed labour in more than 90% of the cases. Risk factors for fistula vary from one context to another. The consequences of fistula go beyond the individual woman and affect relatives, spouses and the community. There is limited information on lived experiences among women with fistula, their spouses, relatives and communities. With the global end fistula campaign on course, there is need for quality and evidence-based fistula prevention, treatment and social reintegration.

Objective: To determine risk factors for obstetric fistula, compare outcomes of early discharge with catheter versus late discharge after catheter removal, and explore life experiences of fistula patients and their spouses in Uganda.

Methods: From 2012 to 2015, we conducted a mixed methods study with four sub studies: A case control study (I), a qualitative study using focus group discussions (FGDs) among women with fistula (II), a qualitative study using in-depth interviews with men whose wives had fistula (III) and a randomized controlled open-label non-inferiority trial among women undergoing fistula repair surgery (IV). Four sub studies were conducted in Mulago (II-IV), Hoima (I & III), Kagadi (I) and Kyenjojo (I) hospitals. In the first sub study (I) that was conducted in western Uganda, we compared background characteristics of 140 cases (women with obstetric fistula) and 280 controls (women without fistula). In the second sub study was the Urogenital Fistula Early and Late Discharge (UFEALD) trial (IV) where we assessed the non-inferiority of early discharge (3-5 days) vs. standard 14 days (late discharge) following surgical repair of fistula in respect to proportion of women with repair breakdown between three days and 12 weeks. We pre-set the non-inferiority margin at 10%. A total of 300 patients were block randomized to two equal groups of 150 each and both groups followed up for 12 weeks. The third and the fourth sub studies were exploratory qualitative studies among women seeking treatment for fistula (II) and spouses whose wives had fistula (III) respectively. The qualitative studies were analysed using content analysis (II) and a composite narrative (III).

Results: Risk factors for obstetric fistula in western Uganda (I) were: caesarean section (adjusted odds ratio [AOR] = 13.30, 95% CI = 6.74–26.39), respondent height of 150 cm or less (AOR = 2.63, 95% CI = 1.35–5.26), baby weight of 3.5 kg or more (AOR = 1.52, 95% CI = 1.15–1.99), prolonged labour (AOR = 1.06, 95% CI = 1.04–1.08). Compared to no education, post primary level of education was protective against obstetric fistula (AOR = 0.31, 95% CI = 0.13–0.72). A total of 25% of the fistulas were due to iatrogenic injury during caesarean section.

The life experiences of women with fistula (II) were characterized by life changes, challenges and strategies to cope. The women were physically changed and challenged, lived in social deprivation and isolation, were psychologically stigmatized and depressed and their sexual life was no longer joyful. The women used both problem- and emotion-focused coping strategies to deal with the challenges. They devised ways to reduce the bad smell of urine in an attempt to avoid any further stigma, rejection and isolation. Amidst coping, they were often left alone and isolated. The women either isolated themselves or were isolated by society, including close relatives and their husbands. Generally women with fistula felt that their marital and sexual rights had been lost.

The men's experiences (III) while living with a wife who had fistula conflicted with Ugandan culture and norms of masculinity. The men's lives were greatly affected and felt 'small'. They however, persevered in the relationship sometimes changing lifestyles but also maintaining what they perceived as roles of men in this context as responsible, caring husbands and fathers. Some men married a second wife but generally viewed marriage as a lifetime promise before God, which should not end because of a fistula. Poverty, inherent love, care for children, and social norms in a patriarchal society compelled the men to persevere in their relationship amidst all challenges.

Four of the 150 (2.7%) women in the early discharge group had fistula repair breakdown compared to three of the 150 (2%) in the late discharge group (Difference [Δ] = 0.7% [95% CI = -3.4–4.9], $p = 0.697$). There were no significant differences in any of the secondary outcomes including complications. A total of 138 (92%) in the early versus 134 (89.3%) women in the late discharge groups had fistula closed and were continent and voiding normally day and night) There were no fatal complications.

Conclusions: Iatrogenic injury during caesarean section, prolonged labour, big baby (3.5 kg or more), short stature (height 150 cm or less), and low/no education are risk factors for fistula (I). Women with a fistula are challenged physically, socio-economically, psychologically and sexually. Their life is full of adjustments to cope with the stigma, social isolation, and marital sex challenges. They use both make problem- and emotion-focused coping as they deal with isolation, rejection and stigma associated with fistulas (Paper II). Like women, men whose wives have fistula face challenges as individuals but also as members of a hegemonic masculinized society (III). They portray themselves as responsible men fulfilling their culturally assigned roles as men. They cannot go away from their wives even though they feel challenged socially by the stigma associated but believe marriage is a God given role they must fulfil amidst other factors they advance for remaining with their wives like poverty and raising children. Early discharge with a catheter was non-inferior to the standard 14 days of inpatient care and for stable patients following urogenital fistula repair, we recommend a reduced period of hospital-based care of 3-5 days from the current 14 days (IV).

Key words: Genital fistula, Obstetric fistula, risk factors, experiences, early discharge, treatment outcomes, sexuality, Ugandan women, spouses, hegemonic masculinity, non inferiority, UFEALD trial.

LIST OF SCIENTIFIC PAPERS

- I. **Barageine JK**, Tumwesigye NM, Byamugisha JK, Almroth L, Faxelid E (2014). Risk Factors for Obstetric Fistula in Western Uganda: A Case Control Study. PLoS One 9(11): e112299. DOI: 10.1371/journal.pone.0112299.
- II. **Barageine JK**, Beyeza-Kashesya J, Byamugisha JK, Tumwesigye NM, Almroth L, Faxelid E (2015). “I am alone and isolated”: A qualitative study of experiences of women living with genital fistula in Uganda. BMC Women's Health 15:73. DOI: 10.1186/s12905-015-0232-z.
- III. **Barageine JK**, Faxelid E, Byamugisha JK, Rubenson B: ‘As a man I felt small’: A qualitative study of Ugandan men’s experiences of living with a wife suffering from obstetric fistula. Accepted: Culture, Health and Sexuality. DOI: 10.1080/13691058.2015.1089325.
- IV. **Barageine JK**, Tumwesigye NM, Mutatina B, Almroth L, Faxelid E, Byamugisha JK. Treatment outcomes of early versus late discharge after surgical repair of female urogenital fistula: A randomised, controlled, open-label, non-inferiority trial at Mulago Hospital, Uganda (Submitted).

These papers will be referred to in the thesis by their Roman numerals I-IV

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List of abbreviations

ANC	Antenatal clinic
AOR	Adjusted Odds ratio
BMI	Body Mass Index
EmOC	Emergency Obstetric Care
FGD	Focus Group Discussions
FIGO	International Federation of Obstetricians and Gynaecologists
FTWG	Fistula Technical Working Group
IDI	In-depth interviews
IOFWG	International Obstetric Fistula Working Group
ISOFS	International Society of Obstetric Fistula Surgeons
ITT	Intention to Treat
LIC	Low income countries
MDG	Millennium Development Goals
MOH	Ministry of Health
NGO	Non Governmental Organisation
OR	Odds Ratio
PMTCT	Prevention Of Mother to Child Transmission
POD	Postoperative day
RVF	Rectovaginal fistula
SEM	Social ecological model
TBA	Traditional birth attendant
UBOS	Uganda Bureau of Statistics
UDHS	Ugandan Demographic and Health Survey
UNFPA	United Nations Fund for Population Activities
VVF	Vesicovaginal fistula
WHO	World Health Organization

Operational Definitions

Any incontinence (Post-repair)	Any leakage following fistula repair irrespective of closure status and includes all patients with leakage due to fistula breakdown and residual urethral incontinence
Early discharge	Discharge of women with a Foley's catheter on third to fifth postoperative days following fistula repair. This was the test/intervention UFEALD trial (IV)
Fistula	An abnormal connection between two epithelial surfaces
Iatrogenic fistula	Fistula caused unintentionally by a medical worker during surgery
Late discharge	Discharge of women on 14 th postoperative day following fistula repair. This is current standard (globally) of care and control group in UFEALD trial (IV)
Obstetric fistula	A fistula resulting from the process of childbirth or its management. For this study it will refer to both urogenital and rectovaginal fistulas following childbirth
Outreach hospitals	These are hospitals that do not offer routine fistula surgeries and in this study, where Mulago staffs visit periodically to repair genital fistula, namely Hoima, Kagadi and Kyenjojo hospitals in western Uganda
Repair breakdown	Fistula hole repaired watertight with no leakage by third day post operatively starts leaking along suture line confirmed by a positive dye test and still leaks 12 weeks after surgery
Residual urethral incontinence	Any degree of involuntary leakage through the urethra following successful fistula closure
Successful closure	Fistula hole repaired watertight with no leakage along suture line confirmed by a negative dye test and remains closed 12 weeks after surgery
Urogenital fistula	This is an abnormal opening in the wall of the urinary tract connecting to the genital tract. The urinary tract: ureter, urinary bladder and urethra, while the genital tract will mean the uterus, cervix and vagina

PREFACE

In third year as an undergraduate student in the Department of Obstetrics and Gynaecology at Makerere University, I learnt that women could leak urine due to fistula when I came in contact with Madina (pseudonym), a patient with fistula. At 14 years of age she conceived and was shirked by her parents. The man who made her pregnant also rejected her and she went and stayed with her elderly, poor and frail maternal grandmother. When it was time for her to deliver, she went to a nearby traditional birth attendant's (TBA) place where she laboured for two days and delivered a dead baby. A day later, she noticed that she could not control her urine and was wet all the time. She went to a nearby dispensary and was advised to go to Mulago hospital for specialist care. Six months later, a neighbour helped with transport fare and she proceeded to Mulago hospital. On arrival, the only professor who managed the condition was away and she was given appointment to come back after 2 months. Since she had no transport she opted to remain on the ward until the only professor would come and fix her problem. It then came to examination time, and there she was to be clerked. As she narrated her story, I wondered what type of illness this was, which doctors could not treat. I did my exams and left her on the ward. Two years later she was still on the ward now as a food vendor still awaiting repair. I eventually graduated and left medical school when she had just had unsuccessful repair. Her picture remained in my minds. I read that fistula was a measure of how poor the maternal health care of a country was and that it was entirely preventable by delivery under skilled care.

In my years of practice, patients with fistula were always left unrepaired with an excuse of emergencies taking up the limited resources. Patients who were referred to Mulago remained on the ward until when they would become frustrated and discharge themselves, vowing never to come to hospital again. For the three years while I undertook the masters degree training in obstetrics and gynaecology at Makerere University, I never got the skill to repair fistula, for the teachers gave all kinds of excuses. Madina was still on the ward awaiting further repair and the famous professor had retired. When I completed the training in obstetrics and gynaecology, I volunteered to work for Medicins Sans Frontieres (MSF) in Bunia, Democratic Republic of Congo during the war. As the only gynaecologist, fistula patients haunted me. I witnessed one who had traumatic fistula after gang rape and insertion of sharp object (into her genitalia) by the rapists. Since the patient was bleeding I had no further excuse but to teach myself how to repair fistula or else she would die. I managed to close the hole with the help of a nurse reading for me step by step of repair from Primary Surgery- a textbook by Maurice King and Peter Bewes. Soon news spread that I could repair fistula and patients filled the ward. I repaired the simple ones and left the difficult ones. I then joined the campaign to end fistula and UNFPA supported me to have an attachment to Thomas Raassen who ably taught me further fistula surgery in a mentorship and coaching programme.

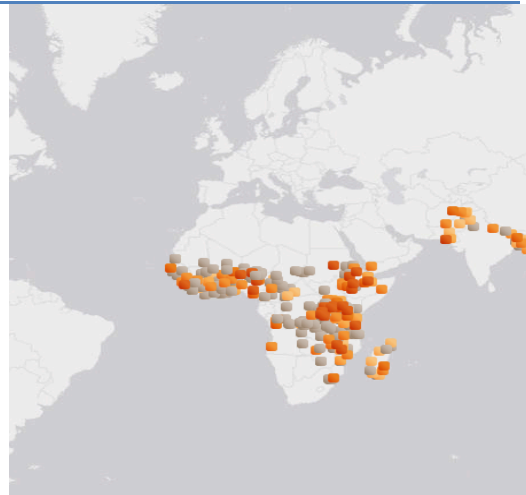
In 2005, I started a fistula unit at Mulago and since then repairs rose to more than 300 per year including Madina who had successful surgery and dignity restored in 2007. Overtime, I realized that there was need for standards but the real truth was that fistula was neglected in all aspects including research. During ISOFS and IOFWG meetings every surgeon had his or her own standards and this motivated me to carry out this project to better understand the condition especially the public health perspective and this has culminated into the work covered by this thesis.

1 BACKGROUND

Globally, the number of maternal deaths has reduced overtime from over 500,000 to 289,000 women dying from pregnancy related complications but still 99% of these deaths occur in low income countries (LICs) [1, 2]. For each maternal death, another 15-30 women suffer serious morbidities one of which is genital fistula, a preventable condition [3]. A fistula is an abnormal communication between two epithelial surfaces [4, 5]. A genital fistula is an opening from the urinary tract or rectal wall connecting to the genital tract, through which urine and/or faeces continually leak. A genital fistula is referred to as an obstetric fistula if it results from the process of labour or its management [6]. Most of the urogenital fistulas in LICs are due to obstetric causes mainly following prolonged and neglected obstructed labour [7-9]. The fistula due to obstructed labour occurs when the baby's head gets impacted in the birth canal for long, pressing the bladder or rectum onto the bony pelvis leading to tissue necrosis (death). The dead tissue eventually sloughs off, creating one or more holes through which urine and/or faeces leak uncontrollably [7-10]. In most cases the baby dies during the labour process, leaving the woman incontinent of urine and/or faeces, bearing the sadness of the stillbirth, and often abandoned by the husband and the society [7]. In addition to the sorrow as well as the shame of loosing a child, the constant smell of urine and/or faeces that the fistula entails, further humiliates the woman by driving away the husband, family and friends [11].

1.1 EPIDEMIOLOGY OF FISTULA

Globally, it is estimated that 2-3 million women are living with fistula [7, 12, 13]. Whereas genitourinary fistulae occur worldwide, most of obstetric fistulae occur in LICs as demonstrated by the WHO fistula map (Figure 1). It is estimated that between 50,000-100,000 new cases occur each year [7, 12]. The incidence is poorly studied and the available rates are mainly those reported in hospital based studies [4]. In sub-Saharan Africa alone, an estimate from a population based survey of severe obstetric morbidity suggested that at least 33,000 new cases occur each year [14, 15]. Women in LICs suffer from fistula because obstetric care is either unavailable, inaccessible, underutilized or of low quality [3, 16]. In Uganda, the actual prevalence of this condition remains unknown, though the 2006 Uganda demographic and health survey (UDHS) shows that 2.64% of Ugandan women had ever experienced symptoms of obstetric fistula and in 2011 UDHS the prevalence had gone slightly down to 2% among women aged 15-49 years [17, 18].



Global fistula prevalence map

Global fistula surgical activity 2013

Figure 1: Global fistula prevalence and surgical activities. Source: WHO and Direct Relief International [19].

1.2 RISK FACTORS AND CAUSES OF FISTULA

Several social, cultural and health system factors contribute to the prevalence of obstetric fistula in LICs [4]. These factors are context bound and through observations by surgeons, some of the identified factors are: lack of emergency obstetric care, child marriage associated with early pregnancy, severe forms of female genital cutting, gender discrimination, poverty, malnutrition and poor health services [20, 21].

Maternal age seems to have a role in development of fistula and patients are reported to be less than 20 years of age when they get fistula. This seems to vary from country to country with a mean age of 22 years in Ethiopia and 28 in Nigeria [22-24].

Other factors that have been cited include prime parity, prolonged labour, stillbirth delivery and poor social economic status [23, 25-27]. In Ethiopia, more than 60% of the women are primiparas when they develop fistula with average labour duration of 3.9 days. The rate of stillbirth varies from country to country with up to 93% among women who sustain fistula in Ethiopia [23, 27]. In Ethiopia 92% of the women who sustained obstetric fistula were illiterate [23, 27]. Similar trends of illiterate women were observed by Wall et al in Nigeria and Raassen in East Africa series with 78% and 42% of women with fistula having no formal education respectively [28, 29].

The main risk factor is thought to be lack of access to appropriate emergency obstetric care. Farhang (1983) found that prolonged obstructed labour was the main cause of fistula in Sokoto Nigeria where most of the deliveries were at home [22]. Access to appropriate obstetric care is compounded by poverty and the dynamics in the health care system including the cost of a caesarean section and availability of service providers [30]. The other risk factors such as young mothers, first pregnancy and cultural practices have been found not to cause fistula in the high-income countries where emergency obstetric care is available [6, 30, 31]. These factors are,

however, very important to consider when targeting services at those women in LICs who are unlikely to obtain timely emergency obstetric care [6, 30, 31].

These above factors in combination with a delay in seeking adequate maternal care often lead to obstetric fistulae. Reasons for not seeking skilled care are various and depend on aspects such as educational level, socio-economic status, culture as well as accessibility to functioning health care facilities [28]. The delays in seeking skilled care during prolonged and obstructed labour compounded by the delay to perform a caesarean section, a key intervention, eventually lead to formation of a fistula. Thaddeus and Maine (1994) developed a model that emphasizes the importance of mapping the factors that may cause delays in different phases of seeking maternal care [32]. In the model, originally developed for maternal mortality, Thaddeus and Maine divided the delay in seeking skilled care into three different phases; delay in the community making the decision to seek care (phase one), identifying and reaching medical facility (phase two) and receipt of adequate and appropriate treatment (phase three).

Socioeconomic and cultural factors have an impact on the decision to seek care. Communication systems and accessibility of health care facilities contribute to the delay in both phase one and phase two whilst the quality of health care might cause delays in either phase one or phase three. These three steps are not independent, it is clear that expectations of delay in transport, lack of staff or low quality of the care provided will affect the decision to seek health care. The third delay is the most crucial to address in the work of improving maternal health. Improving the two first phases would be useless without a well-functioning health care facility [6, 32].

1.3 AETIOLOGY AND PATHOGENESIS OF GENITAL FISTULA

Prolonged and neglected obstructed labour is the predominant cause of obstetric fistula [7, 10, 23, 25]. Other obstetric causes include destructive deliveries, caesarean section with or without hysterectomy, and symphysiotomy. Non obstetric causes include traditional practices like female genital cutting or Gishiri cuts, sexual violence especially in war-torn countries, congenital abnormalities like ectopic ureters, cancers like cancer of cervix, elective gynaecological operations like hysterectomy, and radiotherapy [4, 8]. Other causes of fistula are infections like Granuloma Venereum, Tuberculosis, HIV and Measles [33]. Fistula due to obstructed labour occurs when the baby's head gets impacted in the birth canal for long, pressing the bladder or rectum onto the bony pelvis leading to tissue necrosis (death). The dead tissue eventually sloughs off, creating one or more holes that leak urine and/or faeces uncontrollably [7-10, 34].

