Original Research Article

Role of Hysterlaparoscopy in the evaluation and management of female infertility

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Abstract

Background: Infertility is a burgeoning issue that carries personal and social ramifications in modern society. Precise detection of infertility with an accurate cause is thereforea critical service for couples. The aim of the present study is to investigate combined hystero-laparoscopy as an evaluation tool for infertility in contrast to USG and HSG. **Methods**: A prospective observational study is conducted on a sample size of 120 women with infertility at the department of Obstetrics and Gynecology at Vijay Marie hospital and educational society, Hyderabad. USG, HSG, Hysterolaparoscopy were conducted for these patients and the results were analyzed and compared using a Chi-Squared statistical test. **Results**: The Chi-square tests for two tests (USG vs Laparoscopy and HSG vs Hysteroscopy) comes out with a 95% confidence level that the combined hystero-laparoscopy is more effective than USG and HSG. In the current study population, the trends clearly demonstrate that USG and HSG miss detection of 17% and 20% of the cases when compared to Laparoscopy and Hysteroscopy respectively. Finally, infertility trends in the population with regard to various factors such as age group, type of infertility, BMI, socio-economic status, marital period and ovulation cycles are explored, analyzed and contrasted to existing studies. **Conclusion:** Hysterolaparoscopy is a safe procedure in comprehensive evaluation of infertility which has a higher success and precision rate compared to traditional methods. It also is useful in detecting pelvic abnormalities and other issues which potentially may be missed by traditional imaging techniques.

Key Word: Infertility; Hysteroscopy; Laparoscopy, USG, HSG, Chi-Square statistical testing

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INTRODUCTION

Infertility is defined as the failure to achieve a successful pregnancy after 12 or months more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years[1]. Infertility is a global issue in reproductive health. Worldwide, couples view infertility as a tragedy which carries social, economic and psychological consequences. Hysterolaparoscopy is an excellent diagnostic modality to detect hidden pathology in patients without any overt clinical manifestations. Laparoscopy can reveal the presence of peritubal adhesions, periadnexal adhesions, tubal pathology and endometriosis in 35–68 % of cases even after a normal HSG (Hysterosalpingogram)[2]. Diagnostic hysteroscopy is an equally important modality to detect uterine anomalies and other intrauterine pathologies[3]. Among the many investigations available to evaluate the female partner of the infertile couple, laparoscopy is relatively recent. It has often been used in the evaluation of patients with infertility where other diagnostic methods have failed to come up with a cause. In addition, it has the advantage of being a 'see and treat' modality. Laparoscopy is considered to be the gold standard for the evaluation of the pelvis and is considered

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a safe procedure. It may improve pregnancy rates and quality of life[4]. Diagnostic laparoscopy, which is often combined with hysteroscopy, therefore, is frequently a standard procedure performed as the final test in the infertility work up in many clinics before the couple progresses to infertility treatment[4]. It is generally accepted that diagnostic laparoscopy is the gold standard for diagnosing tubal pathology and other intra-abdominal causes of infertility. Even when tubal patency has been clarified by a HSG, laparoscopy has been suggested as a mandatory step to exclude the presence of peritubal adhesions and endometriosis as a cause of infertility[5]. In light of these facts, the current work is undertaken to evaluate various causes of primary (inability to conceive within one year of exposure to pregnancy) and secondary (inability to conceive following a previous pregnancy) infertility following hysterolaparoscopy. The uniqueness of this study-combined evaluation of female infertility using both hysteroscopy and laparoscopy - stems from the fact that most other works in literature are done with either hysteroscopy or laparoscopy. Therefore, in the present study our aim is to correlate the findings of USG (Ultrasonography) and HSG versus hysterolaparoscopy in infertile patients.

