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COMPARISON OF HYSTEROSALPINGOGRAPHIC EVALUATION AMONG PRIMARY AND SECONDARY INFERTILE WOMEN AT TERTIARY LEVEL HOSPITAL OF NEPAL.

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ABSTRACT

Hysterosalpingography (HSG) is a radiological study done under fluoroscopy to visualize the uterus and lumen of the fallopian tubes as part of assessment for female factor infertility. HSG is a safe and less invasive method of detecting both the tubal and uterine defects. The objective of this study was to find out the incidence of tubal blockage including its site and side diagnosed in subfertile Nepalese. Congenital malformation and surgery related finding of Uterus and fallopian tubes patency are major component of primary and secondary infertile women which is highlighted and compare spectrum role of hysterosalpingography (HSG) findings in both infertile groups were studied. A descriptive cross-sectional study between October 2020 to September 2021, was done at tertiary level hospital of Nepal after taking ethical approval (Ref.F-NMC/516/076-0077)from Institutional Review Committee of National Medical College and Teaching Hospital Birgunj. A total of 116 cases of the infertility meeting the inclusion criteria attending the Department of Obstetrics and Gynecology of National Medical College, Birgunj were enrolled. Out of 116 cases enrolled, 93 (80%) patients belonged to primary infertility and 23 (20%) were of secondary infertility and 55% of the cases were in the 20-25 years age group. Among the primary infertile subjects, 64% of the cases had bilateral patent tubes, 30% of bilateral blocked tubes. Among the secondary cases, 61% had patent bilateral tubes and 22% of the bilateral blocked tubes. With respect to patent tubes bilaterally, 60 cases were of primary compared to 14 cases of the secondary infertility. 69% of them had the infertility history of less than 5 years followed by 26% of the 6 to 10 years of infertile period. The significant number of proximal tubal pathology had the bilateral block n=17 compared to

only n=2 of unilateral pathology. Out of total 42 cases of tubal pathology, proximal bilateral tubal pathology had the highest incidence with 40%.

Key Words: Infertility, HSG, Tubal Patency, Nepal

INTRODUCTION

Infertility has been identified as a problem to couple since the history of mankind. It is a global health issue and a socially destabilizing condition for couples with several stigma including medical, social, psychological burden and marital disharmony. The World Health Organization (WHO) defines infertility as the 'inability of a sexually active, non-contracepting couple to achieve pregnancy in one year'. [1] Infertility affects up to 15% of couple worldwide and 10 to 14 % of Indian population, with up to 186 million individuals living with infertility. [2, 3]. The problem of infertility is common in this part of Nepal. A population based and nationwide prevalence study of infertility in Nepal is lacking. However, a hospital based study conducted in Eastern Nepal found an incidence of 5.45%. [4] Survey in eight districts of Nepal found 7. 4% of females having infertility problem while a gynecological camp showed that 14.2 % women had sub -fertility morbidity in Nepal. [5] Assessment of infertility can be easily done by hysterosalpingography which is affordable, readily available and yields reliable findings. Male factor being a primary or contributing cause in approximately 50% of couples. [1] Causes of male subfertility vary highly, but can be related to congenital, acquired, or idiopathic factors that impairs spermatogenesis. A Global Burden of Disease survey reported that between 1990 and 2017, the age -standardized prevalence of infertility increased annually by 0·370% in women and by 0·291% in men. [6] Infertility causes substantial psychological and social distress and imposes a considerable economic burden on patients and health -care systems.[7,8] Infertility is a complex phenomenon where failure to establish a clinical pregnancy after 12 months (before age 35 years), 6 months (after age 35 years), or anytime (after age 40 years) of regular, unprotected sexual intercourse with potential impact on mental health. [1,9] In primary infertility there is no previous occurrence of pregnancy. [10] Whereas, secondary infertility, indicates occurrence of previous pregnancy. [11] HSG is a radiological study done under fluoroscopy to visualize the uterus and lumen of the fallopian tubes as part of assessment for female factor infertility. It involves contrast instillation via cannulation of the cervix. [12] Factors that may contribute to difficulties in conceiving may be from either or both partners; therefore, it is important to consider all possible diagnoses before going to an invasive treatment. Causes of infertility may be due to male, female, both or unexplained. Evaluation of tubal patency is very much essential in investigating a case of female infertility as tubal factor fault occurs in 30-40 % of female infertile patients. Tubal factors not only contribute to major etiological factors but poses perplexing problems in diagnosis. [13] The disorders of the tube may be pathological or functional. Pathological blockage can occur secondary to any pelvic pathology particularly inflammatory in origin or at times may be due to the congenital defects in the tube. [14]

