IMAGING FINDINGS IN INFERTILE FEMALE PATIENTS WHO UNDERWENT HYSTEROSALPINGOGRAPHY INVESTIGATION AT MUHIMBILI NATIONAL HOSPITAL

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By

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A dissertation/Thesis Submitted in Partial Fulfilment of the Requirements for the Degree of Master of Medicine (Radiology) of
Muhimbili University of Health and Allied Sciences

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April 2011

CERTIFICATION

The undersigned certify that he has read and hereby recommend for examination the dissertation entitled **"Imaging findings in infertile female patients who underwent hysterosalpingography investigation at Muhimbili National hospital"** in fulfilment of the requirements for the degree of Master of Medicine (Radiology) of Muhimbili University of Health and Allied Sciences.

_____

Dr Kazema RR
(Supervisor)

Date: _____

DECRALATION AND COPYRIGHT

I, Ramadhan B Kabala, declare that this **dissertation** entitled "**Imaging findings in infertile female patients who underwent hysterosalpingography investigation at Muhimbili National hospital** " is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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ABSTRACT

Background

Fallopian tube and uterine defects are responsible for infertility in more than 30% of infertile couples. Hysterosalpingography (HSG) is a safe and less invasive method of detecting both the tubal and uterine defects.

Objectives

To describe hysterosalpingography (HSG) imaging findings in infertile female patients investigated at Muhimbili National Hospital (MNH)/Radiology department from July to December,2010

Material and methods

This descriptive cross-sectional study, involved 130 women participants with infertility who attended MNH Radiology department for HSG examination between July to December 2010. Demographic data and radiological findings were reviewed and the obtained data analysed with SPSS version 15. Statistical level of significance was set at $p < 0.05$.

Results

The participants mean age was 30 years and mean duration for infertility was 5 years. Secondary infertility was slightly commoner than primary infertility. Majority (70%) of patients were aged 16-30 years. Abnormal findings at HSG were found in 60% of the patients. Most of these abnormal findings were found in those patients with older age between 31 and 45 years and those with long duration of infertility for more than 5 years. The commonest finding was tubal blockage accounting 41% of cases and the least was uterine congenital abnormality (3.8%). Uterine fibroid was the commonest uterine pathology accounting for 10% of all cases.

Conclusion

Generally, high proportion of patients in this study showed presence of uterine and fallopian tubes pathology. Fallopian tubal blockage was the most diagnosed tubal structural abnormality while the uterine leiomyoma was the highest uterine pathology. There was no

significant difference in the presence of pathology between patients with primary and secondary infertility. However, older age above 30 years were significantly associated with presence of structural abnormality in both uterus and fallopian tubes

Recommendation

HSG is recommended for initial routine work-up of infertile women.

Further studies are needed to establish the aetiologies of these abnormalities.

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ACRONYMS

CI; Confidence interval

HSG; Hysterosalpingography

IRB; Institutional Review Board

LMP; Last Menstrual period

MNH; Muhimbili National Hospital

MRI; Magnetic Resonance Imaging

MUHAS; Muhimbili University Of Health and Allied Sciences

PID; Pelvic inflammatory disease

S.d; Standard deviation

SPSS; Statistical Package for Social Science

UK; United kingdom

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DEDICATION

I dedicate this dissertation to my mother, Asha Ramadhan, my wife Rahma Lugoye Antony and our children Hashim and Aisha.

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1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 Prevalence of infertility

The problem of infertility in our setting is common in day to day practice. Infertility is defined as the inability of a couple to achieve conception after 12 months doing unprotected coitus. Primary infertility describes couples who have never been able to become pregnant after at least 1 year of unprotected sexual intercourse. Secondary infertility describes couples who have been pregnant at least once, but have not been able to become pregnant again. It is estimated that 8 to 15% of all women experience primary or secondary infertility at one point in time in their reproductive life. In tropical Africa, infertility rate is between 10% to 20%, although the prevalence in Congo was reported to be high between 30% to 50% (1, 2, 3, 4). In Tanzania national demographic and health survey conducted in 1999 showed that 2.5% of women had primary infertility while 18% had secondary infertility. The prevalence of infertility was 8.1% in previous study conducted in Moshi northern part of Tanzania with secondary infertility being more common than primary infertility (5).

Primary infertility is relatively low and it exceeds 3% in most African countries (5). Several studies showed that secondary infertility is more common than primary infertility (6, 7, 8). Secondary infertility for women aged 20-44 ranges from 5% in Togo to 23% in Central Africa Republic (5). Some studies done in Turkey and Iran found out that primary infertility was more common, when compared to secondary infertility (9,10). Women with secondary infertility have a higher likelihood of having structural abnormalities in both uterus and fallopian tubes in comparison to those with primary infertility (11,12).

1.2 Radiological investigations of infertility

Hysterosalpingography (HSG) is readily available investigation in our settings, as such is one among the investigations used for evaluation of infertility. It is the best first line anatomic imaging investigation for the basic infertility work. HSG evaluates the cervical canal, uterus, fallopian tubes and the pelvic cavity (13,14).

Hysterosalpingography (HSG) demonstrates the morphology and patency of both the uterine canal and fallopian tubes (15,16). HSG is performed by injecting contrast medium into the uterus and the fallopian tubes and following its flow using fluoroscopy. Uterine abnormalities are outlined by the contrast medium and fallopian tubal obstruction is noted by the absence of free spill into the peritoneal cavity (13,17). In addition to the diagnostic value, HSG may also be used for therapeutic purposes to unblock the blocked fallopian tubes (18,19).

The size of the uterine cavity varies with parity. The endocervical canal is of cylindrical shape with length of 3 to 4cm and width of 1 to 3cm (1). The uterine cavity is sharply defined by HSG having a triangular shape with mild concavity at the fundus. The normal fallopian tube has a length between 10 to 12 cm extending from cornua of the uterus. Its lumen is threadlike with width of 1 to 2mm until reaches ampulla where it expands to 5 and up to 10mm with visible rugal folds.