1.4 TREATMENT OF FISTULA

Fistula has existed since ancient times, with the earliest evidence provided by remains of Queen Henhenit, wife of Egyptian Pharaoh about 2050 BC [35]. Between seventh and ninth century attempts by European surgeons to repair were fruitless with repeated residual defects and no successes leading to the conclusion that fistula

was impossible to close and therefore a life long illness [36]. A fistula was referred to as “catastrophic complication of childbirth “ in the 19th century and fistula patients as “social outcasts” for there was no cure available [37]. The surgical treatment of the three enslaved women (Anarcha, Betsy and Lucy) with fistula by Marion Sims paved way for new surgical techniques [37, 38]. Sims operated Anarcha’s vesico-vaginal (VVF) and recto-vaginal (RVF) fistulas 30 times before cure[37]. It was not until 1852, when Marion Sims published his fistula repair procedure following seven years of experimentation, that successful fistula surgery started[36].

Today the main treatment of fistula remains surgical closure when conservative treatment using Foley’s catheter has failed [39]. Fresh, small fistulae (less than 2 cm) can be treated by continuous bladder drainage with a Foley’s urethral catheter for up to 30 days [6, 39]. There are generally three routes or approaches for the fistula surgery; trans-abdominal, trans-vaginal or a combination of both [8, 40]. Today the trans-vaginal route is the most common and also the most comfortable method for the patients [4, 6]. With the trans-vaginal approach there is an advantages of low postoperative morbidity, short postoperative recovery, minimal blood loss and short operation time. Trans-abdominal surgery is less common and is applied for complex fistulas that need combined routes and also for fistulas, which cannot be accessed vaginally like iatrogenic fistula following caesarean section and gynaecological surgery [4, 6]. Following surgical closure of a fistula, it is standard practice that patients spend at least 14 days in hospital for strict catheter care [4, 41]. The practice of continuous bladder drainage promotes healing by preventing distension of bladder and tension on suture line, which may result in repair failure [4, 41].

In Uganda, fistula care has been integrated in the reproductive health policy at all levels of care [42]. Few hospital are able to carry out fistula repairs, and most of the patients are operated during surgical camps that are periodically organised by local and expatriate surgeons [42-44]. All patients are treated following WHO guidelines [6]. The women are examined before surgery commences to confirm the diagnosis and the fistula is classified according to the Waaldijk classification [45]. Surgery is conducted and the fistula is confirmed closed (water tight closure) by a negative dye test conducted upon the completion of the surgery, and a Foley’s catheter is then introduced for continuous bladder drainage.

1.5 EARLY DISCHARGE OF SURGICALLY TREATED PATIENTS

With the existing backlog, reducing catheter duration to ten days could increase the number of fistula patients undergoing repair by 30% but early discharge would increase it even more [10]. Improvements in surgical technology, analgesia and anaesthesia along with an increasing pressure on hospital resources, have led to a decline in the length of time patients spend in hospital [46]. It has been observed that patients who have undergone bladder surgery like prostatectomy, repair of hypospadias and bladder cancer are satisfied by early discharge with a catheter and results are not negatively affected. This has, however, not been tried in fistula care [47-49]. Reducing the hospitalization time by discharging patients early with a

catheter would increase the number of operated patients hence a step in handling the backlog [7].

Hysterectomies are being done as day cases and generally urology patients are discharged early and with similar satisfaction and quality of life like those who stay longer in hospital [46, 50, 51]. Levy et al (2005) showed that incorporating a protocol based on scientific evidence into the management of surgical patients facilitated safe outpatient vaginal hysterectomy in a majority of patients, and this optimized management may save up to 25% of the cost for these procedures [51]. It must be noted that vaginal hysterectomy is a more extensive surgery compared to fistula surgery though the tissues of women undergoing vaginal hysterectomy are generally healthier.

In a study by Marotte and Smith [52], extra-vesical ureteral re-implantation for the correction of primary reflux was done on an outpatient basis in the majority of children without an increase in morbidity. The length of stay for all children ranged from 5 to 30 hours. When comparing the outpatient surgical group with those hospitalized for one night, there were no significant differences in age, operative times and technique (unilateral versus bilateral) or complications. Other studies in paediatric and adult urology have demonstrated that good results can be achieved with early discharge [46, 48, 53, 54].

1.6 EXPERIENCES OF WOMEN WITH FISTULA

In a UNFPA fistula evaluation, women were asked about non-clinical problems related to obstetric fistula. They were either ashamed to go out of their homes, rejected by their families and community members or stopped from working. Relatives were helpful and supportive in some cases and some women had remarried and got more children [55, 56].

In a Tanzanian study [56], women explained that fistula had separated them from their husbands because it limited their ability to fulfil marital roles. Some women were forced to go back to their parents, and for those who were not divorced, they could not live in the same house or room as their husbands. Failure to control urine and/or faeces, maintain marriages, bear children, or participate in social and economic activities makes fistula patients lose their identity as women, wives, friends, and community members.

Living with fistula is associated with experiences of multiple losses that range from physical, emotional to social. These experiences have a negative impact on woman's identity and quality of life. Despite that the majority of women with fistula lose their babies during delivery, women are unaware of the possibility that after fistula repair they may be able to be mothers again [5, 56, 57].

Women living with fistula view their condition as either a will of God or even a punishment from God. These women are stigmatized and live on the margins of

society due to isolation because of the smell, embarrassment, and fear of ostracism from the community. Women with fistula also have no gainful economic activities and hence they are financially dependent on others. They are perceived as unclean and usually given less priority for hospital admission due to limited number of beds and reproach related to the smell of urine. It is clear that these women have to cope with pain, discomfort, shame, depression, isolation, and stigma from the community, as well as from their own spouses and families [58, 59].

1.7 MALE INVOLVEMENT IN REPRODUCTIVE HEALTH

Globally, male partner involvement in reproductive health including antenatal care, delivery and postnatal care remains a challenge to safe motherhood programmes [60, 61]. Despite the fact that there is limited research on the role of male involvement during pregnancy, delivery and postnatal care, there are promising links to beneficial effects [62-65]. Some studies have demonstrated that prenatal male involvement is associated with beneficial health outcomes such as; higher first trimester antenatal clinic (ANC) visits and reduction in low birth-weight infants [62, 65, 66]. Often family members, and not the woman alone, make decisions about obstetric care. In many cases men control the cash reserves, or their permission needs to be obtained for obstetric care [67].

In Uganda, male attendance in ANC is a fairly new research field. The available estimates depict a low attendance (3% in 2006) but are based on health facility information systems that monitor male attendance in the prevention of mother to child transmission (PMTCT) programs [68]. In the study that investigated the level, perceived benefits and factors associated with male partner attendance in ANC in a peri-urban community in Uganda, Tweheyo et al (2010) found that men who were knowledgeable of ANC services, obtained health information from a health worker, and whose spouses utilised skilled delivery at last pregnancy were more likely to accompany their spouses at ANC, unlike those who wanted to have more children and lived more than 5 km from the health facility. Perceived benefits of attending ANC were: HIV screening, monitoring foetal growth, and identifying complications during pregnancy [69].

Byamugisha R and others [70] found that educated men were more likely to accompany their spouse to antenatal clinics and also identified the main barriers for male involvement in the PMTCT of HIV programme in eastern Uganda. The barriers included health system, socio economic, and cultural factors. The fact that men were not catered for in the clinic setup, the rudeness of service providers, poverty and delivery being seen as women's affairs were hindering factors. A similar study in Kenya found that male partners lack of knowledge of complications associated with delivery, cultural beliefs, high fees charged for deliveries at health facilities, and "un-cooperative" health workers were major contributing factors to low male partner involvement in child birth activities [71].

1.8 GENDER AND OBSTETRIC FISTULA

Gender inequalities persist in regions where obstetric fistula occurs and a woman's value in society is based on her ability to fulfil her role as a wife and mother [72]. The girls marry in their teens, a fact that is condoned by some cultures and religions. The men control the financial resources and women often have to ask for permission from husbands or mothers-in-law to seek health care even when in labour, a situation that creates unnecessary delays especially when obstructed labour eventually sets in [59, 72]. The majority of obstetric fistula patients are young and have no or low level education [7, 59, 73]. Gender based education inequality exists in sub-Saharan Africa and Asia, and this often leaves women with limited employment options and hence financial dependency on husbands [72]. This gender power imbalance also has a negative effect on women's ability to influence sexual and reproductive health behaviours. The girls are victims of gender norms and are less likely to participate in health care decision-making, a situation that diminishes their ability to challenge patriarchal powers that control their sexual behaviour [72].

Whereas efforts to prevent obstetric fistula focus on providing women with skilled obstetric care especially during delivery, there is need to focus on secondary efforts to prevent obstetric fistula [74]. These efforts should target factors that are barriers to access of skilled care e.g. low level or no education, transport to the hospital, and funds to pay for obstetrical care services. However, many women even when facilitated to access care, still attempt to deliver in the villages with a TBA, often with disastrous results, an indicator of a missing link in the health care seeking process [72, 74].

Experts in obstetric fistula assert that the low status of women is a major factor in the occurrence of obstetric fistula and call for the empowerment of women, though no studies have specifically looked at gender power imbalance in relation to childbirth practices as a risk for obstetric fistula [75]. Perception of gender power and its influence on women with obstetric fistula therefore need to be studied, beginning with qualitative studies that examine the perception and experience of gender power imbalance in the women affected [72, 74, 75]. This is one important aspect that I have tried to elucidate in this thesis. It is important to note, however, that addressing women empowerment will only be complete when men are involved [72]. It is critical for fistula programmes to target men's attitudes and behaviours, including increasing communication with their partners on sexual reproductive health and rights issues [76]. Gender imbalance is a clear outcome of broad underlying social constructs, including economic, educational, legal, as well as cultural norms especially in LICs [74]. Systems that include measures to reduce poverty and enhance economic opportunities, assure access to education, and promote equal rights for women are ultimately needed to overcome gender inequities that leave so many women vulnerable to obstetric fistula and other devastating childbirth outcomes [74].

1.9 EXPERIENCES OF SPOUSES OF WOMEN WITH FISTULA

There are hardly any studies that have specifically studied husbands of women with fistula. Literature mainly points out the fact that women are divorced, stigmatized and socially rejected [8, 57-59]. In Tanzania [56], there was consensus among the husbands that a man who continued to live with his wife after she had developed fistula and were leaking urine had to have another woman, and that the wife should understand and accept this. Stigma surrounding the problem of fistula contributed to the husbands' decision to abandon their wives. Some husbands reported being ridiculed in the community. This experience underscores the importance women place on keeping their marital status and of having children. There is therefore need to study the experiences of spouses of women with fistula in order to involve the men in care and rehabilitation as well as prevention of fistula.

1.10 GLOBAL CAMPAIGN TO END FISTULA

The UNFPA-led campaign to end fistula was launched in 2003 with the objective to make fistula as rare in LICs as it is in middle/high income countries [77]. This was in response to a multi-country study that revealed a critical need to lower the incidence of fistula, to treat a growing backlog of cases, and to raise awareness of this severely neglected health and human rights tragedy [78]. The campaign brings together partner agencies at global, national and community levels [79]. The partners range from human rights organizations to research and medical institutions, surgeons and other health care providers, and donors. In addition, the campaign has enabled policymakers, health officials, affected communities and individuals to initiate innovative joint projects, forward-thinking strategic directions, heightened advocacy, and knowledge generation related to obstetric fistula. More than 50 countries are involved. There are an increasing number of MOH-led national working groups in addition to the international working group to enhance coordination and partner collaboration [77, 79]. The campaign focuses on three key areas of intervention: prevention, treatment and social reintegration in addition to raising awareness about gaps in maternal/new-born health services and underlying drivers such as socioeconomic, gender and other forms of inequality [77]. The activities of the campaign are presented in the panel 1.

Highlights from the campaign to end fistula

More comprehensive services are now offered for fistula prevention and treatment, and thousands of the poor and vulnerable women and girls have regained their dignity from the campaign activities. There is a gradual shift from fistula camps to on-going and holistic fistula services in strategically selected hospitals. In 18 countries fistula survivors are involved in the community sensitisation to identify, help other women with fistula, and advocate for improved maternal health (fistula advocates or ambassadors). Partners have helped put in place a comprehensive fistula map that was launched in 2012 and tracks repair services in more than 150 hospitals in 40 countries. From the map, an enormous treatment gap still exists e.g. only 14,000 women globally were operated in 2010 despite the known backlog and annual incidence. The campaign has also developed vital tools including the FIGO-led competency based training manual for fistula surgeons, the fistula costing tool, and the fistula kits (instruments and supplies). In terms of advocacy, the campaign has targeted policy makers, health professionals, media, and the general public with specially designed messages. United Nations has fully embraced this and gazetted May 23rd as fistula day since 2013. The General Assembly's social, humanitarian and cultural committee has adopted a resolution in 2012 on "supporting efforts to end fistula" with support from 168 co-sponsors from all regions globally. The resolution aimed at accelerating progress towards achieving MDG 5, reducing maternal death and eliminating obstetric fistula, in addition to urgent need to address child marriage, raise awareness and intensify actions towards ending obstetric fistula.

Panel 1: Highlights from the campaign to end fistula. Source UNFPA [77] [79]

1.11 HEALTH CARE SYSTEM IN UGANDA

Modern health care in Uganda started in 1897, with the opening of Mengo Hospital by Dr. Albert R Cook and lady Catherine Cook. These later initiated training and expansion of western medicine in the rest of the country through missionary work and the colonial government [80]. By 1961 when the British colonial government created MoH, there were 27 hospitals serving the 7 million population of Uganda. Uganda got independence from Britain in 1962 and soon after 22 new hospitals opened. With a total of 49 hospitals, Uganda was making strides in the health care system but this was short lived by the decline that followed two decades of rebellions that started in the 1970s, which left the health system almost grounded [80].

In 1986 when the current government took over through a rebellion overthrowing the Obote government, the new government had to re-embark on rebuilding the infrastructure and hence adopted a decentralized system that is still growing with the structure illustrated in table 1. Both management and service delivery are decentralized an 72% of the households are within 5 km of health facility, through a deliberate effort by government to build new health centres and rehabilitation of the existing dilapidated facilities [81].

Table 1: Structure of the Ugandan health system

Health level	Location	Health Cadre	Service offered at each level	Population served	Total facilities
H/C I	Village	CHWs	Community link to formal health system	1,000	0
H/C II	Parish	Nurse	Outpatient and community outreach	5,000	3,006
H/C III	Sub-county	Clinical Officer	Basic: preventive, curative, diagnostics and maternity care	20,000	1,082
H/C IV	County	Medical Officer	Maternity care, inpatient care, surgery, blood transfusion and laboratory services	100,000	190
General Hospital	District	Medical Officer	Preventive and curative, maternity care, Inpatient health services, surgery, blood transfusion and medical imaging services	500,000	114
RRH	Regional	Specialist	Comprehensive specialist services in addition to services provided by general hospitals	3,000,000	13
NRH	National	Specialist	Comprehensive super specialized services + all services provided by regional referral hospital.	30,000,000	2

H/C=Health centre, CHWs=Community Health Workers, RRH=Regional Referral Hospital, NRH=National Referral Hospital.

Source: Health sector strategic and Investment plan (HSSIP) III [81], Uganda Health system assessment 2011[82]

In addition to government facilities, there is a flourishing health care service run by: private not for profit facilities (faith based), private medical practitioners, and traditional complementary practitioners (herbalists, bone setters, TBAs, etc., who tend to be the first contact with the patients before they access the formal health care system) [81]. The private sector provides about 50% of the health care services as demonstrated by 2010 structure when 4,394 public and private health facilities in the country existed (Table 2)

Table 2: Health facilities in Uganda

Facility level	Government	Private not for profit	Private for profit	Total
Hospitals	64	56	9	129
HC IV	164	12	1	177
HC III	832	226	24	1,082
HC II	1,562	480	964	3,006
Total	2,622	774	998	4,394

Source: Adapted from HSSIP III [81].

1.12 MATERNAL HEALTH IN UGANDA

Uganda has a total fertility rate (TFR) of 6.2 children per woman [18]. Education and wealth have a marked effect on fertility and mothers with no formal education have on average of three more children than women with secondary or higher education [18]. Similarly, women in the lowest wealth quintile have almost twice as many children as women in the highest wealth quintile [17]. Marriage among young girls is a common practice, with more than 50% of girls married by the age 18 years (median age at marriage is 17.9 years). The median age at first birth is 18.7 years [17, 18]. Health care utilization is still low with 57% of the deliveries occurring in a health facility and only 56% of the women in western Uganda giving birth with a skilled birth attendant [18]. Though there seems to be significant increase in the proportion of women delivering under skilled attendance and in health facilities, the maternal mortality ratio was slightly higher at 438 per 100,000 live births in 2011 compared to 435 in 2006 [17, 18]. The caesarean-section rate in Uganda is 3.1% and this is considerably below the rate of 5-15% recommended by the WHO [17, 60]. The unmet need for caesarean section could be explained by contextual factors like women preferring to deliver with a TBA, workload in the facilities providing emergency obstetric care (EmOC) and the skills of those providing the services. Young medical officers mainly perform the caesarean sections for the gynaecologists are few and unevenly distributed as demonstrated in table 3. Married women in Uganda do not often make decisions on their own and only 60% married women participate in decisions concerning their own health care and the rest have decisions to seek care made by their husbands and relatives [18]. Obstructed labour, which is the commonest cause of female genital fistula, is the second direct cause of maternal mortality (22% of maternal deaths) in Uganda [83].

Table 3: Distribution of obstetricians and gynaecologists in Uganda in 2014

Work place	Number
National referral hospital	55
Regional referral	27
District hospitals	11
Private not for profit	29
Private for profit	12
Others (MoH, NGOs, abroad)	56
Total	190

Source: ISOFS 2014 [84]

1.13 FISTULA CARE WITHIN THE UGANDAN HEALTH SYSTEM

The MoH in Uganda recognizes obstetric fistula as a silent morbidity. This has resulted into a national fistula technical working group (FTWG), which has put an obstetric fistula national strategy aimed at eliminating fistula. Obstetric fistula has also been incorporated in the reproductive health policy and fistula care is provided in an integrated fashion at all levels of care. Despite this policy, very few units do carry out routine fistula repair and most of the patients are therefore worked on in surgical camps organized by local and expatriate surgeons [42-44].

