Original Article Application of the new hydrotubation appliance in hysterosalpingography

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Abstract: Objective: To explore the advantages and safety of the new hydrotubation appliance applied for hysterosalpingography (HSG) in infertile women. Methods: A total of 101 infertile women who scheduled to receive HSG were randomly divided into the experimental group (n=51) and the control group (n=50). Patients in the two groups underwent HSG using the new hydrotubation appliance and a balloon catheter, respectively. The quality, results and time of HSG, the Visual Analogue Scale (VAS) score, the patient's satisfaction degree and the incidence rate of adverse reactions were compared between the two groups, respectively. Results: Baseline data of the two groups of patients were similar. There was no statistically significant difference in the quality of HSG between the two groups (P=0.5476). The two methods had no obvious difference in the test results (P=0.4668), but the operating time in the experimental group was significantly shorter than that in the control group (P<0.0001). Besides, the VAS score in the experimental group obviously decreased during examination (P=0.0002), but there was no significant difference between the two groups in the follow-up at 3 h after surgery (P=0.2300). The patient's satisfaction degree in the experimental group was overtly higher than that in the control group (P<0.0001). As for complications, the incidence rates of lower abdominal pain (P=0.0124), pale complexion (P=0.0267), accelerated heartbeats (P=0.0332) and decreased blood pressure of patients in the experimental group obviously declined (P=0.0009). Conclusion: The new hydrotubation appliance in the diagnosis of infertility by HSG significantly reduced the operating time and relieved the patient's pain with a high satisfaction degree of patients in addition to assuring the accuracy, so it is worthy of clinical promotion.

Keywords: New hydrotubation appliance, hysterosalpingography, infertility, pain relief

Introduction

In recent years, the incidence rate of infertility has gradually increased, currently accounting for about 15-18% of the population at the gestational age [1, 2]. A number of factors such as the fallopian tube factor, ovulation failure and the uterus factor result in female infertility [3-5]. Among them, the fallopian tube factor, taking up about 30-40%, is the leading factor, the most important of which is the fallopian tube jam [6, 7].

Hysterosalpingography (HSG) is the most commonly used method for the diagnosis of tubal patency, with an accuracy of as high as 90-95% [2]. The most common appliance in clinical practice is the "invasive" balloon catheter. Balloon catheters have a variety of disadvantages. For example, the cervix needs to be dilated for the entrance of balloon catheter into the uterine cavity during application, which is an invasive operation; the balloon is inflated to oppress the uterus, thus shielding the uterine morphology and potential problems to a certain extent; sometimes, the catheter head arrives at the uterine horn, which obstructs the fallopian tube opening, thus leading to the illusion of the fallopian tube jam [8, 9]. Therefore, there is an urgent need in the clinic to explore a safe and effective test appliance for HSG.

The new hydrotubation appliance is a minimally invasive new HSG appliance (**Figure 1**), and the contrast agent can be injected for HSG via the placement of the appliance outside the cervix opening through the vagina. Theoretically, the whole operation process is safe, fast and con-



Figure 1. The main view of the new hydrotubation appliance.

venient, which can reduce the patient's pain and surgeon's workload, but there is no clinical large-scale study.

This study mainly studied the advantages and safety of the new hydrotubation appliance in the diagnosis of infertility by HSG compared with those of the balloon catheter.

Materials and methods

General data

The study was approved by the Ethics Committee of Dongying People's Hospital, and all patients were informed of operative details in the preoperative visit, including the introduction of basic operation and the difference from conventional balloon catheter. And all of them signed the informed consent.

A total of 101 female patients who scheduled to receive HSG for infertility in Dongying People's Hospital from October 2016 to June 2017 were selected. Patients were divided into the control group (a balloon catheter, n=50) and the experimental group (the new hydrotubation appliance, n=51) using a random number table.

Inclusion criteria: Patients with no pregnancy for over 1 year without contraceptive measures; patients in American Society of Anesthesiologists (ASA) grade I or II; patients aged 20-45 years old; patients who had a normal menstrual cycle, and were at 3-7 days after the menstrual period.