Although HSG has a lot of advantages as outlined above, but there are some disadvantages accompanying it. These are the possibility of allergic reaction to iodine, pelvic infection, bleeding spots, endometriosis secondary to carriage of endometrial tissue onto extra uterine sites and tubal rupture due to contrast material given under pressure in patient with hydrosalpinx.

Other techniques for assessing structural causes of female infertility such as ultrasound, sonohysterography (Hycospy), laparoscopy, magnetic resonance imaging (MRI) and hysteroscopy are increasingly used elsewhere. HSG is not reliable test for evaluation of extrinsic tubal pathology such as peritubal adhesions compared to other techniques

(20,21,22). However it has the advantage over other techniques by giving a clear tubal resolution and definition (2,15).

In hysteroscopic procedure the scope is used to visualize the inside of the uterus including the openings of fallopian tubes and can be used for treatment of intrauterine pathology. However the procedure may complicate rarely with perforation of the uterus, infection and reaction to anaesthetic agents.

Laparoscopy examination provides accurate information about extrinsic tubal pathology but is poor in diagnosing intrinsic tubal pathology. Laparoscopy is performed under general anaesthesia during the follicular phase of the menstrual cycle. After making pneumoperitoneum, a thorough inspection of pelvis and pelvic organs is performed. This is followed by testing the patency of fallopian tubes using methylene blue. A dilute solution of methylene blue is injected through the cervix via a cannula. The evaluation of adhesions, structural abnormalities of the uterus, endometriosis and fallopian tubes occlusion are sought for.

Laparoscopy also has the advantage of allowing treatment of abdominal pathology such as endometriosis and peritubular adhesions. Moreover, both laparoscopy and hysteroscopy procedures are invasive with related risk of surgical complications, high cost as well as high expertise. They are not able to give detailed information on the uterine, making them disadvantageous over HSG. A study done in India revealed that Hysterosalpingography and Laparoscopy are complimentary rather than competitive procedures (23). Both hysteroscopy and laparoscopy should therefore be reserved for confirmation and treatment of the intrauterine and fallopian tubes abnormalities (24,25).

Ultrasound has a great role in diagnostic as well as therapeutic management of infertility. It can confirm the normal anatomy of the pelvis, assessing ovarian morphology and look for uterotubal and pelvic pathology such as fibroids, hydrosalpinx and endometriosis. Ultrasound is also used in monitoring menstrual cycle so that ovulation can be confirmed in both natural cycles and due to induction agent like clomifene. However ultrasound is poor in confirming the patency of fallopian tubes (26,27).

In experienced hands sonohysterography is safe, well tolerated and easy to assess intrauterine structures more superior than HSG (28,29). In this procedure the cervix is inspected through vaginal speculum and cleansed with antiseptic solution. A polyethylene cannula is introduced and the speculum removed. Then a sterile sheathed vaginal ultrasound probe is introduced. Lastly, an infusion of normal saline is commenced gradually with a slow and sustained flow while scanning the endometrial cavity and myometrium. Several studies showed that sonohysterography (Hycospy) is similar to HSG as regards to the appearance of endometrial cavity but is inferior to it for evaluation of tubal factor (30-34).

Magnetic resonance imaging (MRI) is the study of choice in infertile women with suspected uterine anomalies because of its high accuracy and detailed elaboration of uterovaginal anatomy. It is superior in diagnosing uterine anomalies, but is poor to diagnose intrauterine adhesions and peritubal adhesion as compared to HSG (35).

1.3 HSG Findings

The normal HSG findings in infertile women was found to be low, 16.6% in Uganda and 18.2% in South Africa(2,6), whilst in UK and Nigeria studies showed high proportion of infertile women with abnormality, 51.5% and 60% respectively (3,15).

Almost one quarter of women with congenital or acquired structural uterine abnormalities experience difficult in conception, accounting for up to 10% of infertility cases (2). HSG has been found to be an invaluable procedure for the assessment of intra-uterine lesions(18,36,37).The uterine abnormalities using HSG were present in 25% of South African black patients with half of them having fibroids and only 2.5% of cases had congenital abnormalities(6). However in a study conducted in UK only 15.2% of cases had uterine abnormalities, in which 5.8% presented with congenital abnormalities and 5.5% of the cases presented with fibroids with rest being polyps, Asherman syndrome and post-caesarean scar(15). The congenital uterine abnormalities among Nepalese women with primary infertility are 3.2% whilst those with secondary infertility are 2% (47).

HSG is widely used as a first line approach to assess the patency of fallopian tubes in routine fertility work-up (15,16).Tubal factor remain a cause of infertility which accounts for 35% to 40% of cases of infertility(3,7,23). Previous studies revealed that tubal pathology is significantly associated with secondary infertility(8) .In a study which was done in South Africa among infertile black patients, 81.8% of cases had fallopian tube abnormalities(6). In that study 5% of cases had peritoneal adhesions while the tubal blockage was present in 27.4% of cases and the most common abnormality was the terminal hydrosalpinx(6). Bilateral tubal occlusion was noted in 20% of infertile women in a study done in Kenya. In several studies hydrosalpinx was the most common tubal abnormality (3,6,15). Similarly, series done in Nigeria showed that hydrosalpinx was the most common tubal abnormality which was present in 23.3% of patients. In this study patients with bilateral tubal blockage were 7.5% while 13.3% of cases had unilateral tubal blockage (3).

Tubal blockage was present as the most common tubal abnormality, 37.7% in a study done in Birmingham, UK with hydrosalpinx accounting for 20.6% of cases(15).

In a study done in Turkey, 21% of infertile women had one sided tubal occlusion and 12% had bilateral tubal occlusion. Features for adnexal adhesion were seen among 12% of infertile women in Turkey (9).

Therefore, assessment of the structural integrity of the reproductive tract is essential to fertility evaluation and necessary for all female patients presenting with infertility. Thus HSG still remains a more accurate and efficient method for the diagnosis of intrinsic tubal and uterine pathology.

2.0 PROBLEM STATEMENT

Infertility is a global problem, but the highest prevalence is in low resources areas, particularly Sub-Saharan Africa where infection-related tubal damage is the commonest cause (38). The prevalence of uterotubal structural abnormalities by HSG ranges from about half among women with infertility in Nigeria to three quarter in Uganda and South Africa (2,3,6).