The number of women suffering from fistula in Uganda is estimated at 200,000 and about 1,900 new cases occur each year [85]. The Uganda MoH led FTWG has put in place a fistula strategy based on three identified priorities of prevention, treatment, and re-integration. Under this strategy all the health care service levels have been assigned a specific role based on the identified priorities as shown in Table 4.

Table 4: Task distribution of fistula care services by health care level in Uganda

Level	Fistula care tasks
HC I (VHT)	Case detection, awareness and community mobilisation
HC II and III	Prevention, case detection, follow up and referral
HC IV	Prevention, case detection, follow up and referral
General Hospitals	Simple fistula repairs, monitoring
District Health Office	Building appropriate facility, administrative and multi-sectoral capacity to adequately address obstetric fistula
Regional Referral Hospital	Complex fistula repairs, out-reach, training and technical supervision
National Referral Hospital	Repair of very complex fistula, training and technical supervision
Ministry of Health	Set rights and gender based policy framework, set standards of clinical care and training programs, developing centres of excellence, input with supplies, equipment and training.

Source: Uganda National Obstetric Fistula Strategy [85]

1.14 THEORETICAL FRAMEWORK

This thesis uses the socio-ecological model (SEM) to explain the risk factors for obstetric fistula (I), the experiences of women living with fistula (II), the experiences of spouses living with a wife with fistula (III) and efficacy and acceptability of early discharge with a catheter following surgical repair of urogenital fistula (IV). Within the social ecological framework we nest stigma and coping theories and the hegemonic masculinity to explain the experiences of women with fistula (II) and that of the men whose wives have fistula (III) respectively.

1.14.1 Social Ecological Model (SEM)

The SEM is a theory-based framework for understanding the multifaceted and interactive effects of personal and environmental factors that determine behaviours[86, 87]. The theory hypothesises that it is the interplay of different contexts in which people live that determine health outcome in an individual's life[86]. The SEM model is composed of five nested, hierarchical levels[87]: individual, interpersonal, community, organizational, and policy environment (figure 2). The SEM framework recognises that health experiences and outcomes are often influenced by factors situated within and beyond the individual in this case a woman with fistula[86, 88]. Implicit within this model is the concept of a dynamic interaction between the various factors whose equilibrium ultimately defines the overall health experiences[89], in this case of living with fistula.

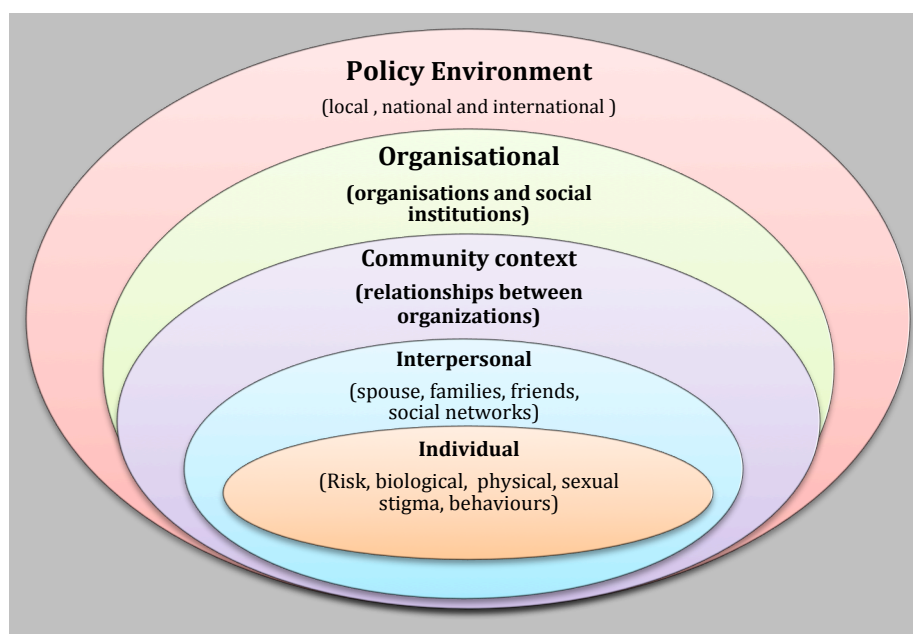


Figure 2. The Social Ecological Model, Source: Modified from Centers for Disease Control and Prevention (CDC)[90].

In table 5, we provide a brief description of each of the SEM levels in relation to our study. Public health prevention and control programs use a combination of interventions at all levels of the model [91]. However, in this thesis we concentrated mainly on the individual, interpersonal and community context levels and less on organisational and policy environment that we hope to address using the rest of the data collected that we have not included in this thesis.

Table 5. Our study fitted in the social ecological model (SEM)

SEM Level	Description
Individual	Characteristics of an individual that influence behaviour change, including risk factors (Biological, socio-demographic and physical factors), gender, age, religious identity, Marital sex, economic status, values, life goals and expectations, stigma, and coping (I-III)
Interpersonal	Formal (and informal) social networks and social support systems that can influence individual experience, including family, spouse, friends, peers, religious networks, customs or traditions. This also extends to support, communication, resources and stigma influence (II-III)
Community	Relationships and informal networks within defined boundaries: built environment, community associations, stigma, community leaders, businesses, and transportation. (II-IV)
Organisational	Organisations or social institutions with rules and regulations for operations that affect how, or how well, for example, reproductive health services are provided to an individual or group. This also included social cultural context, religion and gender norms including masculinity (I & IV)
Policy Environment	Local, national and global policies. This included health system issues including infrastructure, knowledge and skills gap (I & IV)

1.14.2 Stigma and coping

We used stigma theory (**II**), as described by Goffman [92], and the coping theory by Lazarus and Folkman [93], to discuss the experiences of women when they live with fistula. Stigma was used with regard to the way women perceived their lived experiences. We elucidate the central question of interpreting what is at stake for a stigmatised woman living with a fistula in Uganda. The paper also explores the way women coped in their daily lives with this stigmatising condition.

Goffman defines stigma as “an attribute that is significantly discrediting” [92]. Within the social process, a stigmatised person possesses an “undesirable difference” or “deviance” [92]. Stigma is a constantly changing social process that occurs when five interrelated components converge: namely “labelling”, “stereotyping”, “separation”, “status loss and discrimination” and the playing out of “social and political power” [94]. Discrimination can be individual, structural or self-imposed [94, 95]. Anthropologically, the concept of stigma remains empty and decontextualized if not filled with meaning from people’s lived experiences [96]. Stigmatisation is a pragmatic response to “perceived threats, real dangers, and fear of the unknown” [97] and can either be enacted or felt. Enacted stigma refers to the unfair treatment of others towards the stigmatised person, including discriminatory attitudes and acts of discrimination; whereas felt stigma refers to the stigmatised

person's internal feelings of shame (self-stigma) and fear of discrimination (perceived stigma) [98].

Coping occurs in response to a stressful situation and is usually initiated by activities or changes aimed at maintaining one's mental health and emotional wellbeing [99]. Lazarus and Folkman [93] developed a measure called "Ways of Coping", which consists of predicates, each of which portrays a coping thought or action that people engage in when under stress [99]. Two general types of coping are problem-focused coping and emotion-focused coping [93]. Problem-focused coping is aimed at problem solving or the effort to alter the source of stress, while emotion-focused coping is aimed at reducing or managing the emotional distress associated with the situation. Most stressors elicit both types of coping, but problem-focused coping predominates when people feel that something constructive can be done; emotion-focused coping, on the other hand, predominates when people feel that the stressor is something that can be endured [93, 99].

1.14.3 Hegemonic masculinity and Ugandan Patriarchal Society

We used the concept of hegemonic masculinity (III) to explain the experiences of men whose wives had fistula and this was further discussed based on the patriarchal norms of the Ugandan culture [100-102]. Hegemonic masculinity was first proposed in the early 1980s by Connell and has since been widely used but also heavily critiqued [100]. Hegemonic masculinity describes the normative behaviours and practices that allow for male dominance over women [101]. This form of masculinity usually embodies the most honoured way of being a man in a certain cultural setting, which can be a small community or a larger society, and it differs over time [100, 103, 104]. Hegemonic masculinity is the ideal that men measure themselves against and are also measured against by other men [104, 105]. Masculinity is a collective gender identity with a set of behaviours that most men are encouraged to exhibit, which is fluid and socially constructed rather than a natural attribute [102]. This identity includes demonstrating virility and physical and emotional strength while denying weakness. Ideals of masculinity define the means of achieving manhood and men often exaggerate elements of their masculinity to gain approval [102]. Men who cannot live up to the expected gender role develop alternative, non-hegemonic masculinities [100]. In Uganda, hegemonic masculinity encompasses marriage and fatherhood, being a provider for the material needs of the family, offering physical protection and exercising control over one's wife and children [106]. In paper III, we use the concept of hegemonic masculinity and other masculinities to analyse and discuss how living with a wife who has fistula affects men's understanding of themselves as men and how they cope with the challenges and new demands placed on them.

1.15 PROBLEM STATEMENT AND STUDY RATIONALE

There is need for studies to monitor trends in fistula numbers in addition to research focusing on identifying best approaches in the care of fistula patients and impact of existing strategies [107]. The stigma associated with fistula make the patients to live in a state of denial and hiding from the public [56, 108, 109]. The physical, psychological, socio-economic and sexual consequences of fistula to the patients and spouses are neither clear nor well documented in Uganda. It is not known how living with a fistula impacts holistically on the woman and her husband's life. For successful fistula prevention and re-integration policy and programs, there is need for information regarding the challenges encountered by patients, spouses, relatives and communities. Whereas some men stay with their wives, even when they have fistula, others separate or divorce [7, 56, 109]. Literature is silent about extent of involvement of husbands in the care of their spouses with fistula and how fistula impacts on life of the male partners. In addition, there is generally lack of local or international universally accepted standards and guidelines in the care of fistula patients, with few clinical trials conducted to adduce evidence. These knowledge gaps calls for research in the care of fistula patients from prevention, treatment and reintegration.

This thesis focuses on four information gaps concerning genital fistula prevention and treatment in a low resource setting. The gaps investigated are: risk factors for fistula in Ugandan context (**I**), life experiences of women with fistula (**II**), experiences of spouses of women with fistula during the ordeal of living with fistula (**III**) and the non-inferiority of early discharge with a catheter versus late discharge (after 14 days and current standard) in terms of proportions of women with repair breakdowns 12 weeks after fistula surgery (**IV**).

The findings in this thesis have practice, policy and research implications regarding the prevention and treatment of fistula in Uganda and globally. The results address the knowledge gap in understanding the women at risk for fistula in western Uganda, how fistula impacts on life of women and their spouses and whether early discharge after surgery influence treatment outcomes. Early discharge or home based care of operated fistula patients may help in maximizing utilization of the limited resources (space, human and material) and this is crucial in handling the high patient backlog. The results inform reproductive public health policy on the fistula client oriented and culturally sensitive issues that may help in designing intervention programs for prevention of fistula, rehabilitation and re-integration of women affected based.

2 AIM AND OBJECTIVES

2.1 GENERAL AIM

To determine risk factors for obstetric fistula, compare outcomes of early discharge with catheter versus late discharge after catheter removal, and explore life experiences of fistula patients and their spouses in Uganda.

2.2. SPECIFIC OBJECTIVE

The specific objectives were:

1. To determine risk factors for obstetric fistula among women in western Ugandan **(I)**.
2. To explore the experiences of Ugandan women living with genital fistula in order to understand how their lives are affected and how they cope with the condition **(II)**.
3. To understand how fistula affect the men's lives, by exploring how the men describe and explain their situation when living with a wife having a fistula **(III)**.
4. To establish whether the treatment outcome of early discharge with a catheter (3-5 days) was non-inferior to discharge after 14 days of inpatient care in terms of the proportions of women with fistula repair breakdown 12 weeks after surgery **(IV)**.

3 METHODS

3.1 SUMMARY OF METHODS

The studies used mixed methods with both quantitative and qualitative components. In table 6, I present a summary of the methods used in order to answer the different research questions.

Table 6: Summary of the study methods in this thesis

Domain	Research questions	Design	Methods	Paper
Risk factors	What are the risk factors for obstetric fistula in western Uganda?	Case control	140 women with fistula (cases) and 280 without fistula (controls). Interviewer administrated questionnaire, multivariate analysis of background variables.	I
Living with fistula	What are the life experiences of women with genital fistula?	Qualitative (FGDs)	Purposively selected 56 women in 8 FGDs, analysed using content analysis	II
	What are the life experiences of spouses of women with genital fistula?	Qualitative (IDI)	16 IDI with husbands living with wives who have a genital fistula. Narrative analysis.	III
Treatment of fistula	Regarding treatment outcomes, is early discharge with a catheter non-inferior to discharge after 14 days (standard) inpatient care following fistula surgery?	Randomised, controlled, open-label, non-inferiority trial	Following surgical closure of fistula, block randomized 300 women to early (3-5 days) vs. late discharge (14 days), 150 women in each group, primary outcome was proportion of women with fistula breakdown by 12 weeks of follow-up. Analysis by both ITT and per-protocol and results (risk difference) compared to predefined margin of 10%.	IV

As illustrated by the schema (Figure 2) studies in this thesis were conducted at different levels in the natural history of fistula from risk factors to fistula formation, living with fistula, treatment and finally reintegration. Each of the four papers addresses a particular period in the natural course of developing and living with a fistula including treatment.

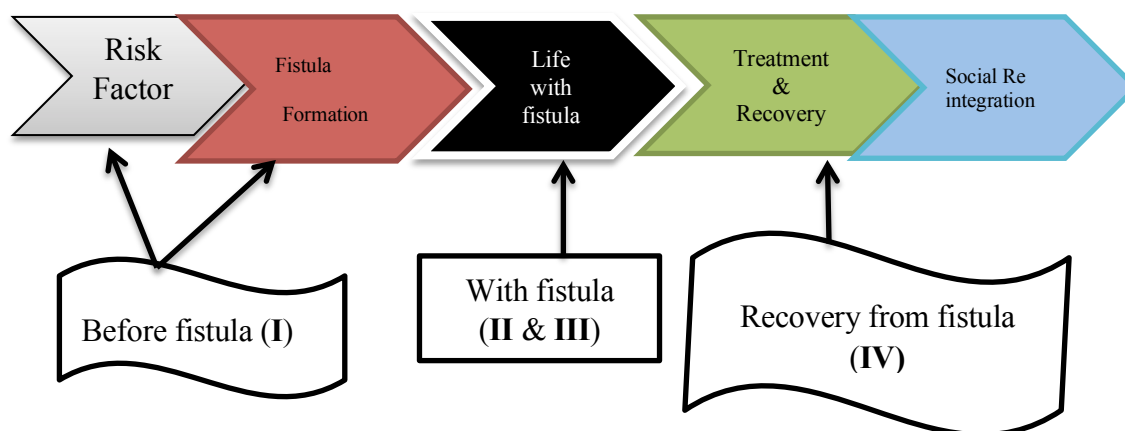


Figure 2: Fistula timeline and positioning of paper in this thesis.

3.2 STUDY AREA AND SETTING

Studies in this thesis were conducted in central and western Uganda in the districts of Kampala (II-IV), Kibale (I), Hoima (I&III) and Kyenjojo (I). The Republic of Uganda is a landlocked country in East Africa that lies astride the equator. The country covers an area of 241,038 square kilometres with 18% of the surface being water bodies and 12% forested and game parks. From the 2014 population and housing census, the country has a population 34.9 million with an annual growth rate of 3.03%. The population of women of reproductive age (15-49 years) is 7.3 million, and 1.5 million births occur annually [110]. Administratively the country is divided into four regions (Central, Eastern, Northern, and Western) with 112 districts (local government administrative units) and ten demographic regions including Kampala the capital city (figure 3).

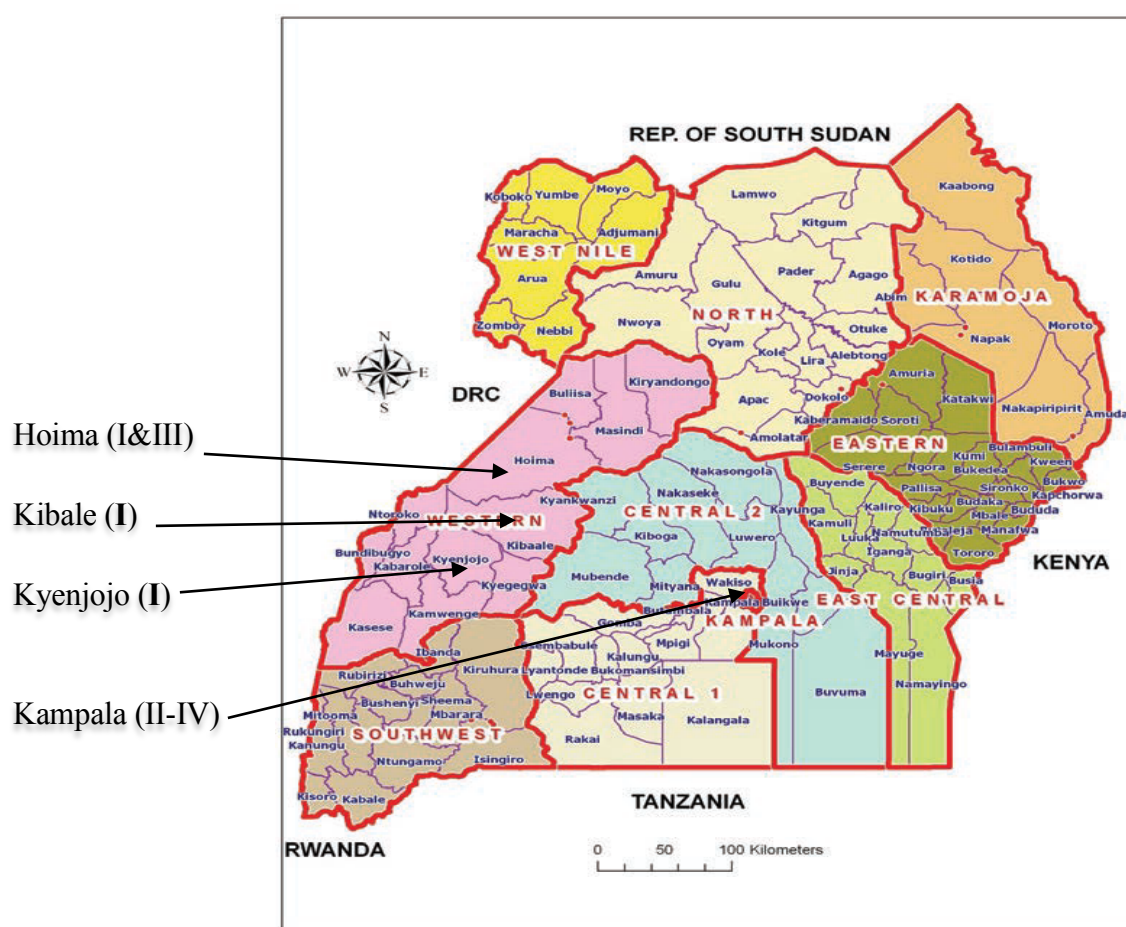


Figure 3. Map of Uganda showing demographic regions and districts [17, 18]. The study sites were in central (Kampala) and western (Hoima, Kibale, and Kyenjojo Districts) demographic regions.

