Aswan Africa Obstetrics & Gynecology Journal, Volume 1/ No. 1/ February 2025 (28-38) online ISSN 3009-6480

Original Article

Comparison between C-arm fluoroscopic imaging system and laparoscopic chromopertubation for the assessment of tubal patency in infertile women

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Abstract

Keyword:
C-arm fluoroscopic imaging system, Laparoscopy, Tubal patency

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Background: Infertility is a critical component of reproductive health, and has often been neglected in these efforts. Infertility can lead to distress and depression, as well as discrimination and ostracism. C-arm fluoroscopic imaging system of infertile women is useful for the assessment of structure of uterine cavity, tubes and their patency. However, although a more invasive procedure such as laparoscopy (L/S) which is regarded as the most reliable method in detection of tubal pathologies in infertility. **Methods**: This was a Prospective cross-sectional study of 100 patients with history of primary or secondary infertility selected from A.B.C (Aswan infertility and baby center) MISSUE (minimal invasive surgery society of upper Egypt). The age group of the patients was between 18 yrs. - 45 yrs. The study population was selected depending upon the total number of patients (fitting the criteria) ABC and obstetrics and gynecology doctors of MISSUE for a period of 1 years (September 2022 to September 2023). The collected data was compiled and proper statistical formulas were applied to analyze the data collected.

Results: The present study include 100 cases of both primary and secondary infertility of which 58 cases (58%) were primary infertility and 42 cases (42%) were secondary infertility. In this study the 6(6%) cases were found in the age group of <20 years followed by 32 (32%) cases in the age group of 21-25 years, 38(38%) cases were in the age group of 26-30 years while 14 (14%) cases were in the age group of 31-35years the age group of 36-40 years 14 (14%) and in age group > 40 years is 6 (6%). In the present study, based on Kuppuswamy index most (30%) of the women had class IV socio economic status in both primary and secondary infertility. In the present study, there were 28 (28 %) cases with History of LSCS, 34 cases (34%) had FTND, 28(28 %) cases had history of abortion, and 10(10%) had previous ectopic pregnancy. Moderate degree of agreement was found between findings of both tests

Conclusions: The results suggest that. C-arm fluoroscopic imaging system is useful as a primary screening procedure, but laparoscopy provides a more accurate assessment of tubal patency in the investigation of infertility.

INTRODUCTION

Infertility is a critical component of reproductive health, and has often been neglected in these efforts.1 The inability to have children affects men and women across the globe. Infertility can lead to distress and depression, as well as discrimination and ostracism.1,2 Approximately 15 % of couples are affected by infertility, Common causes of infertility include male factor (45 %), ovulation disorders (37 %) and tubal damage (18 %). A combination of several factors is found in approximately 20% of all couples worldwide.3 Tubo-peritoneal factors are responsible for about 30-40% of cases of female infertility and hence evaluation of tubal patency represents a key step and a basic investigation in the assessment of infertile women.4,5 Tubal occlusion is the most common underlying cause of infertility.6,7 In Africa Tubal factor infertility ranges from 42 to 77% in the literature.8

C-arm fluoroscopic imaging system with advanced features including pulsed fluoroscopy and last-image-hold capability., laparoscopy with chromopertubation or both can be used to evaluate tubal patency. Owing to its noninvasive nature and low cost, HSG is widely used as a first-line approach to assess tubal patency and uterine anomalies in routine fertility workup.9,10 However, laparoscopy with chromopertubation has been the gold standard for investigating tubal patency.10

Hysterosalpingography (HSG) of infertile women is useful for the assessment of structure of uterine cavity, tubes and their patency.10 However, although a more invasive procedure such as laparoscopy (L/S) which is regarded as the most reliable method in detection of tubal pathologies in infertility.10

First, and most significantly, a benefit of fluoroscopy is its ability to obtain a real-time evaluation with true temporal resolution, including the ability to reposition a patient during an exam, which is often not available on traditional H.S.G and CT or MRI. Second, fluoroscopy exposes patients to potentially lower doses of ionizing radiation than H.S.G, with the average dose approximately 10-50 mGy/min for normal fluoroscopy with a typical fluoroscopy suite setup [7] and with total exam times often under 1 minute. This is compared to the approximately 12 mSv effective dose for a sample CT abdomen/pelvis, and up to 24 mSv for a multiphase CT examination of the same region [8]. Third, fluoroscopy provides the ability for focused and functional examination of a particular region of interest. Lastly, contrast administration with agents including barium and non-ionic compounds can be evaluated in real time

Laparoscopic surgery is performed during the follicular phase. During the laparoscopic observation after the assessment of bilateral ovaries, fallopian tube, uterus and other pelvic structures, tubal patency is evaluated by chromopertubation to detect pelvic adhesions, any existence of endometriosis or presence of other pathologies.9

The present study is carried out to enhance our knowledge in regards to role of A mobile C-arm fluoroscopic imaging system with pulsed fluoroscopy and last-image-hold and laparoscopic chromopertubation as a safe, effective, cost effective and accurate tool for the assessment and planning the protocol for management of infertility.

