Original Article

Efficacy and Safety of Hysterosalpingography in Women with Primary and Secondary Subfertility in a Low Resource Setting

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Abstract

Objective: To assess safety, efficacy, and cost-effectiveness of Hysterosalpingography in women with subfertility

Methodology: In this descriptive study 52 women with sub-fertility were enrolled for Hysterosalpingography. All women with primary /secondary subfertility were included except those who declined to participate or had a history of allergies. Only 2-3 cc of Urografin was injected via 10 Fr Foley's catheter and a plain radiograph was obtained immediately. More dye was injected in small aliquots (2-3 cc) if required and x-ray films were obtained with each. The analysis was done in SPSS version 20.0.

Results: A total of 52 women participated in the study. Thirty nine (75%) women had primary subfertility and 11 (21%) had secondary subfertility. The majority of women 39 (75%) had at least one patent tube. The bilateral proximal blockade was seen in 3 (5.8%) women. The unilateral blockade was noted in 7 (13.5%) women and a similar number of women had dilatation of tubes with the bilateral free spill. The loculated spill was noted in 5 (9.6%) women. Twenty eight (53.8%) women had a completely normal study. This method is associated with lesser radiation exposure, minimal analgesia requirement, reduced cost, and high patient satisfaction.

Conclusion: Modified techniques of tubal assessment should be evaluated further in low resource settings to enable the delivery of fertility services in less privileged segments of society. This newer technique of Hysterosalpingography is successful and safe and the costs suit the low SES communities like Pakistani women.

Keywords: Hysterosalpingography, tubal assessment, safety, efficacy

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Introduction

The recent past has seen marked changes in the treatment of sub fertile couples. It is one of the most rapidly evolving subspecialties in Gynecology. But in a wider aspect of analysis, the benefits of these advances are limited to the affluent parts of the society.[1,2] Although geographical variations exist, the prevalence of fertility is similar in developed and underdeveloped countries ranging from 3.5 to 9%.[3,4] Even in developed countries a large proportion of sub fertile couples have limited resources with poor social support.[4] There is an ongoing debate about the provision of fertility services to the poor.[1]

It has been shown that the problems faced by a poor sub fertile couple are manifold. In developed countries where voluntary childfree status is acknowledged, many women experience infertility as a 'secret stigma',

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however, in developing countries there is no concept of voluntary childfree status. Here motherhood is highly prized and a woman's social and economic worth is linked to reproduction. The distress of these couples is likely to be greater. Although access to care is severely limited in underdeveloped countries, poor couples have poor access to fertility services even in developed countries.[4] Ironically policy makers and scholars are more concerned about fertility control than subfertility in these settings.[5]

Successful treatment of subfertility brings a dramatic change in the life of these sub fertile couples.

This study is an effort to bridge the gap that hampers the provision of fertility services in low resource settings. It presents a modification in the technique of Hysterosalpingography so that it can be performed in settings where fluoroscopy is not available. We aim to observe the safety, efficacy and cost effectiveness of Hysterosalpingography, a newer technique for low resource settings. In this way it will help couples in our local settings as well as areas which have similar economic and social conditions as Pakistan.

Methodology

This was a descriptive study done from 26th January 2015 to 26th May 2016. This study was conducted in a private sector outpatient reproductive health hospital and associated basic radiology lab equipped with a plain X-ray machine (YZ 300, XD 51-20.40/125-T10, 3.2 mm Al).

All women with primary/secondary subfertility were included in the study, except for those who declined to participate or had a history of allergies. Women who had vaginal discharge were treated and called back in the next cycle. This was an observation and no side effects were foreseen however, keeping in line with research ethics, informed consent was obtained after a brief counseling session.

The study sample size was 52 sub-fertile women which was based on the statistical assumptions of 95% confidence level, alpha error of 5% and a prevalence of 3.5-9.0% of subfertility[2].The procedure was performed in the follicular phase immediately after menstruation. An oral spasmolytic and 100 mg Doxycycline was administered half an hour before the procedure. Urinary bladder was emptied before the procedure. In the frog-leg position, vaginal examination was performed to assess the version, size, position, and mobility of the uterus. Using a bivalve speculum, the cervical os was visualized and cleansed with povidone iodine twice. A sterile 10 Fr Foleys catheter with stylet and deflated 3 ml balloon was inserted in the cervical canal with a sponge holding forceps. During insertion, if resistance was encountered uterine sound or tenaculum was used for manipulation.

