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Clinical value of fluid bolus contrast flow meter during hysterosalpingography

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ABSTRACT. The purpose of this study was to investigate the clinical value of the fluid bolus contrast flow meter during hysterosalpingography. Hysterosalpingography information of 342 cases, which included a manual handset group of 213 cases and a bolus instrument group of 129 cases were reviewed. Comparative analysis was used to compare the two groups in order to assess the clinical adverse reactions, contrast agent reflux, and image quality. In the instrument bolus group compared with the manual handset group, the clinical adverse reactions decreased from 75.12 to 31.78% ($P < 0.001$); the backflow phenomenon of the contrast agent decreased from 13.62 to 3.10% ($P < 0.01$); and image quality significantly improved, with the A class film rate increasing from 54.46 to 68.99% ($P < 0.01$) and the C class film rate decreasing from 8.92 to 2.33% ($P < 0.05$). The use of a contrast bolus through the liquid inlet of the hysterosalpingography instrument can provide fully dynamic observation, reducing the contrast agent reflux and adverse reactions as well as improving the image quality and diagnostic accuracy. In addition, the medical staff is not subjected to radiographic radiation. Therefore, it is a safe and reliable imaging method.

Key words: Hysterosalpingography; Fluid bolus contrast flow meter; Infertility; Radiation; Clinical adverse reactions; Clinical value

INTRODUCTION

Female sterility caused by tubal factors accounts for 23.7-35.7% of infertility (Shi et al., 2004), which may be induced by infection, endometriosis, pelvic surgery, trauma, etc. Hysterosalpingography (HSG) is the most common radiographic method for observing the anatomy and structure of the uterus and Fallopian tubes (Eng et al., 2007). For almost a century, it has been a classic screening method for evaluating tubal function. HSG is conducted by the doctor manually pushing the contrast agent. The dose pressure and injection rate is controlled from experience. However, the push injection has two shortcomings. Firstly, the whole dynamic observation cannot be conducted and the capture timing is not easy to control, which affects the quality of the radiographic image and the accuracy of the diagnosis. Secondly, the doctor was hurt for being exposed to a certain dose of radiographic radiation for a long period of time. In February 2013, our hospital purchased an imaging push fluid injection apparatus for HSG that has achieved good clinical results. The purpose of this study was to discuss and analyze the influence of the contrast medium counter-current, radiographic quality during HSG, and clinical adverse reactions.

MATERIAL AND METHODS

General information

From January 2011 to June 2013, 342 HSG patients at our hospital were divided into the manual handset and bolus instrument groups. There were 213 cases in the manual handset group (average age, 28.1 years), which included 91 cases of primary infertility and 122 cases of secondary infertility. This group was examined by a doctor using the direct bolus injection of contrast agent. There were 129 cases in the bolus injection device group (average age, 29.4 years), which included 57 cases of primary infertility and 72 cases of secondary infertility. We used 10-20 mL contrast agent. For this group, the doctor in the control room (no radiographic radiation zone) used the tubal treatment device instead of injecting the contrast agent by hand.

Imaging methods

We used the 500 mA Siemens XG-510A gastrointestinal machine (Siemens Co., Ltd., Germany), letter IDS-1000 digital image processing workstation systems (Shanghai Science and Technology Co., Ltd., Shanghai, China), and ZY-23-D imaging fluid bolus instrument (Kunming SanDao Medical Equipment Co., Ltd., Kunming, China). The contrast agents selected were a non-ionic contrast medium iohexol injections, 20 mL/6 g/branch (Beijing Hokuriku Pharmaceutical Co., Ltd., Beijing, China). The ZY-23-D imaging instrument was used in the fluid bolus group according to the following process: 1) surgery was performed within 3-7 days of a clear menstrual period; 2) sex was prohibited after the clean menstrual period; 3) the bladder was emptied before surgery; 4) routine gynecological examination was performed; 5) those with acute pelvic inflammatory disease, vaginitis, and other contraindications were excluded; 6) 30 min before surgery, an intramuscular injection of atropine (0.5 mg) was administered for bladder lithotomy position and after routine disinfection of the balloon catheter placement; 7) 2-3 mL gas was injected into a tube to gently pull the balloon out, allowing it to close the cervix; 8) the bolus injection devices and balloon catheters were connected and 15