METHODS

Pulsed fluoroscopy (eight frames per second) and continuous fluoroscopy were used with auto-mated exposure control and last image hold for static image capture.

Fluoroscopy time (seconds), field of view (12 in., 9 in., 6 in.), mode (continuous, pulsed), and dose area product (mGycm2) were recorded for each patient. The total estimated surface dose then was calculated.

Hysterosalpingography was performed under fluoroscopy in an outpatient office setting between day 5 and day 11 of the menstrual cycle at least 24 hours after menses had ceased. Prophylactic antibiotics were prescribed at the discretion of the referring gynecologist. Prophylactic antibiotics otherwise we're not prescribed routinely unless the patient had a history or heart murmur that required subacute bacterial endocarditis

prophylaxis. The patients routinely were given premedication with oral ibuprofen 600 mg. A urine pregnancy test (QuickVue One-Step hCG Urine Test; Quidel, San Diego, CA) was performed immediately before the hysterosalpingogram procedure. The hysterosalpingogram was performed with use of a standard technique. The patient was placed in lithotomy position on a radiolucent procedure table (Apix CV Imaging Table; General Electric Company, Fairfield, CT) with the table positioned at maximum height. A vaginal speculum was inserted. After the external os was cleansed with povidone-iodine solution, the cervical os was cannulated with a HSG catheter (H/S Catheter; CooperSurgical, Trumbull, CT; Silicone Balloon HSG Catheter; Cook, Bloomington, IN; HSG & HyCoSy Catheter; Rocket Medical, Hingham, MA). A cervical tenaculum was not used. The catheter balloon was inflated within the endocervical canal or uterine cavity, and contrast injection was performed with fluoroscopic control (OEC 9800; General Electric) (Fig. 1).

Selective salpingography was performed in patients with proximal fallopian tube occlusion (5–7). If there was occlusion of either one or both fallopian tubes proximally during standard HSG, a 40-cm long 5F Berenstein catheter (Boston

Scientific, Natick, MA) was advanced under fluoroscopic guidance and wedged in the cornua of interest. A 9F HSG catheter (Cook) was used in combination with the 5F Berenstein catheter if the 5F catheter alone could not be position securely within the cornua.

Fig 2 (A 9F HSG catheter (Cook)

The C-arm was positioned at the lowest height possible that allowed clearance for craniocaudal and oblique angulation without touching the procedure table base. Initial examination was conducted with use of pulsed fluoroscopy (eight frames per second) with automated exposure control. If more detailed evaluation was required during the course of the examination, then continuous fluoroscopy was used.

The C-arm was rotated in cranial, caudal, and oblique projections as needed to obtain an image of the uterine cavity enface. Static image capture was achieved by use of the fluoroscopic last-image-hold feature. Images of early and maximal opacification of the uterine cavity, fallopian tubes, and peritoneal contrast spillage were obtained. Selected static images were transferred to a picture archive and communications system. Images transferred to the picture archive and communications system were evaluated for diagnostic adequacy. Radiation dose data display was an integral feature of the C-arm and was recorded for each patient. Fluoroscopy time (seconds), cumulative dose (milligray centimeters squared), field of view (normal, magnification 1, magnification 2), mode (continuous, pulsed), and dose area product (DAP, milligray centimeters squared) were recorded. The three fields of view were measured at the skin entrance location with use of digital radiology cassettes. Normal, magnification 1, and magnification 2 had associated areas of 228.34 cm2 ,126.20 cm2, and 75.64 cm2

The skin entrance distance from the source of the beam is constant at 58 cm. The source to the image intensifier distance is constant at 100 cm. The estimated surface dose (ESD) was calculated from the recorded DAP values. The C-arm unit reports the percentage of the total recorded DAP obtained while in the varying fields of view. This percentage was used to calculate the proportional DAP per field of view, which then was divided by the associated area at the level of the patient. The total ESD per patient was calculated by summing the individual ESD calculations across the three fields of view. Hysterosalpingogram findings were recorded. Numerical data analysis was primarily descriptive.

