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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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SALINE INFUSION SONOGRAPHY IN EVALUATION OF SUBFERTILE WOMEN AND ITS EFFECT ON REPRODUCTIVE OUTCOME

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Abstract.

Infertility treatment requires a high-quality service. Initial evaluation of tubal patency and uterine pathology in a cost-effective manner was required to improve treatment success. This study was conducted to evaluates the benefit of saline infusion sonography (SIS) compared to hysterosalpingography (HSG) during assessment of tubal patency and uterine pathology in subfertile women. Prospective interventional clinical trials were applied to 200 (18-35 years of age) women during their infertility evaluation. A questionnaire was used to gather data. SIS performed at cycle day 6-9, checking for tubal patency and uterine endometrial pathology, such as the presence of polyps, fibroids, and congenital uterine anomalies. SIS diagnosed bilateral tubal closure in (7.5%), while previously tried HSG had a higher rate of tubal closure (9.5%), with an extra number of cases was due to false positive as a result of tubal spasm (p 0.371). SIS predict tubal closure with agreement rate of 78.9%, discordance rate of 99.4%, the positive percent agreement value was 93.7%, and the negative percent agreement value was 97.2%. SIS provided more accurate results in diagnosing tubal closure and endometrial pathology than HSG, as SIS had fewer false diagnoses of tubal closure and was more accurate in detecting polyps and fibroids that had been missed by HSG.

Key words. Subfertility, hysterosalpingography, saline infusion sonography, tubal patency.

Introduction.

Infertility is defined as the failure of a female and male to achieve a successful pregnancy after 12 months of trying unprotected regular intercourse due to diseases that impaire their reproductive function [1]. Evaluation and treatment might be initiated after 12 months of trying to conceive in women younger than 35 years, and may be earlier, even at the time of presentation, in women >35 years or when a recognisable pathology known to compromise fertility was identified [2]. Diagnostic infertility assessment should be conducted in an orderly, punctual, and effective manner to identify the actual causes related to female subfertility, with insistence on using the minimal invasive technique with the least cost initially [1].

The female subfertility could be mainly related to ovarian causes, tubal pathology, uterine pathologies, cervical problems and some unexplained conditions. Screening the fallopian tubes for patency was one of the most important initial steps in evaluating subfertility as tubo-peritoneal factors was described in 30-40% of couples and the incidence was further increasing [3], and till now hysterosalpingography (HSG) was regarded as the first choice for initial assessment of tubal patency in-spite of risk of ionizing radiation exposure, followed by laparoscopy or with saline infusion Sonography [4].

Ultrasound imaging was the best modality available for assessment of uterine structure for any present pathology (myometrium, lining endometrium and the cavity) as well as the adnexia, with a trans-vaginal ultrasound (TVU), was better than abdominal as it could discover any underlying uterine pathologies like, fibroids and adenomyosis in the myometrium or polyps, a cause that may be directly related to female subfertility. Other modalities can be used to evaluate uterine pathology, like magnetic resonance imaging (MRI) and 3D ultrasound, which should be kept for characterisation of initial findings obtained after TVU or HSG examination [5].

The true prevalence of diagnosis of intrauterine pathology in subfertile women was difficult to be determine exactly, but some studies reported an incidence between 16–24% [6], others reported higher values (34-62%), and hence exclusion of uterine abnormalities should be performed routinely at the beginning as part of the essential evaluation of subfertile women [7].

General treatment for infertility and in part, the success of assisted reproductive techniques (ART) would be based on developing a receptive endometrium, and every measure aimed to evaluate the uterine cavity properly was important to exclude undiagnosed endometrial pathology that could impair its receptivity prior to infertility treatment, as it actually affects decisions and overall treatment success [8]. In addition, exclusion of closed damaged tubes is essential to be considered before attempting spontaneous pregnancy or even ART, as they can secrete chemicals that affect the molecular environment of endometrial receptivity, which might be a reason for repeated implantation failure [9].