Currently in Tanzania little is known about the magnitude of the problem in terms of common etiological factors; what is the most common cause of infertility, is it ovulatory dysfunction, or is it structural abnormalities or is it hormonal infertility.

Observation of patients attending Radiology department at MNH reveals significant number of women with infertility coming for evaluation of structural abnormalities.

In view of above arguments there is a need to conduct an investigation that is reliable and which is readily available for screening possible structural abnormalities in reproductive anatomy.

This can easily be done by hysterosalpingography (HSG) which is widely available in all regions in Tanzania. It is affordable, readily available and yields reliable findings.

Therefore, this study looks into clinically reliability and usefulness of HSG in evaluation of structural pathology in uterus, fallopian tubes and pelvis.

3.0 STUDY RATIONALE

The prevention of infertility in a population requires an active surveillance mechanism to be in place. Previous studies done in other parts of Sub-Saharan Africa showed that the major underlying cause for the high levels of infertility is the tubal blockage which is a sequel of pelvic infection. These infections follow mismanaged deliveries, abortion and sexually transmitted infections.

This calls for a study that is cheap, available and sensitive to document the pattern of uterine and fallopian tubes diseases that are the culprit of infertility among women in our setting.

In developing countries like Tanzania where resources are still limited, widely available fluoroscopy units can be wisely used to investigate and even manage the women with infertility.

Therefore, the results of this study will reveal the prevalence of uterotubal structural abnormalities that will be used for comparison with other studies elsewhere and assist in planning of future research areas on infertility.

Use of HSG investigation in infertile women may provide important information useful to the Gynaecologist during treatment planning. It will also provide useful information on pattern and proportion of uterine and tubal abnormalities necessary for formulating various strategies for prevention of infertility, as almost all causes of tubal blockage are preventable.

Therefore by knowing these underlying causes, various strategies can be put in place through improving prevention, diagnosis and treatment of infertility at all levels of health care delivery. Hence, this study is significant in the sense that the findings contained herein will contribute to knowledge concerning the role of uterotubal structural abnormalities as the cause of infertility in women.

4.0 OBJECTIVES

4.1 Broad Objectives

To describe imaging findings in infertile female patients who underwent Hysterosalpingography investigation at Muhimbili National Hospital (MNH), Radiology department, July to December, 2010.

4.2 Specific Objectives

1. To determine the proportion of women with congenital uterine anomalies.
2. To determine the proportion of women with tubal blockage.
3. To determine the pattern of uterotubal abnormalities in infertile female patients.
4. To determine association between the type of infertility and diagnosis of abnormal HSG findings.

5.0 METHODOLOGY

5.1 Study Design and Period;

This was a descriptive cross sectional study conducted between July to December, 2010.

5.2 Study setting;

5.2.1 The study was conducted at Muhimbili National Hospital, Radiology department. Patients were referred from gynaecology clinic of MNH by a gynaecologist. HSG procedure was performed by an investigator supervised by a radiologist on duty. The findings were interpreted by the investigator and discussed with the senior radiologist before handled to patients.

5.2.2 **Hysterosalpingography Procedure**; There was no specific patient preparation required and the examination was scheduled during days 7-12 of the menstrual cycle. The endometrium is thin during this proliferative phase, a fact that facilitates image interpretation and should also ensure that there is no pregnancy. The patient instructed to abstain from sexual intercourse from the time menstrual bleeding ended until the day of the study to avoid a potential pregnancy. The patient placed on the fluoroscopy table in the lithotomy or modified lithotomy. The perineum cleaned with savlon and draped with sterile towels. A speculum was inserted in the vagina and the cervix localized and cleansed with savlon. Then a cannula positioned in the cervical canal. A scout radiograph of the pelvis then taken with cannula in place. Water soluble contrast (Ultravisit) about 10-30 ml slowly instilled with fluoroscopic images obtained intermittently to evaluate the uterus and fallopian tubes. The first image obtained during early filling of the uterus and used to evaluate any filling defects or contour abnormality. The second image was taken with uterus fully distended, the shape of the

uterus is best evaluated at this stage. The third image was obtained to demonstrate and evaluate the fallopian tubes and free intraperitoneal spillage of contrast material

5.3 Study Population; The study involved women who were evaluated at the Radiology department due to infertility between July and December, 2010.

5.4 Exclusion criteria; The study did not involve women patients with acute infection of the vagina or cervix and also women with active vaginal bleeding. Other groups of patients that were also excluded from the study were those with sub fertility complaints lasting less than a year.

5.5 Sample size Estimation; Considering the study power of 95%, a random likely error is estimated to be 5%.The sample size of 113 patients were to be studied estimated basing on the general population prevalence of 8.1% of infertile women in Tanzania(5). The standard sample size estimation formula(Kish and Leslie) is $\mathbf{N = z^2p\ (1\text{-}p) \div E^2}$ where Z – is the point of normal distribution corresponding to the significant level of 1.96; p-prevalence from the general population of infertile women which is 0.08; E – Maximum likely error which is 0.05. Therefore the sample size is calculated as follows $N= (1.96)^2*0.0.8(1\text{-}0.08) \div 0.05^2 =113$

5.6 Sampling technique; a consecutive sampling method was used, due to limited time and difficult in defining sampling frame as there is no specific clinic for infertility. Hence all patients referred to the Radiology department for hysterosalpingography examination were included after considering inclusion and exclusion criteria till the sample size reached.

5.7 Data collection; Data collection in this study involved interviewing the patients to obtain the demographic particulars. The special designed clinical surveillance forms (Appendix I) used to collect both demographic and HSG findings. Data collections from each day were done on the same day and then the obtained data were recorded in sheets and

transferred to the analysis program. To minimize the observer bias the report included the documentation from the investigator and certification from a senior radiologist. The findings were then communicated to the patients through the gynaecology clinic as they continued to be followed up.