MATERIALS AND METHODS

The study was conducted on women in the age group of 18 – 40 years, who have both primary and secondary infertility as per WHO criteria. The venue was the department of Obstetrics and Gynecology at Vijay Marie hospital and educational society, Hyderabad. The study was designed to be a prospective, observational one. Considering, on an average, ~180 patients per year undergo hysterolaparoscopy for both primary and secondary infertility at Vijay Marie hospital and using the Krejcie and Morgan table(under the assumptions of population proportion of 0.5 and Confidence 95%), the sample size determined for the present study is 120[6]. The study period was from October 2016 –October 2017. Women getting their tests done at Vijay Marie hospital were evaluated based on a selection criteria and considered for the study. The selection criteria was as follows: women in the age group of 18 – 40 years, having both primary and secondary infertility on whom USG, HSG, Hysterolaparoscopy tests were conducted were included. Women with marital life less than one year, those who had unprotected intercourse for less than 6 months, whose male partners had abnormal semen analysis or were infertile and women with tubal recanalization cases were excluded from the study. The selected patients were briefed about the study, details of the tests and a written informed consent was obtained. Demographic data like age, socioeconomic status and obstetric history along with relevant medical history was recorded on predesigned and pretested proforma. A detailed history, general physical examination including BMI, gynecological examination was done. Hysterolaparoscopy was carried out in the follicular phase of the menstrual cycle (day 6-10) on in-patient basis under general anesthesia. Karl Storz laparoscope (5 mm diameter) was introduced after creating pneumoperitoneum intraumbilically. Thorough inspections of uterus, anterior and posterior cul-de-sacs, fallopian tubes, ovaries, ovarian fossae and rest of the pelvic peritoneum, appendix and liver surface were performed. Any abnormality which was seen was noted down, including adhesions if there were any. Chromopertubation was done in all the cases. Therapeutic interventions were done at the same sitting. These included, when required, ovarian drilling, myomectomy, ablation of endometriotic spots and cystectomy. Karl Storz hysteroscope (4mm diameter) was used for diagnostic hysteroscopy. The hysteroscope was introduced and the cervical canal, uterine cavity, endometrium and both ostia were thoroughly inspected. Therapeutic interventions in the form of synechiolysis, polypectomy, cannulation was also done in same sitting. USG, HSG, Hysterolaparoscopy were conducted for the subjects and the results were recorded for conducting statistical tests. The results were analyzed to establish the standards of Hysterolaparoscopy tests for both primary and secondary Infertility. Also, laparoscopic and hysteroscopic interventions data was recorded and studied to check the type of interventions being done more frequently. Two statistical Chi-square based tests were conducted for the study to establish the standards of USG, HSG, Hysterolaparoscopy. The first test conducted was a Chi-square test between USG and Laparoscopy. The null hypothesis (H_0) formulated for this test was that USG and Laparoscopy tests give same results and the alternate hypothesis (H_1) was that laparoscopy tests provide better results than USG. The second test was a Chi-square test between HSG and hysteroscopy, with a null hypothesis (H_0) of HSG and Hysteroscopy tests giving the same results and an alternate hypothesis (H_1) where hysteroscopy tests provide better results than HSG. The Chi-Square test is intended to test how likely it is that an observed distribution is due to chance. It is also called a "goodness of fit" statistic, because it measures how well the observed distribution of data fits with the distribution that is expected if the variables are independent. The well-known Chi-Square formula was used in this work:

$$\chi^2 = \sum_{i=1}^{n} \frac{(O_i - E_i)^2}{E_i}$$

where, O stands for observed frequency, E stands for the expected frequency and the subscript 'i' indicates the ith sample. After the Chi-square values are computed, the p-

value is calculated to check the significance of the tests. The p-value, or calculated probability, is the probability of finding the observed, or more extreme, results when the null hypothesis (H_0) of a study question is true – the definition of 'extreme' depends on how the hypothesis is being tested. The p-value can also be described in terms of rejecting H_0 when it is true. The α-value (significance level) was chosen to be 0.05 for the analysis. If p-value is less than α, then the null hypothesis is rejected, i.e., the selected sample gives reasonable evidence to support the alternative hypothesis. Finally, the BMI was calculated based on:

$$\boldsymbol{BMI} = \frac{\boldsymbol{Weight\ (Kg)}}{\boldsymbol{Height\ (m^2)}}$$

Standard BMI ranges were used for underweight, normal weight and obesecategories.

