# The analysis of factors influencing the success of diagnosing salpingemphraxis by x-ray hysterosalpingography

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**Abstract.** - OBJECTIVE: The factors influencing the diagnosing of salpingemphraxis by X-ray hysterosalpingography (HSG) are identified and summarized, to provide a reference for improving the precision of the diagnosis procedure.

PATIENTS AND METHODS: In order to analyze the collected data, the methods of stratified sampling and retrospective analysis were adopted. Two county-level medical units, two medical units in prefecture-level cities and two provincial medical units in our province were chosen. Patients were selected from a group of women diagnosed with infertility and probable salpingemphraxis who were admitted to a hospital for further studies between February 2010 and January 2015. From those, 3 individual cases were selected in each month summing up to a total of 1,080 cases. Surgical processes and results were analyzed to identify the determining factors that lead to a precise diagnosis.

**RESULTS:** The success rate of the surgical procedures had nothing to do with the trauma level of hospitals, instead it is positively correlated with the period of sampling (p < 0.05). The precision of surgeries correlates with the age group of the patients, the selection time bracket of samples, the types of contrast agents used, the location of the salpinx, whether anticholinergic agents are used before operations, the depth of catheter with double-cavity saccule, and the procedures for injecting contrast agents (p < 0.05). On the other hand, the precision of the surgeries has nothing to do with the level of hospitals, the types of X-ray machines used or the types of salpingemphraxis. Through multifactor regression analysis, it can be seen that the selection time period of samples, the location of the salpinx, whether anticholinergic agents are used before operations, the depth of catheter with double-cavity saccule and the procedures for injecting contrast agents are independent risk factors that determine the precision of the procedure (p < 0.05).

CONCLUSIONS: Clinical factors that seem to influence the precision of HSG are proposed based on analysis of a large sample in a small area using a stratified sampling method.

Key Words:

Hysterosalpingography; Salpingemphraxis; Stratified sampling; Retrospective analysis; Independent risk factors

# Introduction

According to statistics of WHO, 7%-15% of married couples are infertile. Salpingemphraxis infertility is the most common cause of female infertility, which can make up to 30%-50% of the cases<sup>1</sup>. X-ray hysterosalpingography (HSG) is the most frequently used examination method to evaluate the shape and smoothness of the uterus and salpinx. The procedure is simple, precise and easy to perform, and can generally achieve recanalization of an obstructed salpinx in primary hospitals<sup>2</sup>. Although hysterosalpingography is a very common procedure, studies about the factors guiding its diagnosis both at home and abroad are very limited and include only small samples or limited descriptive analyses<sup>3,4</sup>. Based on this, this research identifies and summarizes the factors that influence a precise diagnosis of salpingemphraxis by HSG, which provides a reference for the improvement of diagnosing salpingemphraxis by HSG.

#### **Patients and Methods**

# Research Objects

HSG has been a standard procedure for many years, carried out in outpatient clinics in as high as 85% of cases. The technologies involved are relatively mature, and prospective control studies are now of little value. Most studies in the past have adopted an analytical-descriptive method to illustrate the value of diagnosing salpingem-

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phraxis by HSG. Therefore, given the existing data, the feasibility of carrying out a meta-analysis is low. A retrospective analysis, however, is well founded due to the ease of obtaining large quantities of complete samples and long followups.

In this research, the methods of stratified sampling and retrospective analysis were adopted to select two county-level medical units, two medical units in prefecture-level cities and two provincial medical units in our province. The method of drawing lots was used, and this was not completed by research designers. From a pool of patients with probable salpingemphraxis infertility who were hospitalized between February 2010 and January 2015, 3 cases were selected in each month (by computer random sampling). The number of cases in the study totaled 1,080. The inclusion criteria were: 1. Availability of complete clinical data. 2. Presence of salpingemphraxis alone, without any other disease in the urinary or genital system that could affect the diagnosis. 3. Diagnoses were ultimately confirmed, judged by resulting pregnancy after the procedure or by results of a second HSG were the salpingemphraxis was not apparent anymore. The exclusion criteria were: 1. HSG and salpingography and fallopian tube recanalization carried out simultaneously, or HSG carried out by stages or HSG repeatedly carried out; 2. Patient non-compliance.

