Saline infusion sonohysterography versus laparoscopy for the assessment of tubal patency

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Abstract: Background: The aim of the present study is to evaluate the accuracy of saline infusion sonohysterography in assessment of tubal patency in 20 infertile women in comparison to laparoscopy. **Methods:** Women with infertility and fulfilling Inclusion criteria will undergo saline infusion sonohysterography and its results will be compared with the results of laparoscopy. **Results:** The results of this study showed that the accuracy of saline sonohysterography in diagnosis of bilateral tubal patency in the infertile patients was sensitivity of 62.0%, a specificity of 52.0%, a PPV of 50%, an NPV of 60%, an FPR of 10% and an FNR of 0.0%. Saline sonohysterography was diagnostic of bilateral tubal patency with a sensitivity of 68.0%, a specificity of 50%, a PPV of 65.0%, an NPV of 45.0%, an FPR of 50% and an FNR of 5.0%. **Conclusion:** In conclusion of our study we found that saline infusion sonohysterography offer much less invasive method than laparoscope for the diagnosis of tubal patency. Saline infusion sonohysterography also can be performed initially to infertile patients. It is simple, fast, safe, well tolerated, inexpensive procedure avoiding anesthesia complications and associated with rare adverse effects. Laparoscopy with chromopertubation is widely accepted as the gold standard method for evaluating of internal pelvic organs and tubal patency. It has the ability to simultaneously evaluate the abdominal cavity and other pelvic structures for an enhanced diagnostic evaluation of other etiologies of sub fertility. On the other hand it has operative risks, expensive, more time consuming and the patient needs a period of postoperative recovery.
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Keywords: Saline; infusion; sonohysterography; laparoscopy; assessment; tubal patency

Introduction

Infertility is defined as one year of frequent, unprotected intercourse during which pregnancy has not occurred. It affects 10% to 15% of couples. Major causes of infertility include male factors, ovarian dysfunction, tubal disease, endometriosis, and uterine or cervical factors **(Jose-Miller et al., 2007).**

Tubal factor infertility is a common problem. Tubal dysfunction is responsible for approximately 30% of infertility cases **(Yildizhan etal., 2009).**

There are multiple etiologic factors responsible for the involvement of the fallopian tube in infertility, which include tubal damage from pelvic inflammatory disease) PID), the use of intrauterine devices, a history of a perforated appendicitis, ectopic pregnancy, and septic abortion. Tubal adhesions and tubal obstruction can also be due to endometriosis and previous surgical trauma **(Kupesic & Plavsic, 2007).**

Programs for investigating infertile patients include a variety of tests: physical examination, laboratory testing, and most of the time, radiologic and surgical studies **(Horowitz et al., 2006).**

Precise evaluation of the uterine anatomy and fallopian tubes is an important step in a routine infertility assessment. Accurate diagnosis of anatomic abnormalities that may hinder fertilization plays animportant role in both infertility screening and the consideration of available therapeutic options **(Hajishafiha et al., 2009).**

Tests to determine if the tubes are open and undamaged are an important part of the infertility workup. Although new methods have become available in recent years, none of them are the best test for each different individual woman and none of them can be a single test to demonstrate the pelvic structure **(Yildizhan et al., 2009).**

Hysterosalpingography and laparoscopy with chromopertubation are the most commonly used methods to examine tubal patency, but in addition to the identified benefits, each method also carries the risk of severe adverse effects **(Kupesic & Plavsic, 2007).**

Although HSG is often the primary test to investigate fallopian tube patency, exposure of the patient to ionizing radiation and contrast medium is an unpleasant issue. Most patients complain of cramping, discomfort and lower abdominal pain during HSG **(Cicinelli et al., 2001).**

Bilateral proximal obstruction of the tube at its junction with the uterus can occur because of a tubal spasm during HSG. Contractions of the uterus can also lead to transient spasms in the interstitial part of the fallopian tube, which can be mistaken for tubal obstruction during HSG, and this entity needs to be

carefully distinguished from pathologic conditions **(Hajishafiha et al., 2009).**