The study was health facility based though two sub studies had a community component (**III & IV**). The health facilities were Mulago National Referral and Teaching Hospital in Kampala district, Hoima Regional Referral Hospital in Hoima District, Kagadi General Hospital in Kibale district, and Kyenjojo General Hospital in Kyenjojo district. The four sites are MoH established sites for fistula treatment.

Mulago provides routine female genital fistula treatment and the other sites provide care in organized surgical camp settings. The western Ugandan districts (Hoima, Kagadi and Kyenjojo) are in a rural setting, generally with poor reproductive indices and the highest fistula prevalence in the country [17, 18]. Patients in the outreach sites are routinely given appointments or mobilized by radio announcements to come for treatment on the dates when there is a visiting surgeon. The patients who report during the routine care and can afford transport costs are referred to Mulago hospital for routine care. All treatment is free for fistula patients. The patients report to the outpatient integrated reproductive health clinics, they are screened, the fistula classified and the then patients are admitted on a female gynaecology ward. The women are then prepared and operated by a Mulago fistula surgeon following a standard WHO and FIGO Guidelines [4, 6].

3.3 STUDY DESIGN

This was mixed methods study with quantitative (I &IV) and qualitative (II & III) components conducted between 2012 and 2015. Quantitatively we had a case control study (I) to establish the risk factors in western Uganda, an area with the highest fistula prevalence in Uganda [17, 18]. The randomised, controlled, open-label, non-inferiority trial (IV) assessed safety of early discharge with a catheter following fistula repair. In the qualitative studies (II & III), we used focus group discussions (FGD) and in-depth interviews (IDI) to explore experiences of living with a fistula among women and the spouses (husbands) of affected women respectively.

3.3.1 Quantitative design

3.3.1.1 Case control study (I)

A case control study is an epidemiological study that compares individuals with a disease or condition (cases) with those who do not have the disease at one point in time [111, 112]. An association with a hypothesised exposure or characteristic of interest is then compared between the two groups. The association between the hypothesised exposure and the disease being studied will be reflected in a greater proportion of the cases being exposed [113]. The cases and controls must have a similar population base in order to reduce differences in the exposure under investigation brought about by different study contexts[112, 113]. Case control studies start with outcome and look backward for exposure factors, are often used to study rare conditions or diseases, and are efficient in time and cost since they don't require follow up [111, 113]. Advantages include possibility to investigate a wide range of possible risk factors and to investigate rare diseases or diseases with a long induction period. Because of the efficiency, a case control design may also be ideal for preliminary investigation of a suspected risk factor for a common condition and conclusions may be used to justify a more costly and time-consuming longitudinal study at a later stage [112]. The disadvantage, however, is that a case control study design cannot be used to compute incidence rates, and are prone bias [111-113]. In case control studies, it might be difficult to select appropriate controls (*selection bias*), obtain accurate unbiased measures of past exposures (*information bias*), and

establish temporal sequence between exposure and disease (*reverse causality*). The case control design is not suitable for investigating rare exposures (unless the exposure is responsible for a large proportion of cases), and is not possible to obtain estimates of disease incidence among exposed and unexposed to a putative risk factor (except if the study is population-based) [111].

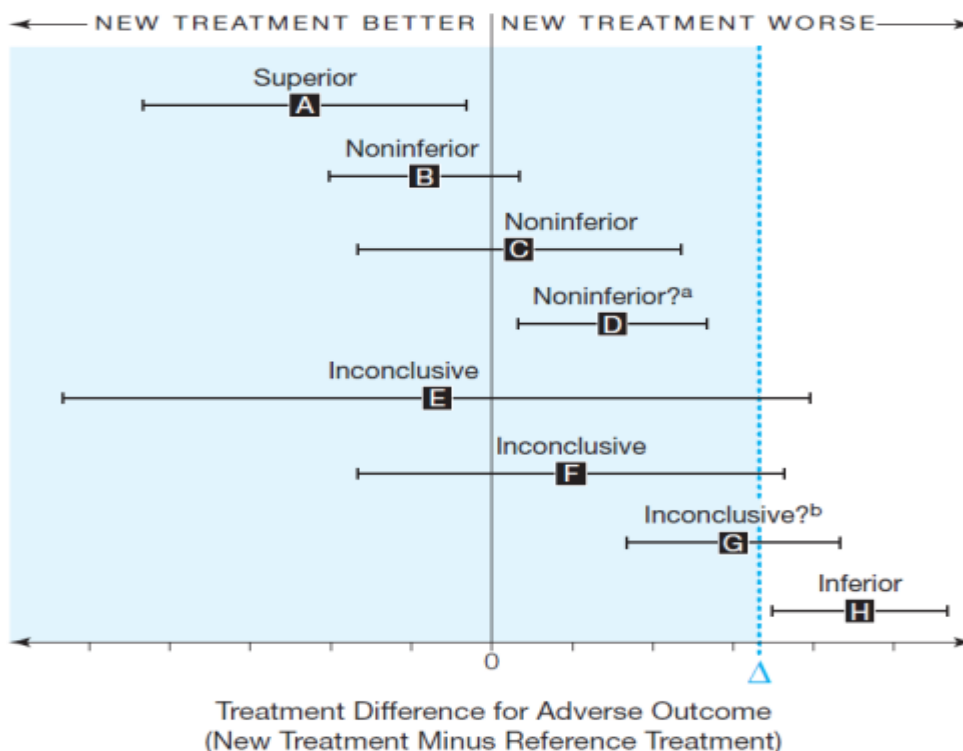
3.3.1.2 Randomised controlled trial (IV)

In a randomised controlled trial (RCT), participants are randomly allocated to receive one of two or more interventions. Intervention in a wider sense refers to any manoeuvre offered to study participants that is likely to have an effect on their health or outcome of interest. Examples of such interventions are prevention, screening, and community programmes. By random allocation, participants have the same chance of being assigned to any of the groups [114]. If the randomisation is properly done, the baseline characteristics are similar across all groups [115]. Because of randomisation, selection bias is minimised hence balancing the known and the unknown factors in the assignment of treatment or intervention [114, 115].

Most RCTs aim to determine whether one intervention is superior to the other. However, other trials (equivalence trials) determine whether a new intervention is therapeutically similar to a reference treatment (active control). A non-inferiority trial, essentially seeks to determine whether a new treatment is not worse than the reference treatment by a relevant difference [116]. The standard null and alternative hypotheses for proving non-inferiority are: null (H_0): $C - T \geq \Delta$ (T is inferior to C) and alternative (H_1): $C - T < \Delta$ (T is not inferior to C) [116, 117]. Here T is the new treatment and C is the active control. Delta (Δ) is the non-inferiority margin, that is, how much C can exceed T with T still being considered non-inferior to C ($\Delta > 0$). Proof of exact equality is impossible to determine hence a non-inferiority margin (Δ) for the treatment effect in the primary outcome is predefined. Non-inferiority and equivalence trials are similar in design and conduct but equivalence is defined as the treatment effect between $-\Delta$ and Δ . For non-inferiority, the question of interest is not symmetric [117]. The new treatment is recommended if it is similar to or better than the existing one but not when it is worse (by more than Δ) and hence superiority of the new treatment is a bonus. Non-inferiority trials therefore are intended to show whether a new treatment or intervention has at least as much efficacy/effect as the prevailing standard or is worse by an amount less than Δ if it has some other advantage e.g. reduced cost, less invasive, fewer side effects (harms), ease of administration and greater availability [116]. In our study (IV) the new intervention was early discharge with a catheter while the prevailing standard was in patient care and discharge after 14 days following urogenital fistula surgery. The predefined margin Δ was 10%.

Interpretation of the results of the non inferiority trial depends on where the confidence intervals (CI) for the treatment effect lies relative to both the margin of non inferiority Δ and the null effect [116, 117]. The interpretation is based on the upper limit of 1-sided 97.5% CI (which is the same as upper limit of a 2-sided 95%

CI) and this is demonstrated in figure 4 that interprets several possible scenarios of observed treatment differences [117].



Key: Error bars indicate 2-sided 95% CI, Tinted is zone of non-inferiority (B, C & D), Inconclusive (E, F, & G), Superior but still satisfies non-inferiority margin (A), and new intervention inferior (H), non-inferiority because CI does not include Δ but new treatment is worse than the standard (a), and CI inconclusive but still plausible that the true difference is less than Δ and the new treatment is significantly worse than the standard (b).

Figure 4: Possible scenarios of observed treatment differences in a non- inferiority trial [117].

3.3.2 Qualitative design

Qualitative research uses distinct methodological inquiry that explores social phenomena. This calls for the researcher or research team to understand the social context of the population being studied [118]. The qualitative data collection methods used in this study were FGDs (II) and IDI (III).

3.3.2.1 Focus group discussions (II)

FGD is qualitative data collection method that enables the researcher to get an understanding of a phenomena from a group of people in an interactive fashion where participants freely discuss with each other [119, 120]. Participants are specifically selected to explore the phenomena in question with the group dynamics and interaction among participants facilitating the collection of relatively detailed information, for participants build on each other's response [118-122].

3.3.2.2 In-depth interviews (III)

An IDI is a qualitative research data collection method in form of a confidential and secure conversation between an interviewer and respondent [118, 121, 122]. The method allows the interviewer to get the inside views, opinions, beliefs or any other social contextual issue related to the topic of study in the respondents choice of environment [122, 123]. We opted to use IDI with men whose wives were having fistula for this was a very sensitive or controversial subject for we had to dig deeper into their intimate lives. The IDI gives the respondent freedom to develop and give perceived meanings to phenomena without being influenced by opinions of others [118, 122].

3.4 STUDY POPULATION

3.4.1 Case control (I)

Cases were patients confirmed to have obstetric fistula irrespective of type and duration. The controls were other women without fistula seeking treatment or attending to patients in the selected study units in western Uganda. Controls with parity similar or higher than the pregnancy that resulted in a fistula in the case were chosen. Controls were also frequency matched to cases within an age range of 5 years. Since the units were the cases and controls attended and were interviewed are community units, we assumed that both cases and controls had similar environmental exposure and were therefore representative of the population. Women with fistula due to causes other than labour process or its management were excluded because the study sought to identify risk factors for obstetric fistula.

3.4.2 FGD (II)

Participants were purposively selected from both women awaiting surgery and those already operated. Women seeking care for a genital fistula, irrespective of whether they were operated or not were asked to participate in the study. The composition of the FGDs was determined a priori based on age, marital status, delivery history, fistula repair history, and length of time they had lived with a fistula to maximise information richness [124]. Altogether, 56 women, aged 14-60 years, participated in the eight FGDs. Number of women in each group ranged from five to ten.

3.4.3 IDI (III)

Women with obstetric fistula seeking treatment in Hoima or Mulago hospital provided contacts to their spouses. They (husbands) were then contacted for interviews at a venue that was convenient to them. Though we initially targeted all men who had ever lived with a wife with fistula irrespective of marital status at interview, none of the divorced/separated men accepted to participate. We had no predetermined sample size and we stopped after 16 interviews when saturation was achieved.

3.4.4 Randomised trial (IV)

Women confirmed to have a urogenital fistula and scheduled for surgery were introduced to the study and assessed for eligibility. We included stable women whose urogenital fistulas were surgically repaired irrespective of route or history of repair as long as the fistula was still closed by second postoperative day when randomization was done. All women whose fistula was one cm or more from the external urethra orifice (all fistulas except VVFIIBb) [125] and where the surgeon confirmed closure of the fistula by a negative dye test at end of surgery were included. In addition, these women had to consent to participate and agree to be followed up at 14 days, 6 weeks and 12 weeks. We excluded women with both VVF and RVF for likelihood of faecal contamination and infection, circumferential fistulas within one cm from the external urethral orifice (VVFIIBb), and a small bladder with length from neck to dome of five cm or less after closure (bladder size was measured by the difference between the external urethral orifice to catheter balloon and the distance between external urethral orifice and dome of the bladder after closure of fistula) [125]. We also excluded those with leakage within three days after surgery when they were allocated the intervention group, fistula following malignancy e.g. cancer of the cervix stage IVA, fistula due to infection e.g. tuberculosis, and those women who were sick and weak after loosing a lot of blood during surgery (severe anaemia).

3.5 SAMPLE SIZE

3.5.1 Quantitative studies

In paper I, we consecutively recruited 140 cases and 280 controls. The sample size was calculated based on the method and formula described by Kelsey et al [126], with a two sided 95% confidence interval, power of 80%, proportion of controls with exposure (proportion of women delivering with no skilled birth attendant in Uganda, a known risk factor for fistula) as 58% [17]. We assumed the proportion of cases with exposure factor would be higher and this was hypothetically estimated at 72.4%.

In paper IV, we randomized 300 women in blocks to the study arms of early and late discharge (153 participants per arm). The sample size was calculated based on proportion of women who remain incontinent due to fistula breakdown following surgical repair. The published estimates of the fistula breakdown for successful programs range from 20-35% of repaired fistula patients [2, 11, 29, 127]. With an equal number of participants in each group, a level of significance of 0.05 for a 95% confidence interval, and a power of 80%, a sample size of 150 patients per group was required. The sample size was calculated using the Openepi calculator for randomised trials based on the sample size formula described by Kelsey et al [128]. It was postulated that early discharge was non-inferior to the standard discharge after 14 days, specifying a non-inferiority margin of 10%, i.e. the difference in the two proportions with fistula breakdown (early discharge minus late discharge) would not exceed 10% based on the previous practical experiences of the fistula surgeon, as no study has assessed early discharge following fistula surgery [41]

3.5.2 Qualitative studies

We had no predetermined sample sizes for the qualitative studies (**II** & **III**). The FGDs and the IDI were to continue until saturation was achieved. This was achieved after 8 FGDs with women (**II**) and 16 interviews with men (**III**)

3.6 DATA COLLECTION METHODS

We used both quantitative and qualitative data collection methods.

3.6.1 Quantitative data collection

Quantitative methods of data collection are used to gather information on aspects of research that are measurable. They are used in hypothesis testing or determining association between explanatory (independent) and outcome (dependent) variables. The variables are then summarised by statistics, charts, tables and graphs. Two of the studies in this thesis used quantitative study design i.e. case control (**I**) and randomised controlled trial (**IV**).

3.6.1.1 Case control (I)

We used a case control design to study the risk factors for obstetric fistula in western Uganda. Western Uganda has been shown in the Uganda demographic studies to have the highest prevalence of fistula of 4% versus the national figure of 2%. We therefore specifically wanted to establish risk factors for obstetric fistula in the western Uganda context. We developed and pretested an interviewer-administered questionnaire that we used to collect the data. The interviewers were midwives who were trained in the data collection methods and were involved in the pretesting of the questionnaire. They were also trained in fistula nursing care and counselling. Women who fulfilled the inclusion criteria were interviewed in three hospitals in western Uganda. The interviews took place in a quiet and private room identified from outpatient department of the respective hospitals. The interviewers were knowledgeable in the local language and would translate the information and fill the data directly in English. The first author checked completeness of filled data files before respondents left the study site.

3.6.1.2 Randomised trial (IV)

We conducted a randomised, controlled, open label, non-inferiority trial (**IV**). In a ratio of 1:1, participants were randomly allocated to either the early (intervention) or the late discharge (control) arm. We used block randomisation (block sizes of six respondents with an equal number of early and late discharges per block). The allocation sequence was computer generated by an independent statistician who also assigned the generated random numbers to the two groups in 50 serialised blocks. The statistician then concealed the allocation through sealed and serialised white opaque envelopes. The research assistants (trained midwives not working on the fistula ward, picked the serialised envelopes in consecutive ascending order and allocated the patients to an appropriate arm upon opening the envelope. The study was blinded to staff in the urogynaecology ward that provided postoperative care. Because of the nature of the intervention, the participants, research assistants, and all

study staff involved in assessing the outcome and in discharging the patients could not be blinded. The procedure and data collection instruments were pilot tested at Mulago Hospital, and minor revisions were made.

All women received standard preoperative care. They were all examined under anaesthesia just before surgery commenced to confirm the diagnosis and the fistula was classified according to the Waaldijk classification [45]. The principal investigator (BJK) then conducted or supervised the operation. Surgery was done following WHO and FIGO guidelines for the management of a fistula [6, 129]. When the fistula was confirmed closed by a negative dye test conducted upon the completion of the surgery a Foley's catheter (French size 16) was introduced for continuous bladder drainage. All women, irrespective of which arm they belonged to, received standard postoperative care up to third day. Research assistants provided counselling and information about the study on a one-to-one basis to all the women who fulfilled the inclusion criteria preceding randomisation.

Baseline data for every enrolled participant were collected through a face-to-face interview using a structured questionnaire administered by the research assistants. The baseline information included the socio-demographic, clinical and surgical profiles.

Those in the early discharge group were told what to do in case of a complication, including seeking first aid from the nearest health facility. In addition, they received a 24-hour telephone number to contact the PI and the chair of the Department of Obstetrics and Gynaecology at Mulago Hospital. Women in the early discharge arm were also instructed on how to empty the urinary bag, how to avoid catheter blockage, and how to clean themselves. All women were given a copy of the written instructions following consent. On the third postoperative day, women allocated to the early group (intervention arm) were discharged, and they came for a review and catheter removal on the 14th postoperative day. While days three and 14 were target days, some women in the early discharge group who had stents that had to be removed before discharge went home after four to five days. These women were still considered compliant with the early discharge group assignment. All patients irrespective of study group had their urethral catheters removed after 14 days at Mulago Hospital. After the removal of the catheter, patients were reviewed again at six and 12 weeks. Patients were given phone call reminders two days before the follow-up visit. All participants' transport and airtime costs were covered by the study.