mL iohexol was extracted; 9) the doctor evacuated the operation room and went to the control room. The radiologists remotely administered the bolus injection using an automatic injection of 30% iohexol contrast agent around 15 mL according to the injection pressure and patient's response to the regulated injection rate and bolus dose. The whole process was observed under fluoroscopic imaging and timely and accurate radiography; 10) timely and accurate records of the clinical response and intrauterine pressure changes were recorded; 11) shooting the pelvic diffusion film in about 25 min; 12) radiologists and the supervising physician read the complete diagnostic report and manually set the inspection process. For the bolus instrument group, the following steps were performed: 1-4) the same procedures were carried out from the manual handset group; 5) doctors wore lead aprons in the radiography room during the direct bolus injection of contrast agent and timely radiography; 6) 25 min of photographic pelvic diffusion film was recorded; and 7) a diagnostic report was written.

Statistical analysis

The chi-square test was used to analyze the data.

RESULTS

Clinical adverse reactions

Table 1 shows the manual handset group's clinical adverse reactions, which included 160 cases (75.12%), and there were 41 cases (31.78%) in the bolus injection instrument group. This was a statistically significant difference ($\chi^2 = 62.27$; $P < 0.001$). The abdominal pain/bulge ratio was 33.33 and 12.40% in the manual handset and bolus instrument groups, respectively, which was a statistically significant difference ($\chi^2 = 18.56$; $P < 0.001$). Nausea and vomiting in the manual handset and bolus injection groups were 22.07 and 10.08%, respectively, which was a statistically significant difference ($\chi^2 = 7.98$; $P < 0.01$). Headache and the dizziness phenomenon in the manual handset and bolus instrument groups were 19.72 and 9.30%, respectively, which was a statistically significant difference ($\chi^2 = 5.56$; $P < 0.05$).

Table 1. A comparison of the clinical adverse reactions and contrast agent reflux between the handset and bolus injection instrument groups.

Group	Cases	Reflux	Adverse reaction			
			Abdominal pain, bulge	Nausea, vomiting	Headache, dizziness	Total
Handset	213	29 (13.62%)	71 (33.33%)	47 (22.07%)	42 (19.72%)	160 (75.12%)
Instrument	129	4 (3.10%)	16 (12.40%)	13 (10.08%)	12 (9.30%)	41 (31.78%)
χ^2		10.61	18.56	7.98	5.56	62.27
P value		<0.01	<0.001	<0.01	<0.05	<0.001

Contrast agent reflux phenomenon

The contrast agent reflux occurred in 29 cases (13.62%) in the manual handset group and 4 cases (3.10%) in the bolus injection group. This was a statistically significant difference ($\chi^2 = 10.61$; $P < 0.01$).

Image quality assessment

According to the radiography films, we divided HSG's developing quality into three classes: A, B, and C. In the grade A films, the uterine cavity and Fallopian tube filling showed good contrasting images that appeared clear, and fine structures such as the mucosa, polyps, and others were displayed satisfactorily. In the grade B films, the uterine cavity and Fallopian tube filling showed good contrast but need to be clearer to meet the diagnostic requirements, and the fine structures were slightly unsatisfactory. In grade C films, insufficient contrast agent was injected into the uterine cavity so the Fallopian tube filling was poor due to poor contrast, and the fine structures were unclear, which affected the diagnosis. According to the above criteria, the image quality (Table 2) between the manual handset group and the bolus instrument group was as follows: the rate of grade A films increased from 54.46 to 68.99%; and grade C films decreased from 8.92 to 2.33%. These findings were statistically significant ($P < 0.05$). The rate of grade B films decreased from 36.62 to 28.68%, which was not a statistically significant difference ($\chi^2 = 2.27$, $P > 0.05$).

Table 2. Comparison of the radiography film quality between the handset and bolus injection instrument groups.

Group	A grade	B grade	C grade	Total
Handset	116 (54.46%)	78 (36.62%)	19 (8.92%)	213
Instrument	89 (68.99%)	37 (28.68%)	3 (2.33%)	129
χ^2	7.07	2.27	6.18	
P value	<0.01	>0.05	<0.05	

DISCUSSION

With the recent increase in diseases such as chronic pelvic inflammation, intrauterine infection, and sexually transmitted diseases, the incidence of infertility caused by tubal factors is rising, and it has become a modern disease that should be monitored by medical workers. This method helps health care providers judge the degree of tubal patency and the site of obstruction as well as the adhesion condition of the fimbria according to the morphological changes of the fimbria and the dispersion of the contrast agent (Lavy et al., 2004; Lindheim et al., 2006). In addition, HSG has a certain therapeutic effect (Kaya et al., 2004; Luttjeboer et al., 2007).