Statistical analysis was performed with use of unpaired Student's t-test to identify any significant difference between fluoroscopy time for patients with a normal hysterosalpingogram result and patients with abnormalities who did not undergo selective catheterization

fig 3 picture of fluoroscopy was used the C-arm

This was a Prospective cross-sectional study of 100 patients with history of primary or secondary infertility selected from A.B.C (Aswan infertility and baby center) MISSUE (minimal invasive surgery society of upper Egypt).

The age group of the patients was between 18 yrs. - 45 yrs. The study population was selected depending upon the total number of patients (fitting the criteria) visiting A.B.C (Aswan infertility and baby center) Gynecology department for a period of 1 years (September 2022 to September 2023).

Inclusion criteria

- Those patients coming for treatment of infertility
- Those patients who are given informed consent.

Exclusion criteria

- Those patients who have not given informed consent
- Women who did not return for laparoscopy evaluation.

• Technical problems related to fluoroscopy and women who became pregnant after hysterosalpingography.

• Women with pelvic infection.

As the patient came to the ABC center, a detailed history pertaining to infertility and other relevant history was asked and recorded, including the data if patient had previous treatment documents. In this first visit of patient, the couple was explained in detail about the normal physiology and the fertile period.

The female was subjected to clinical examination as well as systemic examination along with local and gynecological examination. Then they were subjected to certain basic blood investigations, ultrasonography (USG) pelvis and husband's semen analysis; and patient was asked to follow-up with next menstrual cycle. According to the inclusion and exclusion criteria the patients were subjected to fluoroscopy and Diagnostic laparoscopy.

Patients selected for fluoroscopy and Diagnostic laparoscopic chromopertubation evaluation were admitted in the post menstrual phase. fluoroscopy done and after 1-month diagnostic laparoscopic chromopertubation for tubal patency ovarian drilling, adhesiolysis etc.

were also done if required. All the data was recorded on a predesigned proforma. The collected data was compiled and proper statistical formulas were applied to analyze the data collected.

Statistical analysis

Statistical analysis was done by using descriptive and inferential statistics using Chi-Square test, binary classification and the software used was SPSS 17.0 version, graph pad prism 5.0 versions and $p<0.05$ is considered as level of significance.

RESULTS

The present study includes 100 cases of both primary and secondary infertility of which 58 cases (58%) were primary infertility and 42 cases (42%) were secondary infertility (Table 1).

infertility	**No. of patients**	**%**
Primary infertility	58	58.00
Secondary infertility	42	42.00
Total	100	100.00

Table 1: Distribution of patients according to fertility.

Infertility No. of patients % Primary infertility 58.00 Secondary infertility 42.00 Total 100.00

In this study, the 6 (6%) cases were found in the age group of <20 years followed by 32 (32%) cases in the age group of 21-25 years, 38 (38%) cases were in the age group of 26-30 years while 14 (14%) cases were in the age group of 31-35years the age group of 36-40 years 14 (14%) and in age group > 40 years is 6 (6%). The Mean Age is: 28.40±6.73

(Table 2).

Age (yrs)	No. of patients (N=50)	%
≤ 20 yrs	06	6.00
21-25 yrs	32	32.00
26-30 yrs	38	38.00
31-35 yrs	14	14.00
36-40 yrs	04	4.00
>40 yrs	06	6.00
Total	100	100.00
Mean age	28.40±6.73	

Table 2: Age wise distribution of patients.

Age (yrs) No. of patients (N=100) % ≤ 20 yrs 6.00 21-25 yrs 32.00 26-30 yrs 38.00 31-35 yrs 14.00 36-40 yrs 4.00 >40 yrs 6.00 Total 100.00 Mean age 28.40±6.73

In the present study, based on Kuppuswamy index most (30%) of the women had class IV socio economic status in both primary and

In the present study, there were 28 (28 %) cases with History of LSCS, 34 cases (34%) had FTND, 28 (28 %) cases had history of abortion, and 9(9 %) had previous ectopic pregnancy

(Table 3). Table 3: Distribution of patients according to obstetric history of secondary infertility patients.