Laparoscopy with chromopertubation is widely accepted as the gold standard method for evaluating tubal patency. The advantages of this procedure include an ability to evaluate the abdominal cavity in addition to other pelvic structures. Adding hysteroscopy to the procedure allows for concomitant evaluation of the intrauterine cavity and may identify congenital or endometrial abnormalities **(Saunders et al., 2011).**

On the other hand laparoscopy is an invasive procedure that requires general anesthesia and carries the risk of sever adverse effects, including accidental injury of the intestinal loops, urinary bladder, and pelvic blood vessels **(Hajishafiha et al., 2009).**

Laparoscopy provides a mechanism to diagnose and treat underlying pelvic pathology that may be causative for infertility as well as other symptoms, thereby optimizing both spontaneous and assisted pregnancies **(Burney & Nezhat, 2008).**

Sonohysterography (SHG) is a simple, safe, and well-tolerated examination technique used for investigation of the uterine cavity and fallopian tubes with very few adverse effects and a low occurrence of complications **(Hamilton et al., 2003).**

Sonohysterography can be provided in an outpatient setting, and it is associated with minimal patient discomfort and a low risk of infection. This procedure is noninvasive and rather easy to perform in almost any medical setting because it does not require sedation or anesthesia, nor does it have any adverse effects or severe related complications **(Verma et al., 2009).**

Considering the above merits, sonohysterography can be the preferred first choice investigation to assess tubal patency, which can later be followed by more complex or invasive procedures (**Lakkawar et al., 2011).**

2. Patients and Methods

Research question:

Is saline infusion sonohysterography as accurate as laparoscopic chromopertubation for the assessment of tubal patency in infertile women.

Research hypothesis:

Laparoscopic chromopertubation is more accurate than saline infusion sonohysterography in diagnosis of tubal patency in infertile women.

Objectives:

The aim of the present study is to evaluate the accuracy of saline infusion sonohysterography in assessment of tubal patency in 20 infertile women in comparison to laparoscopy.

Medical application:

Using saline infusion sonohysterography as first choice investigation to assess tubal patency helps in reduction of health care costs in the management of infertility, avoiding the risks and complications of more invasive procedures, time saving, and also associated with minimal patient discomfort.

Participants:

Inclusion criteria:

1- 20 Women of reproductive age range between 18 and 40 years.

2- Duration of infertility more than 1 year.

Exclusion criteria:

1- Patients with a currentgenital tract infection.

2- Patients with undiagnosed amenorrhea.

3- Any patient who has undiagnosed vaginal bleeding.

4- Patients who has any genital tract malignancy.

5- Presence of fluid in the douglas pouch before the procedure of saline infusion sonohysterography.

This study will be conducted in Damanhourteaching Hospital after the approval of the research ethics committee.

20 patients at reproductive age complaining of inability to conceive will be recruited from the infertility outpatient clinic.

A written informed consent will be obtained from all patients before participation.

All patients after consenting will be subjected to:

1-History taking:

Including infertility duration, details of previous investigations.

2-General and abdominal examinations.

3-Pelvic examination:

To exclude cervical and vaginal anatomical abnormalities, and presence of any infection.

4- Saline infusion sonohysterography:

The procedure will be performed during the follicular phase of the menstrual cycle, transvaginal ultrasonography will be performed with endovaginal probe to exclude the presence of fluid in the douglas pouch before SHG, Instillation of sterile saline through a size 8 or 10 Foley's catheter using a sterile 20-mL syringe will be performed under sonographic guidance, The collection of fluid in the douglas pouch after the procedure will be considered an indicator of patency of at least one or both of the fallopian tubes **(Hajishafiha et al., 2009).**

5-laparoscopic chromopertubation:

The laparoscopic examination will be performed under general anesthesia, during the follicular phase of the menstrual cycle, testing for fallopian tubes patency will be done usingmethylene blue dye injected using cervical cannula and the spilling of the dye through the fimbrial ends of the tubes will be noticed **(Hajishafiha et al., 2009).**

Outcome Measures:

The primary outcome is assessment of tubal patency that will be detected by both diagnostic values saline infusion sonohysterography and laparoscopy in infertile women.

Study design:

Comparative clinical trial.