During initial evaluation of female infertility, SIS could provide high-resolution visualisation through transvaginal ultrasound to diagnose both uterine pathology and tubal closure in most cases, with some advantages over other modalities like HSG [10]. Hysteroscopy can definitively diagnose and also treat any discovered intrauterine pathology, and it could be beneficial in the evaluation of tubal patency, but it was more expensive and invasive than both HSG and SIS [11]. MRI could provide superior visualisation with multiple planes for uterine fibroids or pathology, but it was also expensive and not freely available in clinical practice [12]. The present study aimed to evaluate the benefit of routine use of SIS at the basic initial evaluation of the female subfertility for testing tubal patency and endometrial pathology instead of HSG, and to identify the pregnancy rate after SIS.

Materials and Methods.

It was an interventional study, with a clinical trial conducted from January 2022 to January 2024 on 200 subfertile women attending the private out-patient infertility clinic receiving

patients from different parts of Ninavah governorate. The study was approved by the scientific and ethical committee in the College of Medicine/University of Mosul with the reference number (UOM/COM/MREC/20-21(53)/B) on 4/6/2021, and all participants were given informed consent, and their acceptance was assigned before included in this study.

Inclusion criteria: patient age group of (18-35) years, diagnosed with at least one year subfertility, those with previous history of hysterosalpingography were included in the study, the practitioner of SIS was blind to the result of HSG whether it was normal or abnormal during the previous evaluation, further more the patients were not describe a history suggestive for specific pathology, nor receive any treatment that could bias the results between HSG and SIS.

Exclusion criteria: those with active pelvic infection, those aged more than 35 or less than 18 years, those with severe abnormal semen analysis and those with anovulation.

All patients were evaluated clinically by history and clinical examination. Exclusion of active pelvic infection. SIS was timed after other underlying causes of infertility were diagnosed and treated, such as improving semen quality, ovulation induction and timed intercourse to increase the chance of pregnancy and benefit from SIS. Patients were counselled about the procedure, its benefits, and possible complications, and they signed an informed consent before participating in the procedure. SIS was arranged during the early days after menstrual flow have been ceased (follicular phase around cycle day 5-9), a time when the endometrium is relatively thin, and the cervix is open.

The procedure started after emptying the urinary bladder with the woman lying in dorsal recumbent position, transvaginal ultrasound was used for evaluation of the uterus and both adnexa to determine the direction of the uterus, and exclusion of the presence of any fluid within the uterine cavity or in the cul-de-sac. A disposable type Cusco's speculum was used, and the cervix was exposed, and it was swabbed with povidone iodine. A sterilised metal cervical cannula was inserted through the cervical canal and kept in position with pressure on the external os. Some manipulation was required in some patients with acute angulation and those with a narrow cervical os the procedure was repeated after administration of misoprostol the day before the procedure, and actually, no woman was excluded because of difficulty in application. A 20 ml sterile syringe containing warm normal saline was inserted in to the cannula and saline was flushed through the sterile cannula before its insertion to ensure its patency and also to clear any air present (responsible for a possible artifact inside the cavity of uterus), the warm saline was injected into the uterine cavity slowly with sustained pressure to minimize pain and reduce risk of tubal spasm and pressure is maintained in position for a while to help the saline to be passed into the tubes under the persistent force especially when there is a resistance. Then both cervical cannula and Cusco's speculum were removed, a trans-vaginal ultrasound probe was introduced to the posterior vaginal fornix to visualise the uterine cavity distended with saline, looking for any defect or undiagnosed lesions in the uterine cavity, then looking for fluid spilling and spinning around the right and left tubes and