RESULTS

The population used for the current work was studied in terms of several general parameters: age group, type of infertility, BMI, socio-economic status, marital period and ovulation cycles. The age group with the largest percentage of infertility cases was 26-30 (52%). This was followed by the age groups of 18-25 (33%), 31-35 (13%) and 36-40 (3%). Primary infertility was the dominant type (75%) as opposed to secondary infertility (25%). The highest incidence of infertility was in the pre-obese (25-29.9) BMI category (47%) followed by normal (18.5-24.9), obesity class I (30-34.9) and underweight (<18.5) with 36%, 16% and 2% respectively. With regard to socio-economic status, the highest percentage of infertility was seen in class III (48%). This was followed by classes II, IV, I and V with 29%, 14%, 6% and 3% respectively. Most of the infertile subjects were married for less than 5 years (84%). 13% of the subjects were married for 5-10 years and 3% were married for more than 10 years. With regard to ovulation induction cycles, most of the subjects (60%) has more than 4 cycles. This was succeeded by 3, 1 and 2 cycles with 24%, 8% and 8% respectively. The findings from the four different procedures are listed in Table 1. Each abnormality has been clearly identified and its contribution listed in terms of the overall percentage. The largest number of abnormalities for the USG and laparoscopy are polycystic ovaries while the septate uterus and polyp dominate the abnormalities for HSG and hysteroscopy. 92% of the patients required intervention during laparoscopy, with ovarian drilling being the highest at 67%. For hysteroscopy, there was no intervention needed for 60% of the patients, and polypectomy/myomectomy was the dominant intervention at 15% of the cases.

Table 1: Findings from USG, HSG, laparoscopy and hysteroscopy procedures on 120 patients. The incidences for each procedure are displayed in the number (percentage) format.

Findings	USG	HSG	Laparoscopy	Hysteroscopy
Normal study	24 (20%)	100 (83%)	3 (3%)	75 (63%)
Polycystic ovaries	67 (56%)	-	79 (66%)	-
Ovarian cyst	12 (10%)	-	3 (3%)	-
Fibroid	8 (7%)	-	4 (3%)	-
Polycystic Ovaries and Fibroid	4 (3%)	-	3 (3%)	-
Endometrioma	2 (2%)	-	-	-
Adnexal Mass	1 (1%)	-	-	-
Bicornuate Uterus	1 (1%)	-	1 (1%)	-
Polycystic Ovaries and Bicornuate Uterus	1 (1%)	-	1 (1%)	-
Septate Uterus	-	8 (7%)	-	13 (11%)
Unilateral Block	-	4 (3%)	-	-
Bilateral Block	-	4 (3%)	-	-
Subseptate	-	4 (3%)	-	4 (3%)
Ovarian Endometrosis	-	-	5 (4%)	-
Polycystic ovaries and tubal block	-	-	4(3%)	-
Hydrosalpinx	-	-	3 (3%)	-
Tubal block (Unilateral and Bilateral)	-	-	3 (3%)	-
Ovarian and Pelvic Endometriosis	-	-	3 (3%)	-
Polycystic ovaries and ovarian cyst	-	-	2 (2%)	-
Pelvic endometriosis and adhesions	-	-	1 (1%)	-
Ovarian cyst and adhesions	-	-	1 (1%)	-
Polycystic ovaries and adhesions	-	-	1 (1%)	-
Polycystic ovaries, tubal block and adhesions	-	-	1 (1%)	-
Pelvic Endometriosis	-	-	1 (1%)	-
Polycystic ovaries, tubal block and ovarian endometriosis	-	-	1 (1%)	-
Polyp	-	-	-	15 (13%)