Women with infertility and fulfilling Inclusion criteria will undergo saline infusion sonohysterography and its results will be compared with the results of laparoscopy.

Statistical considerations:

Sample size estimation:

The sample size was estimated to be 20 patients.

This sample allows detection with 95% C.I. of at least one tube patent by saline infusion sonohysterography with sensitivity of 94% ± 7% and specificity of 95%, given a prevalence of at least one tube patent of 75 % in the study group, setting the power (β) at 80 % and (α) error at 5 % **(Hajishafiha et al., 2009).**

3. Results:

All results will be arranged, tabulated and statistically analyzed by the appropriate methods. It will be done using SPSS (Statistical Program for Social Science) 16 statistical software as follows:

Description of quantitative variable as mean, SD, and range.

Description of qualitative variable as number and percentage.

Chi-squre test will be used to compare qualitative variables.

Unpaired t-test will be used to compare two groups as regard a quantitative variable.

Spearman correlation between two variables which either positive correlation or negative correlation.

Significance level will be set at 0.05.

Accuracy of a diagnostic test will be evaluated by:

1- Sensitivity.
2- Specificity.
3- Positive predictive value.
4- Negative predictive value.
5- Likelihood ratio's (positive and negative).

In comparison to gold standard (laparoscopy).

P value:

• P > 0.05 insignificant.• P < 0.05 significant.
• P < 0.01 highly significant.

The current study was conducted in Damanhour Medical National Institute during the period between January 2017 and March 2017. A total of twenty infertile patients were included in the study.

This table shows that the mean age in years was 27.30 ± 7.41, the mean weight in Kilograms was 79.60 ± 17.09, the mean BMI in kilograms divided by squared height (in meters) was 28.55 ± 7.21.

Table (1): Demographic data of the infertile patients

Variables	Range	Mean ± SD
Age (years)	19-40	27.30±7.41
Weight (kg)	52-107	79.60±17.09
BMI (kg/m^2)	19.9-39.0	28.55±7.21

SD standard deviation
Kg Kilogram BMI body mass index
[calculated as weight (in kilograms) divided by squared height (in meters)]
Data presented as range, mean ± SD

This table shows that the most of the infertile patients (55.0%) was in the age group of <25 years, while the least of them (20%) was in the age group of 25-35 years. The most of the infertile patients (45.0%) was in the weight group of >80 Kg., while the least of them (15%) was in the weight group of <60 Kg. The most of the infertile patients (35.0%) was in the BMI group of >31 kg/m^2, while the least of them (10.0%) was in the weight group of 28-31kg/m^2.

Table (2): Distribution of Age, Weight and BMI among the infertile patients

	No.	(%)
Age (years)		
<25	11	55.0
25-35	4	20.0
>35	5	25.0
Weight (kg)		
<60	3	15.0
60-70	4	20.0
70-80	4	20.0
>80	9	45.0
BMI (kg/m^2)		
<22	5	25.0
22-25	3	15.0
25-28	3	15.0
28-31	2	10.0
>31	7	35.0

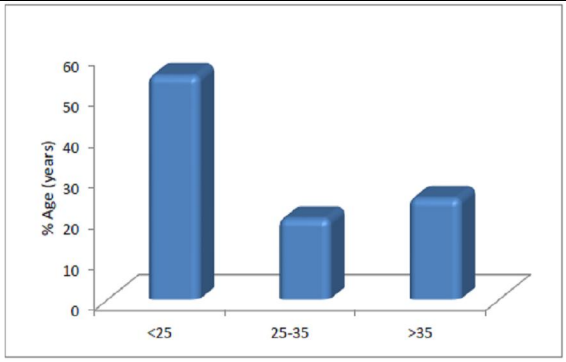

Figure (1): Distribution of Age among the infertile patients.

