



Addis Ababa University

College of Health Science

School of Public Health

The trend of iatrogenic genitourinary fistula and its risk factors among genitourinary fistula patients at Hamlin fistula hospital from 2005 to 2019.

By

Maranata Dawit Ambaw

**Thesis submitted to Addis Ababa University School of Public Health
Department of reproductive, family and population health for partial
fulfillment of the degree of master of public health**

December, 2020

Addis Ababa, Ethiopia

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Assurance of Principal Investigator

All the gathered data was collected appropriately with all ethical considerations were followed in the process. All necessary comments and guidance was gained from my Advisors. The research findings and final thesis maintaining accuracy as much as possible were submitted in time.

Name of student: -----

Signature: -----date-----

Name of Advisor: -----

Signature: ----- date: -----

**Addis Ababa University
College Of Health Sciences
School of Public Health**

This is to confirm that the thesis prepared by Maranata *Dawit Ambaw*, entitled; **‘The trend of iatrogenic genitourinary fistula and its risk factors among genitourinary fistula patients at Hamlin fistula hospital from 2005 to 2019.’** and submitted for fulfillment of the partial Requirement of the Degree of Master of Public Health follow the regulation of the university and fulfills the accepted minimum standards in terms of originality and quality.

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Abbreviations and Acronyms

AAPC	Average annual percent change
APC	Annual percent change
CS	Caesarean section
DRC	Democratic Republic of Congo
EmONC	Emergency obstetric and newborn care
EDHS	Ethiopian Demographic And health survey
HFE	Hamlin Fistula Ethiopia
IF	Iatrogenic fistula
IHI	Institute of healthcare improvement
LMIC	Low and middle income countries
LSHTM	London school of hygiene and tropical medicine
RVF	Recto Vaginal Fistula
SBA	Skilled Birth Attendant
SPA	Service provision Assessment
VCVF	vesico-cervico vaginal fistula
VVF	vesico vaginal fistula

Abstract

Background: Genitourinary fistula is public health importance in low and middle income countries though it has been neglected. It has multiple health adversities to women. It is mainly caused after lack of timely and appropriate intervention mainly cesarean section. But genitourinary fistula can be Iatrogenic because of medical error during obstetric and gynecological surgery like cesarean section and hysterectomy.

Objectives: This study assessed the trend, major surgical procedures resulted in iatrogenic genitourinary fistula and its risk factors.

Methods: a facility based cross sectional study design was deployed. A mixed method that involved both quantitative and qualitative study was done. The study included respondents retrospectively using their medical history from January 2005 to December 2019 at Addis Ababa fistula hospital, Addis Ababa, Ethiopia. All Iatrogenic genitourinary fistula patients who fulfill the inclusion criteria and registered by the Addis Ababa fistula hospital over the study period were included in the quantitative study while clinicians and care providers who were providing service in the facility during the study period considered for the qualitative study. Data was cleaned and analyzed using SPSS version 20.0 software. Descriptive statistics such as frequencies and graphs were used. Results were shown using frequency tables to show Sociodemographic characteristics of fistula patients and frequency of iatrogenic genitourinary fistula by type and by cause. Bar graphs and pie chart was also used. Time trends in incidence of iatrogenic genitourinary fistula were analyzed using linear regression analysis. Annual percent change and average annual percent change were calculated using joinpoint regression analysis on joinpoint regression program version 4.8.0.1. Binary logistic regression model applied to identify risk factors associated with iatrogenic genitourinary fistula. Crude odds ratio and adjusted odds ratio with 95% CI reported. Analysis of qualitative data was done using open code software version 4.02 to code and categorize data.

Result: Total 9229 fistula patients treated at Addis Ababa fistula hospital, of which 643(6.96%) and 8,586(93.03%) were iatrogenic genitourinary fistula and obstetric fistula cases respectively. The mean age of iatrogenic genitourinary fistula patients was 30.02 ± 4.625 years (Range, 17-45 years) and the mean age of obstetric fistula patients was 26.65 ± 6.534 years (Range, 14-42 years). 341(53%) had iatrogenic genitourinary fistula after cesarean section while, 131(20.4),

78(12.1%), 93(14.5%) were after repair for ruptured uterus, hysterectomy for ruptured uterus and gynecological hysterectomy respectively. A significant rising trend in iatrogenic genitourinary fistula was found from 2005 to 2019 (1.55% to 52.9%; $p < 0.001$) but the trend significantly declined in obstetric fistula (98.45% to 47.1%; $p < 0.001$). average annual percent change throughout the year 2005-2019 is 13.2% (95% CI 7.7-18.9). Binary Logistic Regression analysis shows Previous history of obstetric or gynecologic surgery, type of institution at which the surgery is performed; height and parity were found to be factors significantly associated with iatrogenic genitourinary fistula.

Conclusion: Iatrogenic genitourinary fistula has increased over the last 15 years and an urgent action for improved and safe operation and surgical procedure on abdominal and pelvic surgeries is important.

Keywords Iatrogenic, obstetric fistula, cesarean section, hysterectomy

1. Introduction

1.1 Background

Genitourinary fistula is public health importance in low and middle income countries though it has been neglected. It has multiple health adversities to women. It is mainly caused after lack of timely and appropriate intervention mainly cesarean section. But genitourinary fistula can be Iatrogenic because of medical error during obstetric and gynecological surgery like cesarean section and hysterectomy. This injury will cause holes between the vagina and bladder and/or vagina and rectum which eventually led to incontinence of urine and faeces(1).

An iatrogenic genitourinary fistula is an abnormal hole or communication between bladder or ureter and the uterus/cervix/vagina which is most of the time caused by a medical error during surgical interventions mainly during delivery by Caesarean section, repair for ruptured uterus , hysterectomy for ruptured uterus and gynecological hysterectomy(2).Ureteric injuries resulting after Cesarean section, hysterectomy and gynecological hysterectomy, vault fistula after a hysterectomy for gynecological reasons, such as fibroids and finally Vesico cervico vaginal fistulaafter delivery of a live baby by Caesarean section can be categorized under iatrogenic genitourinary fistula. A VCVF located between the lower segment of the uterus/cervix and the bladder strongly suggests an accidental bladder injury (suture or cut) during Cesarean section. Vault fistula resulting after emergency hysterectomy for a ruptured uterus or Caesarean section or are probably iatrogenic genitourinary fistula. Vesico-uterine and VCVF after Cesarean section for a stillborn baby are most likely to be iatrogenic in origin(2).

A medical error can be defined as an intended act either of omission or commission or one that does not achieve its intended outcome, the failure of planned action to be completed as intended or the use of wrong plan to achieve an aim. Throughout the world more than 200 million surgeries are done annually. To address patient's safety during surgeries many nationwide and global initiatives were formed. '100,000 lives campaign' in 2005/2006 is one of them with subsequent '5 million lives campaign' in 2007/2008 by institute of health care improvement (IHI). The other initiative was the WHO safe surgery save lives' campaign in 2009(9).

1.2. Statement of the problem

Birth attendance by skilled care providers has substantially increased in the past decade. Globally, 73% of births attended by skilled birth attendant(3). Though, many countries didn't meet the Millennium Development Goal for maternal mortality reduction by 2015. Annual maternal death is still nearly 300,000 and countries should improve quality of care to plummet maternal and newborn mortality in line with sustainable development goals(4).

A retrospective review of 5,959 genitourinary fistula cases from 11 Sub-Saharan and South Asian countries found 13% of iatrogenic genitourinary fistula cases caused by medical errors during obstetric and gynecologic surgeries in which Eighty percent of these iatrogenic genitourinary fistula cases resulted after surgeries to address obstetric complications mainly cesarean section, hysterectomy and repair of ruptured uterus(2).

Many developed and developing countries have made substantial progress toward the eradication of obstetric fistula which is usually caused by prolonged and obstructed labor. However, even if fistula from prolonged and obstructed labor is eliminated in developed and developing countries iatrogenic genitourinary fistula continues to occur at an alarming rate mainly in low and middle income countries(5). depression and anxiety, Social isolation, Depression and grief related to infertility, Inability to work, and Stigmatization are some of the consequences of genitourinary fistula(1). The consequences of genitourinary fistula can be further complicated by recurring infections, infertility, damage to their vaginal tissue and paralysis of the muscles in their lower legs(6). The consequences of genitourinary fistula can be far more than the visible medical condition. Little evidence is available on mental health, child and fertility issues and coping mechanisms(7).

Some of the determinants for the occurrence of Iatrogenic genitourinary fistula include prolonged labour prior to obstetric surgery, Medical co morbidities/case-mix, hospital type/size/location, technological resources of the health care facility and physician's years in practice, location of training, medical specialization(8).

1.3. Rationale of The study

Despite the fact that there are many researches done that shows the prevalence and risk factors of obstetric fistula, There are limited recent researches done specially in sub-Saharan Africa countries including Ethiopia and other developing countries on trend and risk factors of iatrogenic genitourinary fistula. The number of iatrogenic genitourinary fistula cases can be used to directly indicate the quality of care that the health service gives to the pregnant women. In many low-resource settings, women have heeded the call to deliver at a health facility to prevent fistula and other adverse outcomes. It is imperative that the health system in turn have to deliver quality care to them(10).Maternal mortality is still high in many low and middle income countries and further progress is limited by poor intrapartum care(11).

Pregnancy or childbirth related complications lead to more than 380 preventable deaths of women per day in low and middle income countries(10).improving the quality of labour and delivery is very important for continued reduction in maternal and neonatal deaths(12). Reliable and valid evaluation of quality of intrapartum care is very important to address high maternal and neonatal mortality rates in low and middle income countries but the progress so far is slow. Recent works done to develop and validate instruments for use in sub-Saharan Africa are encouraging but integrating into routine practice is low(13).

The findings from this research will benefit the government to modify the policy of health professionals training in the country to focus more on the quality rather than quantity of graduating health professionals. This study will also benefit to implement nationwide routine monitoring of iatrogenic genitourinary fistula making it as a reportable sentinel event and it will also benefit to develop standardized data collection tools to document information such as the causative surgical procedures and improve quality of surgical care. This research also helps the health system as a whole to realize that as access to emergency obstetric care and essential surgery expands in the country, it's essential that adequate safety standards be established and maintained.

2. Literature Review

2.1. The epidemiology of iatrogenic genitourinary fistula

Genitourinary fistula occur both in developed and in developing countries. Many of genitourinary fistula presenting to a health facility in a developing country particularly in sub-Saharan African countries occur as a result of prolonged and obstructed labor whereas in developed countries it is rare to see genitourinary fistula as a result of prolonged or obstructed labour but most of the time it occur as result of complications of gynecologic surgery or as the result of treatments for gynecologic and other pelvic organ malignancies. Efforts to prevent genitourinary fistula have to be focused on the event that usually leads to fistula formation(1).

Globally an estimated 300,000 women die every year due to pregnancy related complications in which 99% of this maternal mortality occurs in the developing countries(4). Annually between 50,000 and 100,000 new cases of genitourinary fistula occur and above 2 million people currently live with untreated genitourinary fistula throughout the world(5). The eradication of obstetric fistula from the developed countries is a significant achievement of modern obstetrics, Although there are around 3.5 million women in developing countries remain affected with this debilitating condition in of which 130,000 new cases occur each year in Ethiopia, Uganda, Niger, Nigeria, Afghanistan, Sierra Leone, and other parts of sub-Saharan Africa and south Asia. Genitourinary fistula is neglected because it will not result in death and the institutions capacity to treat and rehabilitate patients is very poor(14).

A study which is meta-analysis of Demographic Health Surveys and Multiple Incidence Cluster Surveys done in 19 sub-Saharan countries to calculate prevalence of vaginal fistula symptoms, the rate ranged from 0.4 genitourinary fistula/1,000 women of childbearing age in Burkina Faso to 19.2 genitourinary fistula/1,000 women of childbearing age in Uganda(15). Even if authors stated that the rate of genitourinary fistula to be 7.1 per 1,000 women of reproductive age in Ethiopia, if the causes of incontinence is not excluded this number might be higher. A large Ethiopian community-based study undertaken in 2005 stated that the prevalence of genitourinary fistula is 2.2 per 1,000 reproductive age women(16).

A study done in United States which is released in 2016 found medical error is a third leading cause of death in the country following heart disease and cancer constituting 9.5% of all deaths in United States to be caused after medical error.(48) A study of medical and surgical error claims in Ethiopia to analyze trends observed from 125 decisions made by the federal ethics committee for health professionals ethics review revealed 75.2% of complaints were from hospitals and majority of these complaints were emerged from operating room. 28.1% of complaints were against gynecologists and obstetricians (49).

