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Original Article

A novel disposable intrauterine infusion catheter reduces pain and shortens procedure time compared to a conventional balloon-tipped catheter in sonohysterography: a retrospective cohort study

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Abstract: Objective: To compare pain scores and complication rates between a novel disposable intrauterine infusion catheter (Yikai Medical) and a conventional balloon-tipped 12F double-lumen catheter during hysterosalpingo-contrast sonography (HyCoSy). Methods: This single-center retrospective cohort study included 128 infertile women who underwent HyCoSy between January 2022 and June 2023. Patients were divided into observation group (disposable catheter, n = 64) and control group (balloon catheter, n = 64). Primary outcomes were Visual Analog Scale (VAS) pain scores (intraoperative, 30 min, 2 h postoperative) and complication rates. Secondary outcomes included procedure time and imaging success rate. Multivariate logistic regression was used to identify independent predictors of pain. Results: Baseline characteristics were generally comparable between the groups, although patients in the observation group were slightly younger (P = 0.041). VAS scores were significantly lower in the observation group at all time points (all P<0.001). Overall complication rate was lower in the observation group (15.6% vs. 29.7%) but not statistically significant (P = 0.091). Procedure time was shorter in the observation group (8.28 ± 1.44 vs. 10.49 ± 2.32 min, P<0.001). Imaging success was similar (100% vs. 98.4%, P = 1.000). Catheter type was an independent predictor of moderate-to-severe pain (OR = 0.115, 95% CI 0.050-0.267, P<0.001). Conclusion: The disposable intrauterine infusion catheter significantly reduces pain and procedure time during HyCoSy compared to the conventional balloon-tipped catheter, with comparable imaging success and a trend toward fewer complications.

Keywords: Hysterosalpingo-contrast sonography, pain, complications, catheter, retrospective study

Introduction

Hysterosalpingo-contrast sonography (HyCoSy) is a non-invasive imaging modality that assesses fallopian tube patency by instilling an ultrasound contrast agent into the uterine cavity and dynamically observing its flow through the tubes in real time [1]. Compared with traditional X-ray hysterosalpingography using iodinated oil, HyCoSy offers advantages such as the absence of ionizing radiation, relative procedural simplicity, and good reproducibility [2]. It has thus been widely adopted for the initial assessment of tubal function in infertile patients and is currently considered one of the first-line clinical diagnostic modalities [3].

In HyCoSy, the catheter is essential for effective contrast delivery, and its design significantly affects procedural workflow, patient experience, and complication rates [4]. Currently, the most commonly used device in clinical practice is the conventional balloon-tipped 12F double-lumen catheter [5]. This catheter is fixed at the internal cervical os via balloon inflation to prevent contrast leakage and ensure adequate intrauterine pressure for imaging [6, 7]. However, the process of balloon inflation itself exerts mechanical dilation and pressure stimulation on the internal os and lower uterine segment [8]. This often triggers significant lower abdominal distension and colicky pain; in some cases, patients are even forced to discontinue

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the examination due to pain intolerance. Furthermore, mechanical friction between the balloon and the cervical mucosa may lead to mucosal injury and prolonged vaginal bleeding postoperatively [9, 10]. Although less frequent, complications such as balloon rupture and vasovagal reflex also occur sporadically. Collectively, these factors adversely affect the patient experience and postoperative recovery.

In recent years, driven by advancements in material science and device engineering, a novel single-use intrauterine infusion and hysterosalpingography catheter (e.g., produced by Yikai Medical) has been introduced into clinical practice [11, 12]. This catheter eliminates the balloon design and instead optimizes the flexibility of the catheter body and the morphology of the tip [13]. The aim is to maintain effective contrast infusion while reducing mechanical irritation to the cervix and uterine cavity [14, 15]. Theoretically, this balloon-free design is expected to lower the risk of procedure-related pain and complications. However, high-quality evidence supporting its clinical superiority remains relatively limited, particularly regarding systematic comparative data - either retrospective or prospective - against traditional catheters.

Pain management is a key factor affecting patient tolerance and compliance with HyCoSy. Pain not only imposes physiological and psychological burdens but may also compromise image quality and diagnostic accuracy due to patient movement or tension [16, 17]. Therefore, selecting a catheter that ensures imaging success while enhancing patient comfort is of clear clinical significance. Simultaneously, reducing procedure-related complications is a crucial factor in improving medical safety and patient satisfaction [18-20].