HSG is widely used by clinicians or radiologists in the manual bolus injection of contrast agent, and physicians use their experience to control the speed of the contrast agent bolus and dose. Because of radiographic radiation, they often push a lot of contrast agent in a short amount of time, which can cause intrauterine pressure to rapidly increase and stimulation of the uterus, causing the Fallopian tubes to spasm. Hence, the illusion of a Fallopian tube obstruction can form. According to a report, HSG diagnosis of tubal obstruction and laparoscopy diagnosis found tubal patency; however, tubal spasm may be the main reason, and it occurs in the proximal tube (Hurd et al., 2003). Shah et al. (2005) showed that 16-80% of a single-side obstruction is a functional obstruction, and Roma et al. (2004) reported that due to low-stress tolerance, patients often have obstructions caused by tubal spasm, causing varying degrees of false positives. Thus, HSG tubal spasm is the cause of the false-positive rates (Preutthipan and Linasmita, 2003). Uterus and Fallopian tube spasm inevitably lead to an increase in intrauterine pressure, which makes patients prone to reflux of contrast agent, nausea, vomit-

ing, abdominal pain, exhaustion, and other clinical adverse reactions. Instead of performing bolus injections manually, this tubal instrument uses a computer that accurately controls the pressure and speed so that the bolus injection of the contrast agent is slowly and uniformly administered to ensure stable intrauterine pressures that slowly increase. Moreover, the patient can gradually adapt to the changes in pressure. Besides, contrast agent administered slowly through the Fallopian tubes into the pelvic cavity prevents irritation to the pelvic viscera, and the peritoneal is lighter. Thus, for the uterus, the tubal spasm probability is greatly reduced, and it also reduces the false positive that can be caused by tubal spasm as well as the clinical adverse reactions. Clinical adverse reactions were significantly reduced. The HSG contrast agent reflux phenomenon is a common phenomenon. It occurs when the uterus and Fallopian tubes have an organic disease that causes increased vascular fragility. However, the increased permeability caused by human factors, such as contrast agents, makes the pressure too high and too fast, causing reflux (Peng et al., 2012). When the tubal treatment device was used instead of performing bolus of contrast agent for inspection, bolus injection pressure is low, slow, and it sets the maximum safe injection pressure at 50 kPa. When the intrauterine pressure safety injection pressure is reached, the injection is automatically stopped, and the statistical results show that the phenomenon of contrast agent counter-current decreased from 13.62 to 3.10%. There is a statistically significant difference between the two ($P < 0.001$); thus, using a tubal instrument instead of performing a bolus injection of contrast agent can reduce human factors. Some scholars believe that with a metal tube through artificial injection of contrast agent, the instrument can easy cause endometrial damage, especially in patients with hyperflexion of the uterus, which can counter the phenomenon of increasing contrast agent (Dai et al., 2012). In this study, disposable uterine balloon catheter angiography was used in the manual handset and bolus instrument groups. Ricci et al. (2007) believe that compared with other instruments, the balloon catheter in the uterine tubal infertility check play an irreplaceable role. Dessole et al. (2001) studied four different balloon catheters and compared them. Their findings showed that the different balloon catheter in terms of reliability, ease of use, and contrast agent had no statistical significance. Currently, balloon catheter HSG has been widely used (Boudghène et al., 2001; Prefumo et al., 2002). However, since the presence of the balloon and the balloon catheter tip increases the block area, the display cannot completely show the uterine cavity and cervix. Hence, performing HSG using a balloon catheter for cervical lesions and some endometrial lesions is effective (Dessole et al., 2001; Chen et al., 2011), yet it increases the false positives (Roma Dalfó et al., 2004). In the future, further investigations on the position of the balloon catheter tip, balloon size, and the size of the relationship between intrauterine pressures are warranted.

