

Comparison Between Foley's Catheter and Embryo Transfer Catheter in Sonohysterosalpingography (Sono-HSG) With Foam Instillation (Hyfosy) — A Comparison of Catheter Insertion Time And Procedure Duration

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Abstract

Objective: To compare catheter insertion time and total procedure duration between a Foley's catheter and an embryo transfer (Labotect) catheter during sonohysterosalpingography (sono-HSG) with foam instillation (HyFoSy).

Methods: This randomized clinical trial enrolled 150 women attending the gynecology outpatient clinic, Department of Obstetrics and Gynecology, Cairo University Hospital, Egypt, between August 2023 and July 2024. Participants were randomized by block randomization to Group A (sono-HSG/HyFoSy using a 5–7 French Foley's catheter with balloon inflation) or Group B (sono-HSG/HyFoSy using a Labotect embryo transfer catheter), with an otherwise identical technique. Time of catheter insertion and total procedure time were recorded for each participant and compared between groups using the Mann-Whitney U test (SPSS version 27; $p < 0.05$ considered significant).

Results: The two groups were comparable at baseline for age, gravidity, parity, and previous surgeries. Catheter insertion time was significantly shorter in Group B than Group A (4.4 ± 3.0 vs. 5.3 ± 2.9 minutes, $p = 0.047$). Total procedure time was also significantly shorter in Group B than Group A (14.6 ± 5.0 vs. 16.6 ± 5.6 minutes, $p = 0.026$).

Conclusion: Use of an embryo transfer catheter for sono-HSG with foam instillation (HyFoSy) was associated with a significantly shorter catheter insertion time and shorter total procedure time compared with a Foley's catheter.

Keywords: Sonohysterosalpingography; HyFoSy; embryo transfer catheter; Foley catheter; procedure time; infertility.

Introduction

Infertility is a common and globally distributed health problem. According to the 2023 World Health Organization report, approximately 17.5% of the adult population — roughly one in six people — experiences infertility at some point during their reproductive lifetime, with lifetime prevalence comparable across high-, middle-, and low-income countries (17.8% versus 16.5%, respectively) [1]. This scale of burden underscores the need for accessible, affordable, and high-quality fertility care, including efficient and well-tolerated diagnostic pathways [2]. Female factors contribute to infertility alone or in combination with male factors in a large proportion of affected couples, and tubal pathology is among the most common contributors, implicated in approximately 30–45% of female infertility cases [3]. Causes of tubal damage include pelvic inflammatory disease, endometriosis, prior pelvic or tubal surgery, and congenital anomalies, and tubal factor infertility often has no other clinical signs, making objective assessment of tubal patency an essential component of the infertility work-up [4]. Laparoscopy with chromopertubation (the dye test) remains the reference standard for assessing tubal patency, but its invasiveness, cost, and need for general anesthesia limit its use as a first-line test [5]. Conventional hysterosalpingography (HSG), which uses fluoroscopic imaging with an iodinated contrast medium, has long served as the standard first-line investigation; however, it exposes patients to ionizing radiation, iodinated contrast, and is frequently associated with significant procedural pain and vasovagal reactions [6–7]. Sonographic alternatives have therefore been developed to reduce patient discomfort and avoid radiation exposure. Hysterosalpingo-contrast sonography (HyCoSy) uses saline or an echogenic contrast medium under transvaginal ultrasound guidance, while hysterosalpingo-foam sonography (HyFoSy), first described by Emanuel and Exalto, and uses a purpose-designed gel foam (ExEm® gel) that produces a stable, highly echogenic medium allowing clear visualization of the uterine cavity and tubal lumen [7–8]. Since its introduction, HyFoSy has been evaluated in numerous observational studies and randomized trials and has consistently shown good diagnostic concordance with HSG and laparoscopy, together with a more favorable pain profile, making it an increasingly preferred first-line, office-based test for tubal patency in women with a low pretest risk of tubal disease [4, 7–11]. Multiple systematic reviews and meta-analyses have confirmed that HyFoSy performs at least as well as HyCoSy and is broadly comparable to HSG for detection of tubal occlusion, while offering the added advantage of same-session assessment of uterine cavity morphology [4, 8–10, 13]. Beyond diagnostic accuracy, the technical conduct of sono-HSG/HyFoSy — including the type of catheter used to access the endometrial cavity — can meaningfully affect the patient experience and the efficiency of the procedure. Two broad catheter categories are commonly used: balloon catheters (such as the Foley's catheter), which require inflation of a balloon within the cavity or cervical canal to secure the catheter and prevent reflux of contrast, and non-balloon catheters (such as embryo transfer catheters), which rely on catheter design and, in some

