Original Article

Assessment of Tubal Patency with Selective Chromopertubation at Office Hysteroscopy versus Modified Minilaparoscopy in Infertile Women

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Abstract

Objectives: Tubal factor is the leading cause of female infertility. Diagnostic hysterolaparoscopy with chromopertubation plays a pivotal role in its evaluation. Office hysteroscopy (OH) has gained popularity as the outpatient procedure for diagnostic purposes. OH being a less invasive approach, the current study was undertaken to compare the accuracy of assessment of tubal patency with chromopertubation at OH with modified minilaparoscopy in infertile patients.

Materials and Methods: The present study was a pilot study conducted from March 2017 to August 2018. Eighty patients were recruited. OH was done without anesthesia. Diluted methylene blue dye was injected. The eddy current of blue dye, "Visualizable flow" at ostium, and disappearance of blue dye from the uterine cavity through ostium was documented as evidence of patent tubal ostium. In case of tubal occlusion, uterine cavity became blue due to backflow of dye. After OH, minilaparoscopy with chromopertubation was performed under general anesthesia. Both tubes were assessed separately for tubal patency.

Results: All patients underwent OH followed by minilaparoscopy in the same sitting. OH was 87.5% sensitive with positive predictive value of 95.2%. Compared to minilaparoscopy, OH is 85.6% accurate in predicting tubal patency. The area under receiver operating curve was 0.96 (SE is 0.15 with 95% confidence interval of 0.93–0.99, $P < 0.001$). It implies that, OH should correctly identify all laparoscopic cases with probability of 0.96.

Conclusion: OH chromopertubation can be used as an alternative to laparoscopy for assessing tubal patency with added advantages of lack of requirement of anesthesia, minimal cost, and better patient acceptance. Moreover, the procedure is less time-consuming and less invasive with high sensitivity and moderate specificity.

Keywords: Chromopertubation, infertility, minilaparoscopy, office hysteroscopy, tubal patency

Introduction

Tubal factor is the leading cause (30%) of female infertility.[1] Diagnostic hystero-laparoscopy (DHL) with chromopertubation plays a pivotal role in its evaluation. Since the dawn of its invention, major concerns of laparoscopy were the need to subject the women to general anesthesia, safety of the procedure, cost, possible adhesion formation, and other long-term sequelae like trocar site hernia. Replacing laparoscopy with office hysteroscopy (OH) in infertile patients for assessing tubal patency could help to overcome the above disadvantages. Hence, this study was planned to compare the accuracy of assessment of tubal patency with chromopertubation at OH with modified minilaparoscopy in infertile patients. To the best of our knowledge, no such study has been reported so far.

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Materials and Methods

The present study was undertaken as a pilot study from March 2017 to August 2018 in the Department of Obstetrics & Gynecology. Ethical clearance was obtained from the Institute Ethics Committee for Postgraduate Research, AIIMS, New Delhi, India (IECPG-568/08.12.2016, approved on 22.3.17). Informed consent was obtained from all the patients. Eighty patients who fulfilled the inclusion criteria (infertile women posted for hysterolaparoscopy whose tubal status was not known or had confirmed cornual block on hysterosalpingography [HSG]) were recruited. Patients with confirmed tubal block on laparoscopy, diagnosed hydrosalpinx, and presence of acute pelvic inflammatory disease were excluded from the study. The procedure was performed by a single experienced surgeon between postmenstrual day 5–10 to achieve best visualization. OH was done using 2.9 mm telescope (compact OH) with 0° optic and without anesthesia by vaginoscopic approach without cervical dilatation. Normal saline was used as a distension medium. The uterine cavity, tubal ostia, fundal contour, and cervical canal were assessed. Diluted methylene blue dye, 2–10 ml was injected slowly. Each tubal ostium was assessed separately. The eddy current of blue dye, "Visualizable flow" at the ostium and disappearance of blue dye from the uterine cavity through the ostium was documented as evidence of patent tubal ostium. In case of tubal occlusion, uterine cavity became blue due to backflow of the dye. After tubal patency evaluation, blue dye got self-cleared within 3–4 s. The same procedure was repeated on the other side. After OH, general anesthesia was given. Minilaparoscopy was performed with 2.9 mm telescope and 3 mm accessory port in all the patients. The uterus, bilateral tubes, and ovaries were assessed. The presence of methylene blue dye in Pouch of Doughlas was noted before instillation of dye to help us correlate the findings of OH. Dye (20–30 ml) was injected through the intrauterine Foley's catheter. Both tubes were assessed separately for tubal patency. Port site skin suture was not applied, and adhesive plaster was used to approximate skin edges. Operative time (OT) was documented. For OH, OT was the time from the insertion of hysteroscope through the vagina till the completion of hysteroscopy, whereas for minilaparoscopy, OT was time from skin incision to the application of adhesive plaster. Prophylactic antibiotic dose was given half an hour before surgery and continued till postoperative day 5. The Visual Analog Scale (VAS) score was assessed 2 h postoperatively and at time of discharge. Subsequent follow-up was done at 1 week to assess wound healing.