The balloon was inflated with 2ml water and stylet was removed. Gentle traction was applied and the woman was positioned for X-ray pelvis AP view, x-ray film placed in position, and machine ready for X-ray. Only 2-3 cc of contrast medium (Urograffin 76%, Schering, Germany) was injected and a plain radiograph was obtained immediately. Then the rest of the dye was injected in small aliquots (2-3 cc) as per requirement and a radiograph film similarly obtained with each. When the uterine cavity and tubes were identified, the catheter was removed and women allowed to rest for 15-30 minutes and observed for any side effects and need for more analgesia. Later on women sent home with the contact number of the gynecologist.

Figure I: View of tubes during Hysterosalpingography procedure.

Data was analyzed in SPSS version 20.0. Numerical variables like age and costs were measured as mean and standard deviations. The categorical variables like type of fertility, pain, and satisfaction. frequency and percentages were measured.

Results

A total 52 women were enrolled in the study. None of the referred women refused to participate in the study. In 2 women the procedure was abandoned due to

cervical stenosis. All women were from middle to low socioeconomic background.

The image quality reported by the radiologist was good. Average number of x-ray films taken was 2.48 ± 0.814 and average radiation exposure was 1.4 ± 0.4243 msv. The average volume of Urografin used was 6.9 ± 5.339 ml.

Of the total 52 cases, 39 (75.0%) women had primary subfertility and 11 (21.1%) had secondary subfertility whereas in 2 (3.8%) cases due to cervical stenosis the procedure could not be completed. Twenty eight (53.8%) women had a completely normal study. The majority of women 39 (75.0%) had at least one patent tube.

Bilateral proximal blockade was seen in 3 (5.7%) women. The unilateral blockade was noted in 7 (13.5%) women and out of these 2 (3.8%) had proximal blockade and 5 (9.6%) had distal dilatation and blockade. Seven (13.5%) women had dilatation of tubes with the bilateral free spill. Loculated spill was noted in 5 (9.6%) women.

Forty (80.8%) women reported mild while 10 (19.2%) women reported moderate pain during the procedure. Moderate pain was mostly reported by women having some tubal pathology. None of the women had severe pain. Only 7 (13.5%) women required parenteral analgesia. Oral analgesia in the form of Spasmolytic was sufficient in 43 (82.7%) women. In all women, acute pain settled within half an hour of procedure whereas the feeling of heaviness persisted for 3-4 hours.

In 6 (11.6%) cases antifibrinolytics were required to control post procedure vaginal bleeding. None of the women had significant allergic reactions to the dye. However, 4(7.7%) women needed fresh air a few minutes after the injection of dye which was alleviated on the provision of the electric fan. The mean cost of the procedure was (2530 ± 829 Pak rupees) and most of the women 46 (88.5%) were found highly satisfied with the procedure.

Table I: Characteristics of study patients &procedure

Characteristics of study patients	N (%age)	Characteristics of procedure	N (%age)
Socioeconomic status Middle/lower income	52(100.0%)	**Safety**	
Mean age (years)	25.78 ± 4.63	Procedure completed	50 (96.1%)
Refused to participate	0(0.0%)	Procedure abandoned	2 (3.8%)
Fertility type		Mild pain	40(80.8 %)
Primary sub fertility	39 (75%)	Moderate pain	10(19.2 %)
Secondary sub fertility	11 (21.1%)	Oral analgesia	43(82.7 %)
Cervical stenosis	2 (3.8%)	Parenteral analgesia	7(13.5 %)
Radiographic findings		Post procedure vaginal bleeding	6(11.6 %)
Normal study	28 (53.8%)	Allergic reactions	0(0.0%)
At least one patent tube	39 (75%)	Feeling of suffocation	4(7.7%)
Bilateral proximal blockade	3 (5.8%)	Satisfaction rate	46(88.6%)
Bilateral distal dilatation and blockade	5 (9.6%)	**Efficacy**	
Unilateral blockade	7(13.5%)	Good Image quality	52(100.0%)
Dilatation of tubes with bilateral free spill	7(13.5%)	Average no of x ray films	2.48 ± 0.81
Loculated spill	5(9.6%)	Average exposure to radiation	1.4 ± 0.42 msv
		The average volume of Urograffin used	6.9 ± 5.33 ml
		Mean cost of the procedure	2530 ± 829 PKR

Discussion

This study reveals that Hysterosalpingography has a major decisive role in the assessment of fallopian tubes. It may be combined with interventional procedures such as selective salpingography and tubal recanalization which reduces a significant number of IVF procedures.[6-8] Subfertility is a field of active research. In the last 2 decades, newer interventions like HyCoSy and HyFoSy have been evolved to avoid the pain associated with HSG.[9-11] Many modern investigators have questioned the place of HSG in the modern treatment of subfertility.[12-14] Some authors like Chou PL et al and Alcázar JL et al have argued that a combination of HyCoSy with Chlamydia Antibody Titre (CAT) is a safer and cheaper alternative to hysterosalpingography and HSG is outdated in modern subfertility treatment.[15,16] However the fact that these

cheaper alternatives were not available to our population made the case for our study.