5.8 Data analysis;

The identification number was labelled in each of the filled clinical surveillance form and screened before entering into the statistical package for social science (SPSS). Quantitative data were then tabulated, analyzed and interpreted according to the result obtained. Then all variables summarized and printed out for careful study and a cross tabulation done for defined independent variables in order to obtain table of results. Data entry, filter and analysis was done using SPSS version 15 analysis program. Chi- square statistical test was done to check for statistical significance $p<0.05$.

5.9 Ethical consideration

Research protocol was submitted to the MUHAS Higher Degrees Research and Publications Committee for review, approval and ethical clearance processing. Ethical clearance letter was obtained before commencing the study**.** The aim of the study as well as potential risks and benefits were clearly explained to all participants and a written informed consent in Swahili language was signed by each participant (Appendix II). A participant had the right and freedom to join or leave the study unconditionally. A patient who did not consent for the study but entitled was attended as usual. Confidentiality was observed during performing the HSG procedures as well as during conversation. A written report of findings was given to patient and sent to gynaecologist.

6.0 RESULTS

6.1 Demographic and clinical data

One hundred and thirty (130) patients with infertility were interviewed and investigated. The age ranged from 20 to 44 years showing normal distribution with mean age of 29.87 (Figure 1). The duration of infertility ranges from 1 to 17 years with a mean duration of 4.89 years as shown in table 1**.**

Table 1: Descriptive statistics

	Minimum	Maximum	Mean	S.d	95% CI	p-value
Age (years)	20	44	29.89	4.97	29.01,30.37	0.00
Duration(years)	1	17	4.89	3.67	4.26,5.51	0.00
LMP(days)	7	12	9.97	1.67	9.68,10.26	

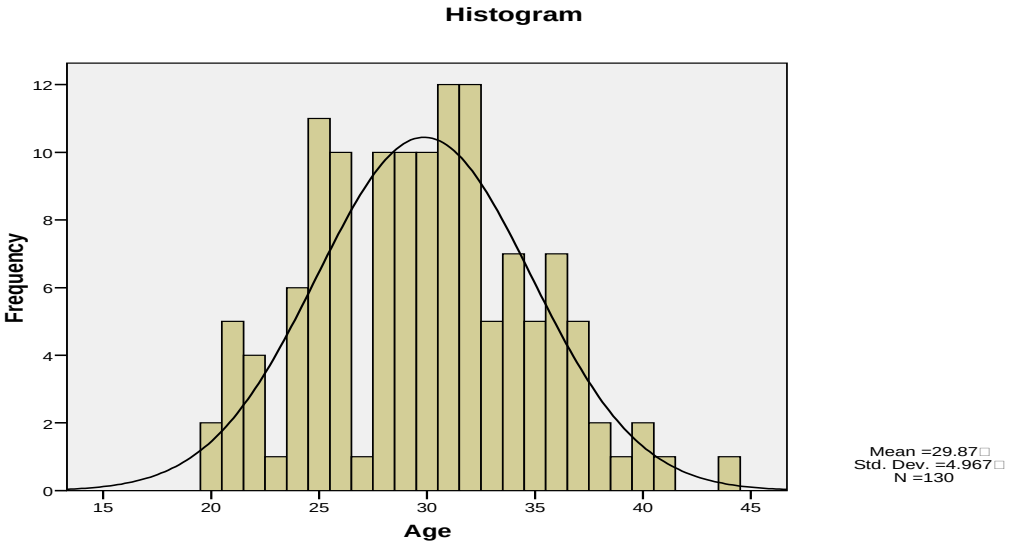

Figure 1: Histogram showing age distribution of patient

Table 2 shows that more participants had secondary infertility 68 (52.3%). More patients 70(53.8%) aged 16-30 years . The young aged group 16-30 years had a high proportion of primary infertile participants(67.7%) while more secondary infertile patients,58.8% were in age 31-45 years which was statistically significant (p= 0.002).

Table 2: Age distribution by type of infertility

	Type of infertility					
Age groups	Primary	%	Secondary	%	Total	%
16-30	42	67.7	28	41.2	70	53.8
31-45	20	32.3	40	58.8	60	46.2
Total	62	47.7	68	52.3	130	100

Pearson Chi-square,x^2=9.209, df=1, p-value=0.002

6.2 Hysterosalpingography findings

6.2.1 HSG findings by demographic characteristic and fertility status of women.

Table 3 shows that patients who aged 31-45 years had more abnormal HSG findings (71.7%) than those of aged 16-30 years. The difference seen is statistcally significant (p-value=0.012). However patients with secondary infertility had slightly more abnormal HSG findings (60.3%) than those with primary infertility (59.7%). This difference is not statistically significant (p-value=0.943). More patients had duration of infertility of 1-5 years (63%) and those with long duration (5-17 years) had more abnormal HSG findings (73%) compared to those with short duration(52%). This difference is statistically significant(p-value=0.021).

Table 3 . **HSG findings by demographic characteristic and fertility status(N=130)**

	HSG Findings		Statistics
	Normal	Abnormal	p-value
Age groups			
16-30	35(50%)	35(50%)	0.012[p]
31-45	17(28.3%)	43(71.7%)	
Type of infertility			
Primary	25(40.3%)	37(59.7%)	0.943[p]
Secondary	27(39.7%)	41(60.3%)	
Duration of infertility(years)			
1-5	39(48%)	43(52%)	0.021[p]
>5	13(27%)	35(73%)	

[p]= Pearson chi square

6.2.2 Pattern of uterine and fallopian tubes abnormalities

The study revealed that fallopian tubal blockage was the highest abnormality affecting 53(41%) infertile women followed by 25(19%) women with uterine abnormality, 23(18%) women with pelvic adhesion and 17 (13%) women with hydrosalpinx as shown in figure 2.