Iatrogenic genitourinary fistula is most of the time caused during medical error in obstetric and gynecologic surgical interventions most often during cesarean section. Retrospective Reviews of fistula case records at repair sites in three countries in 2015 showed that 27% of cases in Bangladesh, 8% of cases in the DRC and 10% of cases in Niger were iatrogenic in origin(10). New Evidence is emerging that maternal morbidity is directly related to quality of care. Iatrogenic causes appear to take the highest proportion of genitourinary fistula mainly in low and middle income countries. In Countries where the volume of surgery has increased rapidly, there is an expected risk that iatrogenic fistula will become normalized rather than seen as a 'never event'(1). The risk of iatrogenic genitourinary fistulas will be dependent on the duration of obstructed labour prior to the Caesarean section, the qualifications and skills of the health professional performing the obstetric intervention, and the safety and appropriate equipment of the facility where the childbirth takes place(17).

Females are most of the time prone to risk during surgical interventions because of anatomical proximity of genital and urinary systems. Even if there are improvement of techniques of obstetric and gynecologic surgery, urethral and bladder injuries may still cause complications with high morbidity mainly excessive blood loss which may require frequent blood transfusion, prolonged operation time, fever and longer hospitalization(18-20). There are various risk factors increasing risk of genitourinary injury in gynecologic operations such as prolonged surgery, presence of active infection during operation, endometriosis, large uterus, previous pelvic operation, pelvic adhesion, gynecologic malignancies and myoma uteri(21). During abdominal hysterectomies the urethral and bladder injuries incidence may range from 0.36% up to 0.5%, 0.1 up to 1.8% in vaginal hysterectomies(22). In case of obstetric surgeries, bladder and ureter injury

risk increases as the number of Caesarean section increases and 1.71% up to 5.13% injuries resulted during hysterectomies with obstetric indication(23).

2.2. Trends of Iatrogenic Genitourinary Fistula

A retrospective review of 5,959 genitourinary fistula cases from 11 Sub-Saharan and South Asian countries found 13% of iatrogenic genitourinary fistula cases caused by medical errors during obstetric and gynecologic surgeries in which Eighty percent of the cases occurred after obstetric surgeries like cesarean section, repair for ruptured uterus and hysterectomy(2).

A two-year retrospective review of all cases that underwent repair for iatrogenic genitourinary fistula at the National Obstetric Fistula Centre, Babbar Ruga, Katsina, Katsina State, North West Nigeria from 1 Jan 2015 to 31 December 2016 found that 117(16.1%) of 728 genitourinary surgeries were from iatrogenic cause(24).

Another study which is a 14 years retrospective study done at Pakistan, institute of medical sciences found rising trend in iatrogenic fistula over the study period (2006–2018) from 43.5% to 71.4% and a decreasing trend in ischemic fistula, from 56.5% to 28.6%, was also observed(44).

A study which is done in England by using national hospital episode statistics found a 37% increase in fistula repair surgery for lower urinary tract fistula between 2002 and 2009, although the numbers were small in global terms. The study also found a 68% increase from 62 procedures in 2002 to 104 procedures in 2009 in primary fistula repair procedures(25). In another study the same authors found that the number of hysterectomies undertaken in England over the same period for selected benign and malignant indications decreased by 12 % (from 43,014 in 2000 to 37,923 in 2008). They also further examined the risk of developing vesicovaginal Fistula and urethrovaginal fistula after hysterectomy in the National Health Service in England. They found overall a 50 % increase over the course from 1 in 681 hysterectomies in 2000/2002 to 1 in 465 hysterectomies in 2006/2008 but it depends on the indication and type of procedure carried(26). In a further study of ureteric injury and urethrovaginal fistula associated with hysterectomy the same group found the risk more than

doubling from 0.29 % (1 in 345 hysterectomies) in 2001 – 2005 to 0.66 % (1 in 142 hysterectomies) in 2006 – 2010(27).

The volume of cesarean section delivery in low and middle income country settings has increased steadily in recent years(28). While the maternal and newborn health community mainly focused expansions of access to emergency obstetric and newborn care, including lifesaving surgeries, there is evidence that many cesarean sections are being performed in settings where necessary safety and quality standards of are not achieved. Evidences from the Fistula care plus project and its partners revealed that an increasing incidence of iatrogenic genitourinary fistula is mainly caused after surgical errors specifically cesarean section and hysterectomy(29). many factors can contribute to this problem like inadequate clinician training, insufficient surgical infrastructure and possibly task shifting may be contributing to this problem(30). researches done on health services in many countries suggests that inadequate access to and overuse of cesarean section now happens at the same time in the same countries(31).

Researchers from the LSHTM presented findings from an analysis of Demographic and Health Survey and Service Provision Assessment (SPA) data in 44 countries. Reviewing self-reported DHS data, Researchers found huge variation in population level cesarean section rates, from 1.5% in Chad to 34% in the Maldives. The analysis also found dramatic urban-rural disparities, up to a 19-fold difference in Ethiopia, and generally higher cesarean section rates in nonpublic facilities, up to a 3.6 ratio between nonpublic public and public facilities in Namibia. While the validity of self-reported data on provider type is not clear, in 28 of 34 Sub-Saharan African countries, more than 20% of women who had had a cesarean section reported that it had been performed by a “non-doctor SBA”. In nearly all Sub-Saharan African countries with data, the percentage of cesareans performed by non-doctor SBA was higher in public facilities(32).

A more recent review of Fistula care plus data found that the proportion of cases classified as iatrogenic genitourinary fistula varied over time among countries, with the highest proportion in Bangladesh (15–36% per quarter). In a survey of clinicians at 18 FC+ supported fistula treatment sites, one-quarter estimated that 25% or more of their cases were iatrogenic genitourinary fistula. Respondents also ranked the procedures contributing to iatrogenic genitourinary fistula in which

cesarean section delivery reported as the most important cause. Reviews of surgical fistula repair cases conducted in three countries found that 27% in Bangladesh, 9.9% in Niger and 8.3% in the Democratic Republic of the Congo (DRC) were classified as iatrogenic genitourinary fistula. In DRC and Niger, cesarean section was the most common causal procedure, whereas in Bangladesh, 75% of iatrogenic genitourinary fistula cases were related to hysterectomy(29).

In Ethiopia the 2016 Ethiopian demographic and health survey found 2% of live births in the 5 years before the survey were delivered by caesarean section (C-section). One percent of the C-sections were decided after the onset of labour pains, compared To the less than 1% that were decided before onset of labour pains and Caesarean section rates are higher among first births (4.3%) than for those of higher orders. The CS rate in urban areas is more than 10 times (11%) that in rural areas (1%). More educated women are more likely to undergo caesarean deliveries. The caesarean rate for deliveries for women with more than secondary education is 21%, compared with women with secondary education (6%), primary education (3%), and no education (1%)(34).

A study conducted at three of Hamlin fistula hospitals (Addis Ababa, Metu and Yirgalem) A total of 2,593 cases of genitourinary fistula were found in the three study centers over the 4-year period. Overall, the trends were the same in all three centers studied. During the four year study period annual genitourinary fistula cases significantly dropped by 20% from 2011 to 2012, 13% from 2012 to 2013 and 20% from 2013 to 2014. A total of 638 (24.6%) women had iatrogenic genitourinary fistula which is mostly result after gynecologic and obstetric surgeries. The proportion of high fistula increased over the years, with 26.9% of the cases being iatrogenic genitourinary fistula in 2011–2012 and 36.2% in 2014–2015 ($P < 0.001$). A significant association between an increasing rate of iatrogenic genitourinary fistula and a decreasing rate of obstetric fistula were found over the study period. A majority of multiparous women had iatrogenic genitourinary fistula (70.3%) than primigravid women (29.7%)(16).

2.3. Reasons and factors associated with iatrogenic genitourinary fistula

The appropriate workforce

There is an insufficient skilled workforce in several areas of the world mainly in low and middle income countries. This may cause extra work load for the workforce who are present and may lead to patient abuse and neglect. Caesarean section is most of the time carried out by the junior physician with minimum training, mentorship and supervision which results in poor decision making which inevitably followed by cesarean delivery in inappropriate cases using inappropriate techniques under inappropriate time. Preoperative risk assessment is likely to be inadequate, with failure to recognize the increased risk of damage to the urinary tract (at caesarean section or hysterectomy) associated with a previous operative delivery(35, 36). In some extent financial incentives may interfere in the choice of mode of delivery instead of clinical indications and lack of knowledge and experience of other ways of delivery like delivery of a dead baby using alternative ways. In the right circumstances emergency caesarean section may be life-saving, but when performed inappropriately it may increase maternal risk whilst being too late to improve perinatal outcome(37).

A study done by London School of Hygiene & Tropical Medicine on The Landscape of Cesarean Section of 44 countries in Sub-Saharan Africa and South and Southeast Asia categorized the person with the highest level of medical training from women potentially multiple responses about who assisted with their delivery into: doctor/Non physician clinicians (which includes medical or clinical officer), non-doctor SBA, and all non-SBA (lower level medical professionals, traditional birth attendants, and relatives). The percentage of women with a cesarean section who reported that the highest health professional assisting their delivery was not an SBA was minimal (median in 44 countries: 0.4%) and most likely represented recall error. However, relatively high levels were seen in Chad and Gambia (4%) and in Senegal (10%). Countries varied widely in the percentage of cesarean section assisted by a non-doctor SBA. All countries in South and Southeast Asia had levels of 20% or below, except for Cambodia (37%) and Timor-Leste (49%). In Sub-Saharan Africa, Rwanda had the lowest level (7%), but 28 of the 34 countries there had levels above 20% and six were higher than 50%. Burkina Faso and Mali had the highest levels, at 70%(32).

In Ethiopia the percentage of live births delivered by a skilled provider increased from 6% in the 2005 EDHS, to 11% in the 2011 EDHS, to 28% in the 2016 EDHS, and up to 50% in the 2019 EMDHS. A similar trend was observed for the percentage of live births which occurred in a health facility, which increased from 5% in 2005 to 48% in the 2019 EMDHS(38).

The appropriate working environment

A safe and equipped work environment is mandatory to minimize risk during surgical procedures which is most of the time low and middle countries lack. There is also inadequate electric power supply for lighting and running water is insufficient for scrubbing and sterilization. The surgical procedure equipment are also most of the time unavailable, in need of repair or unreliable.

To get access to operation room at night may be more difficult because of shortage of appropriate staff and instruments. This can be an additional problem to Delays in preparing the operating room and also members of the families may be gone to purchase drugs and materials from off-site pharmacy before the surgery began. These all are contributors to ‘Maine’s third delay’(39) and can mean that the ‘decision to delivery interval’ in some rural areas can be measured in days than minutes.

Type of Facility Ownership and institutional delivery

A study done by London School of Hygiene and Tropical Medicine on The Landscape of Cesarean Section of countries of Sub-Saharan Africa, South and Southeast Asia to compare percentages of cesareans with a non-doctor SBA by facility ownership in 28 of the 44 countries. In Sub Saharan Africa, 18 of 20 countries with data had a higher percentage of non-doctor SBA cesareans in public facilities than in nonpublic facilities; the widest difference was in Namibia, with 39% in public facilities but only 3% in nonpublic facilities. In South and Southeast Asia, four countries had higher percentages in public facilities (with India having the widest difference between public and nonpublic facilities, at 7% vs. 3%), and four had higher proportions in

nonpublic facilities (with the widest difference in Indonesia, at 10% public vs. 23% nonpublic)(32).

The Ethiopian demographic and health survey revealed that deliveries in health Institution increased from 5%,10%,and 26% in the 2000, 2011 and 2016 respectively. At the same time a significant decrease in home deliveries from 95% in 2000 to 73% in 2016 were found. Delivery in health institution in rural areas also showed an increase from 2% in 2000 to 20% in 2016. Facility delivery among urban women has also increased from 32% in 2000 to 79% in 2016(34).

Increased rate of caesarean section delivery

The last decade have brought a substantial increase in the number of delivery by caesarean section, as a result of this there is expected to be an increasing number of patients with complications associated with this procedure.Caesarean section is currently is one of the the most frequently performed obstetric surgery worldwide, and the number of delivery by Caesarean section increases every year. Taking this into consideration, the obstetricians and their patients should be aware of the potential complications associated with carrying out this procedure(40).

