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**Comparison between hysterosalpingography and laparoscopic chromotubation in evaluation of tubal patency****Prakriti Sitoula¹, Suman Raj Tamrakar²**

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Abstracts

Aims: To compare findings of hysterosalpingography and laparoscopic chromotubation in assessing tubal patency.

Methods: Seventy four infertile female partners were recruited in this comparative study from 10th April, 2018 to 31st July, 2019 in Dhulikhel Hospital after obtaining ethical approval form Institutional Review Committee [Reference number: 25/18, dated 4th April, 2018] . Sample size was calculated by using standard formula and data were analyzed through IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, N.Y., USA) applying appropriate statistical tools.

Results: Of 74 cases, the mean age female partners of was 27.04 years [26.06-28.02, 95% Confidence Interval] with age range was 21 to 37 years. Of them, 44 (59.5%) were primary infertility cases. The average duration of infertility was 5.13 years [4.66-5.60, 95% Confidence Interval]. Of 74 cases that underwent HSG, more than two third cases 51 (68.9%) had patent tubes while maximum cases of laparoscopic chromotubation 65 (87.8%) had patent tubes.

Conclusions: Hysterosalpingography is effective tool but lesser than laparoscopy for assessing tubal patency but In case of doubt with its result, a follow up laparoscopic chromotubation is advised.

Introduction

Infertility is a condition defined by failure to achieve a successful pregnancy after 12 months or more of regular unprotected intercourse.¹ Global estimates suggest that nearly 72.4 million couples experience fertility problems,¹ approximately 10–15% of couples.² One estimate of overall infertility in South Asia, suggests an infertility rate of approximately 10%.³ In former studies at Dhulikhel Hospital (DH), both Karki S, et al⁴ and Tamrakar SR, et al⁵ found three quarters of infertility cases were of primary type.

Mechanical factors account for approximately 30% of infertility in female partners,⁶ and various methods such as transvaginal ultrasonography (TVS), hysterosalpingography (HSG), hysteroscopy and laparoscopy have been used to determine the underlying factors.² Application of accurate and minimally invasive methods has been supported by some clinicians so that unnecessary laparoscopy is avoided. In this regard, HSG is one of the cost-effective methods by which tubal patency can be assessed. Nevertheless, some researchers recommended performing regular laparoscopy even after normal HSG findings as HSG has been reported to be quite specific but not sensitive in detecting peritubal adhesions and infections.⁷ There were very few comparative studies between HSG and laparoscopic chromotubation.

The purpose of this study is to compare the usefulness of the two important diagnostic modalities namely HSG and laparoscopy with chromotubation in evaluating tubal patency.

Methods

This was a comparative study of apparent causes of infertility during HSG and laparoscopic chromotubation in 74 infertile couples seeking treatment in the Department of Obstetrics and Gynecology of Dhulikhel Hospital from 10th April, 2018 to 31st July, 2019. Ethical clearance was taken from the institutional review committee of KUSMS (Ref. 25/18, dated 4th April, 2018). Along with socio-demographic information namely age, ethnicity, address, occupation, and probable causes were explored in the infertile couple.

Female partners with primary or secondary infertility who consented to undergo HSG followed by laparoscopic chromotubation, were included in the study by convenience sampling. While the female partners who denied to participate and already diagnosed to have tubal factors or any kind of tubal surgeries were excluded from the study. Sample size was calculated by using standard formula $n = Z^2 \times P \times Q / e^2$ [where $Z = 1.96$ for confidence interval (CI) of 95%, Prevalence (P) = 0.05 in Asia, $Q = 1 - P$ (1-0.05), allowable error (e) = 5%]. And sample size generated was 72. After informed consent these couples were evaluated by taking history, clinical examination, and necessary investigations as per need. Hysterosalpingography was performed on day 8 to day 10 of the menstrual cycle. Laparoscopic chromotubation was done on first half of next

cycle. Their findings of above mentioned procedures were filled up in proforma and later entered in excel spread sheet for recording for further analysis. Data were analyzed through IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, N.Y., USA) applying appropriate statistical tools. Categorical variables were described as frequency (percentage), mean \pm standard deviation were used for continuous parameters. Categorical variables were compared between two or more groups using the Chi-square test. For all analyses, a two-tailed p-value of <0.05 was considered as statistically significant. And accuracy of HSG were analysed by sensitivity, specificity test, positive predictive value (PPV) and negative predictive value (NPV).

Results

The mean age of 74 female partners who underwent both the procedures (HSG and laparoscopic chromotubation) in the study was 27.04 years [26.06-28.02, 95% CI] with age range was 21 to 37 years. Of them, 44 (59.5%) were primary infertility cases and remaining were secondary infertility. More than three fourths 33 (75%) of the primary infertility and two third 20 (66.7%) of the secondary infertility cases were of 21-30 years (Table 1).