Based on the background outlined above, this study aims to systematically compare the clinical performance of the single-use intrauterine infusion catheter and the conventional balloon-tipped 12F double-lumen catheter in HyCoSy through a retrospective cohort study. We focus specifically on analyzing differences in procedure-related pain scores (intraoperative and short-term postoperative) and complication rates between the two groups, with the goal of providing evidence-based guidance for the rational selection of catheters in clinical practice. We hypothesize that, compared with the traditional balloon catheter, the single-use intrauterine infusion catheter will significantly alleviate patient pain and reduce the incidence of related complications.

Materials and methods

Study design

This was a single-center, retrospective cohort study designed to compare the clinical performance of a single-use intrauterine infusion catheter with that of the conventional balloon-tipped 12F double-lumen catheter in hysterosalpingo-contrast sonography (HyCoSy). The study protocol was reviewed and approved by the Ethics Committee of Jingmen Hospital of Traditional Chinese Medicine. All data were extracted from previously collected clinical records and anonymized to protect patient privacy. All procedures involving human participants were conducted in accordance with the ethical standards of the Declaration of Helsinki (as revised in 2013).

Study participants

Clinical data of infertile patients who underwent HyCoSy at the Reproductive Medicine Center of our hospital between January 2022 and June 2023 were retrospectively collected via the hospital's electronic medical record system. All participants met the following inclusion criteria: (1) age between 20 and 45 years; (2) diagnosis of infertility; (3) regular menstrual cycles (28-35 days); and (4) no history of uterine cavity procedures within 3 months prior to the examination. The following exclusion criteria were applied: (1) severe dysfunction of the heart, liver, or kidneys; (2) known allergy to ultrasound contrast agents; (3) coagulation disorders; (4) acute genital tract infections, such as acute pelvic inflammatory disease or vaginitis, at the time of examination; or (5) confirmed intrauterine pregnancy at the time of examination. Ultimately, all cases included in the analysis possessed complete clinical records.

Sample size description

This study employed a retrospective cohort design; therefore, no prospective sample size calculation was performed. Through systematic

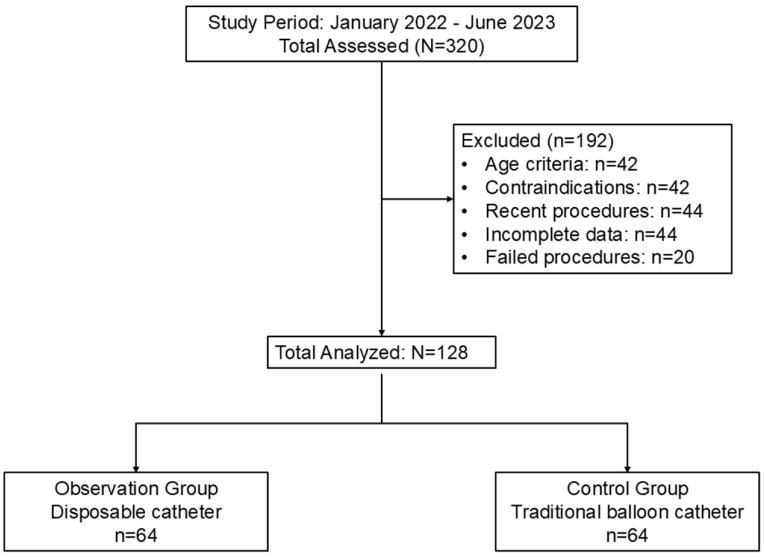

Figure 1. Patient screening flowchart.

screening of medical records, a total of 128 patients who met the eligibility criteria were identified. These patients were naturally divided into an observation group and a control group based on the actual catheter type used, with 64 patients in each group. This sample size is consistent with the typical scale for comparative studies involving two independent groups. Furthermore, referencing previous similar studies and pilot data, this cohort possesses sufficient statistical power to detect intergroup differences in the primary outcome (pain score) (**Figure 1**).

Grouping and catheter types

Patients were divided into two groups according to the type of catheter used: Observation group: A single-use intrauterine infusion and hysterosalpingography catheter (Yikai Medical, Model: GK-3.5, Specification: 3.5Fr, Length: 35 cm) was utilized.