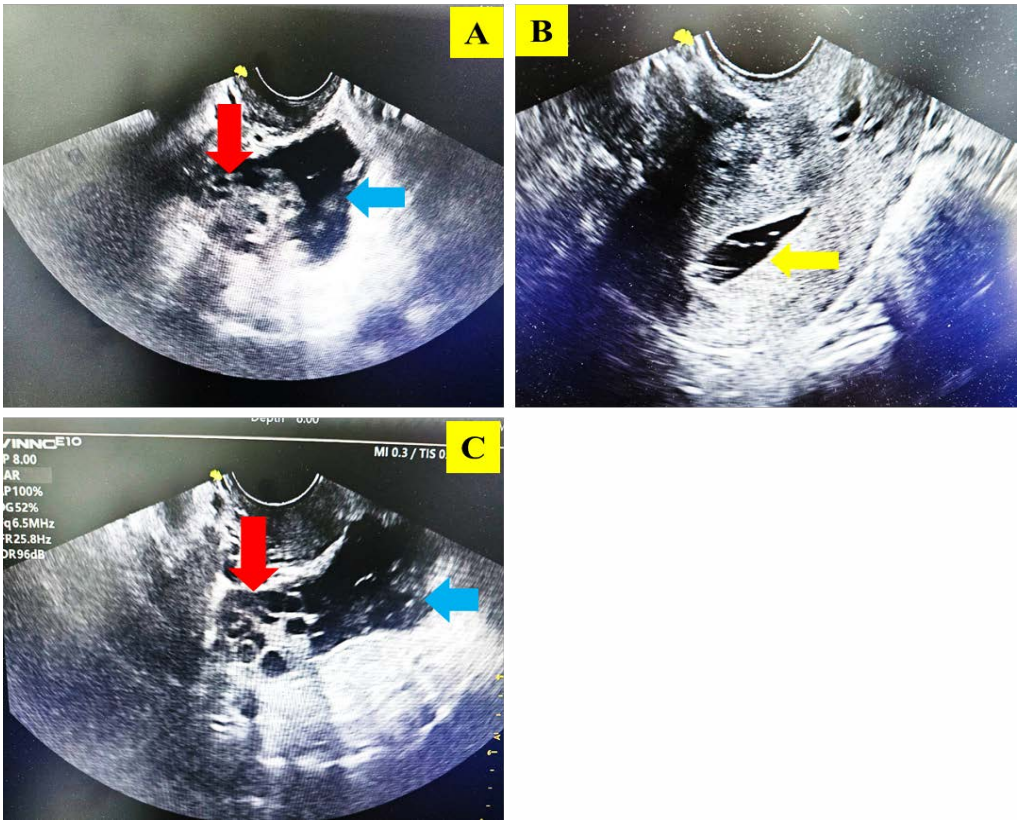

Figure 1. *Images of assessment of tubal patency and normal uterine cavity by SIS. (A) Patent right tube, (B) Normal uterine cavity, (C) Patent left tube. (red arrows: ovary, blue arrows: free fluid spillage from the fallopian tube into the peritoneal cavity, yellow arrow: uterine cavity distended with normal saline with no polys inside)*