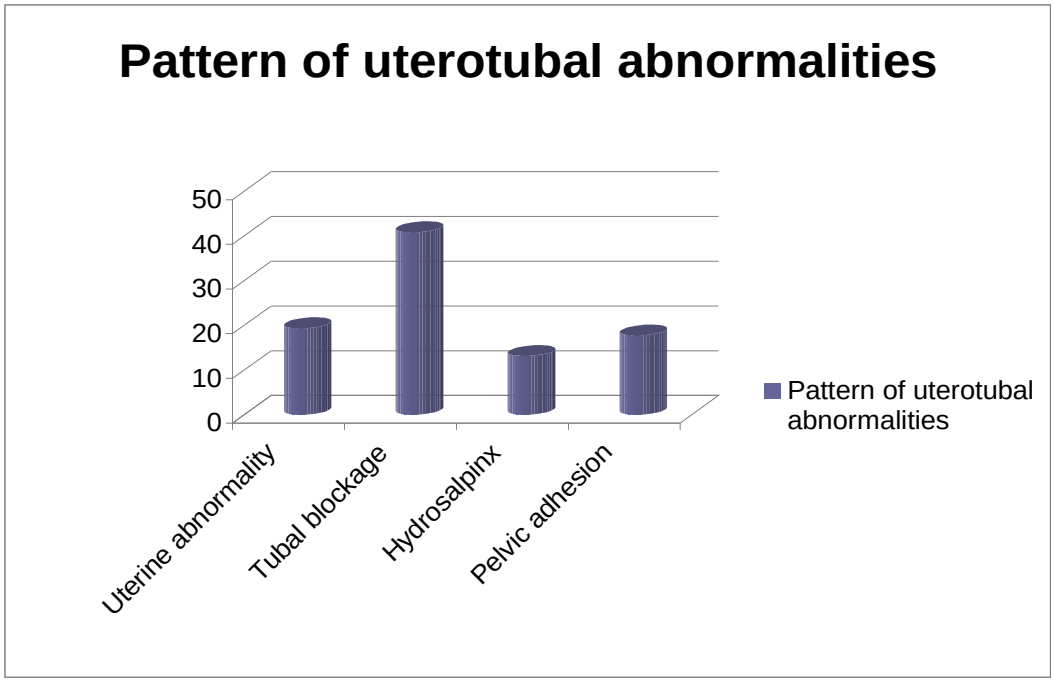

Figure 2. Distribution of uterotubal abnormalities

6.2.3 HSG uterine findings

Table 4 shows that uterine filling defect due to fibroids was the most common abnormality seen accounting for 10% of all patients(figure 4), the irregular uterine cavity which may be due to endometritis or synechiae was seen in 5.4% while patients with congenital abnormality was 3.8% (figure 3).

Table 4: Summary of HSG uterine findings

Characteristics	Frequency	%
Unicornuate	2	1.5
Bicornuate	1	0.8
Arcuate	2	1.5
Irregular uterine cavity	7	5.4
Fibroids	13	10
Normal	105	80.8
Total	130	100

Figure 3: HSG images showing bicornuate uterus.

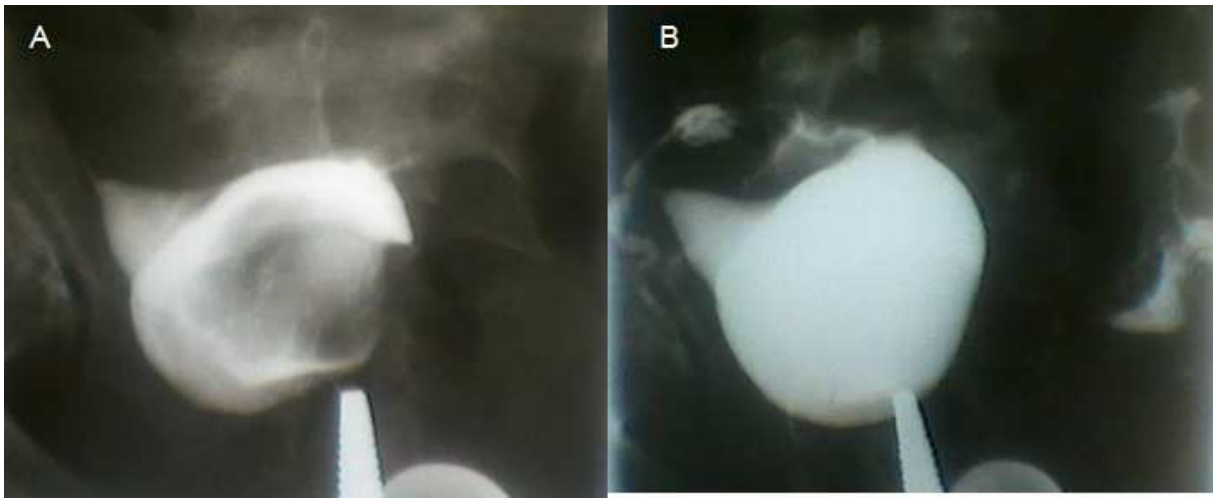

Figure 4: HSG showing filling defect(A) in early image and deformed uterus (B) in late image due to fibroid

6.2.4 HSG fallopian tubes findings

Unilateral tubal blockage either the right or left tube, was the most tubal abnormality observed in 28 patients (21.5%), bilateral tubal blockage was noted in 25 patients (19.2%). Unilateral hydrosalpinx (figure 5) was noted in 11 patients (8.5%) while bilateral hydrosalpinx was seen in 6 patients (4.6%). Tubal adhesions were found in both sides in 11 patients (8.5%) and unilaterally in 12 patients (9.2%). This is shown in table 5

Table 5: Summary of HSG fallopian tubes findings (N=130)

Characteristics	Frequency	%
Bilateral blockage	25	19.2
Unilateral blockage	28	21.5
Bilateral hydrosalpinx	6	14.6
Unilateral hydrosalpinx	11	8.5
Bilateral adhesion	11	8.5
Unilateral adhesion	12	9.2
N	130	