The primary outcome of the study was the proportion of women with a failed fistula closure, defined as a fistula repair breakdown (confirmed by a positive dye test) any time from third postoperative day and still broken down 12 weeks after surgery. Pre-specified secondary outcomes included the proportion of women with complications including catheter blockage, post-repair residual/urethral incontinence, infections, and hospital readmissions. Residual incontinence was based on a clinical assessment

(patient report, examination, and dye test). No urodynamic tests were conducted. The trained research assistants, who were supervised by the PI, assessed both the primary and secondary treatment outcomes.

3.6.2 Qualitative data collection

3.6.2.1 Focus group discussions (II)

We used FGDs to explore the experiences of women living with fistula. The research assistants who were nurse/midwives contacted and requested women with fistula to voluntarily participate in the FGDs. A social scientist moderated the first FGDs and as a learner I observed the process in the beginning. Later I moderated most of the discussions. We used a FGD guide that was developed by a multidisciplinary research team (a fistula surgeon, gynaecologists, a midwife, a social scientist and public health specialists). The FGDs took place in a quiet, private room with a comfortable table, which enabled the women and the moderators to sit around facing one another, with an audio recorder in the middle of the table. All discussions were audio recorded and lasted between 45-90 minutes. The FGDs were conducted in a local language understood by both the participants and the moderators. A pre-defined group selection criterion helped ensure homogeneity in the groups and information-rich discussions. We stopped after 8 FGDs with a total of 56 women, a point when we reached information saturation [118]. At this point we got no new experiences from the women.

3.6.2.2 In-depth interviews (III)

I interviewed men whose wives were suffering from fistula and who consented and agreed to be audio recorded during interviews. I contacted the husbands either directly at the clinic or over the phone to inform them about the study and I also conducted all IDIs. Though initially we intended to interview all men who had ever had a wife with fistula, all the divorced or separated men declined to participate. Men were informed about what participation entailed, and a convenient time and place for the interview was agreed upon. Some interviews were conducted in the hospitals and others in the community. An interview guide was prepared to include the different aspects of interest in the study and to serve as a reminder for the interviewer. Before the interview started the participants consented verbally and in writing to participate in the study and for their voices to be recorded. The interviews were exploratory, conversational and non-judgemental, allowing for silence and reflection and using probing to ensure clarity [123]. Interviews were conducted in the local languages, which the interviewer speaks fluently. Respondents gave an account of their experiences and how they adjusted and continued to live with their wives despite the fistula condition. The consequences of fistula for their sexual relationships were explored in depth, as well as their everyday involvement in the care of their wives with fistula. During the interviews, we were careful to keep an open mind to emerging ideas and unexpected information from the respondents. Men were interviewed one by one as they were contacted until saturation was achieved [118].

3.7 DATA MANAGEMENT AND ANALYSIS

Data from all the FGDs (II) and IDIs (III) were immediately stored on a computer, transcribed and translated into English from the local language. The quantitative data (I and IV) were double entered and cleaned using EpiData version 3.1 software. The data were then exported and analysed with Stata 11.

3.7.1 Quantitative analysis

Categorical variables were analysed using Chi-square and Fisher's exact tests, and for continuous variables, depending on whether normally distributed or not, a student's t-test or Wilcoxon rank-sum test was used.

3.7.1.1 Case control (I)

Data were summarized using descriptive statistics; frequencies, means, medians, standard deviations and ranges, comparing the distribution of the background characteristics of the cases and controls. We then conducted a bivariate analysis to get the odds ratios and 95% confidence intervals, which were used to identify significant factors that were included in the multivariable analysis, where we identified risk factors for fistula. All factors that had a p-value of 0.1 or less at bivariate level and those that were known risk factors in other settings were included in the multivariate analysis. Covariates that were significant at bivariate level ($P < 0.1$) were entered in a multivariate stepwise logistic regression model and were tested for interaction and confounding. Using the backward likelihood ratio method we selected the best fitting model. Duration of labour in hours was the most significant variable in the model and was hence taken as the main predictor for obstetric fistula and used to make interaction terms. We used the log ratio test where the fitness of the model with all the interaction terms included was compared with a fit of the model with none of the interaction terms and the negative two-log likelihood (-2LL) of the full model and the reduced models were compared. Interaction was considered present when the difference between the -2LL were significant at $P \leq 0.05$ with a chi square test. Confounding was considered present if the difference between crude and adjusted odds ratios was greater than or equal to ten per cent. We checked on quality of the model using Hosmer and Lemshow's goodness of fit test [130]. Depending on contribution to the goodness of fit of the model, variables left out were brought back into the model.

3.7.1.2 Randomised trial (IV)

We summarized the data using descriptive statistics; frequencies, means, medians, standard deviations and ranges, comparing the socio-demographic characteristics and clinical profiles in the early and late discharge groups. Since there was no statistically significant difference in the baseline socio-demographic and clinical/surgical characteristics, we assumed the randomisation had taken care of the confounders and we had no reason to do multivariate analysis. We conducted both the intention to treat (ITT) and per protocol analyses for the primary outcome. The ITT population was defined as all randomised patients with data for the primary outcome. The

difference in the proportion with a breakdown in the early group and the late group and its 95% confidence interval were then determined. The 95% confidence interval for the difference was then compared with the pre-set non-inferiority margin for the primary outcome of 10%.

3.7.2 Qualitative analysis

Audio files for all the FGDs (II) and IDI (III) were immediately stored on the computer and backed up. The data was then transcribed verbatim and translated into English from local languages. I together with the social scientist who moderated some of the FGDs translated the interviews. Both the social scientist and I are fluent in the local languages. We listened to the audio interviews and, together with the translator, checked for consistency and a proper interpretation against the transcripts.

3.7.2.1 Content analysis (II)

The FGDs transcripts (II) were analysed using both manifest and latent content analysis [131]. Latent analysis involves interpretation of the underlying meanings of text and requires further abstraction and is more in-depth, while manifest involves analysis of visible and obvious components of the text [131]. The field team, together with the authors of paper II, read through the transcripts and notes from the discussions several times, identifying meaning units. The meaning units were then condensed, coded and put into categories, from which themes emerged as illustrated in table 6. We used open-code software [132] blended with a manual analysis. Open code helped to organise the transcripts into a format to analyse, identifying meaning units, assign codes, categories and themes.

Table 6: Analysis process (II) illustrated using theme marital sexual life no longer joyful

Meaning unit	Codes	Categories	Theme
When it reaches time for sex ... you have to first clean the place and put there the cloth to dry urine, then you lay a polythene cover and by the time you start, urine is much again. This makes him lose the erection and a feeling comes that may be its urine that made him lose the erection. He just forces himself to do it but deep inside, he is not enjoying and even myself, I do not enjoy due to fear that when you increase on the speed, urine will come in large quantity so you do it slowly. In fact, you do not make him happy like how you used to do before the problem. I therefore have no appetite for sex.	Too much cleaning before sex	Sex no longer normal	Marital sex life no longer joyful
	Too much preparation for sex		
	Urine makes him lose erection	Mood changes	
	He forces himself		
	Never in mood		
	I am never in mood for sex.		
	Urine reduces appetite for sex		
	Sex has to be slow	Changed sex life	
	Sex not as before		
	Too much urine		

3.7.2.2 *Narrative analysis (III)*

The transcripts from the IDI with men (III) were read and compared with the audio files several times and analysed using narratives to preserve the stories men told. Narratives rely on extended accounts that are preserved and treated analytically as units rather than fragmented into thematic categories as is customary in other forms of qualitative analysis [133]. Category centred methods of analysis often condense long accounts into short coding units, with snippets of the account often edited out and therefore eliminate the sequential and structural features that are hallmarks of narratives [123, 133]. Acting as ‘narrative finders’ [123], the research team, read the interviews, looking for common stories about the men’s feelings, actions and decisions. The analytic process involved moving between the narratives within each life story and the different life stories to search for common themes and how they were described and justified [118, 133, 134]. We characterised the men’s own behaviour in relation to other people in their environment and how the men justified and explained their behaviour and decisions. As ‘narrative creators’ [123], we constructed one coherent narrative using quotes from the interviews (verbatim) from all the participants to illustrate how the men struggled with handling their own values, hopes and responsibilities for the marriage, their relationship with their wives and relatives, and the expectations and opinions of the family and community.

3.8 ETHICAL CONSIDERATIONS

The protocol for the study (four sub studies) received ethical approval from the Regional Ethics Committee in Stockholm, (Ref #2012/474-31/2, Protocol 2012/2:4), Higher Degrees Institutional Review Board (IRB) at Makerere College of Health Sciences, School of Medicine (#REC REF 2011-104) and the Uganda National Council for Science and Technology (HS1337). Our studies followed fundamentals of ethics guided by the Helsinki declaration where the patients rights were put into consideration and we ensured that the wellbeing of our participants took precedence over interests of science and society [135]. The fundamentals of ethics in research involving humans are enshrined in respect for persons, beneficence, non-maleficence, and justice. The participants in our study had autonomy and voluntarily participated and were free to withdraw at any time during the study. Privacy, confidentiality and protection were provided during the research process and after. We had to weigh the benefit of the research against the risks and especially in paper IV where women were linked to nearest health units and also provided a dedicated telephone to be able to advise in case of emergencies. We also conducted a pilot study to assess whether this design was feasible before final IRB approval was obtained. In addition, we registered the UFEALD trial (IV) with Pan African Clinical Trials Registry (registration number PACTR201300000556261).

All the participants received information about the study and this was translated in Luganda and Runyoro, the local languages in the study areas. The participants gave informed consent after studying the information. The study objectives and processes were explained and all respondents were given time to ask questions and these questions were answered to their satisfaction. The participants then consented

without being subjected to any coercion, undue influence or inducement, and intimidation as laid down in the international ethical guidelines [136].

Our study included some participants who were adolescent/teenage mothers (13-17years of age) who are regarded as minors (**I**, **II** and **IV**). School of Medicine IRB at Makerere University and UNCST approved the participation of these adolescent mothers who consented as emancipated minors [135, 137]. The fact that the obstructed labour, the main cause of fistula, is more common among these young/adolescent mothers meant that excluding them would mean missing an important group. Moreover, at the inception of the study, 16 % and 53% of Uganda women were married by 15 and 18 years respectively with a median age at first birth of 19 years [17]. We therefore, could not miss the risk factors (**I**), their experiences (**II**) and treatment outcomes (**IV**) in this important group.

4 RESULTS

4.1 RISK FACTORS FOR OBSTETRIC FISTULA (I)

We compared background and clinical profiles of 140 cases and 280 controls that satisfied the inclusion criteria. A total of 27 out of 109 (25%) women with urogenital fistula had either high VVF I or ureterovaginal fistula, both of which were considered iatrogenic injuries by the surgeon. General practitioners had performed all the caesarean sections. An obstetrician or a doctor with specialised training performed none of the caesarean sections. There was a high rate of stillbirths among the cases compared with the controls with 100 (71%) of the women with fistula having lost their babies at birth compared to 40 (29%) among the controls ($p < 0.001$). However, the risk factors for stillbirth were correlated to the risk for fistula.

At bivariate analysis, significant results associated with getting fistula were: single marital status, religion, low level of education (both respondent and spouse), and being a peasant farmer. In addition, significantly more of the patients with fistula were living far from the nearest comprehensive emergency obstetric care unit (median 17.5 km compared to 5 km among the controls). The obstetric and physical factors, which were significantly more likely to predispose women to develop fistula included: primipara, use of local herbs in labour, not attending antenatal classes, delivery by caesarean section, women's height of 150 cm or less, delay to decide to seek care, prolonged labour, and delivery of a big baby (3.5 kg or more). At multivariate analysis, all factors, with a p -value ≤ 0.1 at bivariate analysis, were entered into the model. Statistical significant risk factors are presented (Table 7).

Table 7: Risk factors for obstetric fistula (multivariate analysis)

<i>Variable</i>	<i>Crude OR (95% CI)</i>	<i>Adjusted OR (95% CI)</i>	<i>P-Value</i>
Duration of labour (hours)	1.06 (1.04 - 1.09)	1.06 (1.04 - 1.08)	<0.001
Baby weight (Kg)			
Less than 3.5 kg	1	1	
More or equal 3.5 kg	1.59 (1.28 - 1.95)	1.52 (1.15 - 1.99)	0.003
Respondent height (cm)			
More than 150 cm	1	1	
150 cm or less	3.70 (2.22 – 6.25)	2.63(1.35 – 5.26)	0.004
Mode of delivery			
Vaginal delivery	1	1	
Caesarean Section	17.10(9.23 - 31.69)	13.30(6.74-26.39)	<0.001
Respondent's education			
No formal education	1	1	
Primary level	0.71(0.42 - 1.21)	0.63(0.31 - 1.23)	0.176
Post primary level	0.30(0.16 - 0.59)	0.31(0.13 – 0.72)	0.007

The statistical significant risk factors were: caesarean section (adjusted odds ratio [AOR] =13.3, 95%CI=6.74-26.39), respondent height of 150 cm or less (AOR=2.63,

95% CI=1.35-5.26), baby weight of 3.5 kg or more (AOR=1.52, 95% CI=1.15-1.99), prolonged labour (AOR=1.06, 95% CI=1.04-1.08). Compared to no education, post primary level of education was protective against obstetric fistula (AOR=0.31, 95% CI=0.13-0.72) but there was no difference between respondents without education and those with primary level education. All other factors, which were significant at the bivariate analysis, were not significant at multivariate analysis and were therefore excluded from the final adjusted multivariate.

4.2 EXPERIENCES OF WOMEN LIVING WITH FISTULA (II)

We explored experiences of Ugandan women living with genital fistulas in order to understand how their lives were affected and how they coped with the condition. The women gave a coherent story regarding their experience with a fistula. Four themes emerged: living a physically changed and challenging life, living in social deprivation and isolation, living psychologically stigmatised and depressed and living a marital and sexual life that is no longer joyful. The four themes were inter-related and occasionally overlapping from the way the women described their experiences. Generally, the women's experiences were full of life changes and strategies to cope. The coping responses cut across all four themes and are hence not presented separately.

The women were wet all the time, a challenge they had to cope with by devising ways of passing less urine and avoiding being noticed by those around them. In response to the leakage, women drank less to reduce being constantly wet. However, drinking less made them produce concentrated and smelly urine, which led to urine dermatitis and sores on the genitals and thighs. The women had to pad themselves all the time using locally devised pads. The women were always pre-occupied with ways to stop being noticed that they were wet. The women themselves experienced the bad smell of strong urine, a situation that made them feel ashamed. They lived as outcasts in their society. They described how the bad smell would drive away anybody they encountered and they often took much time cleaning themselves to reduce the smell. The women always faced a dilemma between wanting to drink much water to reduce the smell but risking massive leakage, and drinking less water to reduce the leakage but risking the increased smell. To mitigate the physical effects of leakage and the smell, some women had to look for local remedies by using herbal medication though they never achieved the anticipated benefits.

The women felt socially isolated and deprived. Because of leakage, they either isolated themselves or were isolated by relatives and friends. They attributed the isolation to the rejection they received from friends, neighbours and relatives as because of leakage and bad smell, and most of the women practiced isolation as a coping mechanism.

... my friends and my relatives are irritated and they don't want to come to my place anymore. I also don't go to their places because I feel like a burden to them. We both fear each other. The neighbours feel bad when I give food to their children; as a result, they stop their children from coming to my place

or playing from there (FGD 7). I do not have friends anymore; even members of my family do not want to associate with me. I cannot talk to anybody for they are pushed off by the smell of urine. I am alone and isolated (FGD 1).

The women gave various reasons for choosing self-isolation in the ordeal of living with fistula: they could not sit for a long time and chat hence decided to abandon their former peers and friends, relatives had spoken ill of them, could not participate in activities they were culturally supposed to enjoy such as entertainment and cooking for visitors for they would wet themselves as they participated, avoiding public functions and meetings such as funerals and attending church because of the leakage and smell of urine.

The women could not perform what they perceived were their gender roles. They were considered unclean, and whatever they touched would be thrown away – a situation that left them socially rejected. This rejection was across all age groups including relatives and friends. The women with fistula reported ridicule, scorn, verbal abuse and non-verbal mockery (*kwenyinyala*). Being laughed at, verbally abused and mocked prompted the women to further isolation as a form of coping. Women generally agreed that it helped if they never disclosed their illness to relatives and neighbours. The rejection worsened as time went by. Initially many of the husbands had hoped that the problem would go away but when it took time without healing, many of them abandoned and eventually divorced their wives.

Leakage of urine also affected the women's socioeconomic activities. They were unable to continue with income-generating activities to support themselves. They were unprepared to continue working because of the pre-occupation with how to cope with effects of leakage of urine and/or stool. The women would be mocked at work and the women with retail businesses feared that nobody would buy from them if they took their goods to the market. All women disclosed that no one was willing to employ a woman leaking urine, as demonstrated in the following quotes:

This condition has hindered us from doing our usual work that could give us income to support ourselves. ...I no longer take my things to the market because I fear people will not buy from me (FGD3). There is no way how you can hide this problem. It's a difficult thing to hide. Whoever gets to know of your condition, he/she can't accept you to work (FGD 6).

Women with a fistula were stigmatised and depressed. Stigma was also experienced through the behaviours of other people towards women with a fistula. Relatives and neighbours distanced themselves from the women with a fistula because of the perceived fear that the condition might be contagious. The stress of living with a fistula was compounded by worries that there may be no cure for the condition. As a result, some women contemplated ending their lives. Most women had ever had suicidal ideations and felt their life was not worthwhile living.

...People were saying that the condition could never be treated. They said that I would never be o.k. I will have to die with it. I started fearing to live

with the problem the rest of my life. I thought I should just get a rope to hang and kill myself! I was going to do it but my mother stopped me (FGD 8).

The women with fistula felt their marital and sexual lives were no longer joyful in addition to having lost their marital and sexual rights altogether. The women perceived their bodies had changed, and they were no longer like other women since they missed the happiness they formerly enjoyed. Their sex lives had changed. Many described their sex lives to have been negatively impacted because of the excess fluid, which was detestable to both the women and their partners. The women agreed that sex was a major challenge. It was no longer as it used to be, and there were many difficulties to overcome when having sex.

The women had feelings of a physically widened vagina and a loss of appetite for sex. They revealed that their partners told them that sex was not how it was before they developing fistula and was also different from sex with women without fistula. Often spouses divorced the women with fistula and those who stayed together often had separate beds and only came together for sex. The women's right to sex was often denied, and some husbands looked for other "normal" women and left their wives sexually starved. Even when the women tried other men, the fluid was too much and unpleasant, and the men did not return.