Submucous Fibroid	-	-	-	7 (6%)
Synechiae	-	-	-	4 (3%)
T-shape Uterus	-	-	-	1 (1%)
Submucous Fibroid and septate uterus	-	-	-	1 (1%)

In summary, the diagnoses of abnormalities with Hysterolaparoscpy was that 117 cases were diagnosed as abnormal by Laparoscopy and 45 were diagnosed as abnormal by Hyseterscopy. Based on the data listed in Table 1, two Chi-Square tests were conducted as described in the previous section. The computations were carried out using MS Excel and the data output sanity was ensured using SAS software. The results for the first test (H_0: USG and Laparoscopy tests give same, H_1: laparoscopy tests provide better results than USG) are shown in Table 2.

Table 2: Chi-Square test data for comparing USG and Laparoscopy

		Laparoscopy		
		Normal	Abnormal	Total
USG	Normal	2	22	24
	Abnormal	1	95	96
	Total	3	117	120
Expected Findings				
		Laparoscopy		
		Normal	Abnormal	Total
USG	Normal	0.60	23.40	24
	Abnormal	2.40	93.60	96
	Total	3	117	120
Chi-Square Values				
		Laparoscopy		
		Normal	Abnormal	
USG	Normal	3.27	0.08	
	Abnormal	0.82	0.02	
	Total Chi-Square = 4.19			p-Value = 0.04

The observed values are simply extracted from the data of Table 1. The expected value, for example, of cases with normal USG and Laparoscopy is calculated in the following manner

$$E = \frac{(\textbf{Total number of Normal USG cases}) * (\textbf{Total number of Normal Laparocopy cases})}{\textbf{Total number of cases}}$$

As demonstrated in Table 2, the p-value is less than 0.05. Therefore, one can reject the null hypothesis and conclude with 95% confidence that Laparoscopy is more effective than the USG test for infertility diagnosis. In a similar vein, the results of the second test (H_0: HSG and Hysteroscopy tests gives the same results, H_1: hysteroscopy tests provide better results than HSG) presented in Table 3 lead us to conclude with 95% confidence that Hysteroscopy test is more effective than HSG in the diagnosis of infertility.

Table 3: Chi-Square test data for comparing HSG and Hysteroscopy

Observed Findings				
		Hysteroscopy		
		Normal	Abnormal	Total
HSG	Normal	68	32	100
	Abnormal	7	13	20
	Total	75	45	120
Expected Findings				
		Hysteroscopy		
		Normal	Abnormal	Total
HSG	Normal	62.50	37.50	100
	Abnormal	12.50	7.50	20
	Total	75	45	120
Chi-Square Values				
		Hysteroscopy		
		Normal	Abnormal	
HSG	Normal	0.48	0.81	
	Abnormal	2.42	4.03	
	Total Chi-Square = 7.74			p-Value = 0.005

