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ORIGINAL ARTICLE

Evaluation of predictive factors for conception after saline infusion sonosalpingography

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ABSTRACT

Aim To evaluate predictive factors of spontaneous conception after saline infused sonosalpingography (SIS).
Methods A prospective study was conducted from August 2023 to December 2024 in Mosul/Iraq. A total of 100 women were categorized into two groups: pregnant after SIS and non-pregnant after SIS. For the achievement of conception, the two groups were followed for 6 months and their clinical characteristics were compared. Seventy women were polycystic ovary syndrome (PCOS) negative, and 30 were positive.
Results Among 100 women (both with and without PCOS) 58% showed the duration of infertility for positive pregnancy test ≤2 years versus 42% women >2 years. The time ≤2 months to get pregnant after SIS showed 79% women versus 21% >2 months. The pregnancy prevalence of 24% was markedly higher in the first 2 months post SIS equal to 79% (100 women with and without PCOS). The sub analysis of 70 women without PCOS showed the duration of infertility for pregnant women of ≤2 years in 66.7% versus 33.3% >2 years. The time needed to get pregnant after SIS was 60% ≤2 months versus 40% >2 months. Pregnancy rate was 21.1% and higher in the first 2 months after hydrosalpingography equal to 60% in 71 women without PCOS (PCOS positive women were excluded). Anti mullerian hormone showed a significant difference in pregnant women.
Conclusion The SIS had positive effect on spontaneous conception in the first two months after the procedure.
Keywords: female infertility, pregnancy outcome, salpingography

INTRODUCTION

It is well known that chromopertubation enhanced laparoscopy (LC) is gold standard diagnostic technique for tubal patency assessment but its drawbacks are hospital staying, invasiveness and necessity for general anaesthetic equipment (1). X-ray executed Hysterosalpingogram (HSG) is considered a classical technique for estimating patency of fallopian tubes but exposure to radiation and allergy from iodine contrast agents are the main restrictions (2,3). For child bearing aging women, there are multifactorial etiologies influencing pregnancy incidence like uterine, partner, ovarian and tubal factors, nearly 30 to 35% account for tubal factors (4-6) therefore assessing tubal factors is crucial and fundamental point for pregnancy workout (7).
In the last few years saline infused sonosalpingography (SIS) has become the first imaging diagnostic route for evaluating patency of fallopian tubes substituting hysterosalpingography (8,9). No iodine allergy or radiation risk limitations are present (as in HSG) as its dynamic ultrasound imaging tool with saline solution purely or mixed with air pushed to uterus and fallopian tubes (10). On the contrary, SIS is an easier and cheaper procedure than HSG or LC especially when an experienced radiologist could discriminate between fallopian tubes temporal spasm and true occlusion.
Many studies have been suggested that the pregnancy rate is increased following SIS as minor obstructions can be opened by flushed fluid to fallopian tubes (11,12) or have enhancing effect on endometrium perfusion (13) also ovulation induction could be promoted (14).
Having a look on the follow-up facts and different theories, there is a good percentage of patients who have achieved natural pregnancy after SIS interference, subsequently, it has been proposed that expectant management could have a role in some couples without the need for overtreatment and medical resources wasting (11). Yet, couple's clinical characteristics and tubal evaluations results are not being studied widely to help make treatment choices i.e. non- or interventional ways, and also if the expectant management is preferred, the time interval or for how long is not yet well cleared.
The aim of our research was to evaluate whether certain patient clinical features (age, body mass index (BMI), type and period of infertility and anti-mullerian hormone (AMH) serum level have significant and notable function in track down treatment options whether expectant or interventional routes post SIS procedure.

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PATIENTS AND METHODS:

Patients and study design

The study prospectively involved 140 women who were subjected to SIS from August 2023 to December 2024 at an outpatient private clinic for diagnostic imaging at Mosul city/Iraq, of which 100 women where eligible for the study; 40 women were excluded due to loss of follow-up or matched exclusion criteria. Inclusion criteria included female at reproductive age with history of primary or secondary infertility. Exclusion criteria were invasive assisted conception technique (intrauterine insemination exam and *in vitro* fertilization exam) carried out between SIS and conception, pelvic inflammatory disease, inability to have lithotomy position.

The outcome of pregnancy was followed up for 6 months after SIS with patients arranged in two groups according to pregnancy outcome: pregnant women after SIS and non-pregnant women after SIS.