Figure 5. HSG Showing left hydrosalpinx and irregularity in lower uterine cavity

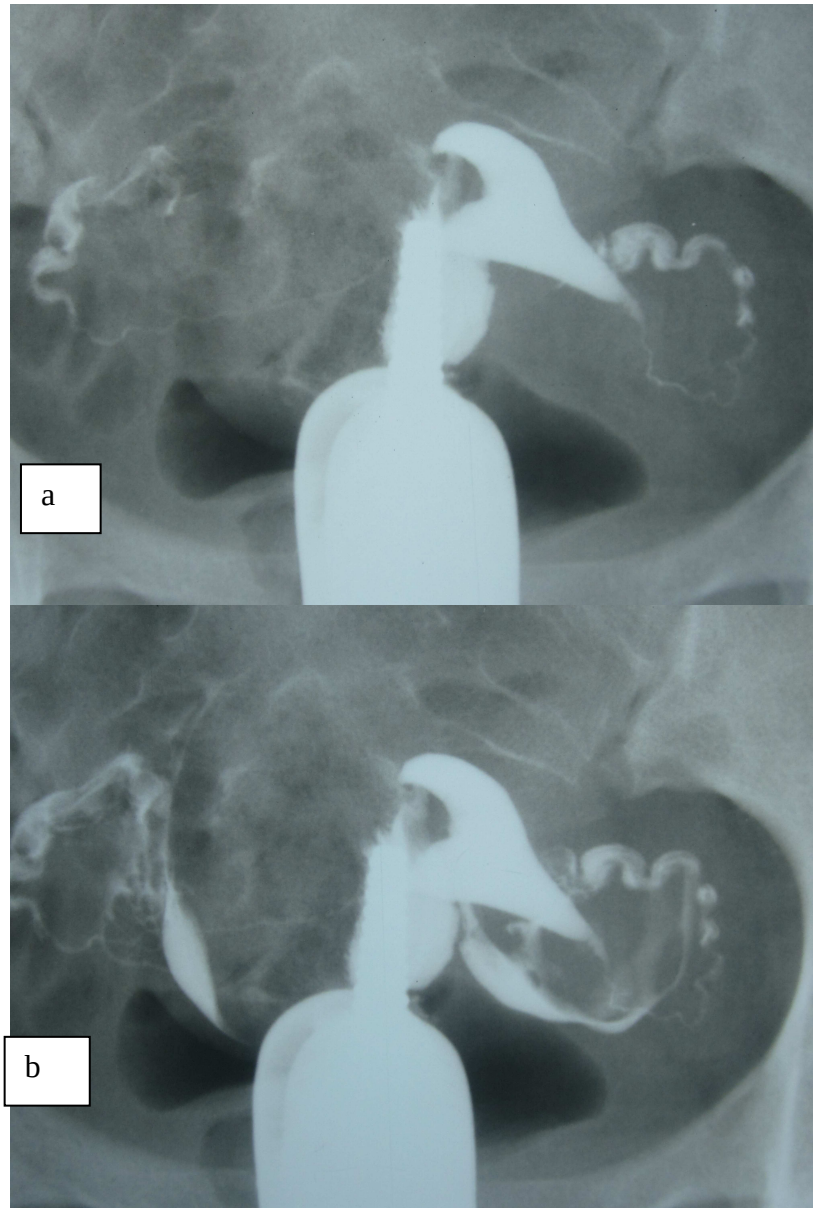

Figure 6. Normal HSG shows filling of uterus and both fallopian tubes in (a) and peritoneal spillage in (b)

7.0 DISCUSSION

This cross-sectional study analysed the findings in HSG as observed in infertile women attended Radiology department at MNH in Dar-es-Salaam. A consecutive sampling method was used due to limited data collection time, accessibility to target group and shortage of resources. The study was also for partial fulfilment of masters of medicine in Radiology.

The sample in this study may not be a true representation of Dar-es-Salaam women inhabitants with infertility as it included only those patients who attended MNH radiology department with infertility. However the sample size was reasonable enough and the age distribution of patients followed a normal distribution curve that gives a confidence in the results obtained. Despite these limitations, the findings discussed below may be useful in planning a more large scale study in the topic of infertility and HSG in general.

Infertility in women is the main indication to undergo hysterosalpingography examination. About 40-45% of infertility is attributed by female factor including cervical factors, endometrial-uterine factors, ovarian factors and peritoneal factors. Male factors attribute for about 25-40% while both male and female factors account for 10% and the remaining 10% is due to unexplained factors. Therefore infertility workup is incomplete without an initial hysterosalpingography examination that will depict abnormality in uterus and fallopian tubes.

In this study more patients had secondary infertility than those with primary infertility which is similar to other previous studies (2,3,6,7,8). However this differs from other studies where it was found that primary infertility is commoner (9,10). This higher rate of patients with secondary infertility compared to the primary infertility can be used as a crude indicator of the possible effects of pelvic inflammatory infections in our setting (3,41).

The participants included in this study were of mean age of 29.89 years which was similar to the mean age of infertile women in Uganda and Nigeria (2,3) and lower than those in Turkey (9) and higher than those in Iran (10).

The mean duration of infertility was 4.26 years which is similar to other studies done in Nigeria and Turkey (3,9). The mean duration of infertility is reported low in other previous studies conducted in Nepal and India (14,37). Most of patients in this study had 1- 5 years of infertility but majority of patients who had long duration of infertility, between 6-17 years, showed significant maximum number of abnormalities (73%). This long duration could be due to hesitancy of patients in seeking early advice fearing for marital disharmony. Another reason that could contribute to this long duration of infertility may be due to unawareness of the importance of early treatment among the infertile couple. The presence of enormous local tradition healing practices as well as other alternative medicine practices could be an important contributory factor for the delay in coming earlier to health facilities.

In the present study of 130 patients, 52 cases (40%) had normal HSG findings. 78 patients had abnormal findings accounted for about 60% of total cases. The reason behind this could be due to the fact that MNH being the tertiary level hospital receiving referrals from periphery health facilities where initial evaluation of infertility causes has been done. Also most of these patients have already seen and evaluated in MNH Gynaecology clinic for other causes of infertility and found normal, hence more likely to have structural abnormalities.

Hysteroscopy is the best technique for the diagnosis of uterine endometrial pathology because small submucosa myoma and polyps can be missed by hysterosalpingography. However no case of abnormal HSG findings will have normal finding in hysteroscopy, meaning false positive rate of HSG is close to zero. In comparison to hysteroscopy the accuracy rate of HSG in diagnosing endometrial pathology ranges from 75% to 90% (4,34). Therefore in this

study there is possibility that few patients who had normal finding could have small submucosa myoma and polyps which were not picked up by HSG.