... My first husband chased me away and I got myself another one I am having today, but we have separate beds. I feel bad to see that I do not feel the warmth of a man and the man also does not feel mine (FGD 5). ... he continued to have sex but he was unstable. He preferred going to his "normal" wife than being with me who leaked a lot of fluid during intercourse. I got a few other friends but the intercourse was still messy due to the release of a lot of fluids and they moved on (FGD 7)

Some women with fistula were forced into sex even when they had pain, a situation that they interpreted as rape. Others were divorced and the women had no choice left since in this setting men are culturally the initiators of sex. The women therefore felt that being divorced and unable to initiate new sexual relationships was a violation of their sexual rights. Fistula had stood in their way, even when they still had a desire for sex.

Our rights were violated. We don't play sex; not because we lack feelings; ... this condition [fistula] made our husbands- the custodians of sex, leave us for other women. Men no longer want to socialize with us and ask for love [sex] because of our condition ...yet sometimes we have feelings for sex. FGD 2

Most of the women abstained from sex for they feared being talked about if sex did not go right. Other women stayed away from their partners to avoid abuse and neglect while the rest separated or divorced because their partners abused, abandoned and or sent them away.

4.3 EXPERIENCES OF MEN WHOSE WIVES HAVE FISTULA (III)

The men wanted to be seen as caring men despite the difficulty of living with wives who had fistula. The men explained their role though it is evident that they told what they wanted other people to hear within the accepted patriarchal society norms. They highlighted factors for the delay in seeking care such as poverty, poor roads, and no means of transport.

We had just migrated to a new district where the means of transport were rare. We were very poor and had nothing, not even a bicycle for transportation. We used 'engozi' (a locally made stretcher carried by four men) to the nearest road. ...finally there came a vehicle carrying charcoal and we hired it. We travelled about 40 km on top of the charcoal to hospital where she was operated promptly but the baby had already died.

The initial experience when a man realized that the wife was leaking urine was a moment of reflection and regret. The men tried to face the difficult situation. They contemplated divorce, thought of witchcraft and faced a difficult physical environment. They also regretted but later adapted and decided to continue living with their wives even when they felt small as men.

She's all wet. She could no longer live like a woman. I thought that she had been bewitched. I sent her back to her parents, but realised that I was not in love with any other person so I decided to bring her back. I had no money to pay bride price for another wife. Life was full of adjustments. Our house smells badly and when visitors come, they put their noses out. Women told me that I was stupid for refusing to divorce a smelling woman. My life turned upside down. I regretted and hated myself. As a man I felt small. I was still a young man just married to a young girl and my brain was excited and on fire. I felt bad because of the urine that did not smell good. I wondered why I was created on this earth and I asked myself many questions. I did not feel for her as I had before.

The men revealed how they had to take over house chores; a function they felt should normally be their wives' duty. The men had to do this even when they faced hostility from fellow men. The men interviewed attributed this obedience and task shifting to the love they had for their wives though they felt it was a punishment from God.

She was responsible for the daily house chores before but after she got the problem, most of the responsibility shifted to me. I had to cook, clean and also wash for her. Some people said I better leave her in her disabled state, not to waste my resources. I would look at the situation and think God is punishing me since he is above all. Because of love for my wife, I persevered and accepted all the suffering. She is all the time wrapping herself in rugs to stop urine leaking through her clothes. It is not pleasing because all the time we have to wash. I have to constantly buy soap. This forces me to have money all the time.

Despite the situation the men remained intimate to their wives. A pregnancy when the wife had fistula was threatening to the men even though they could not abstain. But when they eventually got a baby, it was a reason to continue living with their wives despite the leakage problem.

We tried our best to abstain [from sex] but managed only for six months. When she became pregnant again, I felt this was beyond me. ... She was then taken to the theatre and while I was still thinking, they brought the mother alive and the baby alongside her also alive. I became suddenly overjoyed and told myself finally I have also got a baby boy. I felt happy and actually sang and I said: 'even if there is this problem of leakage of urine at least we have a baby boy.

The men often exchanged bitter words with their wives. They faced the challenge of changed sex. They had both physical pain and psychological pain as they had sex with their wives. Even when other people gave them a challenge, they persevered in the relationship.

We have never fought but we have sometimes exchanged bitter words. I could not have sex with her the way other men have sex with their wives. There is a point I reach and feel sad. When I am in a group of other men, I hear their description of sex with their wives and I realise the big difference. Their wives have real vaginal fluids but mine only brings urine. And as we meet, I would do not get the feeling and I do not like the process. With my wife it is rough, coarse and occasionally I feel a lot of pain. Because she is leaking, when we have sex together, there are lots of fluids, too much water, and I cannot understand it. It is like jumping from one place to another and maybe skipping some steps. When I feel it I almost give up the sexual act. This is actually a big problem for me, but I have to persevere. I do hate myself and say to myself: 'How will I manage? What shall I do? For how long will I

The men also felt the fistula had affected their economic life. Their dream plans had not been successful and this they blamed on the fistula. They felt they had spent a lot of money on the fistula problem and this had affected their life and even extended to their children who were in bad schools.

We definitely never achieved our dream of becoming rich. Twenty years down the road we are still poor. I have tried very much to look after her in hospital and I really care for her so much. I grew up as a young man liking to work and I thought that within six years together, we were going to be rich. My life experience has not been good. I still hate myself for my situation. What I previously planned has all turned upside down. I thought of making a cattle farm but my wife's problem hindered it. I have lived a life wandering from hospital to hospital. I do not have money for our care and I am about to fail looking after the children. They are in bad schools, where I do not want them to be. We

buy a mattress and sleep on it for one year, then it is all in pieces and we need to buy a new one.

The men had no joy but they endured and persevered for they believed they were part of the process and should see it to the end. They decided to remain with their wives because they wanted the wives to contribute to raising the children but the men also had faith in their God.

Surely this is no joy. It has been perseverance and endurance. It is said: 'The one who perseveres is the one who will reap the right fruit'. I married her when she was a small girl. I have tried not to make her more worried because of the problem she has, for she never wanted it. I care for her. She is now generally a strong woman. I have been afraid my wife would die and I lose her. We have developed a spirit of perseverance and tolerance, seeking divine intervention through prayer, and ignoring what other people say. I resolved that no matter what comes in our way I will be with my wife. I neither wanted her to leave the children with another woman, nor did I think that I would be able to look after them alone. I wish God allowed her to heal. I am only interested in her being treated and healed.

4.4 UROGENITAL FISTULA EARLY AND LATE DISCHARGE (UFEALD) STUDY (IV)

We screened 366 women and randomised 300 from 24 April 2013 to 31 January 2015 and follow up was completed on 1 May 2015. The trial profile is presented following CONSORT guidelines (Figure 5).

All women were reviewed after 12 weeks and assessed for the primary outcome. There was no loss to follow up. There was one protocol violation in early discharge arm, because relatives could not accept her at home for fear of complications. One participant came back after discharge because the husband threatened a sexual assault. After counselling the couple, the woman decided to recover at her parents' home.

There were no differences in the baseline socio-demographic profile and clinical profiles between the women in the intervention and the control arms. More than 87% of the women had a telephone, 64% were still married or cohabiting, and less than 25% had gone beyond primary-level education. The women had a relatively high HIV prevalence of 12.4%, and more than 80% of the repairs were done vaginally. Treatment outcomes are presented in Table 8. There was no statistically significant difference between the proportions of fistula breakdown among the women discharged early with a catheter and those discharged 14 days after surgery. Four of the 150 (2.7%) women in the early discharge group had a fistula repair breakdown compared to three of the 150 (2%) in the late discharge group (risk difference $[\Delta] = 0.7\%$ [95% CI = -3.4–4.9], $p = 0.697$). Since the upper limit of the 95% CI (4.9%)

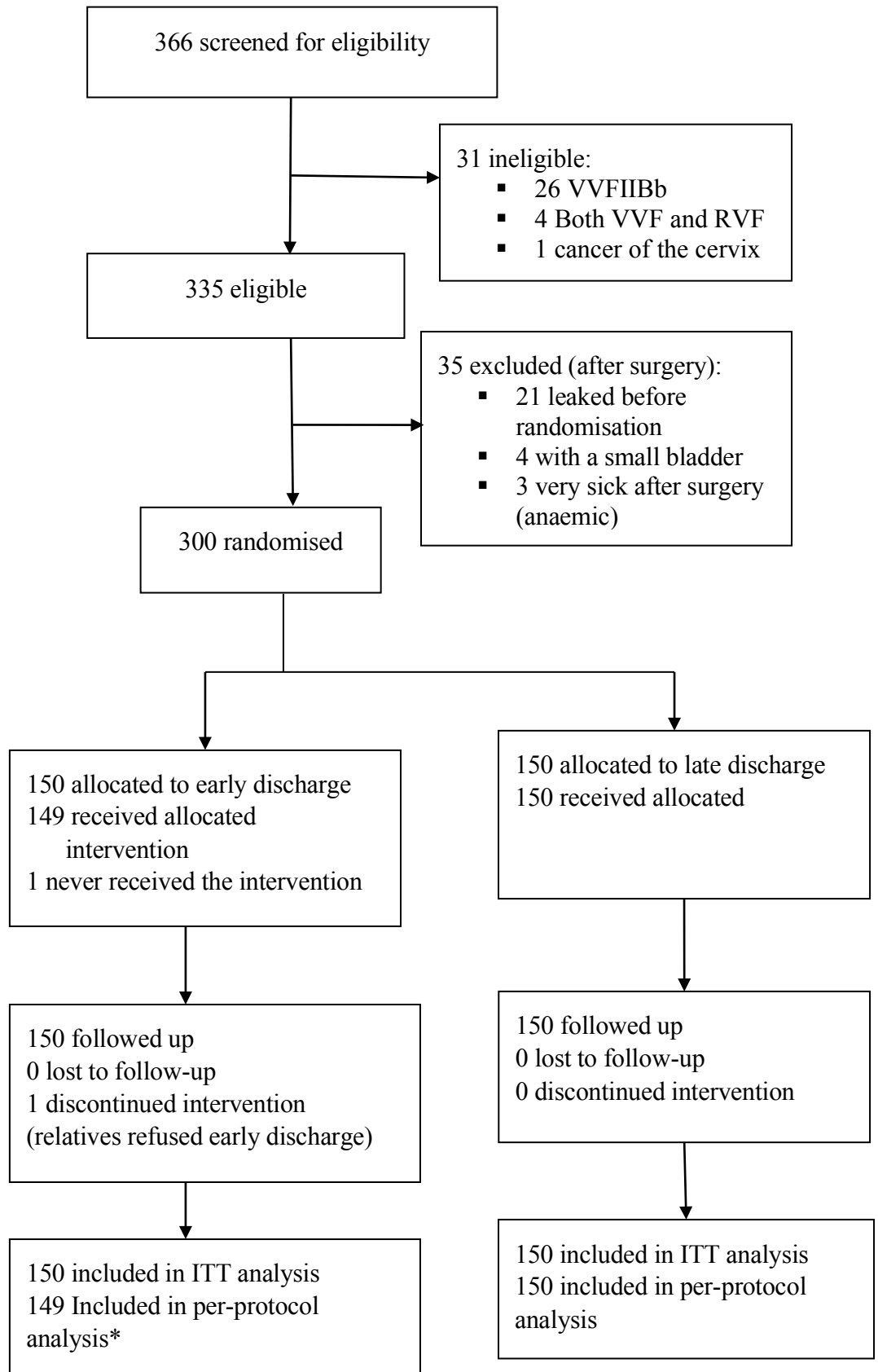
fell below the predefined non-inferiority margin (10%), early discharge with a catheter following surgical repair of a urogenital fistula with a distal margin located more than 1 cm from the EUO was therefore non-inferior to the standard discharge after 14 days of inpatient care.

Table 8: Primary and secondary outcomes

<i>Outcome</i>	<i>Early group n/N (%)</i>	<i>Late group n/N (%)</i>	<i>Difference Δ% (95% CI)</i>	<i>P-value</i>
Primary outcome				
ITT analysis: fistula repair break-down at 12 weeks	4/150 (2.7)	3/150 (2.0)	0.7(-3.4-4.9)	0.704
Per-protocol analysis: fistula repair break-down at 12 weeks	4/149 (2.7)	3/150 (2.0)	0.7(-3.4-4.9)	0.697
Secondary outcomes				
Any incontinence at 12 weeks (urethral incontinence + break-down)	12/150 (8.0)	16/150(10.7)	2.7(-4.1-9.5)	0.430
Post repair urethral incontinence	8/150 (5.3)	13/150 (8.7)	3.4(-2.7-9.9)	0.258
Got complication between 3 days and 12 weeks	7/150 (4.7)	6/150 (4.0)	0.7(-4.4-5.7)	0.779
Blocked catheter from 3rd-14th postoperative day	3/150 (2.0)	2/150 (1.3)	0.7 (-3.0-4.5)	0.653
Got problem with catheter (including blockage)	11/150 (7.3)	7/150 (4.7)	2.6 (-3.0-8.5)	0.332

There were no statistically significant differences between the two groups in any of the secondary outcomes including complications. The secondary outcomes were rare, occurring in less than 10% of the participants. The surgical outcomes were generally comparable between the two groups, with 138 of the 150 (92%) women in the early versus 134 of the 150 (89.3%) women in the late discharge groups cured (fistula closed and women continent and voiding normally by day and night) 12 weeks after surgery ($\Delta = 2.7\%$ [95% CI = -4.1-9.5], $p = 0.430$). There were no fatal complications.

Most of the women expressed that they would prefer to be discharged early after fistula surgery (third post operative day) if they had a choice, with 116 out of 149 women (77.8%) in early group and 92 out of 148 (62.2%). Early discharge was acceptable in both groups though more of the women in early discharge group recommended early discharge ($P=0.003$). The main reasons given by the women for preferring home care were that if discharged early would be attended to by relatives, it was cheap, they were able care for their children and it was easy to clean oneself at home. They also further gave the following reasons why they preferred home care: possibility to attend to minor house chores, a feeling that they were healed, home environment was friendly, free food at home, enough drinks at home, reduced costs and expenses, hygiene better at home, balanced diet at home, and could attend to their businesses among other reasons. Those who did not recommended early discharge with catheter gave reasons such as the fear that the catheter would get blocked, would miss nurse attention, feared getting complications at home, lived far from health centre, risk of rape by husband, people would laugh at her, and need for close monitoring in hospital among other reasons.



* = One protocol violation in the early discharge was excluded in the per-protocol analysis

Figure 5: Urogenital fistula early and late discharge (UFEALD). Trial profile.

4.5 SUMMARY OF FINDINGS RELATIVE TO STUDY OBJECTIVE

The main findings of this thesis are summarised in table 9 with the corresponding objectives we set out to answer.

Table 9: Summary of findings

Paper	Objectives	Findings
I	To determine risk factors for obstetric fistula among women in western Ugandan.	Risk factors are similar to what has been found out in other studies. We however noted a high proportion of iatrogenic fistula (25%) following caesarean section performed by medical officers with no supervision by specialists.
II	To explore the experiences of Ugandan women living with genital fistula in order to understand how their lives were affected and how they coped with the condition.	Women are lonely and isolated. In attempt to cope they often get isolated and this further worsens their physical, psychological, social, economic and sexual situation.
III	To understand how fistula affect the men's lives, by exploring how men described and explained their situation when living with a wife who has a fistula.	Whereas other studies have often indicated that men divorce wives when they get fistula, we realise from our findings (first of its kind) that men were greatly affected by the fact that their wives had fistula. They felt small but they persevered in the relationship with changing lifestyles but also maintaining what they perceived as roles of men in this context
IV	To establish whether early discharge (3-5 days) with a catheter was non-inferior to discharge after 14 days in terms of proportions of women with fistula repair breakdown assessed 12 weeks after surgery.	Early discharge 3-5 days is efficacious, acceptable and non-inferior to discharge after 14 days following urogenital fistula surgery. There are few complications associated with early discharge and nurses in health centre settings can handle these problems.

5 DISCUSSION

In this thesis we concentrated mainly on the individual, interpersonal and community context levels of the SEM and less on organisational and policy environment levels (figure 2) that will be addressed in future papers from the balance of the collected data in this study. The thesis discussion is structured under risk factors for fistula in western Uganda, life with fistula and outcomes of early discharge following surgical repair of fistula.

5.1 RISK FACTORS FOR OBSTETRIC FISTULA (I)

Available literature on risk factors for fistula in Uganda is based on accounts by fistula surgeons who have analysed the patients they operated with no comparison group [11]. The findings reported in such studies may not reflect the true risk factors. In attempt to bridge this knowledge gap, we studied women from western Uganda, an area with the highest fistula prevalence in the country [17, 18]. Our findings show individual (biological and physical), social environment and health system factors that contribute to the risk of a woman getting fistula in western Uganda. Individual plausible risk factors were a big baby (weight of 3.5 kg or more) and short stature (women height of 150 cm or less). The social environment and health system associated risk factors were delivery by caesarean section, prolonged labour, and no education or primary level education.

All other factors reported in other studies as risk factors for fistula [21, 30, 138-142] were not independent risk factors for obstetric fistula among women in our setting. About 50% of the women were married by 18 years of age, despite the legal age at marriage in Uganda being 18 years. However, when adjusted, age at marriage was not a significant risk factor for fistula. Early marriage in this setting was comparable to what has been found in other countries in Africa like Ethiopia, Nigeria and Ghana where marital status has been reported a risk factor for fistula [138, 141, 143]. In this setting, more women among controls compared to cases were married, and the proportion of divorced fistula patients was much lower than in other countries [73, 138, 141, 144]. This could be explained by the contextual factors like culture and religion, whereby society in western Uganda consider divorce as a manifestation of failure and lack of faith among individual men and women involved [145]. Failure to attend antenatal care is reported elsewhere as a risk factor for fistula [21, 138, 146], but this was not in our study. This could be attributed to the intense media campaigns in Uganda to end fistula and to prevent maternal morbidity and mortality. There was delay (first and second) to seek skilled care [147]. Women who had fistula took twice the time to make a decision to seek delivery care compared to the controls yet both groups had a high antenatal care attendance. This delay may be due antenatal care messages that are not well packaged to emphasize timely delivery under skilled care.

Education of women was an important contextual risk factor among women in western Uganda. Women with low level (primary) or no education were more likely

to have fistula than those with post primary level of education. This finding is similar to what has been reported in studies elsewhere in Africa where no or low-level education is a significant risk factor for fistula [11, 141, 143].

Women with fistula generally had a longer duration of labour than the controls; with half of the women with fistula being in labour for more than 21 hours (median duration) compared to the controls whose median duration was 12 hours. This was similar to what was reported in a Kenyan study where women who developed a fistula had a median duration of labour of more than 24 hours [148].