Selected clinical conditions were taken and interpreted as possible influencing factors on pregnancy outcome such as body mass index (BMI), type and duration of infertility, age, AMH for ovarian reserve assessment, polycystic ovary syndrome (PCOS), obstetric and pelvic previous operation, SIS results of bilateral tubal occlusion, patency of at least one tube, patent or closed known side tube due to history of contralateral salpingectomy.

An acknowledged consent was signed by all the participants.

The study was conducted following approval from the Medical Ethics Committee of Mosul Medical College, University of Mosul.

Methods

Candidates were asked to attend no later than the 12th day of their menstrual cycle. The ultrasound exam was done by experienced medical imaging professional with more than 5 years' experience in gynaecological and obstetrical checking.

After bladder voiding, a lithotomy position was adapted by the patient, Cusco vaginal speculum was inserted in a place with cervical disinfection (povidone iodine solution); it was routinely done for all patients. A two-dimensional transvaginal ultrasound probe (GE Versana Premiere, China) was inserted first to assess the uterus and adnexa before saline infusion through the catheter system. The pre-warmed saline solution of about 20 to 35 mL was infused to the uterine cavity to evaluate tubal patency by noticing the fluid spillage in the peritoneal cavity (anteriorly or posteriorly to the uterus) by the transvaginal probe.

The results were classified as: bilateral tubal occlusion, patency of at least one tube, patency of one side tube due to contralateral tube removal (could be due to ectopic pregnancy as a cause). A Versana premiere (GE Health Care, China) with transvaginal transducer frequency range of 4.0-10.0MHz was handled.

Statistical analysis

Shapiro-Wilk test to check the normality of distributions was used, continuous variables presented as mean ± standard deviations (SD) when they fell within the normal distribution, and median and range (maximum, minimum) when they did not. Group based variables were presented as a number of cases and percentages (%). Based on the normality of distribution of the variables, distinction between two independent variables were assessed using the Student-T test for independent variables or the Mann-Whitney U test. The comparative review among group based variables was done using $\chi 2$. Logistic regression analysis was performed to identify variables correlated with spontaneous conception. A p=0.05 was determined as statistically significant.

RESULTS

A total of 24 (out of 100; 24%) women with the diagnosis of infertility conceived within 6 months after doing the hydrosalpingography. The median age for both PCO positive (N=29) and PCO negative (N =71) non-pregnant women was 27.0 years, while for the pregnant group it was 26.0 years (p=0.653). BMI did not show significant difference in the obese women who did not become pregnant comparing to the women who became pregnant, 30 (39.5 %) and 15 (62.5 %), respectively (p=0. 922).

The prevalence of normal SIS in the group of women who got pregnant was 79.2%, as opposed to 93.4% in those who did not get pregnant, while close SIS of the group of women who conceived was 20.8%, as opposed to 6.6% in those who did not conceive (p=0.042). The prevalence of pelvic operation without CS of the group of women who got pregnant was 54%, as opposed to 80.2% in those who did not get pregnant, while pelvic operation with CS, of the group of women who got pregnant was 46%, compared to 20% of those who did not get pregnant (p=0.011). The percentage of women without PCOS was 54.16% of the group who got pregnant compared to 76.31% in those who did not get pregnant, while in the women with PCOS 45.84% women conceived in contrast to 23.68% in those who did not conceive (p=0.037). No significant difference was observed in infertility type, -AMH, AFC. On the other hand, for comparison of pregnant groups, the median of occurrence of pregnancy time after SIS ≤2 months was 1.5 versus 4.5 in those with occurrence of pregnancy time after SIS >2 months (p= 0.000).

The median of duration of infertility in the group ≤2 years was 18 months versus 48 months in those who had the duration of infertility >2 years (p= 0.000).

The cumulative rate of spontaneous pregnancy following SIS within six months was 24% and the rate of pregnancy was markedly higher in the first 2 months after doing the SIS at 79% and in the first month at 37.5 % (Table 1).

Logistic regression analysis showed that no variable capable of influencing the prevalence of pregnancy between the two groups, with an exception of PCO positive women.

A total of 15 (out of 71; 21.1%) infertile women conceived within 6 months after executing SIS.