Exclusion criteria: Patients with acute internal and external genital inflammation; patients with endocrine disorders (such as polycystic ovary syndrome, diabetes mellitus and hyperthyroidism); patients with severe systemic disease; patients intolerant to surgery; patients with positive results in the iodine allergy test; patients with sexual behavior within 5 days before surgery [10].

Methods

All operations in this experiment were performed by the same specialist. Before surgery, the specialist was trained to use the new hydrotubation appliance, and the two test methods were examined. The experiment began to be conducted after the specialist could be proficient in using the methods as required. The experimental process was strictly controlled under the aseptic condition, and all operations were smooth and easy.

The balloon catheter method was applied in the control group. Main operations were as follows. Patients were placed in the lithotomy position; routine disinfection and draping were conducted, and the bivalve speculum was used to expose the cervix, followed by disinfection of the cervix again; the balloon catheter was filled with lipiodol to exclude air in it, and then the balloon catheter was slowly placed into the uterine cavity, and 2-2.5 mL gas was infused into the balloon; after that, the catheter was slowly pulled out so as to block the inner opening of the cervix by the balloon; the bivalve speculum was removed, and the contrast agent was slowly injected through the outer orifice of the catheter, and then entered the uterine cavity through the fallopian tubes; images were collected, and the tubal patency was observed.

The new hydrotubation appliance was adopted in the experimental group. Main operations: Patients were also placed in the lithotomy position: disinfection and draping were conducted. and the bivalve speculum was used to expand the cervix, followed by disinfection of the vagina and cervix; 5-10 mL contrast agent lipiodol was extracted; a syringe was connected to the two ends of the valve of the hydrotubation appliance, and the contrast agent was pushed to the front of the cone-shaped body, so as to empty air in the cannula of the hydrotubation appliance; afterwards, the hydrotubation appliance was inserted into the external cervical orifice, and they were closely fitted; 5-10 mL contrast agent was pushed and injected, the oneway valve was closed, and then the cannula of the appliance was embedded in the fixator and fixed with fingers; after the surgeon left, HSG



began, and images were collected to observe the condition of HSG. At the end of it, the hydrotubation appliance was pulled out, the fixator was removed, and articles used were checked and timely disposed in accordance with the provisions of the hospital.

Testing indicators

The quality, results and time of HSG, the Visual Analogue Scale (VAS) score, the patient's satisfaction degree and the incidence rate of adverse reactions were compared between the two groups, respectively.

Among them, the quality of HSG was divided into four grades: excellent (contrast fluid flow in the uterine cavity and the fallopian tubes could be clearly displayed, the contrast ratio was good, and the states of the uterine cavity, fallopian tubes and fine structures could be clearly observed), good (contrast fluid flow in the uterine cavity and the fallopian tubes could be plainly demonstrated, the contrast ratio was good, and the states of the uterine cavity and fallopian tubes were clearly observed, but that of fine structures showed fuzzy), qualified (contrast fluid flow in the uterine cavity and fallopian tubes could be apparently manifested, but the states of the uterine cavity, fallopian tubes and fine structures were not clear, barely meeting the diagnostic requirements), and disqualified (contrast fluid flow in the uterine cavity and fallopian tubes were indistinct, and the uterine cavity, fallopian tubes and fine structures were

vague, so re-HSG was need-ed).

The results of HSG were divided into three levels: smooth (the resistance was relatively small during the injection of the contrast agent, and the development was rapid through the whole process, smoothly and naturally; the overflowing or spurting contrast agent was displayed in the fimbria end, and the annular hyperechoic zone could be seen around the ovary), poor pass (there was certain resistance when injecting the contrast agent, the

development of the fallopian tubes was a little slower and intermittent, and some areas were slender or nodular; the overflowing contrast agent was displayed in part areas of the fimbria end, and the semi-annular hyperechoic zone could be seen around the ovary), and blocked (there was obvious resistance when injecting the contrast agent, no fallopian tubes or part of fallopian tubes were manifested, no overflowing contrast agent was seen in the fimbria end, and no annular hyperechoic zone appeared around the ovary) [9].