With regard to the contrast agent selection, the effects of the ideal contrast agents should be good and the incidence of the side effects should be low (Chalazonitis et al., 2009). Water-soluble contrast agents, especially for the non-ionic water-soluble contrast agents such as iohexol, etc., gradually replace the iodized oil. Non-ionic water-soluble contrast agents have been used in angiography, and there are fewer severe complications even when the contrast agents flowed into the blood vessels. These are widely used in clinical practice (Johnson et al., 2004). Therefore, we adopted the iohexol contrast agents.

British state-run good clinic practice diagnosis and treatment guidelines recommend that oviduct imaging should be under the perspective of dynamic observation (National Collaborating Centre for Women's and Children Health, 2004). When HSG is manually conducted, because of the high pressure and high speed of the manual push injection as well

as the low viscosity and good fluidity of iohexol, especially in the case of tubal patency, a large number of contrast agents easily flow into the pelvic cavity in a short time. Overlap of the uterus and Fallopian tubes occurs, which causes misdiagnosis and difficulty in observing subtle changes in the uterus. It is difficult to view the fimbria accurately if there is a contrast agent outflow and oviduct morphological change. In addition, since the contrast agent's diffusion time is short, the capture timing is not easy to control, which can lead to subjective timing of the photographs. The display of the uterus and Fallopian tubes is not good in these cases, and sometimes, valuable images can be missed and the quality of radiography is lacking.

The manual handset group relied on conventional static film reading, which will cause a certain degree of missed diagnoses and misdiagnoses (Simpson Jr. et al., 2006). Using ZY-23-D imaging fluid bolus instrument, the contrast agent injection is remotely controlled by a doctor, and the pushing injection speed is slow, well distributed, and stable. The intrauterine pressure rises slowly, and the continuous and dynamic observation can be realized under the whole imaging process. One can leisurely and accurately control the timing of radiography. Subsequently, the image quality is greatly improved; the rate of the grade a film went from 54.46 to 68.99%, and the rate of the grade C class film decreased from 8.92 to 2.33%, which was statistically significant ($P < 0.05$; Table 2). Because of the continuous dynamic acquisition of photographed images in a relatively short period of time (i.e., as the uterus Fallopian tube fills and undergoes a dynamic change process), one can accurately observe the early filling of the uterine cavity by contrast agents. It can clearly show the uterine anomaly and improve the diagnosis of endometrial polyps and uterine anomalies. Conducting a comprehensive dynamic observation for the process of filling the Fallopian tubes and dispersing contrast agent into the pelvis, can accurately diagnose whether the fimbriated extremity of the Fallopian was blocked. This can reduce the false-positive diagnosis and improve the diagnostic rate (Salata et al., 2003; Zheng et al., 2011).

When HSG is conducted by hand, although the doctor conducting the operation is wearing lead clothes near the platform, the bulb tube is located above the examination bed and the radiographic radiation dose is large, and the medical personnel will no doubt be subjected to radiographic radiation. In addition to diagnostic accuracy, these safety issues must be considered. Using the imaging push fluid injection apparatus, instead of artificial angiography examination, allows the medical staff to push the contrast agent injection at a remote compartment. Therefore, the medical staff does not need to be directly exposed to the radiographic irradiation, and the imaging examination becomes an easy procedure (Chalazonitis et al., 2009; Lu, 2011).

Using a pushing instrument for HSG can improve the diagnostic accuracy and image quality. In addition, it can reduce the incidence rate of missed diagnoses and misdiagnoses, reduce the phenomena of contrast agent upstream, and reduce some adverse reactions such as nausea, vomiting, and abdominal pain. Lastly, the medical personnel can avoid radiographic radiation. Overall, it is a safe and reliable imaging examination method to use in clinical practice.

REFERENCES

Boudghène FP, Bazot M, Robert Y, Perrot N, et al. (2001). Assessment of Fallopian tube patency by HyCoSy: comparison of a positive contrast agent with saline solution. *Ultrasound Obstet. Gynecol.* 18: 525-530.

Chalazonitis A, Tzovara I, Laspas F, Porfyridis P, et al. (2009). Hysterosalpingography: technique and applications. *Curr. Probl. Diagn. Radiol.* 38: 199-205.

Chen Y, Zhang Y, Qiu Y, Gui W, et al. (2011). Investigation on effect factors on hysterosalpingography. *J. Chongqing Med. Coll.* 33: 741-744.