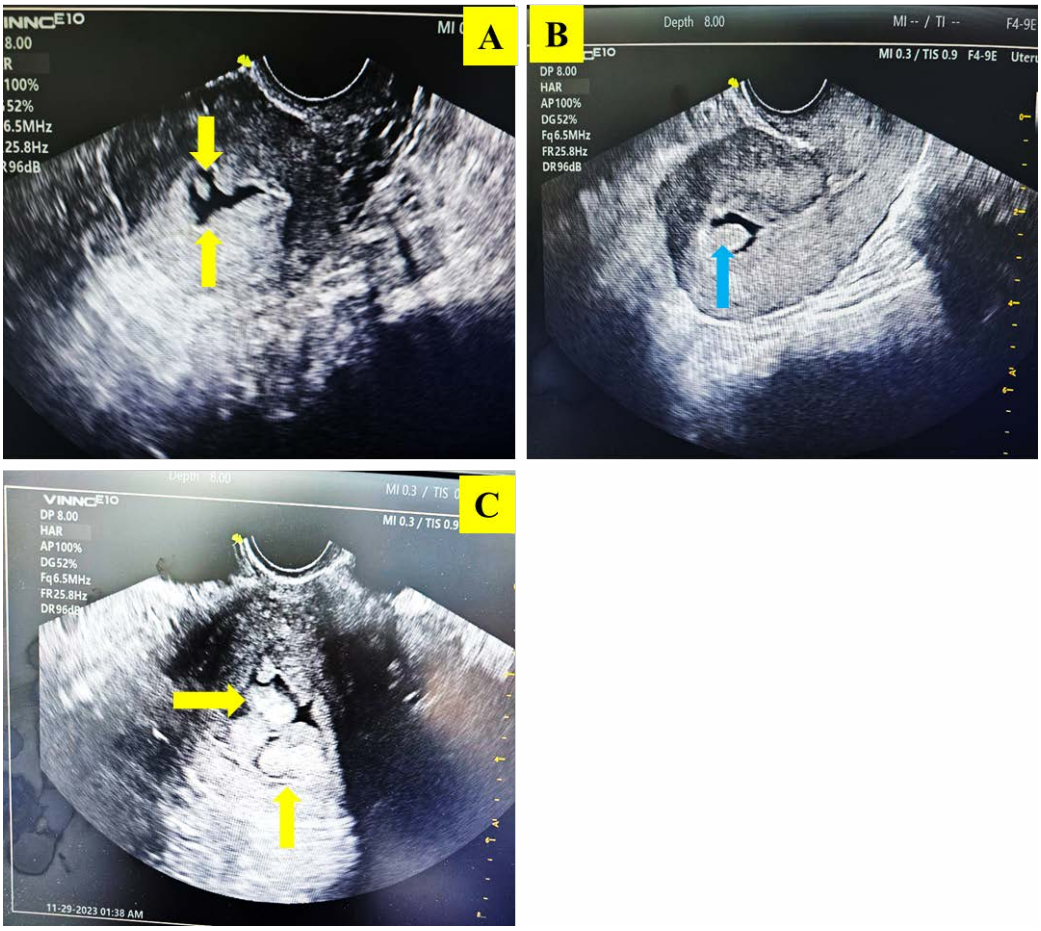

Figure 2. *Images of uterine pathology by SIS with the uterine cavity and polyps inside were outlined by the injected normal saline (A). Multiple small polyps (yellow arrows: multiple polyps protruding in the uterine cavity) (B) Single polyp (blue arrows: single fundal polyp) (C) Multiple large polyps (yellow arrows: multiple polyps).*

ovaries and fluid in the cul-de-sac indicating tubal patency. Antispasmodics and analgesics were administered before the procedure for pain relief, and prophylactic antibiotics were given after, and patient instructed to consult if she had persistant pain, fever or any complication then after (Figure 1 and Figure 2). Regular intercourse during the fertile periods was encouraged, or IUI was performed during the next months. Pregnancy was diagnosed by serum B-hCG and by transvaginal ultrasound.

Study outcome.

The primary study outcome: number and percentage of diagnosis of tubal closure by SIS compared to HSG, and number and percentage of uterine pathology diagnosed by SIS compared to HSG. Secondary study outcome: was a positive biochemical or clinical pregnancy during the first 3 months after the procedure, and any possible complications observed after.

Results and Discussion.

The success of subfertility treatment would be mainly depended on accurate diagnosis and specific treatment for the cause, which can be achieved by a properly organised decision, making pregnancy possible in 85% of cases where the cause is identified, and pregnancy may still also be possible in unexplained causes in the remaining 15% of cases [13]. In this study, 200 infertile women were evaluated by history and examination.

Demographic data: Table (1) shows the results of the demographic data mean in our study sample. The mean age was 29 years, body mass index (BMI) was 27.3 Kg/m2, duration of infertility was 5.04 years, 63% were from urban and 37% were from rural areas, 66% were housewives and 34% were employed.

Basic infertility evaluation: Table (2) shows the type, the causes of subfertility, and the previous history of surgery or pelvic inflammatory disease. The type of subfertility in the study group 63% were primary and 37% were secondary, the main causes of subfertility was female causes with ovulatory dysfunction mainly due to polycystic ovary syndrome accounting for 56% and hyperprolactinemia was responsible for 7.5%, while unexplained account for 29%, bilateral tubal closure in 7.5%, and male factor infertility was present in 69% of couples. History of previous laparotomy was assessed, and it was absent in 88% and present in 12% of female patients (appendectomy 2.5%, tubo-ovarian operation 3%, ectopic pregnancy 2%, myomectomy 2.5% and caesarean section in 2%). The history of pelvic inflammatory disease (PID) was absent in 95.5% and present in 4.5%. Impaired tubal patency is responsible for 30-40% of cases of infertility [3] which is usually checked by HSG, which is non- invasive and cheap, but this test expose both the patient and the examiner to the radiation hazards, and patients had more painful episodes after the procedure. It had