products, an internal metal-reinforced stylet to facilitate insertion and maintain position without balloon inflation [14]. Prior comparative work in the related context of conventional HSG has shown that catheter type and technique influence both the pain experienced during insertion and the time required to complete cannulation; balloon catheters have been reported to reduce pain during contrast injection but to increase post-procedural cramping compared with rigid cannulas, while catheter placement site (cervical versus intrauterine) has been shown to affect both the volume of saline required and, in some series, the degree of discomfort [15-20]. However, comparatively little data specifically addresses how catheter type affects the time needed for cannulation and for completion of the sono-HSG/HyFoSy examination itself, despite the practical relevance of procedure duration to patient throughput and tolerability in a busy outpatient fertility clinic [21-22]. Given this gap, the present study aimed to compare catheter insertion time and total procedure time between a Foley's catheter and an embryo transfer (Labotect) catheter in women undergoing sono-HSG with foam instillation (HyFoSy), in order to inform catheter selection where procedural efficiency is a relevant consideration.

Materials and Methods

Study design and setting

This randomized clinical trial was conducted in the Department of Obstetrics and Gynecology, Cairo University Hospital, Egypt, between August 2023 and July 2024. The study protocol was approved by the institutional Research Ethics Committee, and written informed consent was obtained from all participants.

Participants

A total of 150 women presenting to the gynecology outpatient clinic for hysterosalpingography were enrolled. Inclusion criteria were age 18–42 years; primary or secondary infertility; suspected uterine pathology (fibroids, congenital anomalies, intrauterine adhesions, polyps); recurrent pregnancy loss or recurrent implantation failure; and suspected tubal pathology (hydrosalpinx, previous pelvic surgery, and endometriosis). Exclusion criteria were undiagnosed vaginal bleeding, active menstruation, pregnancy, allergy to lignocaine, and genital tract infection.

Randomization

Participants were allocated using block randomization into 15 blocks of 10 participants each, assigned in chronological order of presentation on the day of testing. The allocation was concealed from participants.

Interventions

Group A underwent sono-HSG with foam instillation (HyFoSy) using a 5–7 French Foley's catheter. The catheter balloon was inflated with 1–2 mL of saline, and a standard transvaginal ultrasound probe was inserted alongside the catheter. Warm sterile saline was instilled into the endometrial cavity via a 20 mL syringe while the transducer was moved from cornua to cornua in a long-axis plane, with the volume instilled titrated to uterine distension and patient tolerance.

After cavity visualization, hysterosalpingo-foam sonography was performed using 16 mL of normal saline mixed with 4 mL of 2% lignocaine gel to visualize the fallopian tubes.

Group B underwent the same sono-HSG/HyFoSy technique, substituting a Labotect (Labor-Technik-Göttingen) embryo transfer catheter for the Foley's catheter.

Outcome measures

For this report, the two outcomes analyzed were:

- (1) Time of catheter insertion, defined as the time from initiation of cannulation to successful placement of the catheter within the endometrial cavity, measured in minutes;
- (2) Total procedure time, defined as the time from catheter insertion to completion of the sono-HSG/HyFoSy examination, measured in minutes.

Sample size

Sample size was calculated using PASS software, with alpha set at 5% and power at 80%, based on data from a previous study. The minimum required sample size was 132 participants; this was increased by 11% to account for possible dropout, yielding a final target of 150 participants.

Statistical analysis

Statistical analysis was performed using SPSS version 27. Categorical variables were expressed as counts and percentages and compared between groups using the chi-square test. Continuous variables were expressed as mean $\pm$ standard deviation (minimum, maximum) and compared between groups using the Mann-Whitney U test. A p value <0.05 was considered statistically significant.