A big baby (weight of 3.5 kg or more) is a known risk factor for obstructed labour and was a significant risk factor for obstetric fistula in this setting. A big baby is more likely to obstruct labour due to the cephalo-pelvic disproportion and this has been reported in other studies [21, 22, 127, 139]. Our findings also showed that a women whose height was 150 cm or less was 2.6 times more likely to develop fistula than one whose height was more than 150 cm. Short stature is a known biological factor associated with high risk of contracted pelvis and cephalo-pelvic disproportion [11, 146, 148, 149]. In settings with accessible, available and affordable obstetric care services, the size of the baby and maternal pelvis are routinely screened for and women appropriately delivered before they get obstructed labour. In high-income countries, this has lead to elimination of obstetric fistula following obstructed labour [7]. There is therefore need to train midwives to assess the size of the baby and the pelvis. Midwives should also be trained in the use of ultrasound to identify large babies followed appropriate referral and a planned delivery by caesarean section for women at risk.

Another contextual risk factor for obstetric fistula in this setting was caesarean section. It is well known that women with fistula are more likely to have delivered by caesarean section since obstructed labour (the cause of more than 90% of all fistulas) is relieved by caesarean section [7, 11]. In our study, 50% of the women with fistula (cases) had had a caesarean section compared to five percent among the controls. A woman having been delivered by caesarean section was seventeen times more likely to be a case than a control at multivariate analysis. The association of caesarean section and fistula in our study is highly significant, and is supported by the types of fistulae found and reports from other studies [21, 139, 150]. Timely caesarean section by an expert surgeon relieves obstructed labour and hence prevents obstetric fistula [8, 10, 127, 139]. However, fistula may also result from caesarean section if performed by a physician either lacking surgical experience or with inadequate equipment [141]. In our study, 25 % of the fistulas followed injury of the ureter or dome of the urinary bladder during caesarean section and were classified as iatrogenic [141, 151]. If experienced surgeons perform caesarean sections iatrogenic fistula might be avoided. The association of fistula to injury by surgeon is not new in Uganda [152]. Vesico-uterine fistulas are often a result of complications encountered during caesarean section rather than direct consequences of obstructed labour [141]. A report from Ghana showed that the prevalence of iatrogenic fistula due to caesarean section was 16 % [141]. Similarly in Cameroon and Nigeria, delivery by

caesarean section was identified as a risk factor for supra-trigonal (above the point of entry of ureters into the urinary bladder) iatrogenic obstetric fistula [21, 139, 150]. The findings in this paper therefore point to a need for urgent iatrogenic injury preventive strategies and remedial measures to be put in place. These remedial measures may include retraining of the medical officers, support supervision, timely patient referral and the need for continuous medical education.

5.2 LIFE WITH A FISTULA (II & III)

We have used the social ecologic model to elucidate the experiences of women living with fistula (II) and as man whose wife is affected (III). To understand the contextual experience of living with a fistula there is need to focus not only on the individual woman but also on her social and physical environment. In this thesis I present some experiences relating directly to the individual woman while not forgetting that the individual is embedded within the environment. The findings show that men and women's experiences are similarly shaped by a variety of factors across the individual, spouse, family, community and organisational domains. Both for the women and the spouses, fistula is seen as a stigmatising condition characterised by change and adjustments in the previously lived life styles. The change is seen as an attempt to cope with this stigmatising condition in the context of a gendered society where expectations and roles defined by society may not be fulfilled as a man or woman. However, both men and women are resilient and persevere as they attempt to look for remedy amidst the social and cultural complexities in the Ugandan society as elucidated below under experiences of women (II) and spouses of women affected by fistula (III).

5.2.1 Experiences of women with fistula (II)

The findings show that the lives of women with a fistula are full of challenges and adjustments. The women affected tried to cope with the stigmatising and traumatic experience. They had to come to terms with their condition and continue to live, to maintain the outlook. They did their best to sustain relationships with spouse, family, peers, neighbours, and the community at large. The women were physically challenged, felt rejected, isolated and stigmatised, and their marital and sexual desires were greatly affected.

Based on the social stigma theory [92], both enacted and perceived (felt) stigma, are weaved into the lived experiences of women with a fistula, making them feel alone and isolated. While trying to maintain mental and emotional wellbeing, the women devised ways to cope with the challenge of leaking urine, though some of the coping strategies turned into stressors that often lead to even greater stigma. The women's lives, while living with fistula, revolved around ways to prevent the leakage of urine or faeces being noticed and reduce the smell. Amidst all these life adjustments to cope with the consequences of the fistula, these women found themselves lonely and isolated.

The four themes that emerged from the analysis of the FGDs (II) are interlinked and women look at themselves in the context of a social environment as woman with specific roles not fully fulfilled but also devise strategies to cope. The women perceived leaking urine to be discrediting, felt different from other women and were isolated from the rest of society. These findings are similar to what has been reported in other low-income settings in Africa and Asia, with the general agreement that a fistula has negative social and psychological implications that result from its physical manifestations [28, 57, 74, 108, 153-159]. The findings show that urinary incontinence following fistula impacts on several aspects of the affected woman's life including physical, psychosocial and economic wellbeing, as has been reported elsewhere [160-162]. Similar to what was earlier reported in Nigeria [28], our findings show that the worst suffering is not from the physical manifestations of the fistula, but rather from the social, psychological and sexual impact the condition has.

Women living with fistula irrespective of age, parity and background, exhibited a typical path or trajectory of illness with a series of events taking place in their lives. Beginning with the physical effects at onset of illness and ramifying to social, psychological and sexual challenges in the course of continued leakage and smell of urine. Our findings show that upon developing a fistula, a woman's life changes suddenly with the onset of symptoms, requiring an immediate lifestyle change to cope with the leakage, such as padding and cleaning herself frequently, drinking less, as well as isolating herself. The women drink less to reduce the amount of urine leakage and in a bid to avoid notice when outer clothes become wet. However, the less they drank, the more the urine became concentrated. Eventually, they acquired "burns" from concentrated urine and from the improvised pads used to avoid being noticed that they were wet. The strong urine created an offensive smell, which pushed away relatives and friends. The women perceived the smell of urine to be a threat and, thus, developed feelings of shame (self-stigma) and a fear of discrimination (perceived stigma) [94, 95, 98]. This marks the beginning of social isolation and rejection from the community. Women's experiences of living with fistula compare with findings from other African settings [28, 57, 74, 108, 153-159]. In Tanzania, Mselle et al. (2011) found that women living with a fistula experienced a deep loss of body control, loss of the social role of being a woman and a wife, loss of integration in the social life and loss of dignity and self-worth [56]. In another study from Tanzania, women experienced social, psychological and economic problems following the physical manifestations of fistulas [163]. Similarly, in Ebonyi State -Nigeria, women endured physical problems including sores and blisters due to constant wetness and friction, which affected their ability to participate in daily chores as women [157].

Within the context of culture and gender, women with fistula had an experience to tell. The findings show that the gender expectations of being an African woman in general, and a Ugandan in particular [164], ceased once the women got fistula. The women stopped having sex and if they had, it were not enjoyable. Most of the women were also divorced and had no living child. This situation made them lose their

dignity as expected by culture as wives and mothers [72]. While in some cases, the community isolated the women with a fistula, in other cases; women actually decided to isolate themselves to avoid abuse, ridicule and perceived stigma. Generally, women experienced a loss of womanhood and its associated roles. This was evident not only with regard to sexual life with their husbands, but also with regard to other social responsibilities, such as cooking, hosting guests and participating in social functions. The woman's social position was indeed lost, and she was often left alone and isolated as has been reported in studies from other parts of Africa [156, 157, 159, 165]. In Nigeria, Kenya, Ethiopia and Ghana, women with a fistula lived socially isolated lives, prohibited from participating in communal activities, and psychologically tortured, as they could not eat or drink with their husbands or relatives [156, 157, 159, 165].

The findings further show that life with a fistula is typically stressful and challenging to the individual women and she can attempt anything possible to cope. As described in the coping theory by Lazarus and Folkman [93], both problem- and emotion-focused coping were exhibited by the women. Women who adopted problem-focused coping were proactive about their condition and future. They tried to clean themselves regularly and remained resilient. Yet others, tried local herbs from traditional healers, hoping the condition would go away. Women with fistula choose coping strategies depending on their local setting, though in general they search for what will make their social outlook improve. For example, in Nigeria, women had to bathe regularly, use old wrappers to form pads and use perfumes and powder to cope with the associated urine smell [157]. Other studies, which have examined the coping responses of women with a fistula, have also found that women with a fistula tend to maintain hygiene and cleanliness and are constantly padded [28, 153, 163]. Women in this study who adopted emotion-focused coping strategies felt shame and tended to avoid others, including peers, relatives and community members. The women lived in a state of self-enacted stigma, isolation and rejection. These women preferred isolation, did not attend social and religious functions and felt it was not worth continuing to have sexual relations with their spouses. Similar findings have been reported from Ethiopia, Tanzania and Nigeria [28, 153].

The women in our study faced stigma from the community, as well as from their own spouses and families. To be stigmatised there must be an attribute that is significantly discrediting to be stigmatised against [92]. Living with a fistula was discrediting and these women could not engage in gainful employment, as they believed that nobody would employ them because of their condition. This meant depending on others who could provide support and help them meet the financial requirements that come with this condition. Other studies have also reported that women with fistulas have no gainful economic activities and are hence, financially dependent on others [58, 59, 166].

Our findings show that the damage in the life of a woman with fistula extends far beyond the physical hole in the bladder and the leakage. Rather, it involves a

complex interaction between the individual affected and others in the social ecological environment: a process that often leaves the woman socially isolated. This means that those involved in fistula care and rehabilitation should extend their focus beyond the individual woman affected and involve families, peers, communities, and social institutions within an existing policy environment. This has been demonstrated in Tanzania, where women were still discriminated against after they had received treatment [59]. In Nigeria, the treated women had to demand a certificate of good health as proof that they had been fully treated and could thus be allowed to participate fully in community affairs [157]. These women's experiences therefore richly inform our knowledge on policy and program in treatment and social reintegration of women affected by fistula. Therefore, community programs may draw lessons from the life experiences of the women affected as elaborated in our study.

5.2.2 Experiences of men whose wives have fistula (III)

Like the women, the spouses were greatly affected by the fistula. When their wives got a fistula the life took a different course. The men were aware of the extended social environment and tried to remain responsible men fulfilling their culturally ascribed roles even when they faced a lot of challenges including role modification amidst gendered masculinity hegemony.

The men had a constant conflict between trying to fulfil the expectations and norms of the hegemonic masculinity that dictates men's ambitions in Uganda and all the challenges of living with a chronically ill wife with a socially stigmatising condition. The men exhibited a strong feeling of responsibility and at the same time frustration that life was not what they had hoped for. The findings reveal that men's experiences and understanding of their identities were deeply affected by their wives' illness. While striving to satisfy the cultural expectations of men to be strong, decisive, sexually active, earning a good living and having a big family, the men struggled to manage the demands their wives' condition caused. These challenges were difficult to reconcile within the expectations of a hegemonic masculinity [72, 101, 102, 167] and the men thus identified themselves as 'small men', hating themselves, having bad sex, being disgusted by the smell and condition of their wives, failing their children and not achieving the economic ambitions they hoped for.

The men gave various reasons for why they chose to continue their marriage with a woman leaking urine. The men referred to love for their wives, marriage being a norm that includes responsibility for a wife and children, the feeling that they were part of the process that led to fistula, the mothers' role in parenting the children, and the lack of money to pay bride price to marry another woman. These reasons are mainly based on the norms of the hegemonic masculinity that the men aspired to [101]. As expected of men in the Ugandan society, the men in our study presented themselves as enablers in accessing health services. The men also underlined their own role in the situation, which neither husband nor wife had wanted or expected. As men, they expected their wives to be responsible for child-care and household chores

and knew that it would be hard to manage the children without a mother. The men did not like the idea of having another woman to care for their children but they also found it difficult to raise the funds for a second wife. In Uganda, men are expected to remain with their wives in order to have a good reputation in the community and to adhere to cultural values [167]. To stay in their marriages was, however, not the obvious option for all men in the study. Some of the men were advised by peers to leave their wives and not to spend money on the sick women. Some men followed the advice to send away their wives, but they soon brought them back home despite the urine leakage.

The men's experiences revolved around social, economic, and sexual challenges of fistula. Furthermore, the men blamed the situation for their inability to achieve a high position in the hierarchy of masculinities on the fistula problem. The men identified themselves as 'small men' and described how they felt, using expressions such as: "I felt small", "I regretted why I was created", "God's punishment", "bad smell", etc. The men eventually, came to terms with reality and decided to persevere and stay with their wives. While acknowledging their non-hegemonic masculinity as small and failing, the men also portrayed themselves as fulfilling the Ugandan male norm of the caring husband and father who does not shirk responsibility [167, 168].

Men also explained how they lost some of their male identity, especially with regard to sexuality. Some of the men felt they were not men having slept in the same bed with a woman leaking urine. To these men sex had changed and was neither similar to what it had been before nor like what their male peers described. The men persevered despite the sense of loss of their male identity in relation to sex, but felt like real men again when their wives delivered. Men identified themselves as providers for their wives and children - a cultural role and a male attribute [167]. Their dreams to become rich were shattered by the money they had to spend on their wives' condition. The men saw themselves as failures because they could not buy the properties they had hoped for and could not pay for good schools for their children. They could, however, not shirk the responsibility of looking after their wives and children. Marriage in the context of their religion was important. They explained that the situation could be God's plan and hence they had to accept it and hope for a cure, if God so wished. Aspects of religion and culture, but also love played an important role in the men's descriptions of their experiences and how they coped with the challenges of fistula. The men, however, did not express any sense of pride about bringing a new positive approach to man/husband-hood. Their experiences were more of doing what they were culturally expected to do in a difficult situation.

The detailed experiences of men whose wives have fistula are not featured in any other studies. Our literature search revealed that the men's experiences of living with a wife who leaks urine are hardly told and the few studies that briefly describe men and fistula report men divorcing their wives with fistula [56, 59, 169, 170]. This makes the Ugandan men's experience a crucial step in bridging this knowledge gap but also makes the comparison of our findings limited.

5.3 EARLY DISCHARGE AFTER SURGICAL REPAIR OF FISTULA (IV)

No randomised trial has assessed feasibility, efficacy, safety and acceptability of early discharge following surgical repair of fistula. Globally the standard of care is 14 days hospital care and discharge after catheter removal. We investigated whether women who had a surgical repair of urogenital fistula could be discharged early without affecting the treatment outcomes or increasing complications. A reduction of time spent in the hospital could result in more patients operated and a reduced fistula backlog. Studies on fistula report that catheterisation is a key determinant of the length of hospital stay following fistula surgery and also highlight that a short duration in the hospital could reduce the treatment costs incurred by the health facility and patient in addition to efficient use of bed space [171-173].

Our results show that it is possible to discharge stable patients who have undergone surgical closure of a urogenital fistula early on the third to fifth postoperative day without significantly affecting the treatment outcomes when compared to the current recommended discharge after 14 days. The results further show that early discharge is non-inferior to discharge after 14 days in terms of the proportions of women with a repair breakdown; for upper limit of the 95% CI (4.9%) fell below the predetermined non-inferiority margin (10%). This study excluded only the circumferential fistulas with 1 cm from the external urethra meatus (VVFIIb) and included all the other types (Waldijk classification [45]) irrespective of complexity and hence results are applicable to the majority of patients with fistula. The results further showed that the proportions of patients with secondary outcomes (post repair incontinence, urethra stress incontinence, catheter blockage, complications) were similar in both groups, demonstrating that patients were able to take care of the catheter at home, without affecting the repair outcome.

The wish of any fistula surgeon is to have the fistula closed and for the woman to be continent by day and night and voiding normally [127] In this study, more than 90% of the women became continent by day and night after surgery, with early discharge results being comparable to late discharge results (92% in the early vs. 89.3% in the late groups). The findings of this study showed a high success rate in both groups that compares with the results reported in other setting with experienced surgeons, with cure rates ranging from 65–95% in the hands of competent surgeons [11, 45, 127]. The high cure rates in both groups could be explained by the surgeons' skills (FIGO accredited), exclusion of VVFIIb and other fistulas with a known factor that affect wound healing such as recto-vaginal fistula, cancer, and anaemia.

These findings are relevant in Uganda, as well as other low-income countries, with a poorly funded health system that is overloaded with patients and with facilities often lacking in quality, equipment, supplies, space, and manpower. With a global estimated backlog of 2-3 million women and the limited time, space, and resources to attend to non-emergency surgeries including fistula repair [13, 42], the findings of

this study become relevant in addressing the backlog. Early discharge has been reported to decrease the burden on the health system by reducing time for inpatient care and gives health facilities opportunities to handle more patients, in addition to improving patient satisfaction and easing recuperation [41, 42, 173]. Even if this study has not assessed the cost benefit aspects of early discharge, it is obvious that decreasing the length of postoperative hospitalisation from 14 to three days has a direct bearing on reduction of facility and patient costs compared to the current practice. Patients who are discharged three to five days following fistula repair release the bed space to other patients, and the cost of each patient is reduced by 9-11 days.

The results also show that it is possible for patients to take care of the catheter while at home, with no more complications compared to when the care is hospital-based. There is no clear advantage of continuing to keep patients in hospital for 14 days or more following a fistula closure. The study is the first to address the issue of early discharge of patients following surgical repair of fistula. We therefore had no similar published studies to compare the results of this study, apart from other urogynaecology and obstetrics studies that advocate for early discharge and without affecting the outcomes of surgery [46-49, 52, 54, 174-180].

5.4 METHODOLOGICAL CONSIDERATIONS

5.4.1 Qualitative papers

Our study was rigorous, is trustworthy but not devoid of limitations, which we discuss below.

5.4.1.1 Rigor

Integrity and competence in qualitative research process (rigor) [181] of findings in this thesis is demonstrated through triangulation, reflexivity, peer debriefing, member check and practice of standard research conduct procedures. Triangulation refers to when a researcher compares the findings of different methods and the perspectives of different people or groups to help produce more comprehensive findings [182]. Triangulation takes several forms but the common ones are methods triangulation, triangulation of data sources and investigator triangulation [183]. In this thesis we used methods triangulation (IDI, FGD and quantitative methods) and investigator triangulation. A social scientist, gynaecologist/fistula surgeon, and midwives collected the data. The co-authors included one obstetrician gynaecologist, fistula surgeon, reproductive health researchers, Midwives, statistician, epidemiologists and global public health researchers. The synergist effect of the different investigators enhanced the needed science of this research.