Table 1. *Demographic data of infertile women who participated in the study.*

Parameter	**Range**	**Mean**
Age (years)	22-35	29 years
BMI (kg/m^2)	22-31	27.3 kg/m^2
Duration of infertility (years)	1-13	5.04 years
Parameter	Character	n(%)
Residence	Urban	126 (63%)
	Rural	74(37%)
Occupation	House wives	134(67%)
	Employed	66(33%)

Table 2. *Clinical evaluation of sub-infertile women in the study group.*

Parameter	**Character**	**n(%)**
Type of subfertility	Primary	126(63%)
	Secondary	74(37%)
Causes of subfertility: Female subfertility	Ovulatory dysfunction	112(56%)
	Hyperprolactinemia	15(7.5%)
	Unexplained	58(29%)
	Bilateral Tubal closure	15(7.5%)
Causes of subfertility	Male subfertility	138(69%)
History of previous laparotomy	No	176(88%)
	Appendicetomy	5(2.5%)
	Tubo-Ovarian surgery	6(3%)
	Ectopic pregnancy	4(2%)
	Myomectomy	5(2.5%)
	Caesarean section	4(2%)
History of present PID	No PID	191(95.5%)
	PID	9(4.5%)

Table 3. *Number and percentage of patients with tubal patency and closure in SIS and HSG.*

Tubal patency	**SIS N**	**SIS %**	**HSG N**	**HSG %**
Patent (negative test)	185	92.5%	181	90.5%
Closed both tubes (positive test)	15	7.5%	19	9.5%
Total	200	100%	200	100%

Table 4. *Calculation of Agreement rate, discordance rate, positive and negative percent agreement of SIS compared to HSG.*

	HSG			
SIS	**Positive (closed tubes)**	**Negative (patent tubes)**	**Total**	**p-value**
Positive (closed tubes)	15	1	16	0.0371
Negative (patent tubes)	4	180	184	
Total	19	181	200	

Table 5. *Agreement rate, discordance rate, positive percent agreement and negative percent agreement for tubal closure by SIS compared to HSG.*

Parameters	**Values**
Agreement rate	78.9%
Discordance rate	99.4%
Positive percent agreement	93.7%
Negative percent agreement	97.2%

Table 6. *Detection of uterine pathology by SIS and HSG.*

Uterine parameter	**SIS (N)**	**SIS (%)**	**HSG (N)**	**HSG (%)**	***P*-value**
Normal uterus	176	88%	190	95%	0.012*
Polyp	13	6.5%	0	0%	0.00**
Submucosal fibroid	5	2.5%	2	1%	0.253
Congenital uterine abnormalities	3	1.5%	4	2%	0.703
Hydrosalpinx	2	1%	3	1.5%	0.653
Adhesions	1	0.5%	1	0.5%	1.000
Septum	0	0%	0	0%	
Total abnormal	24	12%	10	5%	0.012*
Total	200	100%	200	100%	

Table 7. *Complications after SIS.*

Complications	**n(%)**
Significant Abdominal pain at the time of the procedure	192 (96%)
Nausea and vomiting	10 (5%)
Dizziness	8 (4%)
Persistent pain after	162 (81%)
Watery bloody discharge	136 (68%)
Fever	4 (2%)
PID	3 (1.5%)

a sensitivity of 84% and specificity of 75% with low imaging accuracy, which is possibly due to tubal spasm [14]. In our study, SIS was used and compared with the results of HSG used for the same group.