Hysterosalpingography is a combination of a Greek word Hystero-uterus, salphinx –trumpet, graphein- to write. Different contrast media have been used in HSG since the procedure was initially described by

Rindfleisch in 2010.[15] It has been extensively employed in infertility investigations. It is a Fluoroscopic study performance by instilling radio opaque dye into uterine cavity through a catheter/HSG cannula to determine the morphology and patency of both of uterine cavity and fallopian tubes. [16] HSG can be obtained in an outpatient setting with minimal analgesics consisting of premedication with non- steroidal anti- inflammatory drugs (NSAIDs). HSG is contraindicated in the presence of an adnexal mass, pelvic inflammatory disease, history of ectopic pregnancy or an allergy to iodine or radiocontrast dye.[17] In spite of having logical utilization and advantages of HSG there are some disadvantage which cannot be neglected those are pelvic infection, bleeding spots and endometriosis.General objective of this study was to compare the Hysterosalpingographic findings among primary and secondary infertile woman and specific objective were, to find out the proportion of women with congenital uterine anomalies, to assess the proportion of women with tubal blockage, to identify the pattern of uterotubal abnormalities in infertile female women and to determine association between the type of infertility and HSG findings.

METHODS

This was a descriptive cross - sectional hospital-based study conducted in department of obstetrics and gynecology in National Medical College and Teaching Hospital, a tertiary level referral center in central terai region of Nepal near the border of India with high number of gynecological cases from both countries Nepal and India. Inclusion criteria includes women with history of primary or secondary infertility, habitual abortions, suspected anomaly and assessment of tubal patent while exclusion criteria include active or recently treated PID within past three months, history of pelvic tuberculosis, Pre-existing endocrinological disorders (Thyroid disorders; Hyperprolactinemia), suspected pregnancy, recent uterine or tubal surgery, active uterine bleeding, palpable adnexal masses or tenderness on bimanual examination. The duration of the study was complete one year from October 2020 to September 2021. Ethical approval was taken from the institutional review committee (Ref. F-NMC/515/076-0077). All infertile women who came to OPD during the study period were enrolled except those who denied participating in study group.

Sample size:

The study population included Infertile women attending our OPD at the department of obstetrics and gynecology of National Medical College and Teaching Hospital Birgunj who fulfilled the inclusion criteria were entered in the study. Sampling method was non probability purposive sampling method and sample size was calculated using the formula:

Sample size is calculated by using the following formula: $\mathbf{n = Z\alpha^2\ pq/e^2}$

Where,

- n= required sample size
- Z= statistic for a level of confidence (For 95% level of significance, Z = 1.96)
- p= estimated prevalence of infertility (taken as 7.4%)[3]
- e = precision or maximum tolerable error (set at 5%)

Using the formula, sample size of 116 was obtained.

All cases of primary or secondary infertility who came to the Outpatient Department (OPD) of Obstetrics and Gynecology at National Medical College were recorded. Patients attending the OPD who fulfilled the inclusion criteria were enrolled after taking informed consent. Hysterosalpingography was subsequently performed on all patients in presence of an experienced radiologist. All obtained data was recorded as per a premade proforma.