Table 1: Age profile of cases (n=74).

Age (years)	Primary infertility		Secondary infertility	
	Frequency	Percentage	Frequency	Percentage
≤ 20	2	4.5	2	6.7
21-30	33	75	20	66.7
31-40	9	20.5	8	26.7
Total	44	100	30	100

Out of 74 infertile female partners, maximum cases were housewives 65 (87.4%) followed by teachers 4 (5.4%), service holder 2 (2.7%) and one each case (1.4%) of doctor, working abroad and students. The average duration of infertility was 5.13 years [4.66-5.60, 95% CI]. About half of the cases (35, 47.3%) were married for more than 5 years, followed by 29 cases (39.2%) with duration of 3-5 years and rest cases 10 (13.5%) with 0-3 years of marriage.

About two third cases (48, 64.9%) had regular menstrual cycles. There was no statistically significant difference in regularity of menstruation when compared between infertile female partners with primary and secondary infertility groups ($p =$

0.4692). About two third cases (49, 66.1%) had no significant drug history, where as rest cases (25, 33.9%) were on some kind of treatment (for pelvic inflammatory disease, ovulation induction, thyroid disorder and tuberculosis) at the time of study. Almost all cases (66, 89.25%) had anteverted uterus and (68, 91.9%) cases had no history of instrumentation (suction, uterine curettage) in the past.

Out of 74 cases that underwent HSG, more than two third cases (51, 68.9%) had patent tubes (Table 2). Amongst 23 cases with blocked tubes on HSG, 10 cases (43.5%) had bilateral tubal blockage. On laparoscopic chromotubation 65 (87.8%) had patent tubes.

Table 2: HSG and laparoscopic chromotubation findings (n=74).

Tubal status	HSG finding		Laparoscopic chromotubation findings	
	Frequency	Percentage	Frequency	Percentage
B/L patent	51	68.9	65	87.8
B/L block	10	13.5	7	9.5
Right tubal block	9	12.2	2	2.7
Left tubal block	4	5.4	-	-
Total	74	100	74	100

Additional laparoscopy findings

Amongst 74 patents who underwent laparoscopic

chromotubation, more than half cases (43, 58.1%) had normal findings; whereas endometriosis or its consequences was the commonest abnormality in 10 cases (13.6%) (Table 3).

Table 3: Additional laparoscopy findings (n=74).

	Frequency	Percentage
Normal	43	58.1
Endometriosis grade I and II	3	4.1
B/L Endometriotic cyst	2	2.7
Right Endometriotic cyst	5	6.8
U/L Dermoid cyst	5	6.8
Bulky ovaries	5	6.8
Adhesions	3	4.1
Left Mucinous Cystadenoma	2	2.7
Uterine didelphus Unicollis	2	2.7
Bicornuate uterus	1	1.4
Myoma	1	1.4
Left Hydrosalpinx	1	1.4
Total	74	100

Table 4: Findings of tubal patency between HSG and Laparoscopic chromotubation.

		Laparoscopic chromotubation	
		Block	Patent
HSG	Block	9	14
	Patent	0	51

Table 5: Comparison between HSG and laparoscopic chromotubation.

	Block	Patent	P Value
Hysterosalpingography	23	51	0.0052
Laparoscopic chromotubation	9	65	

There was statistically significant difference ($P < 0.005$) in detection of tubal patency, when compared between HSG and laparoscopic chromotubation (Table 5).

Comparison between HSG and laparoscopic chromotubation for evaluating tubal patency showed sensitivity of HSG was 90%, specificity of 78.4%, PPV of 39.1%, NPV of 98% and false positive rate of 21%.

Discussion

In this study, mean age of the cases was $27.04 \pm 3.6\%$ years [26.06-28.02, 95% CI] with age range was 21 to 37 years. A systematic analysis of infertility incidence in more than 190 countries and regions around the world showed that female partners suffered at the age of 20–44 years.³ In another study, the age range was 26 to 30 years.⁸ The mean age of infertile cases was 26.85 ± 4.78 years in the study by Tamrakar SR, et al in the same institute.⁵ Such mean ages of the cases were 26.85 ± 4.78 years, 29.3 ± 4.9 years and 30 years respectively in the studies by Anwar BR, et al, Paliawadana TS, et al and Kabala RB.⁹⁻¹¹

Similarly, in this study primary infertility was 44 (59.5%) and secondary infertility was 30 (40.5%). This result was similar to the study findings from Saudi Arabia¹², Iran¹³, Bangladesh^{9,14} and Sri Lanka¹⁰. But the primary infertility cases were seen more (74.7% and 75%) in same institute^{5,4} while secondary infertility cases were seen more (56.5%) in the study conducted in Eastern Nepal.¹⁵

The average duration of infertility was 5.13 years (9.2%) [4.66-5.60, 95% CI]. About half of the cases (35, 47.3%) were married for more than 5 years in this study. Similar findings with duration of marriage 5.39 years was found in study by Al Turki HA.¹² But mean duration of infertility was 2.92 ± 2.25 years in a study by Paliawadana TS, et al¹⁰ and 4.3 ± 0.5 years in another study by Anwar BR, et al⁹. About 13.5 % of the cases were of marriage duration less than 2 years in the study by Kamali M, et al¹⁶ and mean duration of infertility was a little longer with 7.4 ± 5.2 years.