Statistical analysis

Data analysis was carried out using software STATA version 12.0 (StataCorp, Texas, USA). All continuous variables were tested for the normality assumption using the Kolmogorov–Smirnov test. Descriptive statistics such as mean, standard deviation, median, and range values were calculated for the variables following normality assumption. The comparison of mean values between the subgroups was tested using the Student's t independent test. Frequency data were presented as numbers and percentages. Frequency data across categories were compared using the Chi-square or Fisher's exact test. Receiver operator curve analysis was carried out to find the area under curve for OH. Confidence interval 95% was calculated for all the diagnostic measures for all statistical tests as two-sided probability of $P < 0.05$ was considered as statistically significant.

Results

Selective chromopertubation with OH followed by minilaparoscopy was performed in all the eighty patients in the same sitting.

The baseline characteristics of all the patients are tabulated in Table 1. The mean age was 28.23 ± 3.97 years, and mean body mass index (BMI) was 24.17 ± 1.46 kg/m^2. Primary infertility was present in 80% of the patients. In 95% of cases, husband semen analysis was normal. On OH, uterine cavity, endometrium, patency of ostia, and image quality were assessed [Table 2]. The size of the image and image quality was satisfactory in both OH and minilaparoscopy group in all the cases. On minilaparoscopy, status of uterus and bilateral tubes and ovaries, bilateral tubal patency, and any pathological finding were noted [Table 3]. The uterus was normal in shape and size in 69 cases and ovaries were normal in 67 cases. Fallopian tubes were healthy looking in 62 cases, peritubal adhesions were present in 4 cases, hydrosalpinx in 7, and beaded or tortuous tubes in 7 patients.

Table 1: Baseline characteristics of patients

Baseline characteristics	Number of patients, *n* (%)
Primary infertility	64 (80)
Secondary infertility	16 (20)
Normal menstrual cycle	66 (82.5)
Normal husband semen analysis	76 (95)
History of genital TB	12 (15)
History of PID	18 (22.5)
Clarity of vision-clear	80 (100)

TB: Tuberculosis, PID: Pelvic inflammatory disorder

Table 2: Various parameters assessed on office hysteroscopy

Parameters on office hysteroscopy	Number of patients, *n* (%)
Normal uterine cavity	74 (92.5)
Septate uterus	3 (3.75)
Pale endometrium	2 (2.5)
Endometrial hyperplasia	1 (1.25)
Patent right ostium	62 (77.5)
Patent left ostium	63 (78.75)

On OH, eddy current or visualizable flow was seen in 77.5% through right ostium and 78.5% through left ostium. Delayed or absent visualization of flow on OH was seen in 22.5% on right and 21.25% on left side.

On minilaparoscopy, dye spillage was seen in 83.75% on the right side and 86.25% on the left side. Unilateral tubal block was seen in six patients and bilateral in nine patients.

Each fallopian tube was counted as an independent case. Patency was evaluated in 160 tubes. In 119/136 cases (87.5%), tubes were patent with both methods. Tubal block was diagnosed in 24/160 cases (15%) by minilaparoscopy and in 35/160 cases (21.88%) by OH. Tubal block was confirmed by both OH and minilaparoscopy in 18/160 cases (11.25%). In 17 cases tubal patency was observed by minilaparoscopy but identified as blocked by OH. Out of 24 cases diagnosed with tubal block on minilaparoscopy, 6 were identified as patent on OH making the specificity of OH as 75% with a positive predictive value (PPV) of 95.2% and negative predictive value (NPV) of 51.4% in predicting tubal patency as compared to minilaparoscopy. One hundred and nineteen cases of patent tubes and 18 cases with blocked tubes on OH were concordant with minilaparoscopy, reaching a sensitivity of 87.5% in infertile patients with proximal tubal occlusion [Table 4]. Compared to minilaparoscopy, OH was 85.6% accurate in predicting tubal patency. Receiver operating curve (ROC) analysis was carried out to detect the accuracy of OH compared to minilaparoscopy. The area under curve was 0.96 (SE was 0.15 with 95% confidence interval is 0.93-0.99, $P < 0.001$). It implies that, OH would correctly identify all laparoscopic cases with probability of 0.96.

