

Spontaneous pregnancy rate after Saline Infusion Sonogram done under high pressure (SIS treat)

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Introduction: Failure to achieve conception after 12 months of regular unprotected intercourse is defined as infertility. 1. As there are so many causes of delayed conception, mostly known and some are still unclear, tubal factor has increased since the last decade, reached up to 30-35% of cases suffering from subfertility. 2. Checking tubal patency is an essential step in the investigations done for sub-fertile couples and is typically performed using hysterosalpingography (HSG) or laparoscopy with chromotubation. 3. Both HSG and diagnostic laparoscopy (DL) are painful procedures, with well-known hazards of exposure to iodinated X-ray contrast media and ionizing radiation in HSG and possible anesthesia or operative complications in DL. 4. To overcome these disadvantages, during the last two decades contrast sonography (Hy-CoSy) and saline infusion sonogram (SIS) have been used as alternatives in many countries. One advantage of these techniques is the absence of radiation; another is that these procedures can be performed in an outpatient clinic by a gynecologist. Several studies have shown that these methods have nearly equal sensitivity and specificity compared with laparoscopy as the golden standard for tubal patency checking.^{5,6} Saline infusion sonohysterography (SIS) was first described in 1992 by Bonilla-Musoles et al, its technique entails instilling saline into the uterine cavity under ultrasound guidance; it was mainly used for assessment and better visualization of the uterine cavity.⁷⁻⁹ Recently, SIS was used as the main step for the assessment of fallopian tube patency, because of its simplicity, safety, and high tolerability with a very low risk of complications like; failure to complete the procedure (7%), pelvic pain (3.8%), vaginal symptoms (3.5%), nausea (1%), and post procedure fever (0.8%).¹⁰⁻¹³ The aim of this study was to evaluate SIS done under high pressure (SIS treat) as a treatment procedure, for relieving simple tubal obstruction and on cumulative pregnancy rate in women suffering from infertility. We hypothesized that SIS treat will open the tubes and increase spontaneous pregnancy rate in the treatment group.

Methods: A prospective, interventional clinical trial was done in the period from October 2017 till November 2018 on 106 eligible women. Patients were recruited from Damanhur health insurance gynecological outpatient clinic, ElBehera governorate, Egypt. The institutional review board approved the study protocol and an informed consent was obtained from all participants prior to commencing the study.

Inclusion criteria

- Eligible patients were those women complaining of primary or secondary infertility for at least one year, with normal uterine
- Ovarian factors and semen analysis.

Exclusion criteria

- Age more than 35 or less than 18, any uterine anomalies, ovulation abnormalities,
- FSH > 15 mIU/ mL,
- Known tubal block (diagnosed by HSG or DL) and abnormal male factor.

All patients were asked to come in the early postmenstrual period and underwent routine evaluation with complete history taking and physical examination, evaluation of the uterus and adnexa by vaginal ultrasound to exclude the presence of fluid in the cul-de-sac. With the woman put in lithotomy position, a disposable Cusco speculum was inserted and cervix was washed with an antiseptic solution (povidone iodine).

A sterile pediatric Foley catheter with a guide wire included (10 f) was inserted through cervical canal until it passed the internal os. Women with difficult procedure (due to cervical stenosis or angulation) were excluded. The catheter was flushed with sterile saline prior to insertion to clear it of air, which may cause an echogenic artifact inside the uterine cavity. Its balloon was filled with 1-2 ml of sterile saline solution according to uterine size and its appropriate position was confirmed by a slight pull. Careful attention was given to the exact site and amount of balloon inflation because suboptimal inflation may dislodge the catheter thus hindering proper uterine cavity distention. Also balloon over distention may hinder detection of an endometrial lesion. The speculum then was removed and a Toomey syringe filled with 60 ml of sterile saline solution was attached to the outer end of the catheter. A transvaginal ultrasonic probe was reinserted into the posterior vaginal vault. At first, saline was slowly infused to distend the uterus, examination of endometrial cavity for any undiagnosed lesions was done and then tubal patency was checked under low pressure that just permit proper distention and visualization. Observation of fluid in the cul de sac was considered an indication of tubal patency and the tubes were diagnosed as patent under low pressure. The procedure was repeated gently to exclude tubal spasm. If repeated injections gave similar results, the tubes were considered occluded under low pressure. Women with tubes diagnosed as occluded under low pressure were subjected to gradual increase in the infusion pressure using the Toomey syringe for 5 minutes (SIS treat), until fluid appeared in the cul de sac, otherwise the tubes were considered occluded under high pressure. Prophylactic antibiotic (100mg of doxycycline twice daily for 5 days) was prescribed and an analgesic post procedure, if needed. Patient with tubes patent under low pressure were diagnosed as unexplained infertility (and assigned as Group 1), groups of patients with tubes which are occluded under low pressure are assigned as Group 2 (SIS treat group), this group was further divided into Group 2-a (patients with tubes patent under high pressure) and Group 2-b (patients who were diagnosed with tubes occluded under high pressure). All patients were advised to have regular intercourse in fertile periods for the next 6 months of follow up. Pregnancy was confirmed by serum B-HCG after a missed period and with ultrasonic diagnosis of intact intrauterine gestational sac one week afterwards. The primary outcome was opening the fallopian tubes evidenced by passage of saline into pouch of Douglas detected by TV-US. Secondary outcome was the occurrence of spontaneous clinical pregnancy detected by a sonographically visible gestational sac within the follow up period of six months. The results of all groups were compared to each other.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. Significance of the obtained results was judged at the 5% level.

Results

We compared patients who performed conventional SIS (n = 100 cases) to patients who performed SIS-treat afterwards (n = 84) according to the number of patent tubes. There was a high statistically significant difference in favor of SIS-treat group ($p < 0.001$). Also, there was no significant difference in pregnancy rate between control group 62.5% and Group 2-a 45.7% ($p = 0.226$).

Conclusions

SIS-treat is a whole new procedure for opening fallopian tubes (diagnosed occluded by SIS). Patients who were successfully treated by SIS-treat had cumulative pregnancy rate comparable to patients who were diagnosed to have patent tubes using conventional SIS.

Keywords: Cumulative pregnancy rate, Infertility, Saline infusion sonogram, Transvaginal ultrasound, Tubal factor

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2. Elsharkawy S. Towel curettage for a new definition of postpartum period after cesarean section. *Int J Reprod Contracept Obstet Gynecol* 2018; 7:2537-40.
3. Elsharkawy SS, Dawood WA. Removed versus unremoved vicryl sutures used for subcuticular skin closure. *Int J Reprod Contracept Obstet Gynecol* 2018;7:4877-81.
4. Abd-El Rheem, S.M. and Elsharkawy, S. (2019) Effect of Cumulus Cells on the Efficiency of Vitrified- Thawed Immature Cattle Oocytes. *Open Journal of Obstetrics and Gynecology*, 9, 669-678.
5. Elsharkawy, S.S., Mahmoud, T.H., Elsedek, M.S.-E. and Amer, E.M.A.E. (2019) Endometrial Preparation for Frozen Embryo Transfer by Supplemented Natural Cycle versus Hormone Replacement Cycle in Regularly Cycling Women. *Open Journal of Obstetrics and Gynecology*, 9, 827- 837.
6. El-Rheem, S.M.A., Ghallab, R.S. and El-Sharkawy, S. (2019) SAT, a New Approach in Understanding and Treatment of Subclinical Endometritis in Dairy Cows. *Open Journal of Veterinary Medicine*, 9, 109-119.