Cesarean section is essential surgery that can save mothers and babies live and reduces morbidity. However, cesarean section, even if it's medically indicated, can put women at risk if it's performed under environments with inadequate systems to support appropriate quality of care. Possible adverse outcomes include infection, anesthesia complications, and also iatrogenic fistula. Cesarean section can also increase future risks, such as placental abnormalities that may lead to hemorrhage in subsequent pregnancies. Yet, clinical decision-making protocols and guidance for cesarean section that are clear, practical, and evidence-based do not seem to exist anywhere(40).

Cesarean section rate in Ethiopia increased from 0.7% to 1.9% in 2000 and 2016 respectively. From all the regions in Ethiopia Addis ababa have the highest rate of cesarean section with

21.4% at 2016 and it is the highest increase since 2000. Cesarean section is highest among mothers of urban residence, first births, births from a women who have higher education level and births from women with richest quintile of household wealth(41).

2.4. Conceptual frame work showing the factors associated with iatrogenic genitourinary fistula

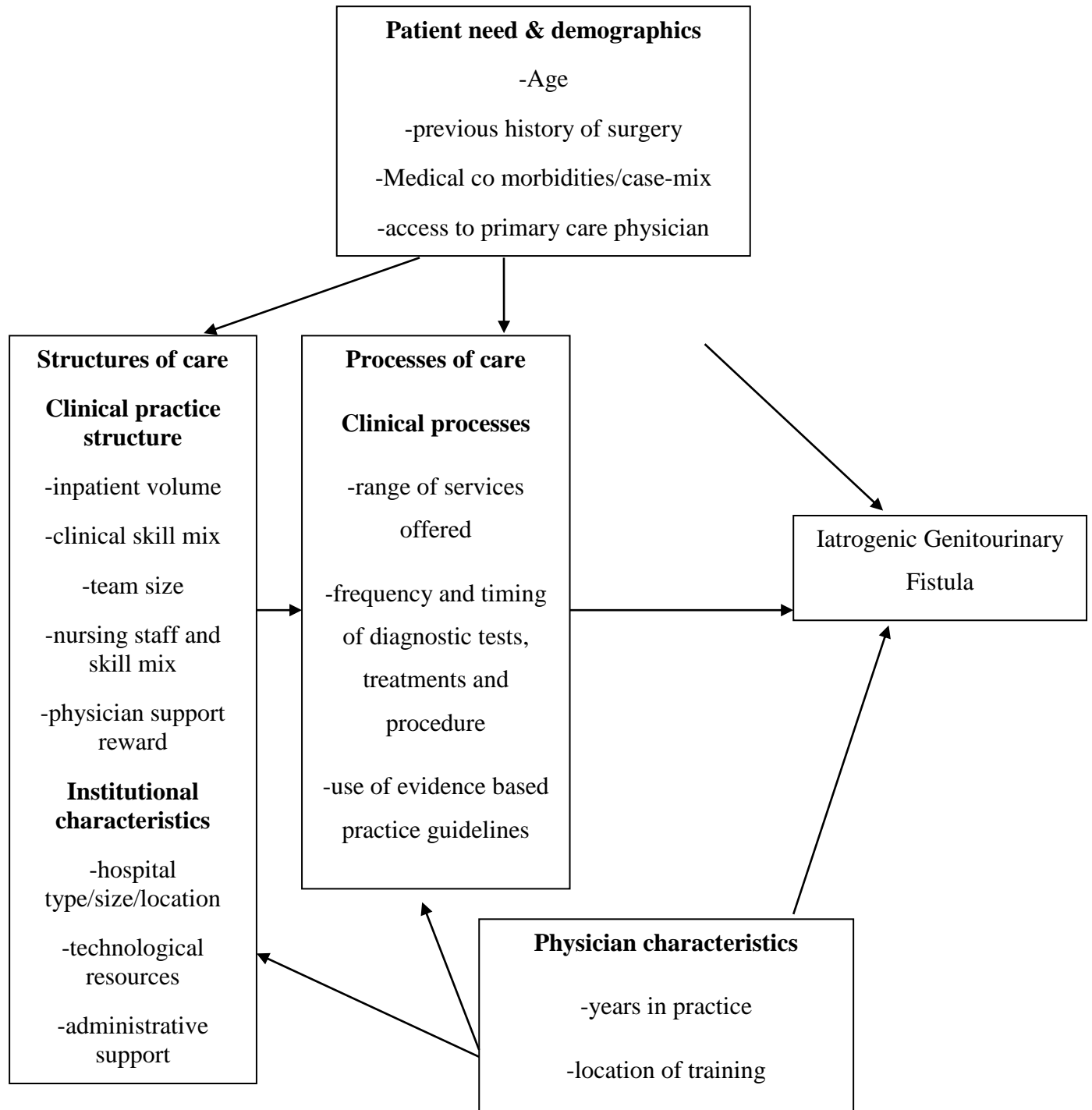


Fig.1.conceptual frame work showing the factors associated with iatrogenic genitourinary fistula

3. Objectives

2.1. General objective

- To assess the trends, major surgical procedures and risk factors of iatrogenic genitourinary fistula from January 2005 to December 2019 at Addis Ababa fistula hospital, Addis Ababa, Ethiopia.

2.2. Specific objective

- To measure the trend of iatrogenic genitourinary fistula from January 2005 to December 2019 at Addis Ababa fistula hospital, Addis Ababa, Ethiopia.
- To determine the major surgical procedures and risk factors for iatrogenic genitourinary fistula from January 2005 to December 2019 at Addis Ababa fistula hospital, Addis Ababa, Ethiopia.

4. Method and Materials

4.1. Study Design: a facility based cross sectional study design was deployed. A mixed method that involved both quantitative and qualitative study was done.

4.2. Study area and period: The study was conducted at Addis Ababa Fistula Hospital which provides curative and rehabilitative care for women who suffer from genitourinary fistula from June 5, 2020 G.C to July 15, 2020 G.C. It is located in the old Airport area/kolfe Keranio sub city behind the Augusta Garment Factory in Addis Ababa. Addis Ababa fistula hospital was founded by Dr. Catherine Hamlin in 1974(42). In addition to the main hospital in Ethiopia's capital, there are five hospitals in the Ethiopian cities of BahirDar, Mekele, Yirgalem, Harar and Metu. Since it's established the hospital treated 55,000 fistula cases and 93% of these fistula cases were repaired successfully. The rest 7% were rehabilitated in the center. The hospitals aim to cure 4000 women annually. This site was chosen as a study area because there is more advantage of the opportunity related to the presence of large number of cases at a single focal point.

4.3. Source and study population

4.3.1. Source population: All genitourinary fistula patients who came to Addis Ababa fistula hospital from January 2005 up to December 2019, Addis Ababa, Ethiopia

4.3.2. Study Population: All iatrogenic genitourinary fistula patients who came to Addis Ababa fistula hospital from January 2005 up to December 2019, Addis Ababa, Ethiopia

4.3.3. Study population for the qualitative study: surgeons, general practitioners and nurses who are currently giving treatment for the genitourinary fistula patients were involved in the qualitative study

4.4. Inclusion and Exclusion Criteria

4.4.1. Inclusion Criteria: All iatrogenic genitourinary fistula patients who visited Addis Ababa fistula hospital, Addis Ababa between 2005 and 2019 were included in the study.

4.4.2. Exclusion criteria: Patients who didn't have complete registered data were excluded from the study.

4.5. Sample size and Sampling procedure

All Iatrogenic genitourinary fistula patients who fulfill the inclusion criteria and registered by the Addis Ababa fistula hospital from 2005-2019 were included in the study. 4 surgeons 2 general practitioners and 2 nurses who are currently giving treatment for the fistula patients at Addis Ababa fistula hospital were involved in the qualitative study.

4.6. Study variables

4.6.1. Dependent Variables: iatrogenic genitourinary fistula

4.6.2. Independent Variables: Age, Parity, Height, Educational status, Region of residence, Type of referral institution, Type of hospital, previous history of gynecologic or obstetric surgery, Frequency of previous surgery, Age at time of fistula occurrence, Age at fistula repair, Type of iatrogenic genitourinary fistula , procedure caused iatrogenic genitourinary fistula , duration of urine leakage.

4.7. Data collection tools and Procedure

For data collection, Data collection checklist which is developed after review of patient's chart and similar literatures was used and data was recorded on data collection checklist through reviewing of patient medical history retrospectively.

Data relating to the availability of iatrogenic genitourinary fistula, Sociodemographic characteristics of fistula patients, previous history of gynecologic or obstetric surgery, Frequency of previous surgery, type of iatrogenic genitourinary fistula, procedure caused iatrogenic genitourinary fistula, age at fistula repair, age at time of fistula occurrence, duration of leaking was retrieved from the patient chart where they are routinely recorded.

Those patients who developed fistula after a major obstetric or gynecologic surgery and presented to the hospital with history of urine leakage were classified under iatrogenic

genitourinary fistula. Whereas those patients who developed genitourinary fistula after prolonged or obstructed labour and presented to the hospital with a history of urine leakage were categorized under obstetric fistula patients.

Three BSc nurses who are currently giving nursing care for the clients under study were recruited for data collection and they were given three days training on data collection tools and techniques. The data was then collected from June 5-July 15 2020GC.

The interview guide was developed by the principal investigator based on literature review that supports quantitative data. Key informant interview was conducted by the principal investigator using semi-structured interview via open ended question and different probing questions was used to get more information. An interview guide was prepared and all respondent were asked in English language. Since the qualitative part is to support the quantitative data eight interview was underwent with the length of interview time 15-30 minutes. Voice recorder was used for the interview.

4.8. Data Quality controls

Prior to data collection period, three days training was given for data collectors. Onsite supervision was given to solve any ambiguity with data collection tools and techniques and the data collection forms were cross checked at the end of each data collection day for completeness and consistency. Reliability and representativeness of a study is partly measured by its quality control approaches in each step of carrier. Thereby in this study, certain quality control measures were taken to assure quality of the study. These measurement strategies include:

1. Exclusion of incomplete data in a specific year of study
2. Inclusion of complete & specific data only in a respective year of study

4.9. Data processing and Analysis

After the collected data checked for completeness and consistency, data was encoded and entered to EPI-data software then to SPSS Version 20.0 software. After entering, data was cleaned, arranged, and analyzed using descriptive statistics. Results were shown using frequency tables for the Sociodemographic characteristics of fistula patients and for the frequency of iatrogenic fistula by type and by causative surgical procedures. Bar graph was used to show the most frequent surgical procedures resulted in iatrogenic genitourinary fistula and Pie chart was used to show the proportion of type of iatrogenic genitourinary fistula.

Time trends in incidence of iatrogenic genitourinary fistula were analyzed using linear regression analysis with SPSS version 20.0 software. Annual percent change (APC) and average annual percent change (AAPC) was calculated for iatrogenic genitourinary fistula using join point regression analysis on join point regression program version 4.8.0.1. This method describes changes in data trends by connecting several different line segments on a log scale at ‘join points.’ The analysis starts with the minimum number of join points (i.e., 0 join point, representing a straight line) and tests for model fit with a maximum join points. Permutation test with a significance level of 0.05 was used to determine the minimum number of “join points” necessary to fit the data. Incidence trend was stated by an Annual Percent Change (APC). Annual Percent Change (APC) were calculated using weighted least-squares regression, in which the independent variable was calendar year and the dependent variable was count of cases in each specific year. Average annual percent change (AAPC) was used to summarize trend from 2005 to 2019. It is computed as a weighted average of the APCs from the join point model, with the weights equal to the length of the APPC interval. Overall trend of iatrogenic fistula and trend irregularities by type were also calculated. Interval estimates for incidence of iatrogenic genitourinary fistula was calculated with 95% confidence interval.

Binary logistic regression model was used to analyze risk factors associated with iatrogenic genitourinary fistula. Crude odds ratio and adjusted odds ratio was calculated with 95% CI.

The qualitative data was gathered through key informant interview and recorded using a voice recorder. The voice recorded was then transcribed. Analysis of qualitative data was done using open code software version 4.02 to code and thematic analysis to categorize data.

4.10. Ethical Considerations

This research project was approved by the Department of reproductive and family and population health, School of public health Of Addis Ababa University research and ethical review committee. Moreover all essential ethical considerations to insure the confidentiality of the identity of patients (fistula patients) was taken. Ethical commitment was also signed. Official letter informing the medical director of the hospital about the objective of the study was written from the university prior to actual data collection period and permission was obtained. During patient chart review confidentiality was kept no patient names were stored and any patient information were not transferred to any other organ. There was not being any harm on patients associated with this research and the patients was not being paid in cash for their information.