Dai YZ, Qiu SF and Zhang QQ (2012). HSG and marked uterine flexion of infertile patients with SSG technology

improvement and applications. *J. China Med. Imaging* 23: 214-216.
Dessole S, Farina M, Capobianco G, Nardelli GB, et al. (2001). Determining the best catheter for sonohysterography. *Fertil. Steril.* 76: 605-609.
Eng CW, Tang PH and Ong CL (2007). Hysterosalpingography: current applications. *Singapore Med. J.* 48: 368-373.
Hurd WW, Wyckoff ET, Reynolds DB, Amesse LS, et al. (2003). Patient rotation and resolution of unilateral cornual obstruction during hysterosalpingography. *Obstet. Gynecol.* 101: 1275-1278.
Johnson NP, Farquhar CM, Hadden WE, Suckling J, et al. (2004). The FLUSH trial - flushing with lipiodol for unexplained (and endometriosis-related) subfertility by hysterosalpingography: a randomized trial. *Hum. Reprod.* 19: 204-205.
Kaya H, Karci M, Ozkaya O and Sezik M (2004). Relationship between the timing of hysterosalpingography before gamete intrafallopian transfer and the subsequent fertility outcome. *J. Obstet. Gynaecol. Res.* 30: 448-453.
Lavy Y, Lev-Sagie A, Holtz, Revel A, et al. (2004). Should laparoscopy be a mandatory component of the infertility evaluation in infertile women with normal hysterosalpingogram or suspected unilateral distal tube pathology? *Eur. J. Obstet. Gynecol. Reprod. Biol.* 114: 64-68.
Lindheim SR, Sprague C and Winter TC 3rd (2006). Hysterosalpingography and sonohysterography: lessons in technique. *AJR Am. J. Roentgenol.* 186: 24-29.
Lu HW (2011). Application of digital hysterosalpingography in infertility diagnosis. *J. Inner Mongolia Med. Coll.* 33: 111-114.
Luttjeboer F, Harada T, Hughes E, Johnson N, et al. (2007). Tubal flushing for subfertility. *Cochrane Database Syst. Rev.* CD003718.
National Collaborating Centre for Women's and Children Health (2004). Fertility: Assessment and Treatment for People with Fertility Problems. RCOG Press, London.
Peng YJ, Li KY, Peng QH, Du XM, et al. (2012). Imaging manifestation of the contrast agent reflux during hysterosalpingography and its clinical analysis. *J. Beihua Univ.* (*Nat. Sci.*) 13: 78-81.
Prefumo F, Serafini G, Martinoli C, Gandolfo N, et al. (2002). The sonographic evaluation of tubal patency with stimulated acoustic emission imaging. *Ultrasound Obstet. Gynecol.* 20: 386-389.
Preutthipan S and Linasmita V (2003). A prospective comparative study between hysterosalpingography and hysteroscopy in the detection of intrauterine pathology in patients with infertility. *J. Obstet. Gynaecol. Res.* 29: 33-37.
Ricci G, Guastalla P, Ammar L, Cervi G, et al. (2007). Balloon catheter vs. cervical vacuum cup for hysterosalpingography: a prospective, randomized, single-blinded study. *Fertil. Steril.* 87: 1458-1467.
Roma Dalfó A, Ubeda B, Ubeda A, Monzón M, et al. (2004). Diagnostic value of hysterosalpingography in the detection of intrauterine abnormalities: a comparison with hysteroscopy. *AJR Am. J. Roentgenol.* 183: 1405-1409.
Salata I, Gottwald L and Sobkiewicz S (2003). Comparison of assessing the patency of the Fallopian tubes during laparoscopy and during hysterosalpingography on television in infertile women with endometriosis. *Ginekol. Pol.* 74: 1014-1017.
Shah SM, Towobola OA and Masihleho M (2005). Diagnosis of fallopian tube patency. *East Afr. Med. J.* 82: 457-462.
Shi YH, Chen ZJ, Gao Q, Yaping J, et al. (2004). Value of hysterosalpingography in diagnosis of women infertility. *J. Med. Imaging* 14: 139.
Simpson WL Jr, Beitia LG and Mester J (2006). Hysterosalpingography: a reemerging study. *Radiographics* 26: 419-431.
Zheng X, Guan J, Tian L, Han H, et al. (2011). Clinical value of real-time dynamic hysterosalpingography. *Chin. J. Family Planning* 1: 30-33.