The median age for PCO negative non-pregnant women was 28.9 years, while for the pregnant group it was 29.06 years (p=0.95). BMI did not show significant difference even in obese women who did not get pregnant comparing to the women who got pregnant, 18 (32.7%) versus six (40.0%) (p=0.59). The AMH showed significant difference in pregnant women comparing to non-pregnant women, 1.5 versus 1.2, respectively (p=0.027) (Table2).

The prevalence of normal SIS in the group of women who got pregnant was 66.7%, in contrast to 91% in those who did not

Table 1 Clinical characteristics of 100 women with and without polycystic ovary syndrome (PCOS)

Variable	Non – pregnant (N=76)	Pregnant (N=24)	p
Median age (min. – max.)	27.0 (15-45)	26.0 (17-45)	0.653
	No (%) of women		
BMI (kg/m^2)			
Underweight (<18.5)	2 (2.6)	0 (0.0)	No pregnant women no p value
Normal (18.5 - 24.9)	29 (38.2)	3 (12.5)	0.607
Overweight (25 - 29.9)	15 (19.7)	6 (25)	0.624
Obesity (≥30)	30 (39.5)	15 (62.5)	0.922
Type of infertility			
Primary	37 (48.7)	10 (41.7)	0.54
Secondary	39 (51.3)	14 (58.3)	
SIS			
Normal	71 (93.4)	19 (79.2)	0.042
Closed	5 (6.6)	5 (20.8)	
Pelvic operation			
Without CS	61 (80)	13 (54)	0.011
With CS	15 (20)	11(46)	
PCO			
NO	58 (76.32)	13 (54.16)	0.037
YES	18 (23.68)	11 (45.84)	
Occurrence of pregnancy time after SIS (months)			
<2		19 (79)	0.0001
>2		5 (21)	
Duration of infertility (years)			
≤2		14 (58)	0.000
>2		10 (42)	
	Median (min. – max.)		
Occurrence of pregnancy time after SIS (months)			
≤2		1.5 (0.5-2.)	0.000
> 2		4.5 (3-6)	
Duration of infertility (years)			
≤2		18 (24-15)	0.000
>2		48 (96-36)	
Anti-Mullerian hormone (ng/mL)	2.3 (0.03-17)	2.5 (0.5-11.8)	0.840
Antral follicle count	7.0 (0.0 -30)	10.5 (0.0-40)	0.061

BMI, body mass index; SIS, saline infusion sonosalpingography; CS, caesarean section

get pregnant, while close SIS, of the group of women who got pregnant was 33.3% compared to 9.0% in those who did not get pregnant, (p=0.004). The prevalence of pelvic operation without CS of the group of women who conceived was 66.7%, in contrast to 89.1% in those who did not conceive, while pelvic operation with CS of the group of women who got pregnant was 33.3%, versus 10.9% in those who did not, (p=0.034). No significant difference was noted in the infertility type and AFC.

Table 2. Clinical characteristics of 71 women without polycystic ovary syndrome (PCOS)

Variable	Non – pregnant (N=55)	Pregnant (N=15)	p
Mean age (±SD) (years)	28.96 ±6.7	29.06 ±7.2	0.950
	No (%) of women		
BMI (kg/m^2)			
Underweight (< 18.5)	2 (3.6)	0 (0.0)	No pregnant women no p value
Normal (18.5 - 24.9)	25 (45.5)	4 (26.7)	0.19
Overweight (25 - 29.9)	10 (18.2)	5(33.3)	0.205
Obesity (≥30)	18 (32.7)	6 (40.0)	0.59
Type of infertility			
Primary	24 (43.6)	5 (33.3)	0.47
Secondary	31 (56.4)	10 (66.7)	
SIS			
Normal	50 (91.0)	10 (66.7)	0.004
Closed	5 (9.0)	5 (33.3)	
Pelvic operation			
Without CS	49 (89.1)	10 (66.7)	0.034
With CS	6 (10.9)	5 (33.3)	
Occurrence of pregnancy time after SIS (months)			
≤2		9 (60.0)	0.02
>2		6 (40.0)	
Duration of infertility (years)			
≤2		10 (66.7)	0.001
>2		5 (33.3)	
	Median (min. – max.)		
Anti-Mullerian hormone (ng/mL)	1.2 (0.03-14)	1.5 (0.5-4.5)	0.027
Antral follicle count	7.0 (0.0 -30)	10.0 (0.0 -26)	0.106

BMI, body mass index; SIS, saline infusion sonosalpingography; CS, caesarean section

On the other hand, for comparison of the pregnant groups, the median of occurrence of pregnancy time after SIS ≤2 months was 1.0 versus 4.0 in those with occurrence of pregnancy time after SIS >2months (p= 0.02).