Congenital abnormalities of the uterine shape are the result of abnormal fusion of Mullerian ducts during the early weeks of gestation. The most common anomaly is the arcuate uterus which has no impact on fertility. In this study it was demonstrated that arcuate, unicornuate and bicornuate uteri were common congenital abnormalities of the uterus encountered 3.8%. This is also quoted in previous studies (1,6,36,42). The common uterine pathology in this study was the presence of fibroids (10%). Fibroids which project in the uterine cavity such as those of submucosa will cause the actual filling defects which can be detected by the HSG. Uterine cavity may be distorted in its shape when the uterus has a large myoma. So HSG is of great value in evaluation of uterine cavity and fallopian tubes patency when planning for the myomectomy.

Irregular uterine cavity which is a sign of infection was present in 5.4%. This may be due to endometritis or synechiae following PID, post abortal or post partum infections (3,41). This distortion of uterine cavity due to both congenital and acquired causes result in infertility due to failure of embryo implantation or spontaneous abortion. Preterm labour, malposition of the foetus and obstructed labour may be another sequel of the uterine cavity distortion.

Previous studies that compared HSG and laparoscopy showed that ,HSG has a high specificity of 80% and low sensitivity of 65% for detecting tubal patency (6,9,15,21). Another study showed that HSG is as accurate as laparoscopy in the diagnosis of tubal patency or blockage (22). Therefore due to its high specificity, making HSG a useful test for ruling out tubal obstruction. When patency is demonstrated in HSG, there is little chance that the tube to be actually occluded.

Most patients in this study (41%) were found to have tubal blockage which is similar to what was reported in Uganda, Nigeria and Pakistan (2,8,36). Other previous studies reported that tubal blockage accounted for less than 41% (3,10,14,15), whilst in South Africa reported to be higher accounting for more than 67.2% (6,7). The main reason for this high proportion of patients with tubal blockage is more likely due to high prevalence of pelvic inflammatory diseases among women in our environment (2,6). Majority of patients with secondary infertility showed higher proportion of tubal blockage which is similar with some previous studies (8,24). In a study done in Nepal revealed the same incidence of tubal blockage in both primary and secondary infertility (47).

However in HSG a common pitfall is non opacification of fallopian tube due to spasm. Though antispasmodic was not used routinely in this study, its use would not have reduced the number of patients with tubal blockage significantly as very few patients show tubal spasm. Another false negative result occurs when there is inadequate wedging of cervical cannula allowing leakage of contrast material into the vagina, thus interfering with generation of sufficient intracavitary pressure and leading to misdiagnosis of tubal blockage. During this study senior radiologist was called upon whenever the procedure was difficult and suspicious of tubal spasm. Contrast intravasation into uterine and ovarian veins can sometimes be mistaken for tubal filling, therefore is important to remember the anatomical locations of these vessels. In order to minimise the chance for contrast intravasation patients were scheduled during menstrual proliferative phase between 7^{th} to 12^{th} day when the endometrium is thin and not fragile.

In our study majority of patients with tubal blockage were of older age (31-45years) in both types of infertility (53.3%). This same result was reported in the literature previously in Nigeria and India (8,24). This could be due to the increased risk of acquiring pelvic infection with age.

Hydrosalpinx which is not detected by pelvic examination can be diagnosed by HSG. Hydrosalpinx is seen as a dilated convoluted tubular structure on HSG which gradually increase in size due to distal tubal occlusion. It is a result of fallopian tubes inflammation following infections like gonococcal, chlamydial or tuberculosis of the genital tract. The fimbrial ends are eventually occluded due to adhesions leading to collection of the secretions in the lumen with gradual distension of the fallopian tube.

In this study 17(13%) patients had hydrosalpinx either unilateral or bilateral which was similar with that reported in previous study done in Uganda (2) and higher than those reported in Iran and Kathmandu (10,14).

Peritubal adhesions occur secondary to previous surgery or inflammation similar to the cause of tubal occlusion. Adhesions around the fallopian tube results in loculation of contrast material that has spilled from the fallopian tubes. Patients with features of pelvic adhesions accounted for 18% of all infertile patients in this study. A study conducted previously in Uganda showed that the peritubular adhesion was high (28%) while that done in Pakistan was low, 7% of all patients (2,36)

This high incidence of tubal related pathology may be due to the following reasons. The first is PID which is reported to be the most common gynaecological disease affecting many African women (2,6,43). The second reason is that, in this group may be non compliance to PID treatment that may lead to sub acute or chronic PID with deleterious effects on the fallopian tubes. This indicates that pelvic inflammatory disease (PID) is still common in our set up and makes it a common cause of infertility.

In this study it was observed that equal proportion of participants in both primary and secondary infertility had utero-fallopian tubes pathology in general. This is different from previous studies which showed the secondary infertile patients to have higher proportion of pathology than primary infertile patients (8,24). A larger sample size would have been appropriate in this study in order to get similar results, because there is slightly higher proportion of patients with abnormality in secondary compared to primary infertility (60.3% vs 59.7%). And also most pathologies are also higher among secondary than primary infertility when considering individual uterotubal abnormalities.

8.0 STUDY LIMITATION

Limitation in design of study was the greatest set back in this study. This was due to time limitations that could not be avoided, hence a non random sampling method was used instead of random sampling method. Also there was no special clinic for infertility at MNH rather patients were seen in usual general gynaecology clinic made it difficult to define sampling frame, hence a consecutive sampling method could not be avoided.

However consecutive sampling method results in more representative sample in comparison to convenient sampling method.

9.0 CONCLUSION

Generally, high proportion of patients in this study showed presence of uterine and fallopian tube pathology. Fallopian tubal blockage was the highest observed tubal structural abnormality while fibroid was the highest uterine pathology. There was no significant difference in the presence of pathology between patients with primary and secondary infertility. Older age above 30 years was more associated with presence of structural abnormality in both uterus and fallopian tubes.