Table 3: Various parameters assessed on minilaparoscopy

Parameters on minilaparoscopy	Number of women, *n* (%)
Patent right tube	67 (83.75)
Patent left tube	69 (86.25)
Normal uterus	69 (86.25)
Shaggy uterine surface	6 (7.5)
Endometriosis	2 (2.5)
Adhesions	2 (2.5)
Normal ovaries	67 (83.75)
Pearly white ovaries	6 (7.5)
Normal Fallopian tubes	62 (77.5)
Peritubal adhesions	4 (5)
Hydrosalpinx	7 (8.75)
Beaded or tortuous tube	7 (8.75)

Table 4: Comparison of tubal patency status on minilaparoscopy and office hysteroscopy

	Minilaparoscopy-patent tube	Minilaparoscopy-blocked tube	Total
OH-patent tube	119	6	125
OH-blocked tube	17	18	35
Total	136	24	160

OH: Office hysteroscopy

On minilaparoscopy, pearly white bulky ovaries were seen in six patients who underwent ovarian drilling by harmonic in the same sitting. Adhesiolysis was done in seven patients with distorted tubo-ovarian relationship due to adhesions.

The mean OT was 3.45 ± 0.73 min in OH and 7.5 ± 2.24 min during minilaparoscopy which was statistically significant ($P < 0.001$).

No major or minor complication occurred in any of the patient. None of the patient had severe pain. The mean VAS score at 2 h postoperatively was 4.65 ± 1.00 and at discharge was 2.78 ± 0.66, and there was statistically significant decrease in VAS score from 2 h postoperatively to discharge. None of the patient had wound infection. Satisfaction rate was 100%. The mean hospital stay was 2.45 ± 0.49 h.

Discussion

Primary infertility is defined as the inability to ever become pregnant after 12 months of regular timed unprotected intercourse or therapeutic donor insemination. Secondary infertility is the inability to conceive further when there is prior conception irrespective of the outcome of prior pregnancy.[1] According to the CDC National Survey of Family Growth data statistics 2011–2015, approximately 12% of married women aged 15–44 years are infertile.[2] Leading causes of infertility include tuboperitoneal disease (40%–50%), disorders of ovulation (30%–40%), uterine factors (15%–20%), and male infertility (30%–40%).[3,4]

Functional fallopian tubes have an important role to play in the reproduction by capturing the ova and transportation of embryos.[5] The role of tubal block or dysfunction in infertility is rising, contributing to 30%–35% of all cases of infertility worldwide.[6] Hence, assessment of the uterine cavity and tubal patency is an important step in the assessment of female infertility. HSG is still the preferred test by many gynecologists as the first step to evaluate tubal patency as it is a day care procedure with no need of anesthesia along with a therapeutic effect of oil soluble contrast media. However, the major disadvantages of HSG are the cornual spasm which gives around 10%–20% false picture of tubal obstruction, painful procedure, radiation exposure, and risk of infection. In a study by Hortu *et al*.,[7] it was found that PPV of HSG was 81.1% but NPV was only 53.2%. In view of the low NPV of HSG, laparoscopy should be done to confirm tubal obstruction. DHL with chromopertubation plays a pivotal role and considered as a major tool in the gynecologist's armamentarium in the evaluation of female infertility.[8-10]

With advancement of minimally invasive surgery, conventional laparoscope has been gradually replaced by smaller diameter telescopes with advantages of smaller incision, reduced risk of injury to pelvic organs, less anesthesia requirement, sutureless procedure, better cosmesis, less postoperative discomfort, shorter hospital stay, faster recovery, and reduced risk of adhesion formation, wound infection, and incisional hernia.[11-14] Minilaparoscopy, i.e., laparoscopy with smaller diameter endoscope is defined by the diameter of telescope by various criteria like O' Donovan criteria[15] or Unify criteria.[12]

Haeusler *et al*. found that microlaparoscope is as accurate as conventional laparoscope (10 mm).[16] Roy *et al*.[17] in their study compared 5 mm telescope with 2.9 mm telescope for diagnostic laparoscopy and found both of them comparable in terms of OT, pain in the postoperative period and duration of hospitalization. No stitch was applied in 2.9 mm group. Hence, looking at the additional advantages of smaller telescope, we used 2.9 mm laparoscope in this study for doing laparoscopic chromopertubation. OH has gained popularity as an outpatient procedure for the diagnostic purposes with distinct advantages of vaginoscopic approach, no anesthesia requirement, reduced postoperative pain increased cost-effectiveness, safety, patient acceptance, and compliance.[18,19] Vaginoscopic approach during hysteroscopy further reduces the pain and discomfort to the patient.[20]

Hence, OH-guided chromopertubation is evolving as less invasive modality than minilaparoscopy for assessing tubal patency. Our study was a pilot study to compare the efficacy of OH with minilaparoscopy (2.9 mm) in infertile patients for the assessment of tubal patency.