Control group: A traditional balloon-tipped 12F double-lumen catheter (Cook Medical, Model: J-ASSC-155000, Specification: 12Fr, Balloon capacity: 1.5-3.0 mL) was utilized.

Examination equipment and contrast procedure

All examinations were performed using standardized equipment and protocols: Ultrasound equipment: GE Voluson E8 ultrasound system equipped with a RIC5-9-D transvaginal 3D volumetric probe. Contrast agent: SonoVue (Bracco, Italy), prepared as a suspension according to the manufacturer's instructions. Perfusion system: ACIST CVi power injector, set at a constant flow rate of 3-5 mL/min. Operators: All examinations were performed by the same team of physicians with over 5 years of experience in HyCoSy procedures.

The examination procedure consisted of the following steps: The patient was placed in the lithotomy position, followed by routine disinfection and draping. Catheter insertion under ultrasound guidance (In the observation group, the balloon was not inflated; in the control group, the balloon was inflated with 1.5-2.0 mL of normal saline). Infusion of the contrast suspension (5 mL SonoVue + 15 mL normal saline) through the catheter. Real-time ultrasound monitoring of the flow of the contrast agent within the uterine cavity and fallopian tubes. Catheter removal after the examination; patients were discharged after 30 minutes of observation with no adverse events.

Outcome measures and data extraction

The following information was extracted from the medical records: Primary outcome measures: Pain score: Assessed using the Visual Analog Scale (VAS, 0-10), recorded at three time points - immediately during the procedure, 30 minutes post-procedure, and 2 hours post-procedure. Complications: Including abdominal pain (>2 hours duration), vaginal bleeding (>3 days duration), infection (body temperature >38°C), vasovagal reaction, and uterine perforation.

Secondary outcome measures: Procedure time: Duration from catheter insertion to the end of imaging. Imaging success rate: Clear visualization of bilateral fallopian tubes; first-attempt catheterization success rate. Contrast reflux: Incidence of contrast agent reflux.

Table 1. Baseline characteristics

Variable	Observation Group (n = 64)	Control Group (n = 64)	t/χ^2	*P* value
Age (years)	29.36 ± 3.74	30.73 ± 3.78	-2.069	0.041
Duration of infertility (years)	3.27 ± 1.67	3.59 ± 2.16	-0.933	0.353
Primary infertility (n, %)	29 (45.3%)	32 (50.0%)	0.125	0.723
History of pelvic surgery (n, %)	21 (32.8%)	21 (32.8%)	0.000	1.000
Uterus position (n, %)			0.144	0.931
Anterior	32 (50.0%)	30 (46.9%)		
Middle	24 (37.5%)	25 (39.1%)		
Posterior	8 (12.5%)	9 (14.1%)		

Statistical analysis

All statistical analyses were performed using SPSS software (version 26.0). Continuous variables were tested for normality using the Shapiro-Wilk test. Normally distributed data were presented as mean ± standard deviation (SD) and were compared between groups using the independent samples t-test. Non-normally distributed data were presented as median (interquartile range) and were compared using the Mann-Whitney U test. Categorical variables were expressed as number (percentage) and were compared using the chi-square test or Fisher's exact test when the expected frequency was <5. To identify independent factors influencing intraoperative pain, multivariate logistic regression analysis was performed. The dependent variable was the occurrence of moderate-to-severe pain (Visual Analog Scale [VAS] ≥4), and the independent variables included catheter type (observation vs. control), age, duration of infertility, and history of pelvic surgery. Odds ratios (OR) and their 95% confidence intervals (CI) were calculated. The Hosmer-Lemeshow test was used to assess the goodness-of-fit of the model. Furthermore, to describe the trend of pain scores over time, repeated measures analysis of variance (ANOVA) was conducted to compare VAS scores at the three time points (intraoperative, 30 minutes postoperative, and 2 hours postoperative) between the two groups, and a trend graph was plotted. All hypothesis tests were two-sided, and a *P*-value <0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 128 patients were included in this study, with 64 assigned to the observation group and 64 to the control group. There were no statistically significant differences between the two groups in terms of duration of infertility, proportion of primary infertility, history of pelvic surgery, or uterine position (all *P*>0.05), indicating good baseline comparability. The only significant difference was in mean age: patients in the observation group (29.36 ± 3.74 years) were slightly younger than those in the control group (30.73 ± 3.78 years; t = -2.069, P = 0.041). Detailed baseline characteristics are presented in **Table 1**.