Obstetric history	No. of patients	%
Previous LSCS	28	28
Previous FTND	33	33
Previous Abortion	28	28
Previous Ectopic	10	10
Total	100	100

Obstetric history No. of patients % Previous LSCS 06 28 Previous FTND 07 33 Previous Abortion 06 28 Previous Ectopic 02 10 Total 21 100

Table 4: Distribution of patients according to tubal patency in. C-arm fluoroscopic imaging system and laparoscopic chromopertubation. Tubal Patency HSG

Tubal Patency	HSG	Laparoscopic chromopertubation
Bilateral Patency	56 (56%)	56 (56%)
Unilateral Patency	16 (16%)	14(14%)
Bilateral Occlusion	28 (28%)	20 (20%)

Laparoscopic chromopertubation Bilateral Patency 56 (56%) 56 (56%) Unilateral Patency 16 (16%) 14 (14%) Bilateral Occlusion 28 (28%) 20(20%)

Tubal patency test was done by injection of methylene blue dye through the cervix and visualization of spillage of dye in the peritoneal cavity. Chromopertubation in primary and secondary infertility group was done and in primary infertility group it was observed that 56 cases (56%) had B/L patent tubes in Hysterosalphingography, 56 cases (56%) had B/L patent tubes in diagnostic laparoscopic chromopertubation. 16cases (16%) had unilateral patency in . C-arm fluoroscopic imaging system ,14 cases (14%) had unilateral patency in Diagnostic laparoscopic chromopertubation, 28 cases (28%) had B/L occlusion in. C-arm fluoroscopic imaging system and 10 cases (10%) had B/L occlusion in Diagnostic laparoscopic chromopertubation

Table 5: Other findings on Hysterosalphigography

Other Findings	No. of patients	%
Shape of the uterus		
Didelphys uterus	1	2
Bicornuate uterus	1	2
Septate uterus	2	4
Cavity of uterus		
Endometrial polyp	2	4.00

The Hysterosalphingography findings in the present study showed 1 case (2%) didelphys uterus, 1 case (2%) of bicornuate uterus, 2 cases (4%) of septate uterus, 2 (4%) cases of endometrial polyp (Table 5)

Table6: Detection of tubal status at HSG and Laparoscopic chrompertubation

HSG	Diagnostic Laparoscopy		McNemer chi-square test value	p-value
	Positive	Negative		
Positive	77	3		
Negative	10	10	15.23	0.0001, Significant
Total	87	13		

C-arm fluoroscopic imaging system Diagnostic Laparoscopy McNemer chi-square test value

p-value Positive Negative Positive 29 1 15.23 0.0001, Significant

McNemer chi-square test value - 15.23, p<0.0001 [Significant] • Positive Likelihood Ratio = 8.18 [1.25, 53] • Negative Likelihood Ratio = 0.28 [0.16, 0.50] • Cohen's Kappa Index Value = 0.505

There was a significant association was found between results of two tests. C-arm fluoroscopic imaging system showed a positive-likelihood ratio value for assessment of tubal status of 8.18%, a negative- likelihood ratio value of 0.28%, Moderate degree of agreement was found between findings of both tests

DISCUSSION

Intra cavitary pathology like endometrial polyps, uterine septum, bicornuate uterus often results in abnormal uterine bleeding, infertility or both. Congenital anomalies of the female reproductive system are associated with higher rate of infertility. C-arm fluoroscopic imaging system is a safe relatively inexpensive, simple and rapid diagnostic test, with continuous film. when performed properly provides valuable information about tubes, uterus and the cervix.11

World Health Organization studies indicate that laparoscopy identifies tubal patency better than. C-arm fluoroscopic imaging system. Nevertheless, both modalities are less than ideal in the accurate identification of tubal status.12

In the present study, the commonest age group was 26 to 30 years (38%). Primary infertility was mainly seen in the age group of 21-25 years and secondary infertility in 26-30 years. The mean age of the study population was 28.40±6.73 years. Park J et al, in their study reported with Participant mean age of 32 years (SD: 2.7), with a range between 26 and 41 years.13

Our study shows that (28%) Bilateral tubal block was detected in. C-arm fluoroscopic imaging system and (10%) in diagnostic laparoscopic chromopertubation. The study by Chakraborti et al (22.7%) and Goynumer G et al (24 %).14,15 156 which shows bilateral tubal block to be the common tubal cause of Infertility.

The present study indicates that Tubal patency plays a major role for conception in the etiology of infertility and evaluation by laparoscopy along with chromopertubation will give a better idea regarding the cause of the patency and management of the condition.

As this study is done in rural setup patients are not always affordable for diagnostic laparoscopic chromopertubation, so the first line of management remains to be Hysterosalphingography by C arm and as it's a non-invasive and low cost which should be followed by Diagnostic laparoscopic chromopertubation.

CONCLUSION

The results suggest that. C-arm fluoroscopic imaging system is useful as a primary screening procedure, but laparoscopy provides a more accurate assessment of tubal patency in the investigation of infertility. In planning of tubal microsurgeries both will be complementary to each other.

Funding: No funding sources Conflict of interest: None declared Ethical approval: The study was approved by the Institutional Ethics Committee

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