Results

Between August 2023 and July 2024, a total of 150 women meeting the eligibility criteria were enrolled and randomized by block randomization, in a 1:1 ratio, to Group A (Foley's catheter, n=75) or Group B (embryo transfer catheter, n=75). All 150 randomized participants underwent the procedure as allocated and were included in the final analysis, with no dropouts or exclusions after randomization (Figure 1).

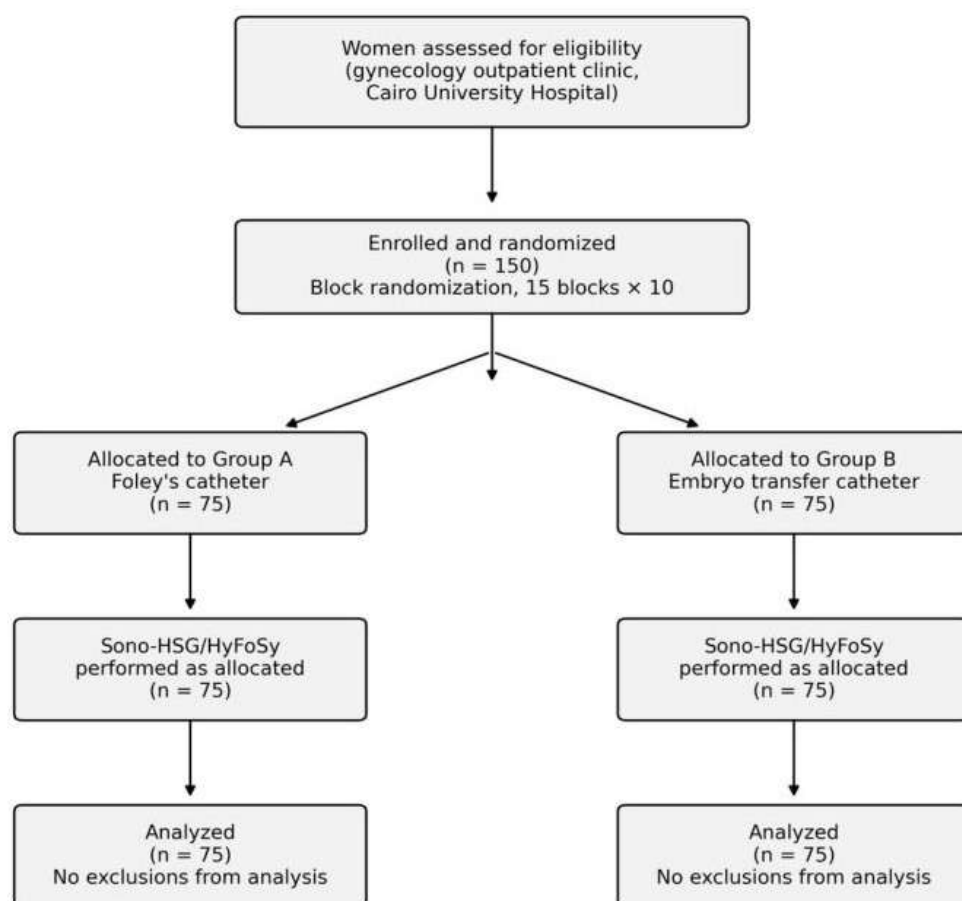


Figure 1: Enrollment, randomization, and analysis flow of study participants

The two groups were well matched at baseline, with no statistically significant differences in age, gravidity, parity, or history of previous surgery (Table 1), supporting the comparability of the two groups for the outcomes examined.

Table 1: Baseline characteristics of the study groups

Variable	Group A (Foley catheter) n=75	Group B (Embryo transfer catheter) n=75	P value
Age (years)	31.7±5.4	31.8±5.5	0.998
Gravidity	1.5±1.5	1.3±1.5	0.360
Parity	0.7±0.8	0.5±0.7	0.179
Previous surgeries	1.3±1.0	0.9±1.0	0.101

Catheter insertion time was significantly shorter in Group B than in Group A (4.4±3.0 vs. 5.3±2.9 minutes, $p=0.047$). Total procedure time was also significantly shorter in Group B than in Group A (14.6±5.0 vs. 16.6±5.6 minutes, $p=0.026$) (Table 2).