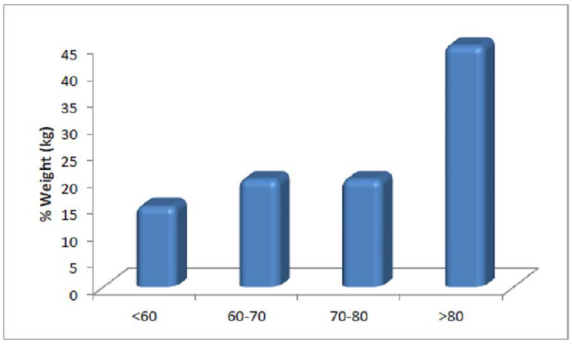

Figure (2): Distribution of Weight among the infertile patients.

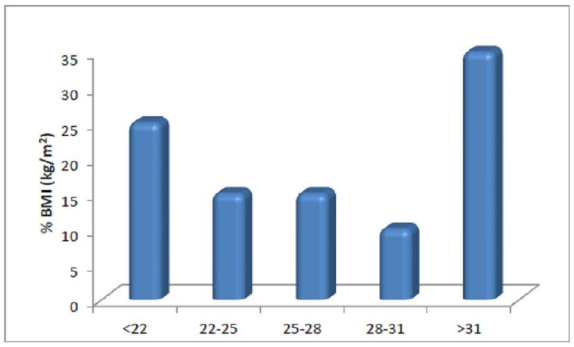

Figure (3): Distribution of BMI among the infertile patients.

This table shows that the most of the infertile patients (60.0%) had primary infertility, while the least of them (40.0%) had secondary infertility. The mean duration of infertility was 4.30 ± 3.29 year.

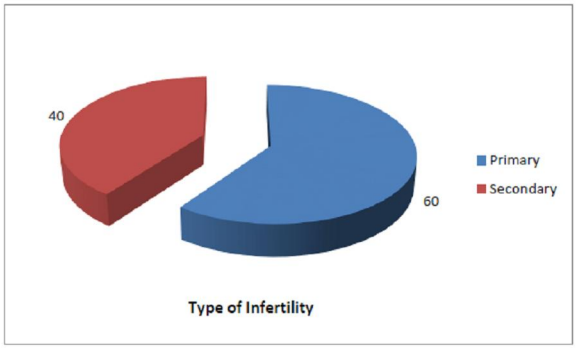

Figure (4): Type and duration of infertility in infertile patients

Table (3): Type and duration of infertility in infertile patients

	(%)
Type of Infertility Primary Secondary	 12 (60.0%) 8 (40.0%)
Duration of Infertility (years) Range Mean ± SD	2-16 4.30 3.29

SD standard deviation
Data presented as number (percentage) or range, mean ± SD

This table shows that the most of infertile patients (85.0%) had positive fluid in the douglas pouch by SIS while the least of them (15.0%) had negative fluid in the douglas pouch, Most of infertile patients (65%) had Bilateral tubal patency by laparoscopy while the least of them (5%) had left-sided tubal block.

Table (4): Tubal test results in infertile patients

	No.	(%)
Saline Sonohysterography		
Positive Fluid in DP	17	85.0
Negative Fluid in DP	3	15.0
Laparoscopic Chromopertubation	**13**	**65.0**
Bilateral Tubal Patency	**4**	**20.0**
Bilateral Tubal Block	**3**	**15.0**
Unilateral Tubal Block	2	10.0
Right-sided Tubal Block	1	5.0
Left-sided Tubal Block		

HSG hysterosalpingogram
DP Douglas Pouch
Data presented as number (percentage)

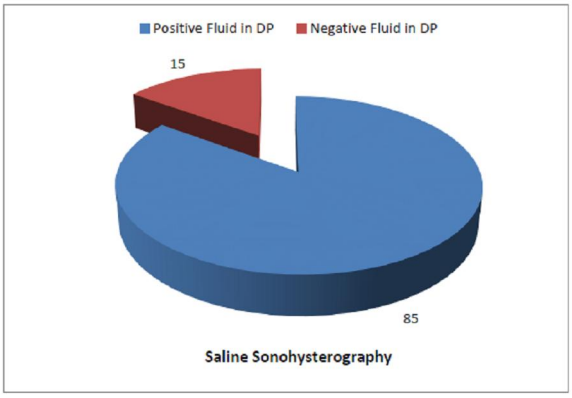

Figure (5): Pie-Chart showing saline sonohysterography results in theinfertile patients**.**