Hysterosalpingography Procedure

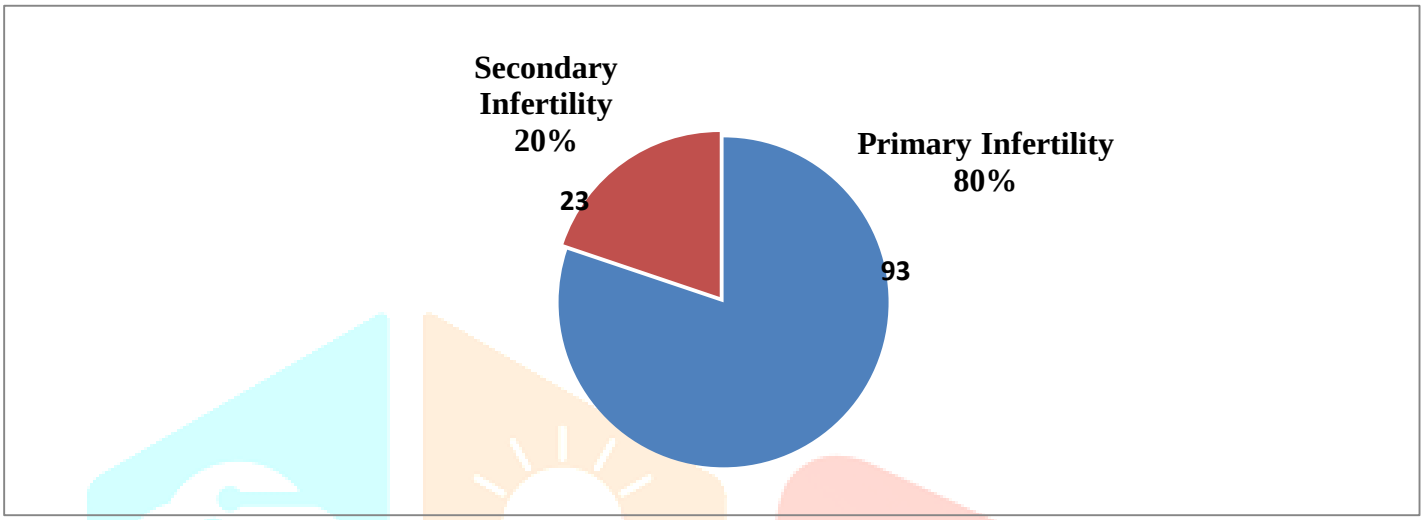
Informed consent was obtained from the patient after due explanation of the procedure and possible complications with reassurance. The examination was performed during days 7–12 of the menstrual cycle (day 1 being the first day of menstrual bleeding). This is because the endometrium was thin during this proliferative phase and also facilitated image interpretation and ensured that there was no existing pregnancy. Contraindication for the procedure included pregnancy, active pelvic inflammatory disease, bleeding, and severe allergy to iodine-based contrast agents. The procedure was performed using fluoroscopy. The patient was placed in supine position on the fluoroscopy table, and a scout film of the pelvis was acquired to assess for proper positioning, technical factors and radiopaque pelvic lesions. The patient was placed in lithotomy position. Using aseptic technique, the cervix was visualized with the aid of speculum and the anterior lip held with a Volsellum forceps. A matching size Leech–Wilkinson uterine cannula or foley's catheter (8F) was inserted into the endocervical canal after sounding the uterus with a uterine sound. Maintaining a seal between the cannula and cervical canal with gentle traction on the Volsellum and pressure on the cannula, 15–20 ml of water-soluble contrast medium, urografin 76% (sodium amidotrizoate + meglumine amidotrizoate) was injected slowly into the uterine cavity. The appearance of the uterine cavity and patency of the fallopian tubes were assessed by direct image intensification. Spot films during the phases of early uterine filling, tubal filling and peritoneal spill were taken. A release film was taken to check for the clearance of the contrast from the pelvic cavity, especially if there was hydrosalpinx. For the detection of minor deformities of the uterine cavity, it was essential to obtain the radiographs of the uterus in the true anteroposterior projection, and this was achieved by the cervical traction and oblique positioning of the patient where necessary.