## Statistical Information

The statistical tables were designed and completed by data compilation members of the research team. Each case was jointly completed by two members, and data were analyzed by statisticians. Statistical variables include: The level of hospitals, time lapse of operations, age group of patients, types of contrast agent used, locations of salpinx, whether anticholinergic agents were used before operations, the depth of catheter with double-cavity saccule, and the procedures for injecting contrast agents. These variables were analyzed in the context of the results of the HSG procedures.

## Statistical Analysis

The data were summarized using Excel. SPSS 20.0 software (SPSS Inc., Chicago, IL, USA) was used for data analysis. Enumeration data are expressed by cases or percentages, and <sup>2</sup>-test was adopted for comparison among groups. A logistic-test was carried out for multi-factors re-

gression analysis. Finally, the Spearman-test was used for correlations. p < 0.05 is considered as of statistical significance.

## Results

# The Analysis of General Information

The levels of hospitals were numbered: "1" represents county-level hospitals, "2" represents hospitals in prefecture-level cities, and "3" represents provincial hospitals. Time periods when the operations were carried out are numbered: "1" represents operations carried out between February 2010 and January 2011, "2" represents operations carried out between February 2011 and January 2012, "3" represents operations carried out between February 2012 and January 2013, "4" represents operations carried out between February 2013 and January 2014, and "5" represents operations carried out between February 2014 and January 2015. Age groups of patients were numbered: "1" ranges from 18 to 23 years (430 cases), "2" ranges from 24 to 29 years (520 cases), and "3" ranges from 30 to 35 years (130 cases). Types of contrast agents were numbered: "1" represents iodinated oil (100 cases), "2" represents meglumine diatrizoate (240 cases), "3" represents ultravist and iohexol (520 cases), and "4" represents isovist/iotrolan (220 cases). Locations of salpinx were numbered: "1" represents near-end (450 cases), "2" represents far-end (460 cases), and "3" represents peripheral tissues (170 cases). Anticholinergic agents used before operations were numbered: "1" represents cases were the anticholinergics were used (460 cases), "2" represents cases were anticholinergics were not used (620 cases). The depths of the catheter with double-cavity saccule were numbered: "1" for cases in which the length of the catheter in the uterine cavity was longer than the depth from the internal ostium of the uterus to fundus (720 cases), "2" for all the other cases (360 cases). The ways of injecting contrast agents were numbered: "1" represents high-pressure injector and constant speed injection (470 cases), and "2" represents manual injections (610 cases). If the operation succeeds after the first attempt, it was be numbered as "1" (760 cases), if the operation did not succeed after the first attempt but needed at least two attempts, it was be numbered as "2" (320 cases). If diagnosis results were true positive or true negative, the case was numbered as "1"(820 cases), while false positive or false negative cases were numbered as "2" (260 cases).

**Table I.** The relationship between the success rate of operations and time period of operations.

	Time period of operations"1"	"2"	"3"	"4"	"5"
Success"1"	110 (50.93%)	129 (59.72%)	145 (67.13%)	170 (78.70%)	206 (95.37%)
1"2"	106	87	61	33	10

The success rate of operations had nothing to do with the level of hospitals, but it correlated with the time periods of operations (F = 136.110, p < 0.001). The more recent the time period, the more successful the procedures were (r = 0.462, p = 0.037) (Table I).

The precision of the diagnosis correlated with the patient's age group, the selection time period of samples, the types of contrast agents used, the locations of salpinx, whether anticholinergic agents were used before operations, the depth of catheter with double-cavity saccule and the method of injection of contrast agents (p < 0.05). However, the precision of diagnosis had nothing to do with the level of hospitals, the types of X-ray machines used or the characters of salpingemphraxis (Table II).