Procedure-related outcomes

The mean procedural time was significantly shorter in the observation group (8.28 ± 1.44 minutes) compared with the control group (10.49 ± 2.32 minutes; t = -6.454, P<0.001) (**Figure 2**). The first-attempt catheter insertion success rate was 100% in both groups. Imaging success rates were 100.0% (64/64) in the observation group and 98.4% (63/64) in the control group, with no statistically significant difference (χ^2 = 0.000, P = 1.000) (**Table 2**).

Comparison of pain scores

Pain scores assessed by the Visual Analog Scale (VAS) were significantly lower in the observation group than those in the control group at all three time points - intraoperatively, 30 minutes post-procedure, and 2 hours post-procedure (all *P*<0.001) (**Figure 3**). Specifically, VAS scores in the observation group were 2.92 ± 1.03, 1.78 ± 0.83, and 0.89 ± 0.56, respectively, compared with 4.63 ± 1.57, 3.27 ± 1.25, and 1.69 ± 0.86 in the control group. The trend analysis of pain scores over time demonstrated more rapid and pronounced pain relief in the observation group (**Figure 4**).

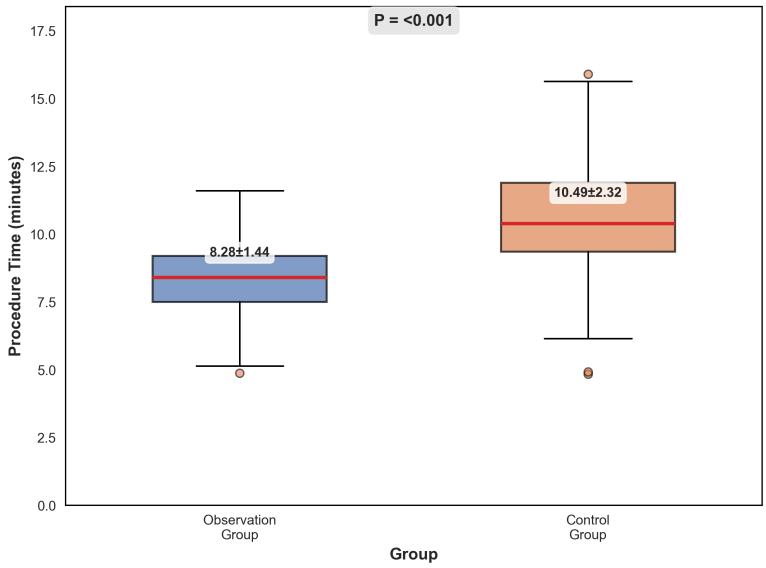

Figure 2. Procedure time comparison.

Table 2. Procedure-related outcomes

Variable	Observation Group (n = 64)	Control Group (n = 64)	t/χ^2	*P* value
Procedure time (min)	8.28 ± 1.44	10.49 ± 2.32	-6.454	<0.001
Successful imaging (n, %)	64 (100.0%)	63 (98.4%)	0.000	1.000

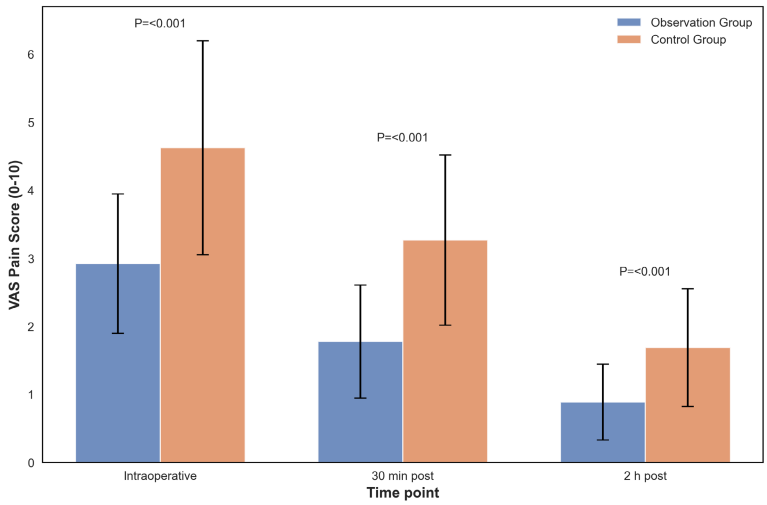

Figure 3. Pain scores at different time points. VAS, Visual Analog Scale.