BMI is an important variable in minilaparoscopy in view of operative difficulty and feasibility. In a study by Roy *et al*., comparing 2.9 mm and 5 mm telescopes in infertile patients, operating time increases as BMI increases.[17] In our study, mean BMI was 24.17 ± 1.46 kg/m^2 and no difficulty was encountered in any of the patient. Risquez *et al*. and Bauer *et al*. found objective reduction of picture size and clarity with minilaparoscopy.[21,22] Bauer *et al*. also compared microlaparoscope with conventional laparoscope and found that extent of abdominal interventions using smaller diameter laparoscopes would be a matter of experience.[22] Roy *et al*. compared 5 mm with 2.9 mm laparoscope and found them comparable with respect to OT with a satisfactory image quality.[17] In our study, diagnostic evaluation by minilaparoscopy with chromopertubation with 2.9 mm telescope was accomplished without any difficulty. The mean OT for OH was 3.45 ± 0.73 min, whereas it was 7.5 ± 2.24 min for minilaparoscopy which is statistically significant ($P < 0.001$). O' Bauer *et al*. found that patients who underwent diagnostic minilaparoscopy were highly satisfied and reported less post-procedural discomfort as compared to conventional laparoscopy.[22] Narrower hysteroscopes tend to lower the incidence of pain associated with OH.[23] In our study also, mean VAS score at 2 h postoperatively was 4.65 ± 1.0 suggestive of moderate pain and 2.78 ± 0.66 at discharge with a statistically significant reduction, $P < 0.001$. In a Roy *et al*.'s study,[17] no wound infection occurred in either group. In our study also, no suture was applied over abdominal wound and wound healing was good at 1-week follow-up. Incision site was barely visible and all patients accepted the procedure well.

Various studies have found the role of diagnostic hysteroscopy in the assessment of tubal patency. Hysteroscopic tubal patency assessment can be done by various techniques such as determination of shift in culde sac volume pre hysteroscopy to posthysteroscopy by ultrasonography,[24,25] Parryscope method using air infusion at time of hysteroscopy which generates air bubbling effect confirming tubal patency,[25,26] selective tubal perturbation[27,28] and visualizable flow effect of hysteroscopic fluid at level of tubal ostia.[29] Torok and Major in 2012 showed that OH-guided selective chromopertubation is an effective highly reproducible technique compared to conventional laparoscopy.[27] Torok and Major[27] in a case series of 35 patients conducted an office-based study, where patients underwent OH-guided chromopertubation with methylene blue dye passed through plastic catheter, tip of which being placed at ostium with the idea that patent tube will allow dye to pass through and no blue fluid will be seen in the uterine cavity. The uterine cavity will turn blue if tubes are blocked. The findings were confirmed with laparoscopy-guided chromopertubation. They reported an accuracy of 83% with a PPV of 87.5% and NPV of 76.7% compared to conventional laparoscopy.[27] Pary *et al*. conducted OH with air infusion into saline (Parryscope technique) in 435 infertile patients. Rapid flow of stream of air bubbles or single large air bubble through the ostia was indicative of tubal patency. If rapid flow of air bubbles was not seen, another 40–60 s observation time was devoted to differentiate transient spasm from occlusion. It showed a high sensitivity of 98.3% for tubal patency and specificity of 69.5%–83.7% depending on the force used during chromopertubation compared with standard chromopertubation.[25] Similarly, Promberger *et al*. retrospectively reviewed the records of 511 patients and compared visualizable flow of saline on hysteroscopy with the outcome of laparoscopic chromopertubation. They found a sensitivity of 86.4% and specificity of 77.6% of hysteroscopy for predicting tubal patency.[29] Ott *et al*. compared the assessment of tubal patency at diagnostic hysteroscopy and laparoscopic chromopertubation and found that hysteroscopic flow through ostia is a reliable marker of tubal patency. Flow of air bubbles or saline toward ostium