In this study, about two third cases (48, 64.9%) of infertility had regular cycles, which was bit different to the findings by Reinaldo SA, et al, where 48.1% cases had regular cycles.¹⁷ Amongst all infertile cases, 91.9 % cases had no history of instrumentation in this study. Daling JR, et al found similar result with no increased risk of infertility in cases that had prior history of instrumentation.¹⁸

About two third of the cases had no significant drug history in this study, and 18.9% cases took medications for pelvic infection which included treatment for Chlamydia infection. In a study of Guven MA, et al, showed high incidence of Chlamydia infection in unexplained infertility.¹⁹ And, Imudia AN, et al found high incidence of infection in infertility cases.²⁰

In this study, amongst 74 cases that underwent HSG, more than two third cases (51, 68.9%) had normal patent tubes. Similar

findings were noted in 83.4% cases in Uganda²¹, in 63% cases in DH, Nepal⁴, in 53.3% cases in India⁸ and in 45% cases in Iran²². Tubal blockage was the causal factor for secondary infertility in the study done by Bhatrai M and Pokhrel (Ghimire) S which was 21%.²³ In the HSG studies by Shrivastava VR, et al²⁴ and Karki S, et al⁴ found tubal abnormalities in 34% and 19% respectively.

The use of laparoscopic chromotubation showed a better result in the evaluation of infertility. In our study, all the cases underwent both procedures. And 23 cases (31.1%) had tubal blockage in HSG and 9 cases (12.2%) were found to have tubal blockage in laparoscopic chromotubation. This means, agreement between HSG and laparoscopy was noted in 39.1 % of the cases. In other studies, by Colta TM²⁵ found 50% agreement. Dhaliwal LK and Agarwal N²⁶ found 59.8% agreement, Srinivasan C²⁷ noted 70% agreement and Hutchines CJ²⁸ observed 71.5% agreement between HSG and laparoscopic chromotubation.

Amongst 74 patents that underwent laparoscopic chromotubation, more than half cases (43, 58.1%) had normal findings; whereas 13.6% had endometriosis of various grades, 4.1% with adhesions, and 1.4% with hydrosalpinx (Table 3). Donnez J, et al²⁹ found that the incidence of pathological factors not revealed by HSG but were disclosed by laparoscopy in 500 infertile female partners. The study showed an agreement in 90% of cases. In total 980 tubes examined, HSG identified fimbrial conglutination in 79 tubes (8%) compared to 154 tubes (15.7%) by laparoscopy. HSG diagnosed 68.8% of the peritubal adhesion confirmed by laparoscopy. Laparoscopy revealed endometriosis in 124 cases (24.8%) and isolated periovarian adhesions in 48 cases (9.6%).

Lavy Y, et al³⁰ assessed the diagnostic benefit of laparoscopy in infertile female partners ($n=86$) with normal HSG and didn't get additional benefit in 95% of cases. However laparoscopy should be recommended in cases with suspected bilateral occlusion on HSG as it altered the original treatment plan in 30% of cases.

Comparison between HSG and laparoscopic chromotubation for evaluating tubal patency showed sensitivity of HSG was 90%, specificity was 78.4%, positive predictive value was 39.1%, and negative predictive value was 98% in this study. Similarly, Duignan NM, et al³¹ found that HSG had sensitivity of 85 % and specificity of 89%. Hutchines CJ²⁸ found that it had sensitivity and specificity of 77% and 90% respectively. Likewise, Swart P, et al³² observed that HSG had sensitivity of 65% and specificity of 83% in their study.

In this study, there was statistically significant difference ($P < 0.005$) in detection of tubal patency, when compared between HSG and laparoscopic chromotubation. Other studies by Lavy Y, et al³⁰ had similar finding. Also Donnez J, et al²⁹ found similar report with statistically significant difference between detection of tubal patency by HSG and chromotubation.

Conclusions

Hysterosalpingography is equally effective tool for assessing tubal patency but in case of doubt with its result, a follow up laparoscopic chromotubation is advised. The laparoscopic evaluation also helps in identifying additional pelvic abnormalities, which otherwise can be missed by HSG. These two procedures are not alternative, but are the complementary methods in the diagnosis of tubal patency.

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