5. Results

5.1 Socio-demographic characteristics of the patients

Table 1 showed the respondents socio-demographic characteristics.

From January 2005 up to December 2019 10,120 genitourinary fistula were treated at Addis Ababa fistula hospital. 9229 of the cases had complete information and included in the study. Woman with iatrogenic genitourinary fistula were 643(6.96%) and the remaining were obstetric fistula 8586(93.03%). The mean age of obstetric fistula patients was 26.65 ± 6.534 years (Range, 14-42 years). In terms of geographic distribution, 2140(24.9%) were from Amhara region 1715(20.0%), 2405(28.0%), 451(5.3%), 843(9.8%), 265(3.1%), 87(1.01%), 290(3.4%), 213(2.5%), 72(0.8%), 105(1.2%) of the patients were from oromia, Tigray, afar, Somali, Addis ababa, SNNPR, Benshangul, Diredawa, Harari and Gambela respectively. Regarding the educational status of the patients 3033(35.3%) of the patients were elementary, 2481(28.9%), 2172(25.3%), 508(5.9%) 392(4.6%), were read and write, high school, diploma and above and illiterate respectively.

The mean age of iatrogenic genitourinary fistula patients was 31.02 ± 4.625 years (Range, 17-45 years). From 643 IF patients, 191(29.7%) were from Amhara region 155(24.1%), 106(16.5%), 49(7.6%), 48(7.5%), 43(6.7%), 22(3.4%), 16(2.5%), 7(1.1%), 4(0.6%), 2(0.3%) of the patients were from oromia, Tigray, afar, Somali, Addis ababa, SNNPR, Benshangul, Diredawa, Harari and Gambela respectively. Regarding patient's previous history of surgery 128(19.9%) of iatrogenic genitourinary fistula patients have previous obstetric and gynecologic surgeries whereas 515(80.1%) of patients didn't have previous surgery. From those patients who had previous surgery, cesarean section is the most frequent obstetric surgery (102, 79.68%) followed by repair for ruptured uterus (26, 20.32%). 99(77.3%) of patients had only one previous surgery whereas 29(22.7%) of patients had two or more previous obstetric surgery.

Table 1 Sociodemographic characteristics of genitourinary fistula patients at Addis Ababa fistula hospital from January 2005 up to December 2019, Sept 2020, Addis Ababa, Ethiopia.

Variable	Frequency (%) (n=9229)
Age (yrs)	
10-19	1878(20.9)
20-29	3923(42.5)
30-39	2996(32.4)
40-49	432(4.6)
Parity	
0	437(4.7)
1	5656(61.3)
2-5	2893(29)
>5	243(4,9)
Height	
1.≤1.50m	3615(39.2)
2. 1.50-1.60m	3709(40.2)
3.≥1.60m	1905(20.6)
Educational status	
illiterate	443(4.8)
Read and Write	2668(28.9)
Primary	3276(35.5)
Secondary	2298(24.9)
Diploma and Above	544(5.9)

Region	
Addis ababa	308(3.3)
diredawa	220(2.4)
Amhara	2331(25.3)
oromia	1870(20.3)
Somali	890(9.6)
Tigray	2512(27.2)
Gambela	107(1.2)
benshangul	306(3.3)
Afar	500(5.4)
SNNPR	109(1.2)
Harari	76(0.8)
Previous history of surgery	
Yes	821(8.9)
No	8408(91.1)
Type of surgery in recent previous surgery	
caesarian section	637(77.9)
repair of ruptured uterus	176(21.5)
hysterectomy for ruptured uterus	0(0)
other	5(0.6)
Frequency of previous surgery	
Once	634(77.5)
Twice or more	184(22.5)

5.2. Type and Etiologic surgical procedures in which iatrogenic genitourinary fistula occurred

From 643 Iatrogenic genitourinary fistula cases, 346 (53.8 %) were VCVF, 179 (27.8 %) were ureteric injuries and 118 (18.4 %) were Vault fistulas. 552(85.5 %) iatrogenic genitourinary fistula cases were following surgery for obstetric complications. The others 93(14.5%) iatrogenic genitourinary fistula cases were following a gynecological procedure. 341(53%) of iatrogenic genitourinary fistula cases were caused after cesarean section, 131(20.4), 78(12.1%), 93(14.5%) were caused after repair for ruptured uterus, hysterectomy for ruptured uterus and gynecological hysterectomy respectively.

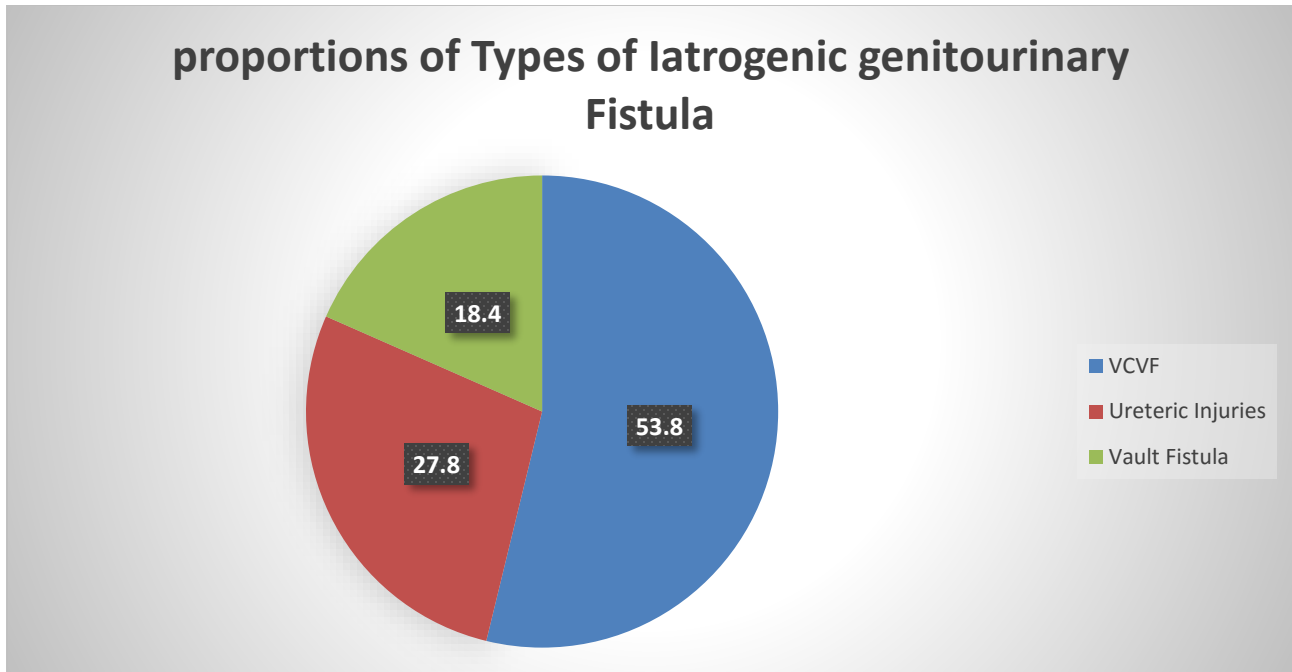


Fig2. Pie chart showing the percentage of type of iatrogenic fistula among iatrogenic genitourinary fistula patients at Addis Ababa fistula hospital, Addis Ababa, Ethiopia

From 643 Iatrogenic genitourinary fistula cases, 533(82.9%) of them are referred from governmental institutions whereas, 36(5.6%), 74(11.5%) were referred from private institutions and non-governmental institutions respectively. 215(33.4%) of IF patients had surgical procedures at primary hospitals and 428(66.6%) of patients had surgical procedures at general hospitals.

Table 2.Type and Etiologic surgical procedures procedure that lead to iatrogenic genitourinary fistula.

Variable	Frequency (%) (n=643)
Etiologic surgical procedure	
Caesarian section	341(53)
Repair for ruptured uterus	131(20.4)
hysterectomy for ruptured uterus	78(12.1)
gynecological hysterectomy	93(14.5)
Type of referral institution	
Private institution	36(5.6)
Government institution	533(82.9)
Non Governmental organizations	74(11.5)
Place of procedure	
primary hospital	215(33.4)
General hospital	428(66.6)
specialized hospital	0(0)
Type of Iatrogenic Genitourinary fistula	
VCVF	346(53.8)
Ureteric injuries	179(27.8)
Vault fistula	118(18.4)

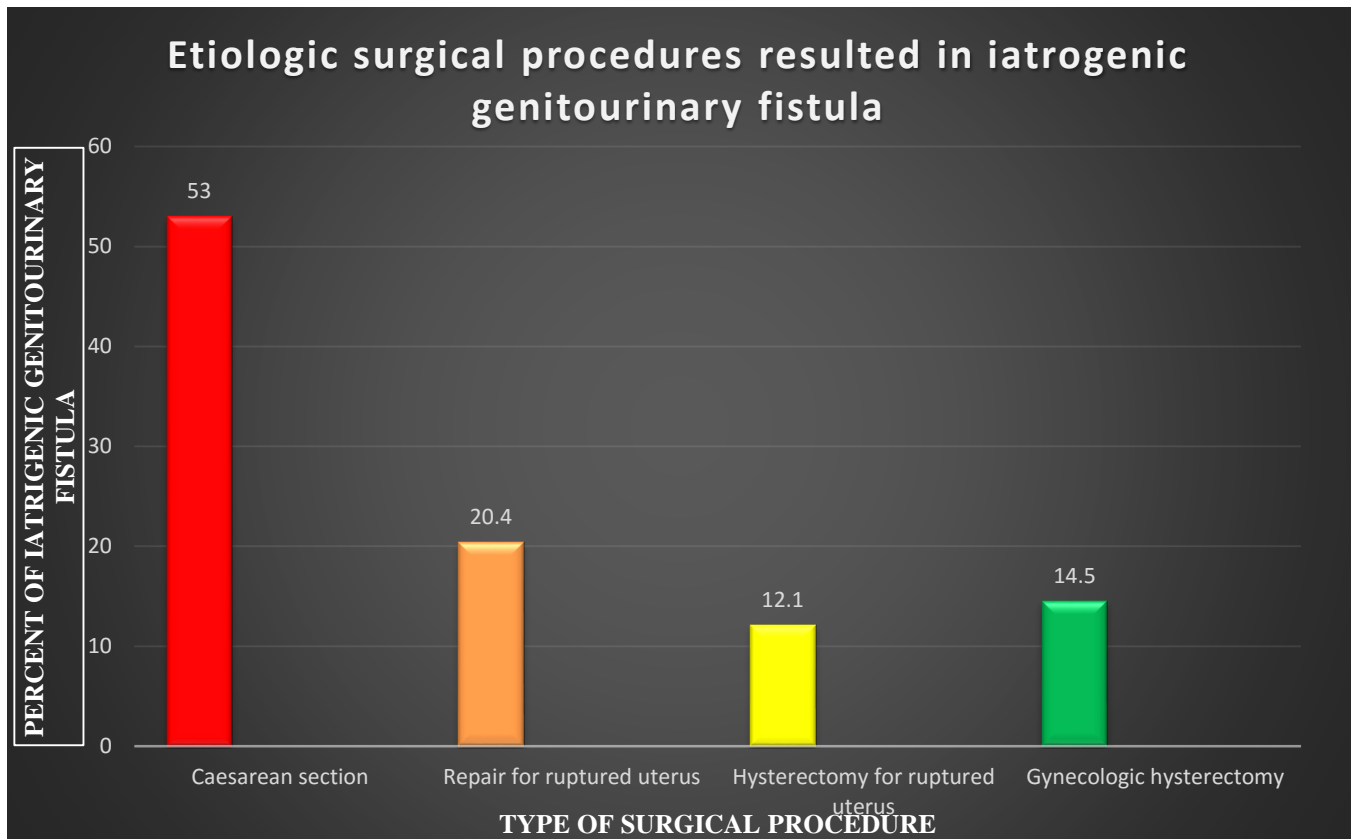


Fig3. Bar graph showing the percentage of major surgical procedures that resulted in iatrogenic genitourinary fistula

The mean age at fistula development was 30.41 ± 4.57 and the mean age at fistula repair was 31.02 ± 4.625 with most (55.8%) of the patients within the 30–39 year age group. The modal parity was 2. A greater proportion of multiparous women had iatrogenic genitourinary fistula (72.3%) compared with primigravid women (27.7%). The mean duration of urine leakage of iatrogenic genitourinary patients was 10.142 ± 9.98 months with minimum of 0.5 month to 46 months of urine leakage.