Reflexivity aims at enhancing researcher's recognition of their own influence on research process such as gender, ethnic background, social status and professional background [181]. In this thesis, the team was cautious of the possible bias that could be introduced and triangulation of investigators with an insider and outsider

view in a way solved this. During data collection we debriefed our peers (researchers) by sharing what was emerging from the FGD And IDIs. The feedback was integrated in the subsequent discussions and interviews. Member checking is a process of confirming or refuting meaning by reflecting it back to the participants to ensure that what was understood was credible [183, 184]. We never went back to the participants after analysis of the data due to logistic reasons but to some degree we did some member check during data collection process when some of the participants listened to the audio files and confirmed what they had discussed. In the entire study, we applied standard techniques of data collection while collecting data. Careful selection of research assistants with experience and training was done. We translated the information to participants and tools into the local languages (Luganda and Runyoro), audio-recorded the FGDs and IDI and audio tapes were transcribed verbatim (**II** and **III**).

5.4.1.2 Trustworthiness

Trustworthiness in qualitative research involves establishing: credibility (confidence in the 'truth' of the findings), transferability (showing that the findings have applicability in other contexts), dependability (showing that the findings are consistent and could be repeated) and confirmability (a degree of neutrality or the extent to which the findings of a study are shaped by the respondents and not researcher bias, motivation, or interest) of the findings [184]. Through a detailed (thick) description of the data collection methods and analysis, credibility and transferability of our findings has been enhanced. In qualitative research, the researcher is the instrument (reflexivity). Validity of the data depends a lot on the skills, competence and hard work of the researcher. The relationship between researcher and informants is inseparable and both sides influence each other. I acknowledge the shortcoming of being a doctor to the women but also being the researcher involved in the data collection and analysis process. On the other hand, confirmability focuses on neutrality of the data rather than neutrality of the researcher [184]. To minimise the power differences between the researcher and respondents, we involved a social scientist in the data collection, transcription and translation. Also, all the FGDs and IDI were audio recorded, analysis had both insider (Ugandan) and outsider (Swedish) perspectives from the research team, and all our conclusions are grounded in the data.

Appropriately and carefully selected respondents enhanced credibility of our findings. The FGDs and IDI were appropriate methods to investigate the experiences of women with fistula and that of their spouses (**II & III**). Credibility is also demonstrated through strategies like member checks, peer debriefing and triangulation.

Dependability was achieved by having senior scientists (Swedish and Ugandan academic supervisors and co-authors) who were not directly involved in the data collection but with the principal investigator read all the transcripts. The Ugandan

team additionally listened to the audio files in the local languages. The whole research team then was involved in the analysis and writing of the papers.

Transferability is enhanced when thorough description of research context and assumptions are made [184]. Socio-demographic characteristics of our participants, data collection methods and analysis are described in-details. Therefore, our results can be transferred to a setting similar to our study setting.

Confirmability seeks to establish that the data and interpretation of the findings are not the inquirer's imaginations but rather are clearly derived from the data. In our case, we read through the transcripts several times and, thereafter, derived codes, categories and themes (II) and a composite narrative (III) from the data. We stayed close to the text and we include thick descriptions reflecting the social reality in the Ugandan context. We also used verbatim quotes to vividly give an opportunity to the reader to make their own judgment about the context. We believe through the rigorous process trustworthiness of our findings is established.

5.4.1.3 Limitations

We do acknowledge our limitations. The triangulation of our data collection methods using FGD (II) and IDIs (III) helped us to get rich data on experiences of life with a fistula to the patient and spouses, but we acknowledge the shortcoming that it was not done concurrently in each sub study, which could have further enriched findings. We initially wished to include spouses of women with fistula irrespective of whether they had stayed married or were separated/divorced (paper III) but we miss the experience of men who divorce their wives for they refused to participate. We also acknowledge the fact that the interviewer being one of the doctors who operated women whose spouses were interviewed could have affected the preparedness of the men to participate in the interview and the responses the men gave. As a limitation, we cannot tell whether this relationship affected the results for good or bad. Also the transferability of our findings to populations and contexts beyond our research context may be limited. Our study is context specific and illustrates the situation of Ugandan couples affected by genital fistula. We have given a thick description of the research methods including a detailed analysis process to enable judgements by other readers on how transferable our findings are to other comparable contexts[118, 134]. Although the research findings are specific to a setting in central and western Uganda, we suspect that the findings may reflect experiences of women and men affected by fistula in similar low resource contexts. The findings on fistula may be transferable (theoretical generalizability) to other women and men with chronic and stigmatising condition in other low resource settings.

5.4.2 Quantitative papers

Quantitative results in paper I may be generalised to other rural districts in Uganda where the health system structures, resource-level and community settings are similar to those of the three district studied (Hoima, Kibale and Kyenjojo). The identified problem of fistulas resulting from injury during surgery may be cutting

across other districts. The results in paper IV could be generalized to other settings where fistulas are prevalent since all treatment followed global guidelines set by FIGO and partners. However, those with circumferential urethra fistulas (VVFIIb) and RVFs need to be looked after for 14 days until evidence is adduced.

In the case-control (**I**), the respondents were asked questions related to several variables of the study that had occurred in the past with varying duration of living with fistula and this could have led to recall bias. Recall bias generated by this phenomenon is, however, unlikely to have played any major role in this study since both the cases and controls were from the same geographical base and hence both groups were prone to the same bias. Hospital controls were recruited among women who were sick or attendants to other patients in the hospital and these women might have different exposure histories compared to if we had recruited women from the community, which was not possible due to logistical reasons. However, the frequency matching by age and the fact that these were hospitals used by local communities counteracted this effect. It was also a limitation that we could not tell which women had cephalo-pelvic disproportion or obstructed labour but no fistula. If known these women should have been excluded since they may be similar to those who developed fistula.

In the randomised trial (**IV**), the comparison of the intervention by socio-demographic and clinical/surgery characteristics showed that randomisation worked well for there were no significant differences in the two arms, hence the association between the intervention and the outcome was not affected by selection bias. In addition, the study was carried out in a FIGO-accredited centre, and FIGO-accredited trainers performed all the surgeries. Methodologically, the permuted blocks ensured the similarity of groups with regard to potential confounders, and the study had a pre-specified non-inferiority margin. We never lost any of the participants during follow up, a fact we attributed to telephone reminders but also that the three months follow up is when the final results of treatment are given and women advised to resume sexual activities. ITT and per-protocol results were similar for there was only one protocol violation. The main limitation of this study was that it was open-label. The nature of the intervention, whereby women were discharged earlier and research assistants together with the surgeons participated in the outcome assessment, could not allow the study to be blinded to either the research team or the participants. We could have used different personnel at each level of assessment and mask them but the resources could not allow. However, the research assistants were unaware of the primary outcome.

6 CONCLUSIONS AND IMPLICATIONS

6.1 CONCLUSIONS

1. Risk factor for obstetric fistula in western Uganda are more or less similar to what has been found in other contexts and include caesarean section (iatrogenic injury), prolonged labour, big baby, short stature, and low/no education. There is a high prevalence of iatrogenic fistula following injury during caesarean section in this setting.
2. Women with a fistula are challenged physically, socio-economically, psychologically and sexually. Their life is full of adjustments to cope with the stigma, social isolation, and marital sex challenges. They use both problem- and emotion-focused coping as they live with fistula.
3. The effects of fistula surpass an individual woman's life and greatly affect spouses. Both women with fistula and men whose wives have fistula do not fulfil their gendered roles as partners in work and love; instead, they devote funds and time to seek for care and treatment of fistula.
4. Men who continue to live with wives who have fistula face challenges as individuals but also as members of a socially gendered and masculinised society. The men have to fulfil their culturally assigned roles as men. Though they feel challenged socially as men they have to remain married to their wives with fistula for they believe marriage is both a culture and a God given role they must fulfil amidst other factors they advance for remaining with their wives.
5. Following surgical repair of a female urogenital fistula, early discharge with a catheter (3-5 days after surgery) is non-inferior to discharge after 14 days of inpatient care. The practice (early discharge) is effective, safe and acceptable and there is no clear advantage of continuing hospital inpatient care for 14 days or more.

6.2 IMPLICATIONS

Below is a list of implications to policy, practice and future research

1. There is a need for improved obstetric care in this setting through in-service training and regular support supervision of service providers in western Uganda and other rural settings to prevent prolonged labour and improve on surgical skills of medical officers. Since specialists in Obstetrics and gynaecology hardly operate the women, we feel these results may be the basis for retraining of the medical officers (GPs) to gain skills. I believe young doctors' skills need to be continuously monitored and improved to avoid iatrogenic fistula.

2. A community intervention education and advocacy programme aimed at making the population aware of the risk factors and burden of fistula on men and women affected should be devised. Also the community programme should target the grassroots with messages on risk factors, availability of treatment and societal role in reducing the stigma and isolation of women with fistula.
3. There is need to scale up implementation of early discharge since it may be a cost saving to both the patients and the health units. If early discharge is implemented, space will be freed for more women to have their fistulas repaired and this may reduce the fistula backlog in Uganda and globally.
4. We recommend further research to:
 - a) Explore the experiences of women following treatment in order to establish the community needs for the women after discharge from hospital and also establish the quality of life the women live after treatment.
 - b) Explore experiences of men who divorce their wives whose views are missed in this thesis.
 - c) Conduct a community-based study to establish community perspectives on female genital fistula including awareness of prevention, treatment and rehabilitation.
 - d) Conduct a cost analysis and cost-effectiveness study to establish the cost differences between early and late discharges of women who have had fistula repair in Uganda and globally.

7 ACKNOWLEDGEMENTS

My sincere thanks and gratitude go to numerous individuals, organizations and entities that have contributed in various ways to this academic process. Without you, the execution of my mission would have been impossible. I will forever be grateful for the cooperation, insights and support I received from all of you. It may be impossible to mention all the contributions from each one of you. However, my deepest and most sincere thanks go out to all of you, including those not mentioned by name, for you all have made through individual or institutional contributions towards my doctoral training.

In a special way, I acknowledge the support from my supervisors led by Prof Elisabeth Faxelid. Elisabeth you are special to me, and thank you for having diligently and professionally managed the team. Even when some would slack, you would quickly bring us back to course through timely and targeted communication. All the Co-supervisors: Josaphat K Byamugisha, Nazarius M Tumwesigye and Lars Almroth, thank you for your stewardship in this journey from concept development up to date. There could not have been a better team than this. I have nothing to pay but just to say thank and wish you a good professional life. I also sincerely appreciate the technical input brought into the project as we made sense of our results while writing the manuscripts by Birgitta Rubenson, Jolly Beyeza-Kashesya, and Mutatatina Boniface. Your contributions made miles further in the journey and thank you.

My dear mentor Florence Mirembe, I don't know how to express my gratitude for the work well done. It was very difficult, but you provided a way when I thought I had reached a dead end in the initial stages when I was sick. At all levels you always smiled and encouraged me. Thank you very much and may God bless you.

This research work was made feasible with a grant from the Swedish International Development Agency (Sida) under the Makerere University and Karolinska Institutet collaboration Phase 3. I am grateful to all those individuals and groups who in one way supported this facilitation like the Swedish Institutet (SI), International science Programme (ISP), the Swedish and Norwegian Embassies in Kampala. Special thanks to UNFPA and Mulago National referral Hospital administration for providing equipment, supplies and space for our study within the campaign to end fistula. This facilitated all women who had fistula including all participants in our study to have free surgical treatment. We also thank TERREWODE for facilitating these women while admitted and contributing part of their transport refund.

To Prof. James Tumwine, thank you for coordinating the Sida Programme in the college of Health sciences. Your excellent coordination ensured a significant reduction in the bureaucratic bottlenecks especially during preparation for our fieldwork. Thank you for your advice, leadership and scientific input on top of your timely actions in the logistical facilitation. Fred Bwanga I also thank you for constantly reminding us about technical requirements and updates.

To the IHCAR family, you were teachers, friends and role models. You always made me feel at home. Thanks to all of you. On a special note, Vinod Diwan, thank you for the initial epidemiological input in the study and facilitating the registration process at KI. To Elisabete Weiderpass and Birger Forsberg, thank you for reviewing my work during the preregistration seminar. Jon Oyvind Odland, Jerome Kabakyenga and Elialilia Okello, Thank you for your constructive comments during my half time control seminar. The comments have had a great influence on the shape of this thesis. Lucie Laflamme thanks you for the wise instructions during the ethics course and Kappa course. To all the faculty members I simply say thank you for the contribution through seminars, courses and meeting. Special note to Goran Tomson, Rolf Wahlstrom, Anna Mia Ekstrom, Stefan Peterson, Cecilia Stålsby Lundborg,

Asli Kulane, Marie Hasselberg, Gaetano Marrone and Andreas Mårtensson and many more, for an excellent learning environment.

The administrative staff at IHCAR will always be imprinted in my minds for making this place a wonderful workplace. Special thanks to Gun-Britt, Kersti Rådmark, Bo Planstedt, Marita Larsson, Marrie Dokken, and the rest of your team for the excellent work. I am also thankful to Andreas, Jacob and Martin for always being there whenever the ‘Ugandan’ computer failed to obey my poor commands.

I enjoyed discussions and lots of useful advice on reading material, data analysis and so on from my peers at Makerere University: Gorrette Nalwadda, Bakeera Solome, Norah Mwebaza, Kiondo Paul, Namusoke Fatuma, David Mukanga, Nakimuli Annet, Kakaire Othman, Ononge Sam, Nakubulwa Sarah, Nakalembe Miriam, Joan Kalyango, Christine Nalwadda, Roy Mayega, Simon Walusimbi, Agnes Nanyonjo, Francis Ochieng, Dan Wamala. In the same vein, I cannot forget the useful insights and good moments I shared with peers at Karolinska Institutet: Patricia Awiti, Ketkesome P, Elin Larson, Anna Bergstrom, Senia Rosales, Edith Tarimo, Hanani Tabana, Rashmi Rodrigues, Sandeep Nerkar, Erika Saliba, Kristi Sidney, Amanda Cleve and Dorcus Kiwanuka Henriksson, Stefan Kohler, Sachiko Lim, Juliet Aweko, Tumaini Nagu, Helga Naburi and all I have not mentioned. Thank you all for being the first point of reference, I learnt more from you as my peers than from the textbooks I read.

To all my colleagues especially the senior staff at the Department of Obstetrics and Gynaecology, Makerere University, thank you for all the encouragement, time and support. Special thanks to the staff of Urogynaecology division (Gynaecology Outpatient, Ward 11, and Urogynaecology theatre) for you have made this work possible. On a special note, Susan Obore, Mwanje Haruna, and Alia Godfrey, thank you for being there for me especially those days I would be away in Stockholm. Thank you for the continued good work where you help these women with pelvic floor disorders to regain dignity.

Special thanks go to my research team in Mulago, Hoima, Kagadi, Kyenjojo and Mubende hospitals. Mulago: Aguttu Margaret, Ouchi Rose, Nyakato Felista, Maureen Ssekisolo, Michael Ssegirinya, Zalwango Teddy, Birungi Joanah, and Tuhirirwe Grace. Hoima: Mastula Kasujja, Mulwany Francis, Achayo Evelyne, Akusekera Eunice, Busulwa Chritine and Proscovia. Kagadi: Nabukera specioza, Olowo Francis, Nzyabake Mary, Nakayiza Annet. Kyenjojo: Anita Babukika, Kisozi Twaha, Kimara Harriet, Africana Bernard, Harriet and Namusisi. Mubende (Screening and follow-up): Alphonsus Matovu, Prossy Nabale and Mirembe Violet. All of you thank you for the efforts and may God bless you and reward you on my behalf, for the job well done.

To leadership at Directorate of Research and Graduate Training (DGRT), under Katunguka Elly Rwakishaya and then Buyinza Mukadasi thank you for your stewardship. Special thanks to Maria Nakyewa, Nestor Mugabe, Allan Kiiza (records), and all your colleagues in the Sida Grant office- you did your best amidst challenges of the system and thank you very much and keep it up.

Despite the PhD training demands, MY SOCIAL NETWORK, you never left me in both good and bad times. You kept me posted of what was happening though I often missed the physical presence. To the members of Nsanbya Biika Oryeho Obeho Group (NBOOG), Abamwe Gangu Association (AGA), Kampala Banyarukiga Tweyambe Group (KABTAG) and Kashambya Kweyamba Group (KKG), thank you for all the help, love and care you extended to our family. Special thanks to Robert Tumukwasibwe, Ambrose Mugisha, Twinomujuni Kafunjo, Rwehunga Phillip, Alex Nyesiga, Mureeba Julius, Twesigye Patrick, Sunday Deus, Ariho Alex Bitwabweine, Orikiriza Kedress and Twebaze Victor for constantly engaging me even when things looked impossible.

Anna_Berit Ransjö Arvidson, thank you so much for being my mother, mentor, and friend in Stockholm. At Dalgängen 4, I became a child and thank you for the home away from home. The cooking lessons, the research methods, the advice, the lift to the T when the weather became difficult in winter, and many other things. Thanks to the lovely family and the sweet music from the piano, and tube fiddle by your dear husband Jan Arvidson that always refreshed me after a hard days work. Thanks to your lovely children and grand children whose company I enjoyed. You will forever be in my heart and I hope one day I would reciprocate if you ever come to Uganda.

I acknowledge the contribution made by my dear Mother Nyabucurera Jovanice (RIP), you laid the foundation stone though you never lived to see the fruits from the flowers. My dear father Wilson Kafunjo (RIP) even when you departed in the middle of the course, you left after doing your part and I remember the encouragement I got from you when I started the PhD training. My dear Father-in-Law Timothy Rwakatarira (RIP), I remember when we were discussing the course and the likely celebrations after but cancer could not let you live to witness. All my relatives, thank you for the support and encouragement, I cannot mention all of your names for we are indeed extended. However let me thank Fred Rutahweire, Molly Nyandudu and Charity Kyarisima for taking care of our upcountry home and property when we are away. Knowing that you are there and caring gave me peace to read and may God reward you.

Finally my dear wife Rosette Barageine, Thank you for being there for me. I know you had moments when you felt the bed was too big (*Mazongoto*) but it is done and I commit and renew our love. Thank you for the care you gave the children, our ailing parents, and me. Thank you for the advice and forgive me for whatever was not right or never fulfilled during the course. In the same vein, I thank our dear children Aine Milly, Agaba Mark and Ashaba Mellisa for being there for me. We challenged each other regarding our reading habits, we shared good moments but I also know you often missed my company. I only commit to be there for you as you continue your education and always remember the wise saying by Albert Einstein "*Education is what remains after one has forgotten everything he learned in school*".

Thank you all and may God bless you

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