VAS scoring criteria: No pain: 0 point; mild pain: 1-3 points; moderate pain: 4-6 points; severe pain: 7-10 points [11].

Statistical methods

All data were analyzed using SPSS 17.0 software. Measurement data were expressed as mean \pm standard deviation ($\overline{x} \pm$ sd), and Student's t-test was selected for independent sample as the statistical method. Count data was expressed as the number of cases and percentage (%), and chi-square test or Fisher's exact test was taken as the statistical method. Ranked data was expressed as the number of cases, and Mann-Whitney U rank-sum test was chosen as the statistical method. Since only one patient in each group failed to complete the experiment, the intention-to-treat analysis was not conducted in this study. P<0.05 represented that the difference was statistically significant.

Table 1. Baseline data

	Experimental group (n=50)	Control group (n=49)	Statistical value	Р
Age (years)	27.50±5.33	28.22±4.71	0.7158	0.4758
BMI (kg/m²)	21.54±1.77	21.22±1.51	0.9908	0.3242
ASA				
I	48	49		0.4949
Ш	2	0		
Last menstrual time (d)	5.00±1.43	4.92±1.15	0.3126	0.7552
Infertility time (years)	2.94±1.36	2.78±1.26	0.6230	0.5348
History of hysterosalpingography				
Yes	20	18	0.1116	0.7384
No	30	31		
Infertility				
Primary	37	32	0.8856	0.3467
Secondary	13	17		

Note: BMI, body mass index; ASA, American Society of Anesthesiologists.

Table 2. Comparison of the quality of hysterosalpingography be-tween the two groups

Group	Case	Excellent	Good	Qualified	Disqualified
Experimental group	50	40 (80.0%)	3 (6.0%)	5 (10.0%)	2 (4.0%)
Control group	49	41 (83.7%)	5 (10.2%)	2 (4.1%)	1 (2.0%)
Statistical value		2.122			
Р		0.5476			

Table 3. Comparison of the results of hysterosalpingography between the two groups (strip)

Group	Case	Smooth	Poor pass	Blocked
Experimental group	100	36 (36.0%)	21 (21.0%)	43 (43.0%)
Control group	98	32 (32.6%)	28 (28.6%)	38 (38.8%)
Statistical value			1.524	
Р			0.4668	

ss index (P=0.3242), ASA grade (P=0.4949), last menstrual time (P=0.7552), infertility period (P=0.5348), history of HSG (P=0.7384), and the type of infertility (P=0.3467), and the results showed that there were no significant differences (**Table 1**).

Quality of HSG

There was no significant difference between the two groups in the distribution of the four grades of the qual-

ity of HSG: excellent (40 vs. 41), good (3 vs. 5), qualified (5 vs. 2) and disqualified (2 vs. 1). The overall comparison of the quality of HSG between the two groups of patients revealed that there was no statistically significant difference (P=0.5476, Table 2).

Comparison of the results of HSG between the two groups of patients

As manifested in **Table 3**, it could be seen that there was no significant difference in the result of hysterosalpin-

Results

Comparisons of baseline data between the two groups of patients

In the initial phase of the experiment, a total of 104 patients were enrolled in the study, in which 3 patients did not meet the inclusion criteria, 1 patient (experimental group) refused to participate in the experiment in the later period, and 1 patient (control group) was unable to participate in the experiment for other reasons. Therefore, the data of a total of 99 patients was finally included in this experiment (**Figure 2**).

Baseline data of the two groups of patients was compared, including age (P=0.4758), body ma-

gography (P=0.4668). The results were smooth (36.0% vs. 32.6%), poor pass (21.0% vs. 28.6%) and blocked (43.0% vs. 38.8%).