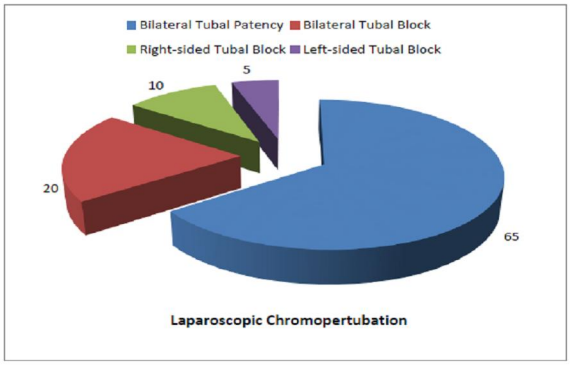

Figure (6): Pie-Chart showing laparoscopic chromopertubation results in infertile patients.

This table shows that there were no significant statistical differences between infertile patients with bilateral tubal patency, unilateral tubal block, and

bilateral tubal block regarding age, weight, BMI, type or duration of infertility.

Table (5): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding demographic data, type and duration of infertility

	Infertile patients with bilateral tubal patency∫ (n= 14)	**Infertile patients with unilateral tubal block∫ (n=4)**	**Infertile patients with bilateral tubal block∫ (n=2)**	***P***
Age (years)				
Range	19.0-40.0	20.0-37.0	23.0-33.0	.444#
Mean ± SD	26.0±7.4	31.5±7.8	28.0±7.1	
Weight (kg)				
Range	52.0-107.0	58.0-74.0	85.0-101.0	.138#
Mean ± SD	81.6±17.8	66.0±6.6	93.0±11.3	
BMI (kg/m^2)				
Range	19.9-39.0	20.0-35.0	19.0-19.0	.067#
Mean ± SD	30.6±6.8	26.0±6.4	19.0±0.0	
Type of Infertility				
Primary	8 (57.1)	2 (50.0)	2 (100.0)	0.461@
Secondary	6 (42.9%	2 (50.0)	0 (0.0)	
Duration of Infertility (years)				
Range	2.00-6.00	2.00-9.00	4.00-16.00	0.047#
Mean ± SD	3.36±1.45	4.75±3.10	10.00±8.49	

SD standard deviation Data presented as range, mean ± SD; or number (percentage)
∫Tubal patency or block diagnosed based on laparoscopic chromopertubation
@ Analysis using one-way ANOVA Test # Analysis using Chi-squared Test NS non-significant

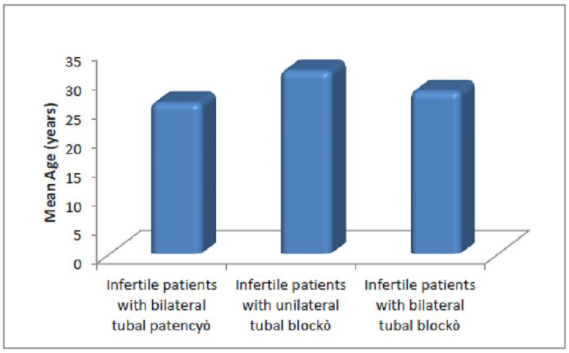

Figure (7): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding age of patients.

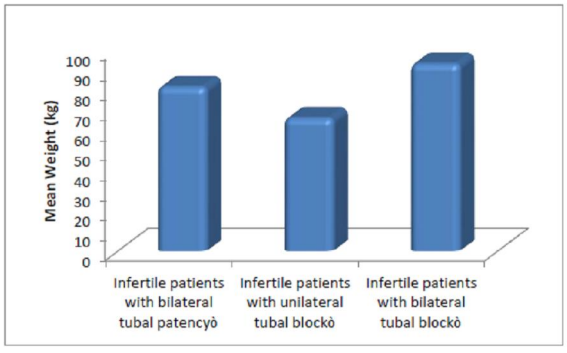

Figure (8): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding weight of patients.