The examination was declared normal when HSG demonstrated regular outlined triangular uterine cavity without filling defects, with opacification and visualization of normal caliber bilateral fallopian tubes and free peritoneal spillage of contrast media. Failure of opacification of fallopian tubes was considered to be blocked (unilateral or bilateral). Dilated fallopian tubes was labeled as hydrosalpinx (unilateral or bilateral) and demonstration of alternating dilatation and narrowing along the length of fallopian tubes called beaded. Similarly, uterine abnormalities were classified accordingly, as congenital (Mullerian duct anomalies) and acquired (synechiae, fibroid). All obtained data was entered in Microsoft Excel. Data analysis was done as per statistical standard protocol using IBM SPSS (version 20).

RESULTS

Among 116 infertile patients 93 patients were primary infertility and 23 patients were secondary infertility details in figure 1.

Figure 1: Pie diagram depicting type of infertility.



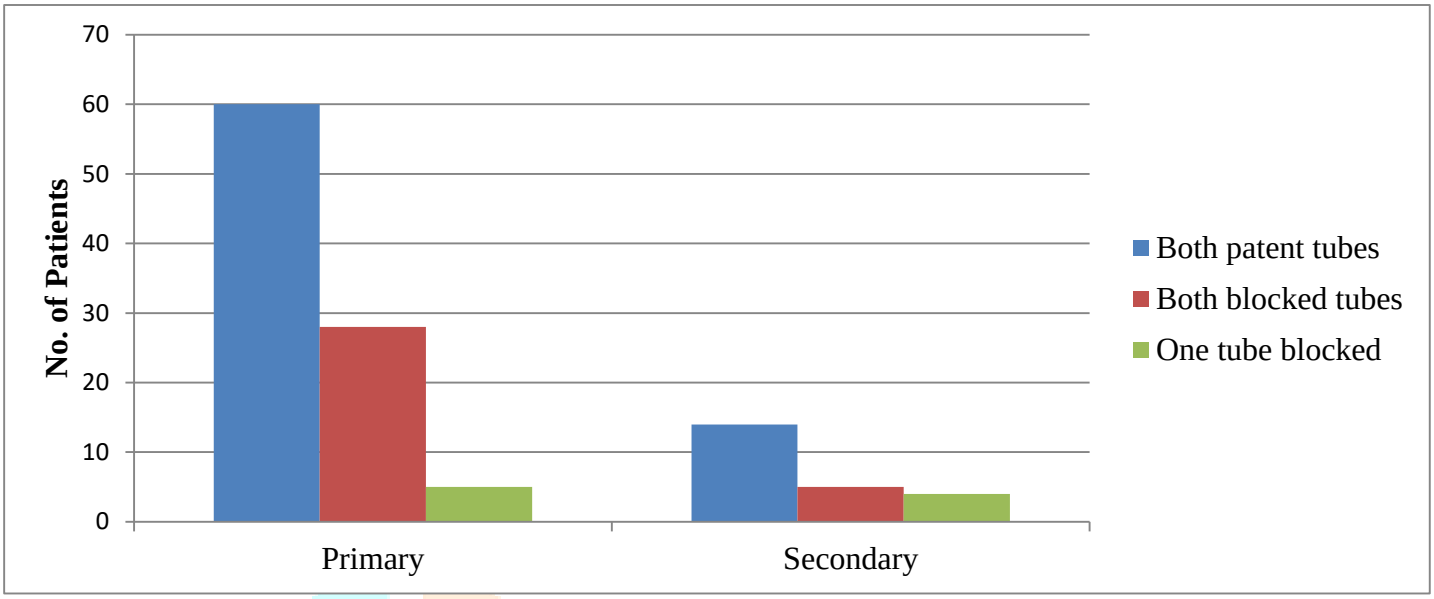
Out of 116 infertile patients studied, a total of 55% are in the 20-25 years age group. Among the primary infertility, 62% of them belong to the 20-25 years age group followed by 32% in 26-30 years age group. Similarly, for secondary infertility 65% of the infertile subjects belonged to 26-30 years of age group followed by 20-25 years with 26%, details shown in table 1.