10.0 RECOMMENDATIONS

More than half of patients investigated in this study had uterotubal abnormalities, thus making HSG being effective method for initial work-up of infertile women. Equipment and consumables associated with this investigation should be readily available.

Further studies are needed to investigate the etiologies of these abnormalities at the earliest , this could be a measure to bring down the occurrence of such conditions.

There is a need of more studies on HSG findings using much bigger sample sizes to be conducted in Tanzania.

There is a need to raise public awareness on causes and risk habits leading to infertility.

A large combined study with gynaecologist to find causes of infertility among the remaining 40% infertile women with normal HSG findings is recommended.

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APPENDEX:I. DATA COLLECTION SHEET

Part I. Demographic data

AGE	Last Menstrual Period(LMP)	Type of infertility	Duration of infertility

Part II. Clinical data

1. What are HSG findings?
   a) Normal
   b) Abnormal
2. Uterine abnormalities noted in 1 b) above
   a) Yes
   b)No
3. If yes in 2 above, which type
   a) Unicornuate uterus
   b) Bicornuate uterus
   c) Septate
   d) Irregular uterine cavity
   e) Filling defects/fibroids
4. Fallopian tubes abnormalities noted in 1b?
   a) Yes
   b) No
5. I f the answer is Yes in 4 above, which type?
   a) Right unilateral blockage
   b) Left unilateral blockage
   c) Bilateral blockage

6. Are there extrauterine abnormalities noted?

a) Yes

b) No

7. If the answer is Yes in 6 above, which type?

a) Adhesion

b) Mass

c) Other ,mention……..

APPENDEX: II. Consent: English version

Informed Consent Form

Greetings!

I am Dr .Ramadhan Bihindi Kabala, a postgraduate student at Muhimbili University of Health and Allied Sciences (MUHAS), investigating on the structural abnormalities of the uterus an fallopian tubes as the causes of infertility among the patients who attend the Gynecology clinic at Muhimbili National Hospital(MNH) using Hysterosalpingography(HSG) investigation.

The main objectives of this study is to assess the usefulness and ability of the HSG investigation to detect the abnormalities that cause the failure to conceive the pregnancy which will help the Gynaecologist in treatment plan of the patient.

I f you agree to participate in this study ,you will be asked some questions and being investigated for the patency of your fallopian tubes and uterus using HSG by introducing the contrast media through the vagina and then x-ray images will be taken for interpretation.

The HSG results and all information collected will be entered in the computer without your name, but just using the identification number. We expect no harm to happen to you during the course of this study but you will experience some pain during the procedure and bleeding spots after the procedure. The study participation is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated as per usual Hospital protocol for all patients with infertility.

It is our expectation that information that will be gained from this study will be of benefit for many infertile couples and the community at large..

In case you will have any other questions regarding this study, please feel free to contact the investigator, Dr. Ramadhan Bihindi Kabala ,P.o.Box 65001, MUHAS, Dar es slaam. Mobile phone ; 0713 682 405

If you have any questions concerning your rights as a participant, you may contact Prof. E.F. Lyamuya, Chairman of the college research and publication committee, P.O. Box

65001, Dar es Salaam. Telephone: 2150302/6. Do you agree to participate? (*Tick the response*) .....YES …….NO.

I, ……..have read the consent form and my questions have been answered and I agree to participate in this study.

Signature of Participant……..

Signature of Investigator…….

Date of signed consent…….

APPENDEX: III. Consent: ***Swahili version***

FOMU YA RIDHAA YA KUSHIRIKI UTAFITI

Salaam!

Ruhusa ya Kushiriki Utafiti Kuhusu *"uwezo wa kipimo cha HSG kuonyesha magonjwa yaletayo ugumba kwa wanawake katika chumba cha uzazi na mirija ya kupitisha mbegu"*

Mimi naitwa Dr. Ramadhan Bihindi Kabala, ni mwanafunzi wa udhamili chuo kikuu cha tiba Muhimbili. Ninachunguza sababu zinazosababisha ugumba kwa kutumia kipimo kinaitwa HSG kwa wagonjwa wenye matatizo ya kupata mimba wanaotibiwa katika kliniki ya magonjwa ya wanawake ya hospitali ya taifa Muhimbili(MNH). Dhumuni la utafiti huu ni kuonyesha uwezo wa kipimo cha HSG kuonyesha magonjwa mbalimbali katika chumba cha uzazi na mirija ya kupitisha mbegu za uzazi ambayo yanasababisha tatizo hili la ugumba na ili matokeo yake yaweze kutumika kumuongoza Mganga katika matibabu ya mgonjwa mbeleni.

Kama unakubali kushiriki kwenye utafiti huu, utaulizwa maswali, utapimwa chumba cha uzazi na mirija ya kupitisha mbegu za uzazi kwa kuingiza dawa ukeni na kasha kupiga picha kwa kutumia mionzi ya inayoitwa x-rays. Majibu ya picha zako yataingizwa kwenye kompyuta na nambari ya utambulisho; jina lako halitatumika kwenye maelezo ya utafiti. Tunategemea kwamba hakuna madhara yoyote makubwa yatokanayo na utafiti huu, zaidi ya kusikia maumivu kiasi wakati wa kufanya kipimo na matone kidogo ya damu baada ya kumaliza kipimo. Kipimo hiki hakina athari yoyote kwa afya yako

Kushiriki kwenye utafiti huu ni kwa hiari na kutokubali kushiriki au ukijitoa hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtu mwenye matatizo ya kupata uzazi. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia. Kama una maswali au maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Dr. Ramadhan Bihindi Kabala, MUHAS, P.O. Box 65216, Dar es Salaam. 0713 682 405.

Kama una maswali kuhusu haki yako kama mshiriki wasiliana na Prof. E. Lyamuya, Mwenyekiti wa kamati ya utafiti, P.O. Box 65001, DSM. Simu 2150302/6. Je, umekubali kushiriki? .....NDIYO, ...HAPANA

Mimi……..nimesoma maelezo na maswali yangu yamejibiwa na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki……