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Original Research Article

Study of correlation of clinical and laparohysteroscopic diagnosis among infertile patients

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ABSTRACT

Background: To find the prevalence of infertile patients during the study duration of 24 months. To study the indications and findings of diagnostic hysteroscopy and laparoscopy and to correlate the laparo-hysteroscopy findings with the clinical diagnosis of the patients.

Methods: Hospital based observational cross-sectional type of study for a duration of 24 months. 80 infertility patients in between the age of 18-40 years who underwent laparo-hysteroscopy were selected. Descriptive statistical analysis was carried out in the present study. Data analysis done by using SPSS (Statistical Package for social sciences) version 25:0. Using KAPPA statistics significance was assessed as 5% level of significance.

Results: Pre valance of infertile patients during the study duration was 6.06%. Majority of patients (34) 42.5% were in age group 26-30 years. 80% of patients had primary and 20% had secondary infertility. 43 patients i.e. 53.75% of study patients had some abnormal findings which were diagnosed with the help of laparoscope. Maximum patients had pelvic pathology (endometriosis) as an abnormality constituting 20% of the study group followed by 15% of tubal pathology. 29 patients i.e. 36% of study patients had some abnormal findings which were diagnosed with the help of hysteroscope. 11 (13.75%) patients had synechiae followed by 10 patients i.e. 12.5% had intrauterine septum on hysteroscopy.

Conclusions: Laparo-hysteroscopy has proved to be an effective, safe and minimally invasive tool in evaluation and treatment of infertile patients.

Keywords: Primary and secondary infertility, Laparohysteroscopy, Clinical diagnosis

INTRODUCTION

Infertility is defined as the failure to conceive after 1 year of unprotected intercourse. Infertility can be primary, in women who have never conceived or secondary, in women who have previously conceived.¹ Infertility varies across regions of the world and is estimated to affect 8 to 12 per cent of couples worldwide.^{2,3}

Diagnostic laparoscopy was found to be the safe and cost effective in the initial management of young women with infertility, particularly when infertility treatment dropout

rates exceed 9% per cycle.⁴ Hysteroscopy has not only proved to be a better tool for easy visualization of the uterine cavity but also a more accessible investigation for therapeutic procedures of the uterine cavity. Diagnostic hysteroscopy has also become an important investigative tool for detecting uterine pathologies.^{5,6} Patient's history and less invasive diagnostic tests such as, pelvic sonography, Hysterosalpingography (HSG), chlamydia antibody tests are less efficient compared to laparo-hysteroscopy in work up for infertility. Hence the present study aims to find out the prevalence of infertility patients and to correlate clinical findings with the laparo-hysteroscopic findings in infertile patients.

METHODS

This was an hospital based observational cross-sectional type of study. The study was conducted in B. J. Government Medical College and Sassoon general Hospitals, Pune. The study period was of 24 months from September 2017 to September 2019.

Study group

Infertile patients attending gynaecology OPD and gynaecology operation theatre of government medical college were screened and included in study after prior written informed consent form.

Sample size

80 patients with infertility who were investigated by Laparo-hysteroscopy were selected. Laparo-hysteroscopy findings were noted and correlated with the clinical diagnosis of the patient.

Study approval

Approval taken from Institutional Ethical Committee of B. J. Government Medical College & Sassoon General Hospitals, Pune India.

Data analysis

Data was collected, compiled, tabulated and was analyzed with the help of different statistical tests. Descriptive statistical analysis was carried out in the present study. Data analysis done by using SPSS (Statistical Package for social sciences) version 25.0.

RESULTS

Age wise distribution of study group

In the study, we had maximum number of patients (34), in the age group 26-30 years accounting for 42.5% of study

patients as shown in Table 1. In the study mean age of infertile patients was 27 years. Prevalence of infertile patients during the study duration was 6.06%.

BMI wise distribution of the study group

Majority of subjects in study had BMI between 18.5-24.99 (healthy) i.e., 37 patients as shown in Table 2 accounting 46.3% of study population.

Distribution of symptoms in age group

Most frequent symptom associated with infertility in our study group was irregular menstruation seen in 18.8% of group as shown in Table 3.

Frequency of type of infertility

In the study group, 80% of patients had primary infertility as shown in Table 4 and figure 4 i.e., they have never conceived priorly. And 20% had history of secondary infertility.

Diagnosis made on clinical examination and supportive investigations

Majority of patients i.e., 29 (36.3%) were suspected to be of tuberculosis on history, clinical and investigational findings as shown in Table 5, followed by ovarian abnormalities i.e., PCOS in 22 (27.5%), patients in 20 (25%) patients the diagnosis could not be made i.e., they were of unexplained in nature.

Tuberculosis

For diagnosis of tuberculosis with the help of Investigations, 34 (42.5%) patients had raised ESR while 19 patients 23.75% had montoux positive. In the study 11 cases were TB PCR positive and only 3 cases were positive on AFB sputum culture.

Table 1: Age wise distribution of study group.

Age group (in years)	Number of patients	(%)
≤20	2	2.50
21-25	31	38.80
26-30	34	42.50
3-35	9	11.30
>35	4	5.00
Total	80	100.00

Abnormal laparoscopy findings

In our study maximum patients had pelvic pathology (endometriosis) as shown in Table 6 as an abnormality

constituting 20% of the study group followed by 15% of tubal pathology. 24 patients had positive findings in the form of tubal block, adhesions or tubo ovarian mass on laparoscopy suggesting the diagnosis of tuberculosis.

Table 2: BMI wise distribution of the study group.

BMI	Number of patients	(%)
<18.5	4	5.0
18.5-22.99	37	46.3
23.00-24.99	19	23.8
25.00-29.99	19	23.8
≥30.00	1	1.3
Total	80	100.0

Table 3: Distribution of symptoms in age group.

Symptoms	Number of patients	(%)
Irregular menstruation	15	18.8
Oligomenorrhea	6	7.5
Amenorrhea	4	5.0
Dysmenorrhea	3	3.8
Backache	3	3.8
Pelvic pain	2	2.5
Dyspareunia	2	2.5

Table 4: Frequency of type of infertility.

Infertility	Number of patients	(%)
Primary	64	80.0
Secondary	16	20.0
Total	80	100.0

Table 5: Diagnosis made on clinical examination and supportive investigations.

Clinical Findings	Number of patients	(%)
TB	29	36.3
PCOS	22	27.5
Endometriosis	6	7.5
Unexplained	20	25.0

Table 6: Abnormal laparoscopy findings.

Laparoscopy findings	Number of patients	(%)
Myoma	5	6.25
Uterine anomaly	2	2.5
Ovarian pathology	10	12.5
Tubal pathology	12	15
Adnexal mass	9	11.25
Endometriosis	16	20

Table 7: Abnormal hysteroscopy findings.

Hysteroscopy findings	Present	
	No.	%
Myoma	9	11.25
Polyp	4	5
Septum	10	12.50
Synechiae	11	13.75

Some patients had more than one pathology and hence the total number of pathologies is more than the total number of patients evaluated.

Abnormal hysteroscopy findings

Most frequent abnormal finding diagnosed with the help of hysteroscope was presence of synechiae or adhesions in

the uterine cavity i.e., 13.75% making the diagnosis of tuberculosis as shown in Table 7.

Correlation of clinical and laparoscopic diagnosis for Tuberculosis

Diagnostic accuracy for detection of tuberculosis by laparoscopy was 93.75% with sensitivity of 100% with agreement of 85.95% as shown in Table 8.

Table 8: Correlation of clinical and laparoscopic diagnosis for tuberculosis.

TB on clinical diagnosis			TB of laparoscopy		Total
			Present	Absent	
Present			24	5	29
Absent			0	51	51
Total			24	56	80
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	Kappa
100	91.07	82.76	100	93.75	0.8595

Table 9: Correlation of clinical and laparoscopic diagnosis for PCOS.

PCOS on clinical diagnosis			PCOS of laparoscopy		Total
			Present	Absent	
Present			10	12	22
Absent			0	58	58
Total			10	70	80
Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy	Kappa
100.00	82.86	45.45	100.00	85	0.547

Table 10: Correlation of clinical and laparoscopic diagnosis for endometriosis.

Endometriosis on clinical diagnosis			Endometriosis of laparoscopy		Total
			Present	Absent	
Present			6	0	6
Absent			10	64	74
Total			16	64	80
Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	Kappa
37.50	100.00	100.00	86.49	87.5	0.489

Table 11: Diagnosis of tuberculosis by various modalities.

Tuberculosis diagnosis	Clinical	Laparoscopy	Hysteroscopy
No. of patients	29	24	10

Correlation of clinical and laparoscopic diagnosis for PCOS

In the study 22 cases were diagnosed to have PCOS clinically and with non-invasive modality like ultrasound while only 10 cases on laparoscopy had features suggestive of PCOS. Diagnostic accuracy for detection of tuberculosis by laparoscopy was 85% as shown in Table 9.

Correlation of clinical and laparoscopic diagnosis for endometriosis

In the study 16 patients had features suggestive of endometriosis and there was 87.5% of diagnostic accuracy with laparoscopy as shown in Table 10.

DISCUSSION

Factors from either male or female or both partners may contribute to development of infertility, hence it is important to rule out all possible factors in an infertile couple. Despite an extensive and complete evaluation in both partners, sometimes the cause cannot be diagnosed, whereas, in few couples more than one cause is identified.

In the present study after thorough history and physical examination all the couples were subjected to multiple directions of investigation culminating in laparo-hysteroscopy which is the gold standard test for diagnosis of infertility. Among the total patients who attended the gynaecology OPD and OT, the number of infertile patients were calculated and prevalence of infertility was found out to be 6.06%.

Effect of age on infertility

With increasing age there is decline in fecundity, the decrease usually starts at the age of 32 years with a dramatic fall after the age of 37.⁷ As the age advances, with each subsequent menstrual cycle follicular atresia or apoptosis occurs.

Effect of BMI on infertility

Menstrual dysfunction and anovulation are usually seen in overweight women. Overweight and obese women are also at a higher risk of infertility and poor reproductive outcome. According to WHO Classification of BMI and nutritional status, in our study 19 patients i.e. 23% were in preobesity group. Obesity is believed to disrupt ovarian function by depressing sex hormone-binding globulin, increasing insulin resistance and raising free androgens.⁸⁻¹⁰

Frequency of types of infertility

In study 64 (80%) patients had primary infertility and rest 20% had secondary infertility. Zhang E. et al, 11 reported that out of 132 infertile patients, 71 (53.8%) women had primary infertility and the rest 61 (46.2%) had secondary infertility.

Clinical diagnosis

Majority of patients i.e., 29 (36.3%) were suspected to have tuberculosis on history, clinical and investigational findings, this was followed by ovarian abnormalities i.e. PCOS in 22 (27.5%) patients, whereas in 20 (25%) patients the diagnosis could not be made and hence they were considered unexplained in nature.

Tuberculosis

One of the most common causes of female infertility especially in developing world is female genital tuberculosis (FGTB). Parikh et al found the prevalence of

TB in patients with infertility to be 39% (100), diagnosed mainly on clinical suspicion and other non-invasive conventional modalities. The study agrees with these findings as we found 36.3 % with TB.

In study total 29 patients had tuberculosis. The diagnosis of tuberculosis was made with the help of various investigations, 34 (42.5%) patients had raised ESR while 19 patients (23.75%) had positive montoux test.¹¹ cases were TB PCR positive and only 3 cases were AFB sputum culture positive. While in a study done by Khanna A, 26 patients were TB PCR positive and 3 patients had positive AFB culture reports.¹²

In the study 10 patients had tubal block suggesting the diagnosis of tuberculosis. While on laparoscopy tubal block, adhesions or tubo-ovarian mass also suggest the diagnosis of tuberculosis. Hence total 24 patients were diagnosed with tuberculosis.

For diagnosing tuberculosis on hysteroscopy intrauterine synechiae and small uterine cavity were taken into account and we found that 13.75% of the patients to be of tuberculosis as shown in Table 11.

Clinically 29 patients were suspected to have tuberculosis. We found that 24 patients had positive findings in the form of tubal block, adhesions or tubo ovarian mass on laparoscopy and 10 patients had intrauterine synechiae on hysteroscopy. TB PCR was positive in 11 cases, while in a study done by Khanna et al, 6 cases that were diagnosed as tubercular on laparoscopy, 5 were positive for endometrial TBPCR 12 and only 26.3% of patients who were positive for TBPCR had findings that were suggestive of tuberculosis on laparoscopy

Polycystic ovarian disease

PCOD was detected in 22 (27.5%) patients. While ovarian pathologies were diagnosed by laparoscopy in 10 (12.5%) and simple ovarian cysts were found in 12 (15%) patients. Study done by Singh et al found laparo-hysteroscopic abnormalities in 68% patients and polycystic / multicystic ovaries in 26% which was the 2nd most common finding.¹³

Endometriosis

Endometriosis was the most common cause 16 patients (20%) of infertility observed in our study as per laparoscopic diagnosis, while it was not diagnosed on clinical examination. It can directly cause infertility or may be a contributing factor for the same. It can cause infertility as a result of adhesions or because of anatomic distortion. Physical examination i.e., clinical history and per speculum examination of patients with endometriosis were usually normal and rarely helped in making the diagnosis.