DISCUSSION

In the current study, majority of the study group population was in the age bracket of 26-30 (52%) followed by 18-25 (33%) age bracket. In a study conducted inRef.[7], the majorities were switched amongst these very two age groups themselves with 43.6% and 33% for 18-25 and 26-30 respectively. This minor difference aside, this data shows that majority of the cases occur in the cumulative age bracket (18-30), which is more or less intuitively expected. When studying the type of to the type of infertility, the current study population can be dissected with respect to age-group, socio-economic status, BMI and marital duration, to produce some interesting data points. Primary infertility was the dominant type in every age group with a U-shaped distribution: 18-25 (85%), 26-30 (71%), 31-35 (60%) and 36-40 (100%).With regard to socio-economic status, most of the primary infertile patients belong to class II (47%) and most of the secondary infertile patients belong to class III (50%). It is interesting to note that for both primary and secondary infertility, the highest incidences were in the overweight category (46% and 50% respectively), the second highest percentage was that of the normal BMI category with 36% for both primary and secondary infertility cases. 91% of primary infertile patients had a marital life of less than five years, in agreement with Ref.[8](91.5%) while 63% of secondary infertile patients had a marital life of less than five years, in contrast to Ref.[8] (where >5 years was the majority category with 52.2%). With regard to USG findings, 20% of the patients were reported as normal and the largest abnormalities attributed to Polycystic ovaries (56%). In the study reported in Ref.[9], out of 45 patients reported with abnormal USG, 24 (44.9%) were due to polycystic ovaries which was the most common finding. In tune with the current study, minor findings (<5%) included fibroid uterus, ovarian cyst, endometrioma and uterine polyp.In the current study, the diagnosis of polycystic ovaries is 10% more by Laparoscopy as compared to USG. Majorityof the infertility patients were identified as normal by HSG (83%). A small fraction (7%) were diagnosed for each of the following: septate uterus and tubal block. Among the 100 women with normal HSG, after further Hysterolaparoscopy, 8% were identified with tubal block and 9% with septate uterus.The HSG test with septate uterus has been recognized as the most common cause associated with the correct predication (and reason) of reproductive failure. In other studies[10,11,] 112 women out of 193 with normal HSG reports used Hysterolaparoscopy and 35 of those were declared to have abnormal tubes and uterus. Compared to USG, Laparoscopy identified 17% more cases with abnormalities which helps in identifying more accurate reasons for infertility. In another study[7] of pelvic pathology by laparoscopy for 51.7% of the cases, ovarian pathology was the most common finding (20.7%), followed by pelvic inflammatory disease (17.5%), tubal block (7.7%), fibroid (6.6%) and endometriosis (5.4%). This agrees with the trends seen in our current study. Hysteroscopy identified 20% more cases with abnormalities as opposed to HSG. Polyp (13%) and septate uterus (11%) were identified as the largest source of abnormalities from this procedure. Results from another study in literature[12] revealed that myoma and polyp were detected in 10% of the study and synechiae in 8.3% of the study. Similar to as reported in this study (18.3%), about 20% of hysteroscopic examinations shows some grad of intrauterine abnormalities. Finally, the interventions performed for the Laparoscopic and Hyseteroscopic procedures are addressed. For Laparoscopy, ovarian drilling (67% of all the patients) was the most common one. There were instances where more than one intervention was carried out and most of these has ovarian drilling as one of the interventions. For Hysteroscopy, there was no intervention for 60% of the patients, and the two most commonly used ones were polypectomy/myomectomy (18%) and septal resection (15%). The limitations of the current study include the fact that all four tests were not performed on some of the patients. Further some of the results drawn from the data would have been more impactful if the same size was larger. Finally, the effectiveness of the Laparoscopic and Hystereoscopic interventions could not be measured as the period of the study was constrained for the purposes of pregnancy outcome determinations only.

CONCLUSIONS

Combined hysterolaparoscopy is a safe, effective and reliable method in comprehensive evaluation of infertility. Although USG and HSG are generally done as the initial investigation for assessment of infertility, many a times, especially in cases of long term unexplained infertility, positive findings may be missed. Further, correctable structural abnormalities in the pelvis may be missed by routine pelvic examination and imaging procedures. Hysterolaparoscopy is a very useful tool in detecting these missed pelvic abnormalities in patients with normal ovulation. Further as demonstrated in the current study, endometriosis, pelvic adhesions, and uterine septum may not be picked up by routine imaging procedures. With the low complication rate, minimal time requirements, dealing with abnormal findings therapeutically at the same sitting, a negligible effect in the post-operative course and significant advantage over HSG and USG, hystero-laparoscopy should be considered as a definitive day care procedure for evaluation and

treatment of female infertility. Diagnostic hystero-laparoscopy is invaluable in routine infertility work up.

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