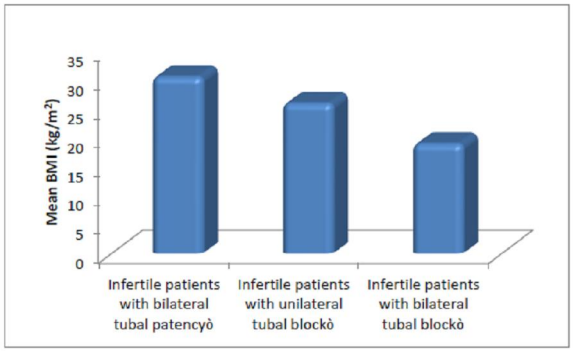

Figure (9): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding body mass index.

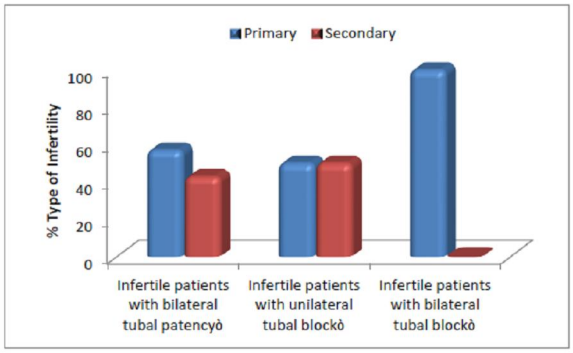

Figure (10): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding type of infertility.

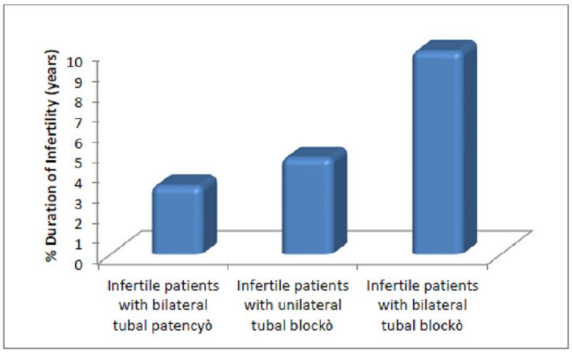

Figure (11): Comparison between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding duration of infertility.

This table shows Accuracy of saline sonohysterography in diagnosis of bilateral tubal block in the infertile patients.

Saline sonohysterography was diagnostic of bilateral tubal block with a sensitivity of 100%, a specificity of 90.0%, a PPV of 50.0%, an NPV of 100%, an FPR of 10.0% and an FNR of 0%.

Table (6): Accuracy of saline sonohysterography in diagnosis of bilateral tubal block in the infertile patients in relation to lap as a gold standard.

Diagnosis of Bilateral Tubal Block	Sensitivity	Specificity	PPV	NPV	FPR	FNR
Saline Sonohysterography	62%	52.0%	50.0%	60%	10.0%	0.0%

PPV positive predictive value
NPV negative predictive value
FPR false positive rate
FNR false negative rate

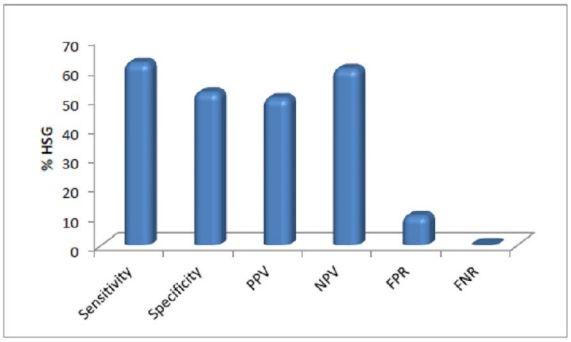

Figure (12): Accuracy of saline sonohysterography in diagnosis of bilateral tubal block in the infertile patients.

This table shows false positive and false negative cases of saline sonohysterography in the diagnosis of bilateral tubal block in the infertile patients.

Table (7): False positive and false negative cases of salinesonohysterography in diagnosis of bilateral tubal block

Diagnosis of Bilateral Tubal Block[j]	%	FPR	%	FNR
Saline Sonohysterography	10% (2 cases)	1 case had patent both tubes 1 case of unilateral tubal block:	0%	-

[j]Tubal patency or block diagnosed based on laparoscopic chromopertubation
FPR false positive rate
FNR false negative rate

This table shows Accuracy of saline sonohysterography in diagnosis of bilateral tubal patency in the infertile patients.