Table 2: Catheter insertion time and total procedure time by study group

Outcome	Group A (Foley catheter)	Group B (Embryo transfer catheter)	P value
Time of catheter insertion (min), mean ± SD (range)	5.3±2.9 (2–10)	4.4±3.0 (2–10)	0.047
Total procedure time (min), mean ± SD (range)	16.6±5.6 (10–30)	14.6±5.0 (10–30)	0.026

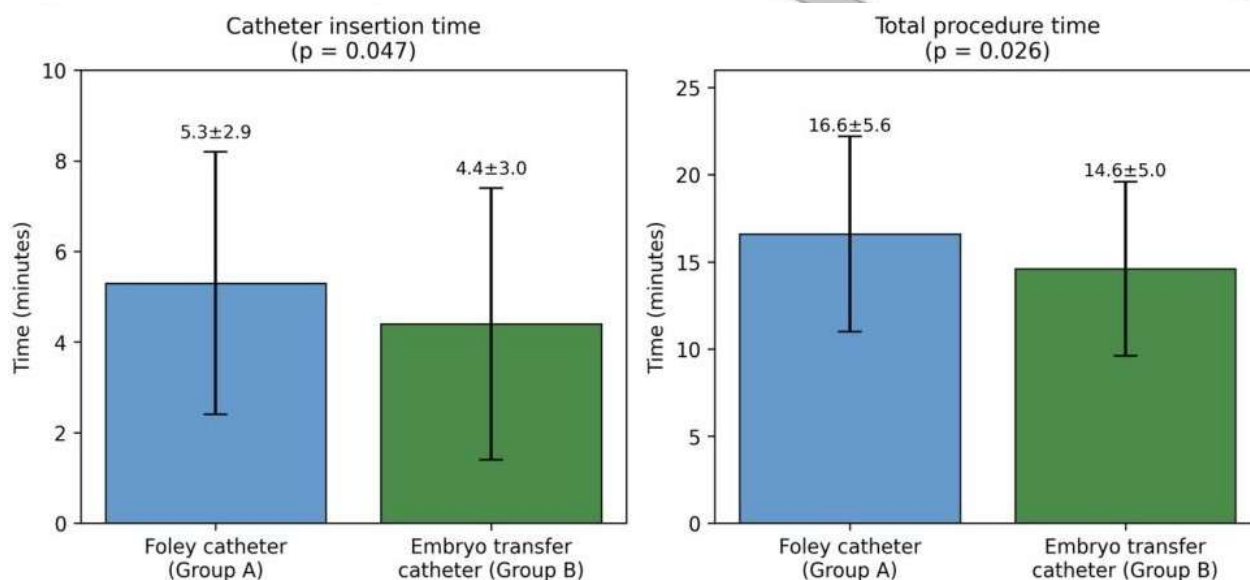


Figure 2: Mean catheter insertion time and total procedure time by catheter type, with error bars representing one standard deviation.

Overall, both time-based outcomes measured in this study — catheter insertion time and total procedure time — favored the embryo transfer catheter over the Foley's catheter, with the difference reaching statistical significance for both endpoints.