5.3 Trend of Iatrogenic Genitourinary fistula

The iatrogenic genitourinary cases increased from 1.55% to 52.9% between 2005 and 2019, while obstetric fistula decreased from 98.45% to 47.1% (Table 3) (Fig 5). In terms of yearly trend of the causative surgical procedure for iatrogenic genitourinary fistula development, cesarean section showed a continuous rising trend over the years. Furthermore, gynecologic hysterectomy was found to be a minor contributor to iatrogenic genitourinary fistula. (Fig 6))

Table 3. Trend of iatrogenic genitourinary fistula and obstetric fistula at Hamlin fistula Ethiopia, Addis Ababa, Ethiopia.

Year	Fistula type			
	Obstetric fistula		Iatrogenic genitourinary fistula	
	Frequency	Percentage	Frequency	Percentage
2005-2006	2375	98.45	37	1.55
2007-2008	2253	98.05	44	1.95
2009-2010	1717	96.69	57	3.31
2011-2012	1329	93.46	87	6.54
2013-2014	610	81.7	112	18.3
2015-2016	423	78.73	90	21.27
2017-2018	350	64.29	125	35.71
2019	172	47.1	91	52.9

The iatrogenic genitourinary fistula showed a significantly rising trend over the years with ($p < 0.001$). From genitourinary fistula patients treated at Addis Ababa fistula hospital 1.97% of the cases were classified as iatrogenic genitourinary fistula over the year 2005–2009, 9.16% in 2010-2014 and 47.65% in 2015-2019. R^2 change is 0.123 which is interpreted as 12.3% of change in iatrogenic genitourinary fistula cases can be explained by a change in year. B coefficient is 4.23 with 95% confidence interval of (3.04, 5.42).

There is a significant association between a decreasing annual rate of iatrogenic genitourinary fistula with year of admission with p value < 0.001 . B coefficient is -94.143 with 95% confidence

interval -109.85, -78.43. This can be interpreted as for every unit increases in year of admission the number of obstetric fistula cases decreased by 94.143.

Overall trend of iatrogenic genitourinary fistula cases among iatrogenic fistula patients at Addis Ababa fistula hospital, Addis ababa, Ethiopia 2005-2019 GC.

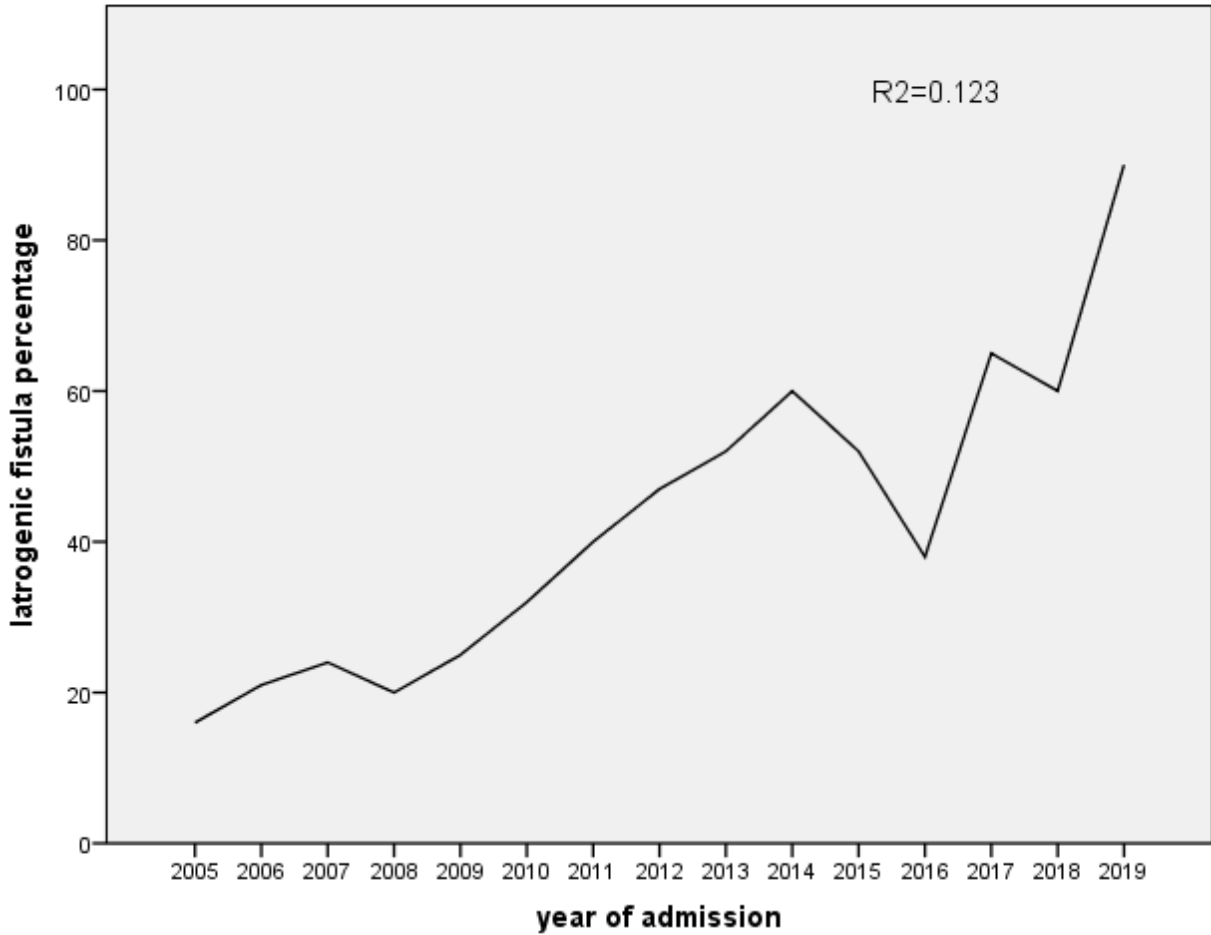


Fig4. Overall trend of iatrogenic genitourinary fistula cases among iatrogenic fistula patients at Addis Ababa fistula hospital, Addis Ababa, Ethiopia 2005-2019 GC.

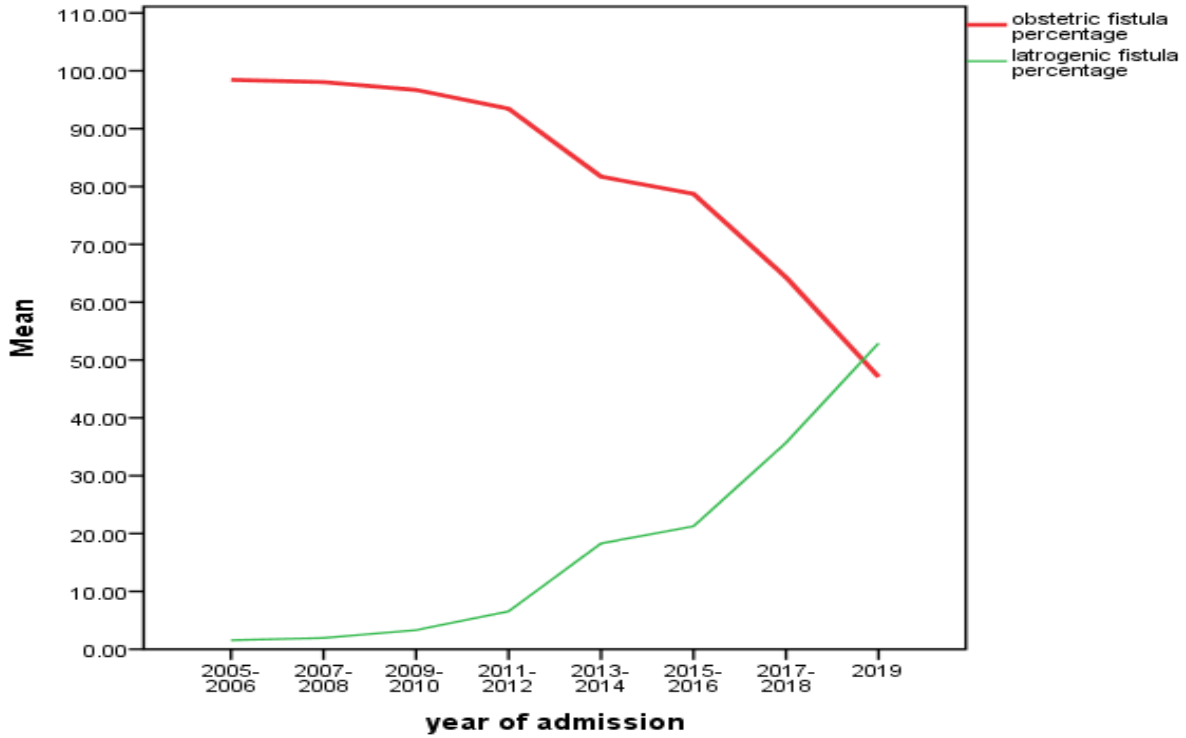


Fig5. Yearly trend of iatrogenic genitourinary fistula and obstetric fistula among genitourinary fistula patients at Addis Ababa fistula hospital, Addis Ababa, Ethiopia 2005-2019.

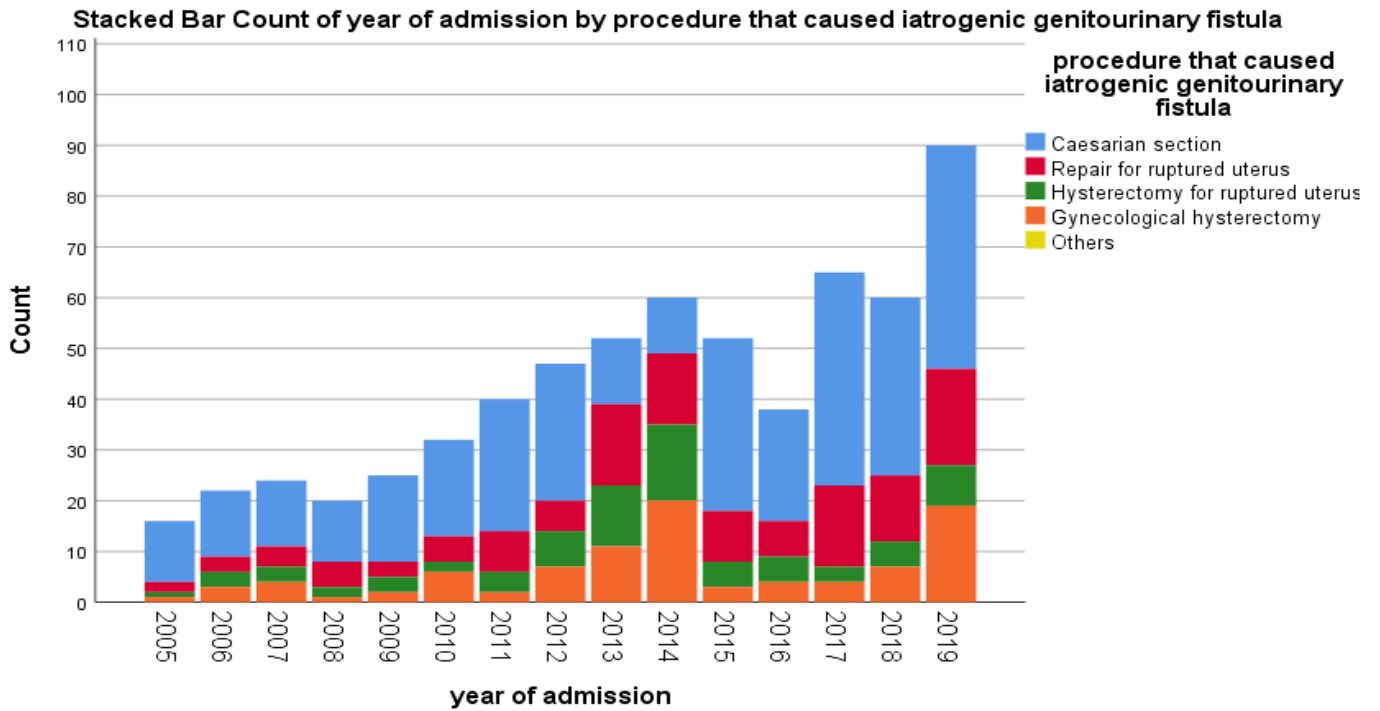


Fig6. Yearly trend by etiologic surgical procedure for iatrogenic genitourinary fistula among iatrogenic fistula patients at Addis Ababa fistula hospital, Addis Ababa, Ethiopia 2005-2019.