SIS results were compared with patients previous results of the previous HSG at their previous infertility evaluation within the last 6 months (Table 3). The SIS results shows that tubal patency at least patent one tube was diagnosed in 92.5% (n: 185) and closure of both tubes was diagnosed in 7.5% (n: 15) these result were then compared with the HSG results, presence of patent one or both tube was present in 90.5% (n: 181) and bilateral closed tubes was present in 9.5% (n: 19), that there were four patients were diagnosed to have bilateral tubal closure by HSG (false positive) which were proved to be patent on SIS and one patients was diagnosed by SIS to have patent tubes (false positive) proved later to be closed. Six patients had a difficult procedure, required repetition of SIS (twice) and were diagnosed to have patent tubes. SIS was more accurate in detecting tubal patency than HSG, either due to the higher efficacy of the techniques or the lower rate of tubal spasm, making false positive diagnoses of closed tubes less likely. This higher efficacy and accuracy of SIS than HSG in the detection of tubal patency was observed by other studies like that in 2015, with 86.5% shows tubal patency by SIS and 81.7% by HSG [15].

Table (4) describes the number of positive cases by SIS compared to HSG, with a p-value of 0.371, tested by the McNemar test (no significant difference at p-value <0.05). Calculation of Agreement rate, discordance rate, positive and negative percent agreement values for SIS.

Table 5 shows that the Agreement rate of the SIS was 78.9%, its discordance rate was 99.4%, and the SIS has a positive percent agreement (PPA) of 93.7% and a negative percent agreement (NPA) of 97.2%.

Results from HSG evaluation of tubal patency in a study by Panchal and Nagori (2014) were compared to our study. The study describes a sensitivity of 84% and a specificity of 75%, with low imaging accuracy and false positive diagnoses were explained as possibly due to a higher risk of tubal spasm [14]. A study by Rezk and Shawky (2015) showed that SIS was better than HSG in evaluation of tubal patency with values for sensitivity (52%), specificity (95%), PPV (79%) and NPV (84%) compared to (38%, 96%, 79%, 80%) in HSG [15].

Saline Infusion Sonography evaluation for the presence of uterine pathology was described in Table (6). The table describes that a normal uterine cavity was observed in 88% and 96.5% of cases evaluated by SIS and HSG, respectively and the presence of uterine pathology in 12% and 5% of cases in SIS and HSG, respectively. Uterine polyps were present in 6.5% and 0%, and submucosal fibroid was present in 2.5% and 1%, respectively. Congenital uterine malformations were present in 1.5% and 2%, respectively. Hydrosalpinx was diagnosed in 1% and 1.5%, respectively. Adhesions were present in 0.5% and 0.5% of cases evaluated by SIS and HSG, respectively. In our study SIS was better than using HSG in diagnosing endometrial pathology, there was a significant difference in the detection of uterine cavity abnormalities by SIS and HSG (12% compared to 5%) this difference is mainly due to higher detection rate for polyps (6.5%, 0%) by SIS compared to HSG, the previously done in the same patients and passed without detection because of the technique used or its limitation, thus SIS has higher accuracy in diagnosing uterine cavity abnormalities and it could uncover the undiagnosed possible underlying cause for infertility. Evaluation of subfertile women with SIS after initial trans-vaginal ultrasound examination is advised for better detection of focal uterine cavity abnormality, especially polyps, before deciding on hysteroscopy for conformation and therapy, this was also concluded by a study by Bhumija 2022, with better sensitivity of SIS than TVU (90.3% and 95.77%, respectively) in detection of endometrial pathology [16].

The table showed a significant difference with p- value ≤ 0.05 in the case of a normal uterus, and the percentage of abnormal uterus between the results of SIS and HSG. There was a highly significant difference at p-value ≤0.01, for the percentage of cases of polyps diagnosed by SIS compared to HSG. There were no significant differences in the percentage of diagnosis of submucosal fibroid, congenital uterine abnormalities, hydrosalpinx, and adhesions between SIS and HSG. There were no cases of uterine septum identified in the study (p- value was tested by the McNemar test).

Complications after Saline Infusion Sonography: The possible complications encountered after SIS were described in Table (7). The most experienced symptoms immediately after the procedure were pain in 96% of cases, nausea and vomiting occurred in 5%, dizziness felt in 4% and persistent pain during the subsequent days was described in 81%, watery or bloody discharge was noticed in 68%, reactionary fever was developed in 2%, and aggravation of PID was observed in 1.5% of cases.