The median of duration of infertility ≤2 years was 24 versus 66 in those whose with the duration of infertility >2 years (p= 0.001). The cumulative rate of spontaneous pregnancy following SIS within six months was 21.1% and the rate of pregnancy of 60% was notably higher in the first 2 months after SIS (Table 2).

Logistic regression analysis showed that AMH was the only independent variable capable of influencing the prevalence of pregnancy between the two groups: OR (odds ratio)=1.58; 95% CI: 1.11, 1.67 (p=0.03).

DISCUSSION

The advantage of SIS was very clear in women with short duration of infertility, low prevalence of CS operation, and higher AMH level; this fact encourages expectant management rather than overtreatment and wasting medical resources. The results support the fact that infertility period is positively allied with

spontaneous pregnancy after executing SIS, (14-16); it can be explained by the presence of continual obstruction of the fallopian tubes resulting in long term inflammatory process affecting the internal tubal structures (15,17). The AMH showed no significant difference when 100 patients were included (with and without PCOS factor), which could be explained by the high number of small peripheral follicles in the ovaries causing false high serum AMH level. In sub-analysis of 71 women (not having PCO factor), AMH was the sole factor in declaring dissimilarity in the prevalence of spontaneous conception among the two groups. This emphasizes AMH value as a potent predictive variable (14,16,18). Pregnancy rate was 24% in the group with 100 women included (with and without PCO), which is comparable to 26.59% in other studies (11); it may be attributed to the small percentage of bilateral tubal occlusion of 10% in our study comparing to 9.5% in other studies (11). However, pregnancy rate of 16% was found in some studies (18) with bilateral tubal occlusion of 13.4%. BMI showed no statistical difference between the two groups, which is in disagreement with other reports (18,19) showing that obesity may cause irregular menstrual cycle, anovulation, higher miscarriage rate, poor fertility treatment response and reduce the rate of pregnancy; this may be attributed to the relatively small sample of the study.

Conception in first month after SIS showed a higher percentage of 37.5%, which is compatible with prior studies (11,14,20) encouraging the suggestion that spontaneous pregnancy is favoured during the same cycle of menstruation following SIS.

The mean time to pregnancy within 6 months passing SIS in our study was 1.7 months, which was lower comparing to other studies, 3.4±2.9 (18) and 5.3 (11). This supports the expectant management for a certain period of time for infertile couples following SIS for the achievement of spontaneous pregnancy and decreased overtreatment and medical risks.

Unexpectantly, five patients with bilateral obstruction of the fallopian tubes conceived spontaneously following SIS, which was reported in other studies (15,18). It might be due to the removal of the debris and secretion inside tubes by the mechanic process of liquid passage, and spasm of tubes, which also contributes to the false positive tubal occlusion.

A coherence review for randomized trials achieved that tubal intervention may give significant raise in the conception odd and live birth as in other studies (21, 22). This favourable and effective impact could be clarified by a breakdown of minor adhesions by contrast agent passage, which also clears debris and plugs of mucus. The passage of agent may also expand tubal stenosis (20,21).

The restraint of this study is a relatively small sample and limited period of follow-up to months. A larger sample size is recommended to validate the study results.

In conclusion: our study supports the favourable and positive effect of SIS on the achievement of spontaneous pregnancy. This is true within the first month and encourages choosing expectant management overtreatment and assisted reproductive technique especially in women with short duration of infertility, lower CS interference and good AMH serum level.

Author Contributions

Conceptualization, D.R. and L.A.; Data curation, D.R. and L.A.; Formal Analysis, M.A. .; Investigation, D.R., M.A. and L.A.; Methodology, D.R., and M.A.; Project administration, M.A. and L.A.; Software, M.A. and D.R.; Visualization, D.R. and L.A.; Writing – original draft, D.R and M.A; Resources, L.A. and M.A.; Supervision, D.R. and L.A.; Validation, D.R, AND; Writing – review & editing, D.R, M.A. and L.A. All authors have seen and approved the final manuscript.

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Conflicts of interest: None to declare.

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