Joinpoint regression analysis was also done to calculate annual percent change (APC) and average annual percentage change (AAPC) of iatrogenic genitourinary fistula cases over the years from 2005-2019.

Table 4 annual percent change and average annual percent change of iatrogenic genitourinary cases over the years from 2005 to 2019 at Hamlin fistula hospital, Sept 2020, Addis Ababa.

Year	APC(95% CI)	AAPC(2005-2019) (95% CI)
2005-2013	19.89(9.8,27.2)	13.2(7.7-18.9)
2013-2016	-6.39(-3.7,15.7)	
2016-2019	23.28(12.9,34.6)	

The overall Iatrogenic genitourinary fistula rate increased significantly by 13.2% (95% CI 7.7, 18.9) per year from 2005-2019. A change point occurred over the years 2013-2016 where Iatrogenic genitourinary fistula cases decreased significantly with APC of -6.39% (95% CI -3.7,15.7) but it significantly increased far more rapidly over the years 2016-2019 with APC of 23.28% (95% CI 12.9,34.6).

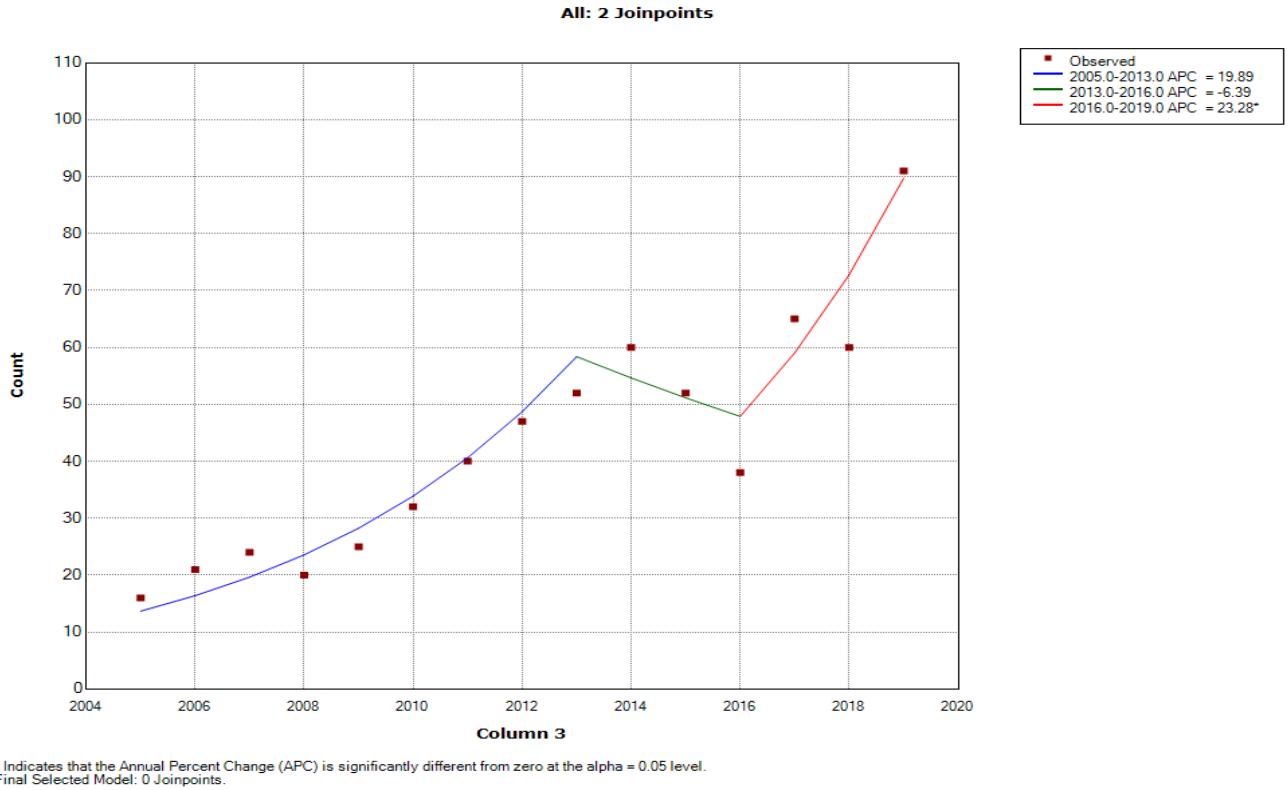


Fig 7. Joinpoint regression analysis of iatrogenic genitourinary fistula cases at Hamlin fistula hospital, Addis Ababa, Ethiopia.

5.4 Logistic regression analysis

Table 4 portrayed the binary logistic regression analysis between iatrogenic genitourinary fistula and various predictors.

History of surgery either obstetric or gynecologic was found to be significantly associated with iatrogenic genitourinary fistula **{AOR=2.38; 95% CI (1.03-3.42)}**.

Type of referral institutions was also found to be significantly associated with iatrogenic genitourinary fistula. Those patients who are referred from governmental institutions were 2 times **{AOR=1.71; 95% CI (0.97-3.34)}** more likely to develop Iatrogenic genitourinary fistula than those who are referred from private hospitals.

Height of the patients were also found to be significantly associated with iatrogenic genitourinary fistula. Patients with height of $\geq 1.60\text{m}$ and above were 6 times **{AOR=6.32; 95% CI (4.71-7.89)}** more likely to develop iatrogenic genitourinary fistula respectively compared to those with height of 1.50m and below. This can be interpreted as those patients with a height of 1.60m and above were 6 times more likely to have iatrogenic genitourinary fistula than patients with height of $\leq 1.50\text{m}$.

The other variable that was found to have a significant association was parity. Those woman with parity of 2 up to 5 were 7 times more likely to develop iatrogenic genitourinary fistula compared to those with parity ≥ 5 **{AOR=7.67; 95% CI (1.34-10.41)}** **{AOR=0.92; 95% CI(0.73-1.48)}**, respectively .

Table 5: Logistic regression analysis for factors associated with iatrogenic genitourinary fistula

Category	Iatrogenic genitourinary fistula			
	No (%)	Yes (%)	COR(95% CI)	AOR(95% CI)
	8588(93.4%)	643(6.96%)		
Parity				
0	430(98.39%)	7(1.61%)	1	1
1	5482(96.97%)	171(3.03%)	1.91(0.89,4.1)	1.23(0.53,3.41)
2-5	2242 (83.56%)	441(16.44%)	12.08(5.68,25.67)***	7.67(1.34,10.41)***
≥5	432 (94.73)	24(5.27%)	3.41(1.45,8.00)***	0.92(0.73,1.48)
Height				
≤1.50	3520(97.37%)	95(2.63%)	1	1
1.50-1.60m	3500(94.39%)	208(5.61%)	2.20(1.71,2.81)***	1.41(0.81,2.26)
≥1.60	1566(82.16%)	340(17.84%)	8.04(6.35,10.17)***	6.32(4.71,7.89)***
Type of referral institution				
Private institution	818(95.78%)	36(4.22%)	1	1
Government institution	6145(92.01%)	533(7.99%)	1.97(1.39,2.78)***	1.71(0.97,3.34)***
Non-Governmental organizations	1623(95.63%)	74(4.37%)	1.03(0.68,1.55)	0.92(0.43,1.53)
Previous history of surgery				
No	7833(93.87)	515(6.13)	1	1
Yes	693(84.40)	128(15.61)	2.80(2.28,3.46)***	2.38 (1.03,3.42)***

Adjusted for Height, Parity and Type of referral institution and previous history of obstetric or gynecologic surgery, P-value<0.001***

Qualitative findings

As stated on the study design mixed methods involving both qualitative and quantitative data collection was used. Eight participants were interviewed on the qualitative section. The qualitative study was conducted to elicit information on factors that can affect the occurrence of iatrogenic genitourinary fistula, proposed strategies to decrease incidence of IF and challenges in decreasing incidence of IF. Interview was done with eight health professionals (3 were females and 5 were males). Four of the participants were specialist medical doctors, 2 general practitioners and 2 Bsc nurses in which all of them are working at Addis Ababa fistula hospital. Their age ranged from 29-54 years. In terms of work experience, participants had worked in treatment of obstetric and iatrogenic fistula patients for a range of from 2-12 years. Three major themes were defined in qualitative data analysis: factors that contribute to the occurrence of IF, opinion towards strategies to decrease incidence of iatrogenic genitourinary fistula and challenge in decreasing incidence of IF.

Participants were referred to as P1 – P8 and each key informant interview were held using a semi-structured interview guide with probing questions.

Table 6: Summary of thematic and Categorical presentation of qualitative data analysis, Sept 2020, Addis Ababa, Ethiopia.

NO	Themes	Categories
1	Factors that contribute to the occurrence of IF	-physician who is performing the obstetric and gynecologic surgeries year of experience in relation with IF -Type of health institution in relation with IF -association between increasing rate of Obstetric surgeries and IF
2	Action to be taken to decrease incidence of Iatrogenic genitourinary fistula	-government and Stakeholders contribution -proposed ideas on strategies to decrease incidence of iatrogenic genitourinary fistula.

3	Challenges in decreasing incidence of IF	-challenges from the health institutions performing obstetric and gynecologic surgeries. -challenges from higher health authorities

Factors that contribute to the occurrence of IF

Theme: Factors that contribute to the occurrence of IF

Category: physician year of experience and training in relation with IF

Participants were asked about the factors that can contribute to the occurrence of iatrogenic fistula. Most of the participants mentioned the health professional who is performing the surgical procedure experience in the profession and lack of continuous in job training as a factor contributing to If.

“I think the physician’s experience of performing obstetric or gynecologic procedures matters the most for the occurrence of If. If you have enough years of experience in performing the surgery it’s unlikely that you will make mistakes during these operations” (29 years old female Bsc nurse with 2 year experience, P-4)

In addition to physician’s year of experience in the profession other participants mentioned the lack of continuous in job training as a factor contributing to occurrence of iatrogenic fistula

“In my opinion most of the medical errors during surgeries occur because of lack of appropriate in job training for the health professionals to update their knowledge on new medical practices.” (34 years old female general practitioner with 4 years’ work experience, P-6)

Her idea was supported by the other participant

“Knowledge and practice only gathered from universities and colleges are not enough to make qualified surgeons, in-job training is must to increase the physician’s knowledge and practice on surgical techniques. (32 years old male general practitioner with 3 years of work experience, P-2)

The other participant mentioned poor history taking practice of the health professional as a factor contributing to occurrence of iatrogenic fistula

“Poor history taking from the patient on other co morbidities and previous history of surgery if any can lead to unintentional medical errors during surgical procedures.”(39 years old male surgeon with 6 years of work experience, P-5)

Category: Type of health institution in relation with iatrogenic genitourinary fistula

Participants mentioned type of health institution at which the obstetric and gynecologic surgeries performed as a factor contributing to occurrence of iatrogenic genitourinary fistula.

“I believe the type of hospital at which the procedure performed will contribute to iatrogenic fistula occurrence. Many hospital especially primary hospitals both private and governmental lack instruments and technological advancement to perform obstetric and gynecologic surgeries” (43 years old male surgeon with 10 years of work experience, P-7)

The other participant mentioned governmental hospitals mainly rural governmental hospitals, medical errors during surgeries occur because of lack of necessary equipment for the surgery.

“one of the factors can be rural governmental hospitals at which most of them obviously lack the necessary medical and surgical equipment that are necessary to perform surgeries following proper surgical quality and safety” (49 years old male gynecologist with 12 years’ work experience,P-8)

Category: association between increasing rate of Obstetric surgeries and iatrogenic genitourinary fistula

Participants mentioned an increasing level of obstetric surgeries especially cesarean section including elective cesarean section contributes a lot to the occurrence of medical error during surgical procedures

“Nowadays cesarean section became the most frequent obstetric surgery performed in Ethiopia including elective cesarean section. I believe cesarean section is an essential obstetric surgery to save mothers and baby’s life only if it’s performed in appropriate environment and indication.”(32 years old male general practitioner with 3 years’ work experience, P-2)

His idea was supported by the other participant:

“I think non-essential or elective cesarean section rates are contributing a lot to the occurrence of iatrogenic genitourinary fistula cases. Cesarean section can put women at risk if it’s performed under environments with inadequate systems to support appropriate quality of care” (39 years old male surgeon with 6 years’ work experience, P-5)

Theme: Action to be taken to decrease incidence of iatrogenic genitourinary fistula

Category: Government and Stakeholders contribution

All participants were asked about their opinion on what the government and other stake holders have to do to decrease incidence of iatrogenic genitourinary fistula. Two (n=2) participants mentioned improving the surgical quality and safety through monitoring and supervision as a strategy to decrease number of IF.