Comparison of complication rates

The overall complication rate was 15.6% (10/64) in the observation group, compared with 29.7% (19/64) in the control group; however, this difference did not reach statistical significance (χ^2 = 2.853, *P* = 0.091). Regarding specific complications, the incidence of abdominal pain (>2 hours) (7.8% vs. 17.2%) and prolonged vaginal bleeding (>3 days) (4.7% vs. 9.4%) was lower in the observation group, but neither difference was statistically significant (abdominal pain: χ^2 = 1.786, *P* = 0.181; vaginal bleeding: Fisher's exact test, *P* = 0.492). Rates of infection, vasovagal reactions, and uterine perforation were low in both groups and showed no statistically significant differences (**Table 3**).

Multivariate regression analysis of factors associated with pain

Multivariate logistic regression analysis revealed that, after adjusting for age, duration of infertility, and history of pelvic surgery, catheter type was an independent predictor of moderate-to-severe intraoperative pain (defined as VAS ≥4). Patients in the observation group (using the single-use intrauterine infusion catheter) had a significantly lower risk of moderate-to-severe pain compared with those in the control group (using the traditional balloon-tipped double-lumen catheter) (β = -2.163, OR = 0.115, 95% CI: 0.050-0.267, *P*< 0.001). In contrast, age, duration of infertility, and pelvic surgery history were not significantly associated with pain scores (**Table 4**).

Discussion

This study employed a retrospective cohort design to systematically compare the clinical performance of a novel single-use intrauterine infusion catheter with that of the conventional balloon-tipped double-lumen catheter in hysterosalpingo-contrast sonography (HyCoSy). The main findings can be summarized as fol-

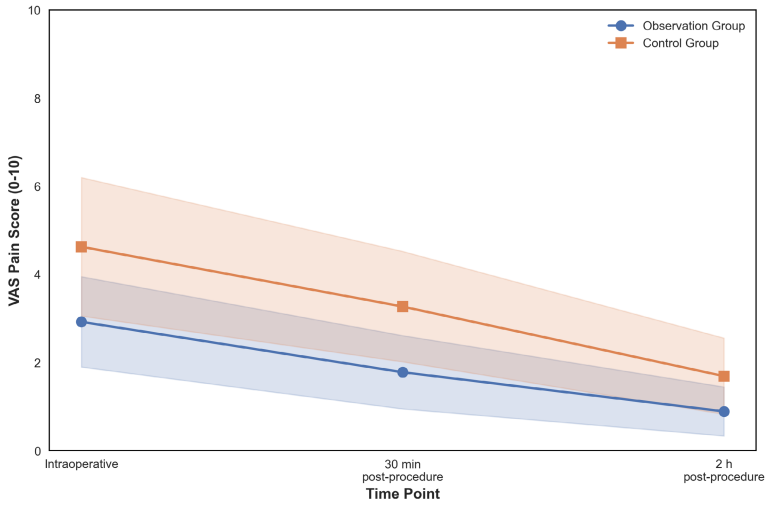

Figure 4. Pain score changes over time. VAS, Visual Analog Scale.

lows: compared with the traditional balloon catheter, the use of the single-use intrauterine infusion catheter significantly reduced pain scores during and shortly after the procedure, shortened procedural time, and showed a trend toward lower overall complication rates while maintaining comparable imaging success.

In our study, VAS scores in the observation group were significantly lower than those in the control group at all three time points - intraoperatively, 30 minutes post-procedure, and 2 hours post-procedure - consistent with our hypothesis and suggesting a clear advantage of the balloon-free design in alleviating patient discomfort. This benefit may be explained by multiple mechanisms. First, from a mechanical perspective, the conventional catheter relies on balloon inflation (typically with 1.5-3.0 mL of saline) to anchor at the internal cervical os, which directly exerts traction and compression on the densely innervated cervical tissue, often triggering spastic pain [21]. Second, from a hydrodynamic standpoint, the presence of the balloon may distort normal uterine cavity morphology, leading to uneven contrast flow and localized pressure elevation, thereby exacerbating pain perception [22]. Notably, vagal reactions occurred in 3.1% of patients in the control group but were absent in the observation group, further supporting the hypothesis that balloon-induced stimulation may activate pelvic autonomic reflexes [23]. Moreover, multivariate logistic regression confirmed catheter type as an independent predictor of moderate-to-severe pain (OR = 0.115, $P<0.001$), underscoring the pivotal role of catheter design in pain management [24].