The main drawbacks of Hysterosalpingography are its invasive nature and associated discomfort. In the current study around one fifth of the patients experienced moderate pain which was mainly due to tubal pathology and settled within half an hour after standardized management. Handelzalts JE et al has reported that hysterosalpingography is a highly stressful experience associated with fear, anxiety, pain and information seeking.[17] Various pain relief methods have been used including NSAIDs, local application of lidocaine cream to the posterior fornix of the cervix uteri, paracervical lidocaine injection, pre-procedure misoprostol and use of warm contrast medium, with variable effect.[18-20] We propose this modification in technique to reduce the procedure related pain.

Radiation exposure of the ovaries is another issue. Techniques have been developed to reduce this exposure[21]. Recently, Imaoka I et al has shown that Magnetic Resonance Imaging is a non-invasive method of imaging the reproductive tract that avoids radiation[22] but its cost was a major limiting issue in our population.

We did not stratify women at the start of the study according to patient characteristics because it has been shown that the accuracy of HSG is similar in all subgroups.[23]

In our study, the main principles of radiographic visualization were followed. These include visualization of the reproductive tract in the follicular phase of the menstrual cycle, use of spasmolytics, antibiotic prophylaxis, cervical cleaning and aseptic technique. Timing of Hysterosalpingography is important to avoid an undiagnosed pregnancy. The use of spasmolytics reduces spasm of fallopian tubes during intervention which appears as a bilateral tubal blockade (false positive finding). It is important to adhere to aseptic measures and provide antibiotic prophylaxis since the cervical barrier is crossed during the procedure. These principles have been followed by most of the authors who reported Hysterosalpingography.[24,25]

Due to deviation from the standard technique, there are several points of discussion in our study. The first and foremost is the use of a simple x-ray instead of fluoroscopy. The main purpose was to facilitate poor women but the results were very encouraging. The overall image quality was good. Almost half of the women (53.8%) had normal studies and were spared from further investigations. As reported by Berker B et al there is little change in management plan in these women even if they undergo laproscopy.[26]

In the current study majority of women (75%) had at least one patent tube. This was very reassuring for these women who had a remote chance of access to advanced assisted reproductive techniques. Other issues include use of frog leg position instead of lithotomy position, limited use of uterine sound and tenaculum and use of water-soluble instead of lipid soluble contrast medium. Although visualization of the cervix is better in the standard lithotomy position, this procedure was done on an x-ray table in a frog leg position. Pillows were placed under the hips to elevate the pelvis and the operator was experienced in pelvic examination. Vaginal examination was used to detect the version of the uterus. Kiykac Altinbas S et al has shown that Foley's catheter with a stylet is associated with lesser discomfort than a metal cannula and can negotiate the cervical os.[27] Uterine sound was used in a few cases where uterus was retroverted and it was not possible to engage the os with Foley's catheter. A sponge holding forceps was used instead of a tenaculum as a routine. The purpose was to avoid pain. In a few women with primary subfertility where there was little space for sponge holding forceps, an attempt was made to introduce Foley's catheter directly under vision which was successful most of the time. Johnson N et al has reported that lipid soluble contrast medium has better success in demonstrating patency of fallopian tubes[28]. However, these are associated with a slightly higher risk of allergic reactions. Water soluble contrast medium was used in our study mainly due to safety reasons. We advised women to empty the bladder before the procedure. The purpose was to reduce patient's discomfort during the insertion of speculum and to remove bladder artifacts in the x-ray film. Some authors have used full bladder while using the fluoroscopic technique. This is because a full bladder reduces anteversion of the uterus which facilitates catheter entry.

All measurable parameters were very reassuring. The incidence of the tubal blockade was 19.3%. This is lesser than that reported by Taimoora Al Subhi, et al, probably because of lesser pain there was lesser spasm of the fallopian tubes.[29] Little amount of contrast medium and limited radiological exposure was needed to adequately visualize the reproductive tract. On an average, only 7 ml of contrast was used per woman. This approach markedly reduced analgesic requirement and risk of allergic reactions. Higher pain

scores were only seen in women who had significant pathology in this study. This finding has been reported by Atalabi OM et al as well.[30] It also resulted in a high patient satisfaction rate in this study. Due to limited handling, post procedure bleeding was seldom reported. The cost of the procedure was small and easily manageable for the women.

Conclusion

Our modified technique of Hysterosalpingography was found safe and effective in low resource setting in experienced hands. Randomized controlled trials are needed to evaluate its effectiveness in a wider perspective and comparative interventions. The benefits of advances in assisted reproductive techniques are not accessible to a majority of sufferers due to a high cost. Innovations to reduce cost will make these interventions available to the poor couples.

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