“There have to be routine monitoring of the surgical quality and safety of the institutions performing major obstetric and gynecologic surgery by higher health authorities. Most of the obstetric surgeries mainly cesarean section is being done in resource poor settings with poor

surgical quality and safety.”(35 years old female Bsc nurse with 6 years of work experience, P-4)

Her idea was also supported by the other participant

“Obstetric surgeries mainly emergency cesarean sections have to be supervised by senior surgeons to make sure that it is performed based on the guideline maintaining proper surgical quality and safety.”(43 years old male surgeon with 10 years’ work experience, P-7)

Other participants mentioned proper documentation of iatrogenic fistula cases at nationwide level including the most frequent procedures resulting in this type of fistula, improve technological resources of the health institutions.

“in my opinion if the number of iatrogenic fistula cases including frequent surgical procedures resulting in iatrogenic fistula is not documented well, there will be less chance that the government and other stake holders give more attention to the growing incidence of this type of fistula.”(29 years old female Bsc nurse with 2 years’ work experience, P-1)

“I think most of this occurred because of poor technological resources of the health institutions performing the surgery especially in hospitals located in rural areas. The government and other stake holders have to work to improve the technological resources of the health institutions to reach to minimum acceptable surgical quality and safety.”(39 years old male surgeon with 6 years’ work experience, P-5)

His idea was also supported by the other participant

“Hospitals have to be equipped with technologically up-to-date resources in order to decrease medical errors during obstetric and gynecologic surgery” (34 years old female general practitioner with 4 years’ work experience, P-6)

Category: proposed ideas on strategies to decrease incidence of iatrogenic genitourinary fistula

One participant mentioned about the importance of formulating quality improvement teams in every hospital performing major surgical procedures.

“I think quality improvement teams should be formulated in every hospital to monitor every major surgeries performed to make sure that It follows proper surgical quality and safety standards.”(32 years old male general practitioner with 3 years of work experience, P-2)

The other participant mentioned about continuous in job training to improve the knowledge and surgical procedure practice of the physician performing obstetric and gynecologic surgeries.

“I think the government should give continuous and effective in job training for the physicians performing surgeries to improve their knowledge towards surgical quality and safety.”(41 years old male surgeon with 8 years’ work experience, P-3)

Theme: Challenges in decreasing incidence of IF

Category: challenges from the health institutions performing obstetric and gynecologic surgeries

Participants were asked about the challenges to decrease incidence of iatrogenic genitourinary fistula. Three participants mentioned lack of high-quality surgical care, particularly safe cesarean section, lack of quality assurance systems and supervision of clinicians performing the surgical procedures.

“I think one of the challenges is the poor surgical quality in which many obstetric surgeries particularly cesarean section performed.”(41 years old male surgeon with 8 years’ work experience, P-3)

His idea was also mentioned by another participant who mentioned lack of quality assurance systems in health institutions as a challenge to decrease incidence of iatrogenic fistula

“I can mention many challenges to decrease incidence of iatrogenic fistula but the most important challenge is lack of quality assurance systems in many governmental and private hospitals.”(39 years old male surgeon with 6 years’ work experience, P-5)

“Many of the surgical procedures particularly surgeries performed at private hospitals lack supervision by senior surgeons or other higher authorities.” ” (34 years old female general practitioner with 4 years’ work experience, P-6)

Category: challenges from higher health authorities

Five participants mentioned lack of routine monitoring of iatrogenic genitourinary fistula, lack of Standardized training regimens for clinicians and absence of evidence of the increasing number of iatrogenic genitourinary fistula as a challenge to decreasing incidence of IF.

“higher health authorities including regional health bureaus and federal ministry of health did not implement routine monitoring of iatrogenic fistula that may be resulted in poor attention given to iatrogenic fistula,”(29 years old female Bsc nurse with 2 years’ work experience, P-1)

“in my opinion many physicians especially who have no enough experience in performing obstetric surgeries lack standardized training on quality surgical care,” (32 years old male general practitioner with 3 years of work experience, P-2)

“Our government and many NGO’S are mainly focused on obstetric fistula that might be resulted from less research and less evidence is available on the number of iatrogenic fistula cases and factors contributing to it.”(49 years old male gynecologist with 12 years’ work experience, P-8)

6. Discussion

This facility based retrospective cross sectional study has attempted to assess the trend, major etiologic surgical procedures and risk factors for the occurrence of iatrogenic genitourinary fistula over the study period from 2005 to 2019 among genitourinary fistula patients at Hamlin fistula hospital, Addis Ababa, Ethiopia.

This study revealed that 6.96% of genitourinary fistula patients are classified as iatrogenic genitourinary fistula whereas 93.4% of fistula patients are classified under obstetric fistula patients which is commonly caused after prolonged and obstructed labor. This study found almost similar result as reviews of surgical fistula repair cases conducted in two African countries which found that 8.3% in the Democratic Republic of the Congo (DRC) and 9.9% in Niger were iatrogenic origin(10). and Relatively lower level of iatrogenic fistula cases were found in this study than an 18 years retrospective study which is done in 11 sub-Saharan African countries that found 13.2% of fistula cases classified under iatrogenic genitourinary fistula(2).

Another study which is a two year retrospective review of all cases that underwent repair for iatrogenic genitourinary fistula at the National Obstetric Fistula Centre, Babbar Ruga, Katsina, Katsina State, North West Nigeria from 1 Jan 2015 to 31 December 2016 found that 16.1% of 728 fistula repair surgeries were from iatrogenic cause(24). A study which is a six year retrospective review conducted in India reported 39% of genitourinary fistulae were iatrogenic in origin(43). .

The other study done in Pakistan institute of medical sciences, Islamabad found that 58.5% of fistula patients who are presented during the study period from 2006 to 2018 were classified under iatrogenic fistula patients(44). This finding is relatively higher compared with this study and the study done in 11 sub-Saharan countries which found 13.2% prevalence of iatrogenic genitourinary fistula. This high discrepancy in prevalence of iatrogenic genitourinary fistula from country to country might be because in African countries specially in sub-Saharan countries obstetric fistula which is commonly caused after prolonged and obstructed labor takes many proportion of the overall genitourinary fistula cases. But in developed countries obstetric fistula

takes smaller proportion of the overall fistula cases than iatrogenic genitourinary patients. Another reason for this discrepancy might be because of the study area at which this study done is only limited to one hospital which is giving most of the treatment for fistula patients in the country but doesn't include regional hospitals.

Regarding causative surgical procedures for iatrogenic genitourinary fistula this study also revealed the most frequent surgical procedures in which iatrogenic genitourinary fistula occurred. 53% of IF cases were caused after cesarean section which is almost the same as the findings on an 18 years retrospective study of iatrogenic genitourinary fistula cases at 11 sub Saharan African countries which found 57.4% of cases were caused after cesarean section.

Another study which is a two year retrospective review of cases that underwent repair for iatrogenic genitourinary fistula at the National Obstetric Fistula Centre, Babbar Ruga, Katsina, and Katsina State, North West Nigeria from 1 Jan 2015 to 31 December 2016 found that 73.6% of iatrogenic genitourinary fistula cases were caused after emergency cesarean section(43).

However the findings from this study is contrary to 14 years retrospective study 2006-2018 G.C. done at institute of medical sciences, Islamabad, Pakistan which reported that the major surgical procedure that resulted in iatrogenic genitourinary fistula cases were hysterectomy (52.5%) followed by hysterectomy for ruptured uterus (26.4%) and cesarean section(19.9%)(44).

Following cesarean section this study also found the most frequent surgical procedures resulted in iatrogenic genitourinary fistula were Repair for ruptured uterus, hysterectomy for ruptured uterus and gynecologic hysterectomy constituting 20.4%,12.1% and 14.5% respectively whereas the finding of 18 years retrospective study of iatrogenic genitourinary fistula cases at 11 sub Saharan African countries revealed hysterectomy (19.8 %)is the major surgical procedure that resulted in iatrogenic genitourinary fistula following cesarean section followed by gynecological hysterectomy (19.6 %), ruptured uterus repair (3.1 %)(2).Therefore the findings from this study shows there is a need for advanced training for improved decision-making and surgical skills in both obstetric and gynecologic surgeries, especially for safe cesarean delivery and hysterectomy.

Unnecessary cesarean section delivery including elective cesarean delivery rate have to be lowered to decrease the incidence of iatrogenic genitourinary fistula.

Regarding the type of iatrogenic genitourinary fistula this study found almost similar findings with other researches done in different countries. Of the 643 IFs, 346 (53.8 %) were VCVF, 179 (27.8 %) were ureteric injuries, and 118 (18.4 %) were Vault fistulas. This finding is almost similar with the report of retrospective study done in 11 sub Saharan countries found that 33.9 % were ureteric injuries, 22.5 % were vault fistulas, and 43.6 % were VCVF(2).The findings from two-year retrospective insight of all cases that underwent repair for iatrogenic genitourinary fistula at the National Obstetric Fistula Centre, Babbar Ruga, Katsina, Katsina State, North West Nigeria from 1 Jan 2015 to 31 December 2016 reported 62.7% of IF cases were VCVF. These types of IF mainly result after obstetric surgeries like cesarean section and repair for ruptured uterus. The high proportions of this types of fistula indicates the need to supervision and monitoring of obstetric surgeries by quality improvement teams in every hospital performing this surgical procedures.

The other objective of this study was to assess the trends of iatrogenic fistula cases over 15 year's period. The causes of genitourinary fistula in low and middle income countries is prolonged and obstructed labour which eventually lead to obstetric fistula but not linked to iatrogenic origin which is result after medical error during surgeries. However, cases of iatrogenic genitourinary fistula appear to be increasing in recent years. This study revealed the rising trend of iatrogenic fistula over the study period with only 1.55% of the total genitourinary fistula patients at the beginning of the study period 2005–2006 were iatrogenic in origin, 18.3% in 2013-14 and 52.9% in 2019. The continuous rise in iatrogenic genitourinary fistula cases were found to be significant ($p < 0.001$). A decreasing trend in obstetric fistula, from 98.45% to 47.1%, was also observed. On Linear regression analysis R^2 was found to be 0.123 which can be interpreted as 12.3% of change in iatrogenic genitourinary fistula cases can be explained by a change in year of admission. B coefficient is 4.23(95% CI 3.04, 5.42) which can be interpreted as for every unit increase in year of admission iatrogenic genitourinary fistula cases increased by 4.23. Join point regression analysis was also done to calculate the annual percent change and the average annual percent change of iatrogenic genitourinary fistula. The average annual percent

change over the years from 2005 to 2019 was found to be 13.2 % (95% CI 7.7, 18.9). A change point occurred over the years 2013-2016 where Iatrogenic genitourinary fistula cases decreased significantly with APC of -6.39% (95% CI -3.7,15.7) but it significantly increased far more rapidly over the years 2016-2019 with APC of 23.28% (95% CI 12.9,34.6).

Another study which is a 14 years retrospective study done at Pakistan, institute of medical sciences found rising trend in iatrogenic fistula over the study period (2006–2018) from 43.5% to 71.4% and a decreasing trend in ischemic fistula, from 56.5% to 28.6%, was also observed(44). The recent decrease in obstetric fistula cases can be explained by an increasing access to skilled birth attendants on the last decade. But alarmingly increasing cases of iatrogenic genitourinary fistula cases over the last decade and half indicated the need to work on improving not only access to skilled birth attendant but on quality of health service specially surgical quality and safety have to be given emphasis.