Comparisons of the operating time and the pain score

It was surfaced that the operating time in the new hydrotubation appliance group was significantly shorter than that in the balloon catheter group (4.10 ± 0.53 min vs. 15.68 ± 2.15 min, P< 0.0001). During operations, the VAS score in the experimental group was also significantly lower than that in the control group (1.20 ± 0.88 vs. 2.08 ± 1.35 , P=0.0002, **Table 4**), but in the follow-up at 3 h after surgery, there was no significant difference in the VAS score between

0 1				
Group	Experimental group (n=50)	Control group (n=49)	Statistical value	Ρ
Operating time (min)	4.10±0.53	15.68±2.15	36.92	<0.0001*
VAS score				
Intraoperative	1.20±0.88	2.08±1.35	3.853	0.0002*
Postoperative 3 hours	1.08±0.70	1.24±0.66	1.208	0.2300
Adverse feelings of patients				
Discomfortableness	10 (20.0%)	35 (71.4%)	26.40	<0.0001*
Pain	5 (10.0%)	25 (51.0%)	19.72	<0.0001*
Liquid leakage	2 (4.0%)	5 (10.2%)	0.6592	0.4168
Overall satisfaction (%)	98.00	75.00	22.65	<0.0001*

Table 4. Comparison of operating time and overall satisfaction between the two groups

Note: VAS, Visual Analogue Scale. *P<0.001.

Table 5. Comparison of the incidence rate of adverse reactions between the two groups

Group	Experimental group (n=50)	Control group (n=49)	Statistical group	Р
Lower abdominal pain	2 (4.0%)	10 (20.4%)	6.255	0.0124**
Nausea	3 (6.0%)	5 (10.2%)		0.2909
Vomiting	0	1 (2.0%)		0.4949
Pale complexion	0	5 (8.2%)		0.0267**
Accelerated heartbeats	1 (2.0%)	8 (16.3%)	4.535	0.0332**
Decreased blood pressure	1 (2.0%)	12 (24.5%)	10.97	0.0009*
N *P .0.004 **P .0.05				

Note: *P<0.001; **P<0.05.

the two groups (1.08±0.70 vs. 1.24±0.66, P= 0.2300, **Table 4**).

Overall satisfaction degree of patients

The comparison between the two groups in **Table 4** demonstrated that the application of the new hydrotubation appliance apparently reduced the incidence rate of adverse reactions in patients, mainly manifested as discomfort (20.0% vs. 71.4%, P<0.0001), pain (10.0% vs. 51.0%, P<0.0001) and liquid leakage (4.0% vs. 10.2%, P=0.4168). Moreover, the overall satisfaction degree of patients in the experimental group was also obviously higher than that of patients in the balloon catheter group (98.0% vs. 75.0%, P<0.0001).

Comparison of the incidence rate of adverse reactions between the two groups of patients

In terms of adverse reactions, the application of the new hydrotubation appliance significantly lowered the incidence rates of lower abdominal pain (P=0.0124), pale complexion (P= 0.0267), accelerated heartbeats (P=0.0332) and decreased blood pressure (P=0.0009), but there were no significant differences in nausea (P=0.2909) and vomiting (P=0.4949) between the experimental group and the control group (Table 5).

Discussion

Due to the accumulation of factors such as work. life and the environment at this stage, the number of female patients with infertility increases year by year, and the fallopian tube jam accounts for a large proportion of them [12]. Therefore, the fallopian tube jam test method becomes very important, including ultrasonography, hydrotubation, X-ray HSG and laparoscopy, in which HSG is the most standard and widely used method [13, 14]. Currently, HSG in clinical practice is performed us-

ing the balloon catheter, but this method has many problems, so HSG experience bringing pain to patients needs urgently to be improved [15].

The new hydrotubation appliance applied in this study is a minimally invasive HSG appliance. During its operations, the cervix needs not to be expanded. The whole uterine cavity can be completely displayed only through pushing and injecting the contrast agent via the placement of the appliance outside the cervix opening through the vagina, thus achieving natural development of the fallopian tubes. Operations can be completed without entering the uterine cavity, so patients suffer from little pain.

The quality of HSG is the key to determining the success or failure of HSG. The traditional balloon catheter method generates good HSG quality, which presents a good view for the operator to observe the condition of the fallopian tube jam [16]. In the course of this experiment, there was no obvious difference between the two methods in the HSG quality, deducing

that the new hydrotubation appliance can be well applied in clinical practice in light of the HSG quality.