Discussion

In this randomized comparison of two catheter types used for sono-HSG with foam instillation (HyFoSy), use of an embryo transfer catheter was associated with a significantly shorter catheter insertion time and a significantly shorter total procedure time compared with a Foley's catheter. These findings add practical, procedure-efficiency data to a growing body of literature establishing HyFoSy as a safe, well-tolerated, and diagnostically accurate office-based alternative to conventional hysterosalpingography for tubal patency assessment [4-11]. The mechanism underlying the observed time difference is likely related to differences in catheter design rather than to the sono-HSG/HyFoSy technique itself, which was otherwise identical between groups. Both catheters used in this study have a comparable outer caliber; the principal functional difference lies in catheter rigidity and the mechanism of intrauterine fixation. The embryo transfer catheter used in this study incorporates a firmer, metal-reinforced inner shaft that eases passage through the internal cervical os and reduces the need for adjunctive instrumentation, such as a tenaculum, to stabilize the cervix during insertion [13, 21]. In contrast, the Foley's catheter is softer and more flexible, which can make initial cannulation less predictable, and additionally requires an extra procedural step — inflation of the retention balloon with saline — to secure the catheter tip within the cavity before contrast instillation can begin [19-20]. Together, these design differences offer a plausible technical explanation for the shorter insertion and total procedure times observed with the embryo transfer catheter in the present study. These results are consistent with, and extend, earlier comparative work on catheter type in related transcervical procedures. In hysterosalpingography, de Mello et al. and Varpula both reported that flexible balloon catheters altered the pain and cramping profile of the procedure relative to rigid metal cannulas, with balloon catheters producing less pain during instrumentation but more pain after the procedure, reflecting a trade-off between catheter rigidity, insertion mechanics, and patient comfort rather than a uniform advantage for either design [16-17]. Similarly, in the context of saline infusion sonohysterography, Alborzi et al. and later Vitagliano et al. examined how the site and technique of balloon catheter placement affected pain and the volume of saline required, without identifying a consistent time-based advantage for one balloon position over another, suggesting that the specific device and stabilization mechanism — rather than balloon presence alone — may be the more relevant determinant of procedural efficiency [19-20]. Our findings build on this literature by directly comparing a balloon catheter (Foley's) against a non-balloon, rigid-shafted catheter (embryo transfer catheter) with respect to insertion and total procedure time specifically, an outcome that has received comparatively limited direct attention in the sono-HSG/HyFoSy literature to date [21-22].

The clinical relevance of these findings lies primarily in procedural efficiency rather than diagnostic performance, which was not evaluated in this analysis. HyFoSy is increasingly used as a first-line, office-based tubal patency test precisely because it avoids the resource burden, radiation exposure, and discomfort associated with conventional HSG, and can be performed by the treating gynecologist within a routine outpatient visit [5-6, 13, 22]. In this setting, even modest reductions in insertion and total procedure time — on the order of one and two minutes, respectively, as observed

here — may meaningfully improve clinic throughput over the course of a busy fertility workup schedule, and may also translate into a shorter duration of instrumentation and cervical manipulation for the patient, which could plausibly reduce cumulative discomfort, although pain outcomes were outside the scope of this report. Catheter selection in clinical practice is nonetheless likely to be influenced by multiple factors beyond procedure time alone, including catheter cost and availability, operator familiarity and preference, and case-specific technical considerations such as cervical stenosis or a markedly anteverted or retroverted uterus, where balloon fixation may offer practical advantages [13, 21]. The present findings should therefore be interpreted as one relevant input — favoring the embryo transfer catheter on procedural efficiency grounds — to be weighed alongside these other considerations rather than as a categorical recommendation for one catheter type over the other.

Strengths and limitations

Strengths of this study include its randomized design, a sample size derived from an a priori power calculation, consistent baseline characteristics between groups, and conduct within a single center by the same group of operators, which minimized inter-operator variability as a potential confounder of procedure timing. Several limitations should also be acknowledged. First, only two catheter types were compared, and the results may not generalize to other balloon or non-balloon catheter designs. Second, blinding of the operator to catheter type was not feasible given the visibly different devices, which could theoretically influence timing through unconscious variation in technique, although the same standardized technique was intended for both groups. Third, the single-center design and the fact that all procedures were performed by a limited group of experienced operators may limit generalizability to less experienced operators or other clinical settings. Finally, this report focuses specifically on catheter insertion time and total procedure time; other outcomes collected as part of the parent study, such as pain perception, were not analyzed here and are outside the scope of this report.

Conclusion

Among women undergoing sono-HSG with foam instillation (HyFoSy), use of an embryo transfer catheter was associated with a significantly shorter catheter insertion time and a significantly shorter total procedure time compared with a Foley's catheter. These findings suggest that catheter design meaningfully affects the procedural efficiency of sono-HSG/HyFoSy and may inform catheter selection when minimizing procedure duration is a priority in busy outpatient fertility practice, though confirmation in larger, multicenter studies is warranted.

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