Regarding the factors associated with iatrogenic genitourinary fistula this study found that previous history of obstetric or gynecologic surgery was one of the factors significantly associated with iatrogenic genitourinary fistula. Those with no previous history of obstetric or gynecologic surgery were found to be 0.42 {**AOR=0.42; 95% CI (0.34-0.51)**} times less likely to develop iatrogenic genitourinary fistula than those with previous history of obstetric or gynecologic history. This finding is consistent with similar researches done in different countries. A research done at Kilimanjaro medical center, Tanzania on women who were treated for iatrogenic ureter and bladder injuries after obstetric and gynecologic surgical procedures showed prior uterine operation, endometriosis, cervical myoma and prior pelvic radiation are the factors associated with iatrogenic genitourinary fistula(45). The retrospective study done in 11 sub-Saharan African countries also mentioned Scar tissue and adhesions from prior laparotomies can create challenges for providers performing obstetric and gynecological surgery that might result in occurrence of iatrogenic genitourinary fistula(2). Participants on qualitative section of this study also mentioned poor history taking from patients on previous history of surgery and other medical co-morbidities can lead to unintentional medical errors during obstetric or gynecologic surgery.

The other factor that was found to be significantly associated with iatrogenic genitourinary fistula is the type of health institution in which the surgical procedure takes place. This study found that those patients who had obstetric or gynecologic surgical procedures at governmental institutions were 2 times **{AOR=1.71; 95% CI (0.97-3.34)}** more likely to develop Iatrogenic genitourinary fistula. This might be because of poor surgical quality of care, lack of technological resources and lack of continuous in job training for the physicians who are performing the surgical procedures in these hospitals. There are limited researches done that shows the association between the type of health institution and iatrogenic genitourinary fistula. But this finding can be associated with the rate of delivery by cesarean section in this hospitals. A study done by LSHTM on The Landscape of Cesarean Section of 44 countries in Sub-Saharan Africa and South and Southeast Asia to compare percentages of cesareans with a non-doctor SBA by facility ownership in 28 of the 44 countries. In Sub-Saharan Africa, 18 of the 20 countries with data had a higher percentage of non-doctor SBA cesareans in public facilities than in nonpublic facilities; the widest difference was in Namibia, with 39% in public facilities but only 3% in nonpublic facilities. In South and Southeast Asia, four countries had higher percentages in public facilities (with India having the widest difference between public and nonpublic facilities, at 7% vs. 3%), and four had higher proportions in nonpublic facilities (with the widest difference in Indonesia, at 10% public vs. 23% nonpublic)(32).participants on qualitative section of this study also mentioned the type of hospitals specially rural government hospitals(primary hospitals) lack the necessary medical and surgical equipment to perform obstetric and gynecologic surgeries following proper surgical quality and safety.

This study also found that height of patients were significantly associated with iatrogenic genitourinary fistula, Patients with height of $\geq 1.60\text{m}$ and above were 6 times **{AOR=6.32; 95% CI (4.71-7.89)}**, more likely to develop iatrogenic genitourinary fistula compared to those with height of 1.50m and below. This can be interpreted as those patients with a height of $\leq 1.50\text{m}$ and below were 5 times less likely to have iatrogenic genitourinary fistula than patients with height of $\geq 1.60\text{m}$. Unfortunately, there is no previous research done that shows the association between heights of the patients with iatrogenic genitourinary fistula. Previous evidence shows that short stature women especially those women with height of 1.50m and below were 10 times more likely to have obstructed labour that eventually may lead to obstetric fistula(46). But this study

shows that unlike obstetric fistula short stature is not linked to the occurrence of iatrogenic genitourinary fistula.

This study also found parity of women was significantly associated with iatrogenic fistula patients. Those woman with parity of 2 up to 5 were 7 times more likely to develop iatrogenic genitourinary fistula compared to those with parity ≥ 5 {**AOR=7.67; 95% CI (1.34-10.41)**} {**AOR=0.92; 95% CI(0.73-1.48)** }, respectively. Although there is no previous evidence that link parity of the patients with iatrogenic genitourinary fistula this association can be explained by the formation of scar and adhesion from previous repeated deliveries especially if previous deliveries were made by cesarean section.

This study also involved qualitative study to aid the findings of quantitative study. The key informant in qualitative study was focused on three Themes. The key informant's opinion on factors that contribute to the occurrence of iatrogenic fistula, common surgical procedures that resulted in occurrence of iatrogenic genitourinary fistula and challenges in decreasing incidence of IF. Most of the participants(n=6) mentioned the health professional's surgical procedure experience in the profession who is performing surgery, lack of continuous in job training and type of hospital at which the procedure performed as a factor contributing to If. Participants also mentioned an increasing level of obstetric surgeries especially cesarean section including elective cesarean section and the environment at which the surgeries are performed including availability of necessary medical and surgical equipment in hospitals especially rural governmental hospitals contributes a lot to the occurrence of medical error during surgical procedures.

The participants were also asked about their opinions towards what the government and other stake holders have to do to decrease the incidence of IF. Improve the technological resources of the hospitals, formulate quality improvement teams, continuous in job training, improve surgical quality and safety through monitoring and supervision and proper documentation of fistula cases at nationwide level are the strategies raised by the participants.. Three participants mentioned lack of high-quality surgical care, particularly safe cesarean section, lack of quality assurance systems and supervision of clinicians performing the surgical procedures. Five participants

mentioned lack of routine monitoring of iatrogenic genitourinary fistula, lack of Standardized training regimens for clinicians and absence of evidence of the increasing number of iatrogenic genitourinary fistula as a challenge to decreasing incidence of IF.

7. Strength and limitations of this study

Strength of the study

- There are very limited researches done related to trends of iatrogenic genitourinary fistula and its associated risk factors, so the finding of this research will be very useful resource for further research regarding the topic.
- One of the strength of this study is it was supported by qualitative data (utilization of a triangulation mixed method designed for the study).

Limitations of the study

- Since all information was taken from patient's chart, there is incompleteness of data to have full information
- There are limited researches done regarding factors associated with iatrogenic genitourinary fistula to discuss the findings with other studies.

8. Conclusion

This study observed a rising trend in iatrogenic genitourinary fistula and declining admission of obstetric fistula over 15 years at Hamlin fistula Hospital. This implies an urgent action for safety and quality surgical procedure on abdominal and pelvic surgeries is important. This study also revealed the most frequent surgical procedure resulting in iatrogenic genitourinary fistula in which cesarean section is the most frequent surgery that resulted in iatrogenic fistula followed by repair for ruptured uterus, hysterectomy for ruptured uterus and gynecologic hysterectomy.

Previous history of surgery,height,type of health institution at which the surgery is performed and parity were also found to be factors that are significantly associated with IF on binary Logistic regression analysis. On qualitative key informant interview participants mentioned health professional's surgical procedure experience in the profession, lack of continuous in job training and type of hospital at which the procedure performed as a factor contributing to If.

9. Recommendations

From the results of this study, the following recommendations are made:-

- Strengthen provider, health facility, and system capacity to provide and sustain quality services.
- Improve health institution's surgical quality and safety through supervision and monitoring of surgical procedures by quality improvement teams.
- Modify the policy of health professionals training in the country to focus more on the quality rather than quantity of graduating health professionals.
- Advocate for regular investigation and standardized classification of iatrogenic genitourinary fistula
- Increase awareness about iatrogenic genitourinary fistula trends among obstetric, midwifery, and safe motherhood communities of practice at the national level
- develop standardized data collection tools to document information, such as the causative procedure and facilitate high quality surgical care
- Advocate for iatrogenic genitourinary fistula to be a reportable, sentinel indicator of basic surgical systems gaps that undermine a minimum acceptable standard of care.
- Implement further research in the topic involving other hospital in the country currently giving treatment for fistula patients.

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Annex 1

**Addis Ababa University, college of health sciences school of public health,
department of Reproductive, family and population health**

A study Information Sheet (SIS) of research proposal

Title of the research: - The trends of iatrogenic genitourinary fistula and its risk factors among genitourinary fistula patients at Hamlin fistula hospital, Addis Ababa in the last 15 years (2005-2020)

Genitourinary fistula is public health importance in low and middle income countries though it has been neglected. It has multiple health adversities to women. It is mainly caused after lack of timely and appropriate intervention mainly cesarean section. But genitourinary fistula can be Iatrogenic because of medical error during obstetric and gynecological surgery like cesarean section and hysterectomy. This injury will cause holes between the vagina and bladder and/or vagina and rectum which eventually led to incontinence of urine and faeces

The objective of this study is to assess the trends and major causes of iatrogenic fistula and its risk factors from January 2005 to December 2019 at Hamlin fistula hospital, Addis Ababa. The reason for conducting this research is because Despite the fact that there are many researches done that shows the prevalence and risk factors of obstetric fistula, There are limited recent researches done specially in sub-Saharan Africa countries including Ethiopia and other developing countries on trend and major causes of iatrogenic fistula

Significance of this research:-The findings from this research will benefit the government to modify the policy of health professionals training in the country to focus more on the quality rather than quantity of graduating health professionals and to implement routine monitoring of iatrogenic fistula, potentially terming it as a reportable sentinel event, and developing standardized data collection tools to document information, such as the causative procedure and facilitate high quality surgical care

Study procedure:-Data relating to the type of fistula, treatment provided, age, date of admission and parity, length of hospital stay will be retrieved from the patient's medical history where they are routinely recorded.

Confidentiality/Justice/Privacy:- During patient chart review confidentiality will be kept and any patient information will not be transferred to any other organ. There will not be any harm on patients associated with this research and the patients will not be paid in cash for their information. Ethical commitment will be also signed. Official letter informing the medical director of the hospital about the objective of the study will be written from the university prior to actual data collection period and permission will be obtained

Annex 2

CHECK LIST/QUESTIONNAIRE

Name of the data collector_____

Qualification_____

Date of data collection_____

Signature_____

S.no	Study variables	Response	Remark
	Patient identification number	_____	
1. Socio-demography of the patients			
1.1	Age at fistula occurrence	_____	
1.2	Age at fistula repair	_____	
1.3	Education level	1. Illiterate 2. Real & write 3. Elementary 4. High school 5. Diploma Of above	
1.4	Parity	_____ -	
1.5	Height	_____	
1.6	Region of residence	1. Addis Ababa 2. Diredawa 3. Amhara 4. Oromia 5. Somali 6. Tigray 7. Gambella 8. Benishangul 9. Afar 10. SNNPR 11. Harari	
1.6	Referred institution	1. private institution 2. government institution 3. Non-Governmental organizations	
1.7	Type of hospital referred from	1. primary hospital 2. General hospital 3. specialized hospital 4. other _____	

2. History of fistula patients

2.1	Year of admission	_____	
2.2	previous history of gynecologic or obstetric surgery	1.obstetric surgery 2.gynecologic surgery	
2.3	If the answer to the above question is 1 specify	1.caesarian section 2.repair of ruptured uterus 3.hysterectomy for ruptured uterus	
2.4	Frequency of previous surgery	1. Only once 2. Two times and above	
2.5	Iatrogenic genitourinary fistula	1.YES 2.NO	
2.6	Type of Iatrogenic genitourinary fistula	1.VCVF 2.Ureteric injuries 3.Vault fistula	
2.7	Procedure caused Iatrogenic genitourinary fistula	1.Caesarian section 2.Repair for ruptured uterus 3.hysterectomy for ruptured uterus 4.gynecological hysterectomy 5.others_____	
2.8	Duration of urine leakage	_____months	

ANNEX III

Consent for key informant interview

Hello good morning/good afternoon **I am Maranata Dawit** MPH student At Addis Ababa University school of public health, department of reproductive, family and population health, I am here to conduct a research on trends of iatrogenic genitourinary fistula, major causes and its risk factors among obstetric fistula patients at Hamlin fistula hospital,addis Ababa in the last 15 years. I am seeking of your participation on this study. Your participation is voluntary, confidential and you can withdraw your participation at any time. I am going to record your voice on our conversation with this electronic device and take a note for the sake of the study.

Are you willing to participate?

If yes continue, if No, say thanks and skip to the next participant.

Annex IV

Questionnaire for key informant interview

I. General Information

1. Interviewee Code _____

2. Sex Male

Female

3. Educational status

Nurse

General practitioner (GP)

Specialist (please specify the specialty) _____

If other, Please specify _____

4. Year of experience in diagnosis and treatment of fistula patients? _____

II Interview Questions

1. What do you say about the factors that contribute for the occurrence of iatrogenic genitourinary fistula?
2. Do you think technological resource of the hospital at which the surgery is performed have anything to do with occurrence of iatrogenic genitourinary fistula?
3. Do you think hospital type, size or location matter for the occurrence of IF?
4. What can be the challenges to decrease the incidence of iatrogenic genitourinary fistula?
5. What is your opinion about the government and other stake holders have to do to decrease incidence of iatrogenic genitourinary fistula?
6. If you have anything to add, please describe.