Ultrasound evaluation is usually the initial step in infertility evaluation and ultrasound-based evaluation could be used to evaluate tubal patency and endometrial pathology [17]. In our study evaluation of tubal patency and intrauterine pathology was done by SIS performed on initial evaluation of subfertile women as it is cheap, readily available by the infertility specialist that could give proper evaluation and being the least invasive in

diagnosing tubal patency in most cases with less false positive diagnosis of closed tubes as compared with HSG as it had only a false diagnosis of patent tubes in 2% compared to 13.4% of cases, in a study by Abbas et al. [18].

SIS was also safe not like HSG when there was a risk of radiation exposure for vital organs such as the ovaries and bone marrow, and a dose risk effect had been assessed by many studies like a study by Hamid HO 2021, as there was a risk of developing cancer and many harmful hereditary effects, especially the test was always required to be performed at young age group with tendency for repeated testing during infertility evaluation [19].

According to a study by Ambildhuke et al. ,2022 who regarded laparoscopy as the standard method for diagnosis of subfertility caused by tubal factor, it was important to evaluate the structure of both fallopian tubes and the condition of both fimbria, which could localise the site of obstruction and could visualise any adhesion and endometriosis. But it was invasive, costly, and general anaesthesia was required with its added risks [20]. similar benefit during tubal evaluation by SIS could be obtained to a lesser degree that it was possible to outline the fimbrial end, and it's motility when the saline surround the ovary and that tubal part [4], more important a study by Küllahçıoğlu et al., denoted that bilateral tubal closure were not usually identified by laparoscopy in the majority of their studied sample (as 82.97% had normal finding) who had no risk factors for tubal abnormality as history of PID, ectopic pregnancy, previous pelvic surgery or laparotomy [21], and it was better to limit laparoscopy for evaluation of patients with underlying risk factors and relays initially on a less invasive and a least expensive methods.

Pregnancy rate after SIS: In our study the cumulative pregnancy rate in first three months after SIS was 43%, this pregnancy rate was shown by similar study by beatriz ferro et. al, 2023 which highlight a pregnancy rate of 16% especially during the first month after SIS [22], and higher percentage of 40.9% [23], or 26.59% have been also reported [24]. This may be attributed to better diagnostic accuracy by SIS for the possible underlying causes for female subfertility that were missed by HSG, as many underlying endometrial polyps were diagnosed by SIS and then conformed and resected by hysteroscopy in addition there were less false positive diagnosis of tubal closure, that might unnecessarily mistaking patient treatment decision. This role of SIS in proper subfertility diagnosis and treatment decision combined with improved patient life style, ovulation and semen parameters and possibly IUI would improve pregnancy results and would encourage its use in the initial infertility evaluation instead of HSG, As it had the same positive effect of HSG on tubal patency possibly by releasing tubal debris or mucus plugging, breaking filmy adhesions, and even may open tubal convolutions [23-25]. and could improve endometrial receptivity through a similar possible endometrial abrasion [24] with better diagnostic accuracy and with no hazards of radiation.

Limitation.

In dealing with tubal patency testing laparoscopy, the gold standard test for evaluation of tubal patency, in our study was only restricted for cases when tubal closure was diagnosed or for other indication like exclusion of endometriosis and not used routinely for all cases as it is invasive, costly test and there is a risk of general anaesthesia. Also, hysteroscopy may better diagnose endometrial pathology but in our study, it was only used after evaluation with SIS or HSG, which were used at the initial infertility evaluation. Laparoscopy and hysteroscopy may be used in further studies for proper evaluation between results of SIS and HSG.

Conclusion.

SIS really was a safe, cost-effective test for evaluation of subfertile women for both tubal patency and endometrial intra-cavitary lesion with minimal complications. It was better to be used at the initial assessment for subfertility instead of HSG, and before deciding on laparoscopy and/or hysteroscopy, and the latter two chould be restricted only to selected cases for confirmation of suspected pathology and/or to provide possible treatment.

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