Saline sonohysterography was diagnostic of bilateral tubal patency with a sensitivity of 95.0%, a specificity of 50%, a PPV of 85.0%, an NPV of 75.0%, an FPR of 50% and an FNR of 5.0%.

Table (8): Accuracy of saline sonohysterography in diagnosis of bilateral tubal patency in the infertile patients

Diagnosis of Bilateral Tubal Patency	Sensitivity	Specificity	PPV	NPV	FPR	FNR
Saline sonohystero-Graphy	68.0%	50%	65.0%	45.0%	50%	5.0%

[j]Tubal patency or block diagnosed based on laparoscopic chromopertubation
PPV positive predictive value
NPV negative predictive value
FPR false positive rate
FNR false negative rate

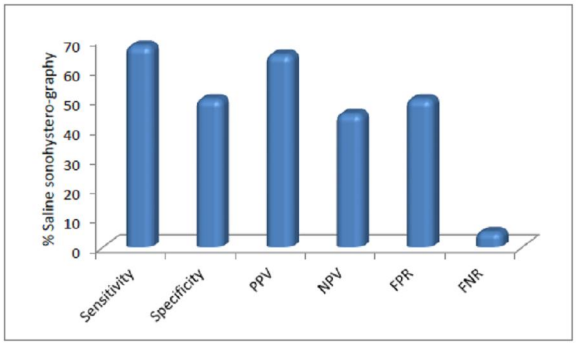

Figure (13): Accuracy of saline sonohysterography in diagnosis of tubal patency in the infertile patients

This table shows false positive and false negative cases of saline sonohysterography in the diagnosis of bilateral tubal patency in the infertile patients.

Table (9): False positive and false negative cases of saline sonohysterography in diagnosis of bilateral tubal patency

Diagnosis of Bilateral Tubal Patency		FPR		FNR
Saline Sonohysterography	50% (10 cases)	5 cases of unilateral tubal block: 2 right-sided tubal block 3 left-sided tubal block	5.0% (1 cases)	1 case of bilateral tubal patency

Tubal patency or block diagnosed based on laparoscopic chromopertubation
FPR false positive rate FNR false negative rate

4. Discussion

The fallopian tube is not a passive conduit for gametes and early embryos; it plays an important role in many reproductive functions such as sperm transport and capacitation, ova retrieval and transport, fertilization, embryo storage, nourishment and transport **(Patil, 2009).**

The fallopian tube plays an important role in picking up ovum and transporting ovum, sperms, and the fertilized zygote. However, patency alone is not enough, normal function of the tube is equally important. Fallopian tubes are vulnerable to infection and surgical damage which impair its function **(Shrivastava et al., 2009).**

There has been a significant increase in cases of infertility and sterility in the last decade. Approximately, 10-15% of couples in reproductive age are affected by the inability to conceive and bear a child **(Lakkawar et al., 2011).**

Tubal factor infertility is a common problem. Tubal dysfunction is responsible for approximately 30% of infertility cases **(Yildizhan et al., 2009).**

In the United States, more than 1 million women are treated for PID every year, and 200,000 to 300,000 of them require hospitalization. The situation is even worse in developing countries where health care is not readily accessible **(Wani et al., 2014).**

Tubal occlusion, peritubal and periovarian adhesions are factors responsible for inhibition of ovum pickup and transport. In developed countries the major cause of tubal infertility is pelvic inflammatory disease **(Haider et al., 2010).**

Tubal adhesions and tubal obstruction can also be due to endometriosis and previous surgical trauma **(Kupesic and Plavsic, 2007).**

The evaluation of tubal patency is traditionally considered fundamental in the study of causes of infertility. It represents one third of the total cost in the management of the infertile couple **(Severi et al., 2011).**

Various methods exist for the evaluation of tubal patency and tubal integrity as a key component of the diagnostic work-up in infertile couples. These include: Laparoscopy, Hysterosalpingogram, Selective salpingography and tubal catheterization, Salpingoscopy, Falloposcopy, Hystero contrast sonsgraphy and Fertiloscopy **(Patil, 2009).**