Table 1: Age Distribution

Age (Years)	Primary infertility N (%)	Secondary Infertility N (%)	Total N (%)
20-25	58 (62%)	6 (26%)	64 (55%)
26-30	30 (32%)	15 (65%)	45 (39%)
>30	5 (6%)	2 (9%)	7 (6%)

Of all the recruited infertile cases, 63.79% (n=74) had bilateral patent fallopian tubes. Tubal blockage in one or both tubes was present in 36.21% (n=42). Amongst the primary infertile subjects, 64% cases had bilateral patent tubes, 30% had bilateral blocked tube and 6% had unilateral block. Whereas, amongst secondary infertile subjects, 61% of the cases had patent bilateral tubes, 22% had bilateral blocked tubes and 17% had unilateral tube block, details in figure 2.

Figure 2: Bar diagram depicting tubal factors.



Majority (n=19; 45%) of infertile patients with tubal blockage had proximal fallopian tube as site of obstruction, details in table 2

Table 2: Site of Obstruction (For 42 cases)

	Bilateral N (%)	Unilateral N (%)	Total N (%)
Proximal Tubal	17 (40%)	2 (5%)	19 (45%)
Mid segmental	-	3 (7%)	3 (7%)
Distal tubal	9 (21%)	4 (9%)	13 (31%)
Combined	7 (17%)	-	7 (17%)
Total	33 (79%)	9 (21%)	42 (100%)

Observations regarding tubal factors based on duration of infertility are summarized in **table 3.**

Primary infertility has tubal block in 25 cases with duration of 1-5 years that account for 76% , 5 cases with duration of 6-10 years shows 15%, 3 cases with duration of 11-15 years with 9% of cases while secondary infertility has tubal block in 3 cases with duration of 1-5 years that account for 33%, 5 cases with duration of 6-10 years shown 56%, 1 case with duration of 11-15 years with 11%. None of our enrolled cases showed any form of congenital or acquired uterine abnormality on hysterosalpingography.

Table 3: Incidence of Tubal Factor Based on Duration of Infertility

Duration of infertility (yrs)	Tubal block in primary infertility	Tubal lock in secondary infertility
1-5	25	3
6-10	5	5
11-15	3	1

DISCUSSION

Infertility is a global health problem with an increasing incidence in developing countries like Nepal. Although, population based nationwide prevalence study regarding infertility is lacking, hospital based studies have detected an incidence of 5.45%. [4] Hysterosalpingogram (HSG) still remains an initial imagining modality in evaluation of uterine cavity and fallopian tube lumen of infertile women and is best imaging modality to examine fallopian tubes.[18]. Majority of our patients (n=93) had primary infertility than secondary infertility. The valuable role of HSG as an initial imaging modality for evaluation infertility in primary and secondary infertility cases. However, as this study was a hospital based single center study, results may not represent entire population. Other investigations like laparoscopy or hysteroscopy may add precise of HSG in identifying uterine and tubal abnormalities. Therefore, further multicentric studies and additional diagnostic techniques like hysteroscopy or laparoscopy in conjunction with HSG are needed to be carried out to determine diagnostic accuracy of HSG.[19]

CONCLUSION

This study emphasizes on the fact that HSG is as old as the infertility investigation itself. Abnormal HSG's findings are frequently highly predictive of severe pelvic disease and counseling of treatment options does not require diagnostic laparoscopy. Patients with suspicious HSG's more often have normal tubes but also have a significant likelihood of tubal or associated pelvic disease and these patients require confirmatory laparoscopy. Normal HSG's usually having a high negative predictive value. Nevertheless, incidence of associated pelvic disease in the normal HSG group is high enough to indicate diagnostic laparoscopy if nonsurgical treatment is unsuccessful. Hysterosalpingogram is valuable also in increasing the intraluminal environment of the fallopian tube and endometrial cavity but is limited in its ability to evaluate other pelvic pathology such as peritubal adhesion endometriosis. Laparoscopy along with hysteroscopy will accomplish all these goals but this approach is a more invasive and costly method of diagnosis. HSG as a procedure can be used as an initial screening, cost-effective and diagnostic test in low risk patients such a infertility patients with no history of PID, low socioeconomic status, endometriosis and who did no conceive inspite of ovulation induction to evaluate tubal patency and in high risk patients such as elderly patients, patients who had been investigated, are counseled and subjected to laparoscopy.

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