Another key factor affecting HSG is the accuracy of the HSG results [17]. Theoretical analysis illustrates that the balloon is inflated to oppress the uterus, thus shielding the uterine morphology and problems to a certain extent; sometimes, the catheter head arrives at the uterine horn, which obstructs the fallopian tube opening, thus leading to the illusion of the fallopian tube jam. The new hydrotubation appliance can completely display the entire uterine cavity without balloon inflation, so its diagnostic accuracy is higher than that of the balloon catheter [18]. However, in this experiment, the HSG results were comparable between the two groups of patients, which revealed that there were no statistically significant differences, so it is believed that the accuracy of the new hydrotubation appliance in HSG is higher.

The biggest advantages of the new hydrotubation appliance provided in this experiment lie in simple and safe operations, little pain suffered by patients, independent operations by the surgeon without joint implementation of gynecology and intervention departments. The operating time in the experimental group and the control group were 4.10±0.53 min and 15.68±2.15 min, respectively. The use of the new hydrotubation appliance overtly reduced the operating time and shortened the time of the entire HSG. Conventional balloon catheters have to pass through the cervix to enter the uterine cavity. especially when they are inflated by a dilator or balloon, and patients will feel severe pain and discomfort then. However, the new hydrotubation appliance has only to be connected to the external opening of the cervix with no need of deep insertion, and patients will feel no pain or even feel unconscious after operations [19]. A comparison of the VAS score between the two groups revealed that the VAS score in the experimental group was significantly lower than that in the control group. It can be concluded from the above analyses that the new hydrotubation appliance applied in HSG not only reduces the doctor's operating time, but also significantly alleviates the patient's pain, so it is a better clinical examination appliance.

In routine HSG, patients often experience various discomforts, sometimes significantly lower-

ing the quality of HSG, worsening the patient's HSG experience, reducing the degree of the patient's satisfaction with the HSG process, doctors and the hospital as a whole [20, 21]. In this experiment, adverse reactions of three kinds of patients were mainly selected, in which the incidence rates of discomfort and pain in patients in the control group were significantly higher than those in patients in the experimental group. In addition, it was just because of these adverse reactions during surgery that the overall satisfaction degree of patients in the experimental group was higher than that of patients in the control group. As such, it can be seen that the application of the new hydrotubation appliance shortens the operating time, relieves pain, further reduces adverse reactions of patients, improves the patient's overall satisfaction degree and achieves the best effect of clinical treatment.

Adverse reactions triggered by HSG are also one of a series of problems perplexing doctors. Among them, severe lower abdominal pain will suspend HSG halfway, thus leading to re-HSG, increasing the workload of doctors, and deepening the patient's pain [22]. Nausea and vomiting can lead to aspiration, which endangers the life of patients and increases the risk of HSG operations. Besides, the stable cardiovascular system during surgery is one of the main indicators for evaluating whether the surgery is successful. Pale complexation, accelerated heartbeats and decreased blood pressure all indicate that the cardiovascular system has been significantly affected, which will lead to the failure of operations, affect the patients' subjective feelings and even result in serious medical events. Therefore, reducing the occurrence of adverse reactions as much as possible is of vital importance for the successful and smooth implementation of HSG [23, 24]. In the implementation process of this experiment, the application of the new hydrotubation appliance for HSG obviously reduced the incidence rates of the lower abdominal pain, pale complexation, accelerated heartbeats and decreased blood pressure, thus ensuring the smooth implementation of the HSG process and the stability of various indicators of patients during surgery. For nausea and vomiting with originally low incidence rates, there were no significant differences between the two methods, thus reducing the risk of aspiration during operations and increasing the safety of operations.

However, this study also has some shortcomings. Firstly, the collected baseline data of patients were not detailed enough, which may affect the data analysis in the later period. Secondly, there was no long-term follow-up after patients receiving HSG, so that the longterm effects of this method on patients were not observed.

In summary, in addition to guaranteeing the quality and accuracy of HSG, the use of the new hydrotubation appliance apparently reduces the time of HSG, relieves the operator's work-load, significantly alleviates the patient's pain, reduces the adverse reactions caused by HSG, and increases the patient's overall satisfaction degree, so it is worth the promotion in clinical practice.

Disclosure of conflict of interest

None.

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