Hence there is often a significant delay in diagnosis of this disease. The poor negative predictive value of the pelvic

examination was also demonstrated by Nezhat et al in a study of 91 patients, in which 47% of patients with surgically confirmed endometriosis and chronic pelvic pain had normal bimanual examinations.¹⁴ The gold standard for the diagnosis of endometriosis is visual inspection by laparoscopy, preferably with histological confirmation, especially in those with a non-classical appearance, as mild endometriosis can only be detected on laparoscopy.¹⁵ In the study endometriosis was mainly a diagnosis made by laparoscopy with negative predictive value of 86.49 and diagnostic accuracy of 87.5%.

Unexplained infertility

In our study in 20 patients (25%) the diagnosis of infertility could not be made and were unexplained in nature. In a study done by Maheshwari et al, 2008 the diagnosis of unexplained infertility was made in (22.4%) of patients.¹⁶ It is estimated that a standard fertility evaluation will fail to identify an abnormality in approximately 15% to 30% of infertile couples.¹⁷

Abnormal findings diagnosed by laparoscopy

43 patients i.e. 53.75% of study patients had abnormal findings which were diagnosed with the help of laparoscope. In the study maximum patients had pelvic pathology (endometriosis) as an abnormality constituting 20% followed by 15% tubal pathology.

Some patients had more than one pathology and hence the total number of pathologies is more than the total number of patients evaluated. Mehta et al in their study found that endometriosis (41%) and adnexal adhesions (29%) were the most common abnormalities detected on laparoscopy.¹⁸

Abnormal findings diagnosed by hysteroscopy

In our study 29 patients i.e. 36% had some abnormal findings which were diagnosed with the help of hysteroscope. Nayak et al noted significant hysteroscopy findings in 18% of patients. In the study 11 (13.75%) patients had synechiae on hysteroscopy, while in a study done by Begum et al synechiae were found in 5 (3.7%) study patients which were corrected by adhesiolysis 10 patients i.e., 12.5% in our study had intrauterine septum as hysteroscopic abnormality, similarly in a study done by Nayak et al intrauterine septum was the most common abnormality.^{19,20} While in a study done by Kabadi et al the incidence of uterine anomaly diagnosed by hysteroscopy was (13.8 %) Septate uterus is associated with highest reproductive failure rate, 65% losses occur in the first trimester.^{21,22} Surgical correction of septum improves the pregnancy outcome, with 80% term deliveries, 5% preterm deliveries and 15% pregnancy loss.¹¹ These are correctable abnormalities that are unfortunately missed by routine pelvic examination and usual imaging procedures, hence diagnosis and treatment with hysteroscopy helps in increasing the fertility rates in these infertile patients.

In the study 6.25% patients had myoma as hysteroscopic abnormality while in a study done by Mehta et al it was 8%. Complete excision of myoma i.e., hysteroscopic myomectomy increases the fertility rates and decreased the menstrual complaints.²³ The study was done to found out the indications of the laparo-hysteroscopy. And to determine the correlation of clinical and laparo-hysteroscopic diagnosis among infertile patients. There is limited literature on the correlation between the two. This study helped in determining prevalence of infertility, agreement and diagnostic accuracy of the laparo-hysteroscopy and clinical diagnosis of infertile patients.

CONCLUSION

Infertility is a worldwide problem affecting 50-80 million people during their reproductive lives. The consequences of infertility for women are devastating. Infertility leads to marital instability, depression, low self-esteem and negative attitudes. Because of diagnostic and therapeutic benefits laparo-hysteroscopy helps in formulating a specific plan of management and identifying the patients who will require ART at the earliest, thus avoiding further emotional and financial trauma to the couples. Hence, diagnostic laparo-hysteroscopy has proved to be an effective, safe and minimally invasive tool in evaluation of infertile patients with tubal or pelvic causes of infertility when all other examinations and investigations were normal especially in our study in diagnosing genital tuberculosis which is a diagnostic dilemma being a paucibacillary disease with varied clinical presentations, diverse imaging and laparoscopy results. The conclusion of our study is that in modern era laparo-hysteroscopy stands best tool for diagnosis as well as for therapeutic purposes and for making the diagnosis especially in certain cases such as GTB and endometriosis which can be missed during general clinical examination easy and at an early so as to restore fertility.

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