The optimal initial infertility investigation protocol is diagnostically accurate, expeditious, cost-effective, dependable, and minimally invasive **(Saunders et al., 2011).**

Saline infusion sonohysterography is a safe, well tolerated, quick and easy method for obtaining information on tubal status and the uterine cavity **(Saunders et al. 2011).**

Diagnostic laparoscopy is the standard means of diagnosing the tubal pathology, peritoneal factors, endometriosis and intra-abdominal causes of infertility **(Parveen et al., 2010).**

Not only does this help in identification of unsuspected pelvic pathology but also contributes to decision making of infertility treatment **(Parveen et al., 2010).**

In the current study for evaluation of tubal patency using saline infusion sonohysterography we found that majority of the infertile patients (75.0%) were in the age group of 23-35 years. This result was similar to **Pujar et al., 2010** who found that majority of patients (63.2%) are in age group of 25-34 years. The mean age of the infertile patients was (27.30 ± 7.41). This result was inconsistent with **Al-Rubaii, 2011** who reported that the mean age is (31.21 ± 4.66) and this may be due to late age of marriage.

In the present study (60.0%) of our patients had primary infertility. This result was consistent with result of **Pujar et al., 2010** who reported that (75%) of the patients have primary infertility. This result agree with that result reported by **Al-Rubaii, 2011** who published that (66 %) of patients have primary infertility, and similar to that result reported by **Lakkawar et al., 2011** who reported (58%) of the patients have primary infertility.

In this study we found that the mean duration of infertility was (4.30±3.29) years. This result was inconsistent with **Pujar et al., 2010** who reported that the mean duration of infertility is (7.7) years and this may be due to patients having been seeking fertility early.

In our study Saline sonohysterography was diagnostic of bilateral tubal block with a sensitivity of 100%, a specificity of 90.0%, a PPV of 50.0%, an NPV of 100%, an FPR of 10.0% and an FNR of 0%.

In the current study for evaluation of tubal patency using saline infusion sonohysterography we found that (85.0%) of infertile patients were

considered positive for fluid in Douglas pouch, while (15.0%) of infertile patients were considered negative for fluid in Douglas pouch.

These results agree with **Pujar et al., 2010** who reported that (89.3%) of infertile patients are positive for fluid in Douglas pouch, and (10.7%) of infertile patients are negative for fluid in Douglas pouch. These results were consistent with those results found by **Al-Rubaii, 2011.**

Our study shows that there were no significant statistical differences between infertile patients with bilateral tubal patency, unilateral tubal block, and bilateral tubal block regarding age, weight, BMI, type or duration of infertility, This was comfirmed by study done by Almashed et **al., 2016.**

Against our study a study investigated the exclusion of pelvic factor of infertility through the same tests, namely SHSG and laparoscopy In their study endometriosis was diagnosed laparoscopically in 344 out of 1080women. Only 44 women (13%) with endometriosis showed bilateral tubal block **(Bulletti et al., 2008)**.

In another study it was found that 68 infertile patients underwent hysterosonosalpingography using saline as contrast medium, and then further assessment by laparoscopy was performed to them Sensitivity and specificity of hysterosonosalpingography for the assessment of tubal patency was 100% and 66% respectively. Negative predictive value was 100% and positive predictive value was 61%. **(Radic et al., 2005).**

A study found that the comparison of the three dimensional SHSG to diagnostic laparoscopy with chromopertubation in the assessment of tubal patency. The sensitivity of three dimensional SHSG for detecting tubal patency was 100% with a specificity of 67%. The PPV, NPV were 89% and 100%, respectively. The concordance rate was 91% **(Chan et al., 2005).**

Conclusions:

In conclusion of our study we found that saline infusion sonohysterography offer much less invasive method than laparoscope for the diagnosis of tubal patency. Saline infusion sonohysterography also can be performed initially to infertile patients. It is simple, fast, safe, well tolerated, inexpensive procedure avoiding anesthesia complications and associated with rare adverse effects.

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