# Multi-factors Regression Analysis

Selection time periods of samples, locations of salpinx, whether anticholinergic agents were used before the procedure, the depth of catheter with double-cavity saccule and the method of injection of contrast agents seem all to be independent factors influencing the precision of the diagnostic procedure (p < 0.05) (Table III).

## Discussion

This large-scale study aims at analyzing the value of HSG in diagnosing salpingemphraxis in China. The cases analyzed encompass the latest five years. The factors influencing the results of the procedure are discussed. The following conclusion was drawn: Selection time periods of samples, locations of salpinx, whether anticholinergic agents were used before operations, the depth of catheter with double-cavity saccule, and the of method of injection of contrast agents are all independent factors determining the precision of the procedure.

**Table II.** The influential factors of the precision of the diagnostic procedure..

		Diagnosis results are "1"	"2"	χ²	P
Age group of patients	"1"	366 (85.12%)	64	35.447	< 0.001
	"2"	370 (71.15%)	150		
	"3"	84 (64.62%)	46		
Selection time period of samples	"1"	114 (52.78%)	102	122.842	< 0.001
	"2"	147 (68.06%)	69		
	"3"	168 (77.78%)	48		
	"4"	190 (87.96%)	26		
	"5"	201 (93.06%)	15		
Types of contrast agents used	"1"	55 (55.00%)	45	65.914	< 0.001
	"2"	158 (65.83%)	82		
	"3"	407 (78.27%)	113		
	"4"	200 (90.91%)	20		
Locations of Salpinx	"1"	292 (64.89%)	158	75.703	< 0.001
1	"2"	409 (88.91%)	51		
	"3"	119 (70.00%)	51		
Usage of Anticholinergic Agents	"1"	320 (69.57%)	140	17.736	< 0.001
	"2"	500 (80.65%)	120		
The depth of catheter with	"1"	500 (69.44%)	220	49.644	< 0.001
double-cavity saccule	"2"	320 (88.89%)	40		
The method of injection of	"1"	423 (90.00%)	47	90.176	< 0.001
contrast agents	"2"	397 (65.08%)	213		

Table III. Multi-factors regression analysis.

Factors	β	Wald	ρ	OR	95% CI
Selection time periods of samples	0.127	5.527	0.041	2.632	1.747-3.201
Locations of salpinx	0.242	5.326	0.043	1.857	1.207-2.624
The usage of anticholinergic agents	0.168	4.629	0.047	1.102	0.632-2.847
The depth of catheter with double-cavity saccule	0.326	4.857	0.045	1.322	0.954-3.204
The method of injection of contrast agents	0.254	5.965	0.039	2.457	1.634-3.527

Even though there are currently multiple examination techniques that can be used to diagnose salpingemphraxis infertility, namely hysteroscopy, laparoscopy, hysterosalpingo contrast sonography and three-dimensional dynamic MR hysterosalpingography, HSG is still the most widely applied method used to screen, diagnose and treat salpingemphraxis. Among patients with tubal infertility, more than 90% are diagnosed with salpingemphraxis. Tubal distortion and peripheral adhesions are caused by inflammation<sup>5</sup>. HSG is an invaluable technique for diagnosing developmental variations in the uterus and salpinx, for evaluating intrauterine adhesions and the degree of salpingemphraxis and for judging the cause of lesions in the uterus and salpinx. Adhesions, blocks and hydrops can be accurately diagnosed. Furthermore, the character of lesions leading to salpingemphraxis and the locations and degree of such lesions can be clearly visualized. What's more, the operation effects after salpingostomy and umbrella-end-ostomy can also be evaluated<sup>6</sup>.