Although the difference in overall complication rates between the two groups (15.6% in the observation group vs. 29.7% in the control group) did not reach statistical significance ($P = 0.091$), the observation group showed consistently lower incidences of common complications - specifically abdominal pain (7.8% vs. 17.2%) and prolonged vaginal bleeding (>3 days; 4.7% vs. 9.4%). This trend is likely attributable to the balloon-free design, which avoids mechanical friction against the cervical mucosa and excessive stimulation of the myometrium [25]. Regarding procedural efficiency, the mean operation time in the observation group was approximately 2.2 minutes shorter than that in the control group, primarily due to the elimination of balloon inflation and deflation steps, thereby streamlining the workflow. This reduction not only enhances clinical throughput but may also indirectly improve patient experience by minimizing exposure time to anxiety and discomfort [26].

Our findings align with existing literature demonstrating the advantages of non-balloon catheters. For instance, Xu et al. [27] demonstrated in a prospective study that non-balloon catheters significantly reduced pain during intrauterine procedures. A small-sample domestic study also suggested a similar trend [28]. The contribution of our study lies in providing more robust retrospective evidence through a larger sample size (n = 64 per group), systematic multi-timepoint pain assessments, and comprehensive documentation of various complications. Although the overall complication rate was lower in the observation group, the difference did not reach statistical significance, possibly due to insufficient sample size to detect rare events (Type II error). Future prospective studies with larger cohorts are warranted to confirm these trends.

Strengths of this study include the use of standardized procedural protocols to minimize

Table 3. Complication rates

Complication	Observation Group (n, %)	Control Group (n, %)	χ^2	*P* value
Abdominal pain	5 (7.8%)	11 (17.2%)	1.786	0.181
Vaginal bleeding >3 days	3 (4.7%)	6 (9.4%)	-	0.492*
Infection	2 (3.1%)	1 (1.6%)	-	1.000*
Vagal response	0 (0.0%)	2 (3.1%)	-	0.496*
Uterine perforation	0 (0.0%)	1 (1.6%)	-	1.000*
Total complications	10 (15.6%)	19 (29.7%)	2.853	0.091

* indicates the use of Fisher's exact test.

Table 4. Multivariate logistic regression analysis

Variable	β coefficient	Odds ratio (95% CI)	*P* value
Catheter type (Observation vs. Control)	-2.163	0.115 (0.050-0.267)	<0.001
Age	0.074	1.077 (0.963-1.204)	0.196
Duration of infertility	0.015	1.015 (0.819-1.257)	0.893
History of pelvic surgery	0.256	1.291 (0.529-3.150)	0.574
Constant	-1.742	0.175 (0.006-5.540)	0.323

operator bias, multivariate adjustment for potential confounders such as age and duration of infertility, and dynamic evaluation of pain over time. Nevertheless, inherent limitations of a retrospective design must be acknowledged. First, despite statistical adjustments, residual confounding or selection bias cannot be entirely ruled out. Second, data were derived from a single center, potentially limiting generalizability. Third, pain assessment relied solely on subjective VAS scores; future studies could incorporate objective physiological indicators (e.g., heart rate variability) for validation [8]. Finally, long-term outcomes (e.g., subsequent pregnancy rates) and health economic analyses were not evaluated.

Based on our findings, we propose that the single-use intrauterine infusion catheter represents a valuable tool for optimizing the HyCoSy experience - particularly beneficial for patients with heightened pain sensitivity, those with special cervical conditions (e.g., stenosis or incompetence), or high-volume outpatient settings where procedural efficiency is critical [29]. Looking ahead, we recommend conducting multicenter, prospective, randomized controlled trials to generate higher-level evidence and further explore the utility of this catheter in specific populations (e.g., patients with uterine malformations) and its long-term clinical impact.

Conclusion

In summary, in hysterosalpingo-contrast sonography (HyCoSy), the use of a single-use intrauterine infusion catheter, compared with the traditional balloon-tipped double-lumen catheter, significantly reduces patient pain, improves procedural efficiency, and maintains high imaging success rates with a favorable safety profile. This approach offers a new evidence-based option for enhancing patient comfort and optimizing clinical workflows in routine practice.

Disclosure of conflict of interest

None.

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