Table 5: Systematic review of previous studies

	Type of study	Number of patients/number of Fallopian tubes studied	Method used at hysteroscopy	Sensitivity, *n* (%)	Specificity, *n* (%)	Limitations of study
Habibaj *et al.*, 2012[24]	Prospective	56 patients	Diagnostic hysteroscopy followed by transvaginal ultrasound to see fluid in pouch of doughlas	94.7	94.4	Lack of anatomical specificity, generally it is not possible to determine whether unilateral tubal obstruction is present
Torok and Major, 2012[27]	Prospective	35 women/70 fallopian tubes	Selective pertubation with office hysteroscopy with methylene blue dye	87.5	100	
Parry *et al.*, 2017[25]	Prospective	435 patients, 89 had abdominal surgery as well	Through air infusion into saline during flexible office hysteroscopy (parryscope technique)	98.3-100	83.7	
Carta *et al.*, 2018[28]	Prospective	47 women/92 fallopian tubes	Office hysteroscopy-guided selective chromopertubation	85.7	87.8	19 patients out of 47 did not undergo confirmatory laparoscopy
Promberger *et al.*, 2018[29]	Retrospective	511 women/998 fallopian tubes	Visualizable flow effect in Fallopian tube ostia on hysteroscopy	86.4	77.6	Cold saline may induce tubal spasm Incomplete description of tubal ostia in 49% cases leading to high dropout rate Surgeon bias-many of cases done for tubal pathologies and hysteroscopy results were interpreted after laparoscopy
Yucel *et al.*, 2018[31]	Prospective	64 women/128 fallopian tubes	Hysteroscopic chromopertubation with methylene blue dye	85.85	59.09	Failure to observe flow of methylene blue in the distal segment of tube over the adjacent ovary Small number of patients
Ott *et al.*, 2020[30]	Prospective	72 women/144 fallopian tubes	Visualizable flow at hysteroscopy	85.3	66.1	Comparing flow effect's accuracy between proximal and distal tubal occlusions would lead to overinterpretation of results, due to low number of distal occlusions. Distension pressure was not measured during hysteroscopy, may affect predictive value of hazy hysteroscopic picture and other findings, nor chromopertubation pressure standardized

was considered as positive flow effect or patent tube.[30] They found 61.1% patent tubes on laparoscopic chromopertubation and in 65.3% ostia on hysteroscopy. Positive hysteroscopy flow effect had sensitivity of 85.3% and specificity of 66.1% in predicting tubal patency. The presence of peritubal adhesions and hydrosalpinx were associated with false normal results. Bilateral tubal occlusion was suggested by hazy hysteroscopic picture. Yucel *et al*.[31] also compared hysteroscopic chromopertubation with methylene blue dye with laparoscopic chromotubation and found it to be highly sensitive 85.85% with moderate specificity 59.09% as compared to laparoscopy. Nearly similar results were found in our study. Sensitivity of OH found in our study was 87.5%, specificity was 75% with a NPV of 51.4%, and PPV of 95.2% in predicting tubal patency as compared to minilaparoscopy. Compared to minilaparoscopy, OH is 85.6% accurate in predicting tubal patency. ROC analysis was carried out to detect the accuracy of OH compared to minilaparoscopy. The area under curve was 0.96 (SE is 0.15, with 95% confidence interval is 0.93–0.99, $P < 0.001$). It implies that, OH should correctly identify all laparoscopic cases with probability of 0.96. The various studies based on hysteroscopic tubal patency assessment are compared in Table 5.[24-31]

Direct observation of ostia and high intrauterine pressures during hysteroscopy minimizes the false-positive results secondary to spasm as compared to HSG. Promberger *et al*. also found that if tubes come into contact with cool saline, especially before laparoscopic chromopertubation, ostia may go into spasm leading to higher tubal occlusion rate during chromopertubation, and hence, a higher false-positive hysteroscopic flow rate.[29] Parry *et al*.[26] found the tubal spasm during Parryscope technique. Even pain can lead to spasm which can be overcome by the use of smaller sized hysteroscope without high pressure distension of the uterine cavity.

Conclusion

OH chromopertubation was found comparable to modified minilaparoscopy in diagnostic accuracy to assess tubal patency in patients with cornual block on HSG. It was 87.5% sensitive with a PPV of 95.2%. OH chromopertubation accurately identified all laparoscopy cases with a probability of 0.96 by ROC analysis. Hence, OH chromopertubation alone is an effective, precise, and minimally invasive approach with no complications to assess tubal patency in infertile patients with cornual block. OH chromopertubation can be used as an alternative to laparoscopy for assessing tubal patency with added advantages of lack of requirement of anaesthesia, minimal cost, use of non-allergenic contrast, better patient acceptance, less time required, and procedure being less invasive with high sensitivity and moderate specificity.

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Conflicts of interest

There are no conflicts of interest.

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