Although a large number of studies both at home and abroad have reported on the clinical applications of HSG, large-scale data about the procedural conditions of HSG have not yet been analyzed. This lack of empirical data hampers the improvement of the technique. By way of this study, it was discovered that the success rate of the procedure has nothing to do with the level of hospitals where it is performed, which means it has nothing to do with the experience and proficiency of operators and the high-end degree of equipments in hospitals. This result corroborates the common knowledge that HSG is simple and easy and can be widely performed. While at the same time, the success rate was directly proportional to the time period when the procedure was performed.

There are no "golden criteria" and the conditions under which HSG is performed are still mainly subjective and not based on strong empirical data<sup>7</sup>. Therefore, this study takes into ac-

count every detail in the process of performing an HSG, in order to analyze if it is an independent factor that affects the precision of the procedure. The younger the patients are, the greater the precision rate of HSG. This is probably because confusion with conditions such as hydrops, tumours, operation history and intrauterine peripheral tissue adhesions, is avoided since the cause of salpingemphraxis in the younger age groups is mainly inflammatory8. With the constant improvement of contrast agents, the flow velocity and absorption rate of water-soluble contrast agents are higher than those of iodinated oil. Water-soluble contrast agents are smooth, have better contrast effects and lower side effects. Compared with ionic contrast, water-soluble non-ionic contrast agents have better qualities and lower occurrence rates of iodine adverse effects. Compared with high-permeability contrast agents such as ultravist, the renal toxicity of equal-permeability contrast agents such as isovist is lower<sup>9</sup>. Near-end obstruction images of salpinx are manifested in three forms of cusp type, filling-defect type and obtuse type, which are considered to be caused by endosalpingitis adhesions, air bubble blocks, salpinx convulsion or membranous adhesions. Researches have shown that 63% of unilateral near-end obstructions of salpinx are probably distortions caused by changes in the fundus and near-end locations of the salpinx, which make the flows of contrast agents not smooth and favor the occurrence of a pseudo-obstruction<sup>10</sup>. HSG pseudo-obstructions may not be smooth due to factors such as the stimulations to the uterus caused by cathetering and by uterus and salpinx muscle spasms. Spasmolysis by muscle injecting 654-2 to near-end pseudo-obstructions of salpinx can increase the re-passing rate to 35%<sup>11</sup>. The location of the catheter with doublecavity saccule on the top has advantages such as improving the comfort of patients, increasing the smoothness of the salpinx, increasing the displaying rate of salpinx and reducing the usage of contrast agents and exposure agents, but it can lead to false positive results. When the length of the catheter in the uterine cavity is longer than the depth from the internal ostium of the uterus to the fundus, the top of the buckling catheter has cornua on only one side, which causes the cornua and salpinx on the same side to develop badly, or even to not be visible, this leads to a wrong diagnostic result and the occurrence of a false positive. Shortening the length of a balloon catheter in the uterine cavity or the direction of the head of a mobile catheter could reduce false positive results12. When encountering resistance in the process of traditional manual injections, appropriate compression or compression through the increase of the usage of contrast agents could enhance the effects of diagnosis and treatment. However, the differences of compression among individuals are significant and cannot be standardized. Injecting contrast agents by American Mark V Provis type high-pressure injectors, setting a safety protective pressure limit and real-time pressure display, multiple connector control methods and remote control of injections, the shape of the uterus and salpinx are fully displayed. Intelligent operations could record uterus and salpinx perfusion pressure in each radiographic process, thresholds of uterus and salpinx perfusion pressures can be explored, and the diagnostic value of hydrodynamic injection is evaluated.

### Conclusions

Through a large-sample, small-area, stratified sampling method, it is understood that selection time period of samples, locations of salpinx, whether anticholinergic agents are used before operations, the depth of catheter with double-cavity saccule and the method of injection of contrast agents are all independent factors of the precision of HSG.

#### **Conflict of Interest**

The Authors declare that there are no conflicts of interest.

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