

Complications of Hysteroscopy: A Prospective, Multicenter Study

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Objective: To estimate the incidence of complications of diagnostic and operative hysteroscopic procedures in the Netherlands and describe their nature.

Methods: Data on complications were recorded by 82 hospitals in 1997. Participating hospitals had a 100% response rate. Any unexpected events that required intraoperative or postoperative intervention were defined as complications in two groups: approach (entry-related) and technique-related (caused by surgical instruments).

Results: Thirty-eight complications occurred among 13,600 hysteroscopic procedures (rate 0.28%). Diagnostic hysteroscopic procedures had a significantly lower complication rate (0.13%) than operative procedures (rate 0.95%; $P < .01$). Fluid overloads of distention medium were recorded five times (rate 0.20%). The most frequent surgical complication was perforation of the uterine cavity (rate 0.76%). Approximately half the perforations (18 of 33) were entry-related. Bleeding caused by perforation was seen in 0.16% of cases. Incidences of complications were: intrauterine adhesiolysis 4.48%, endometrium resection 0.81%, myomectomy 0.75%, and removal of a polyp 0.38%.

Conclusion: Diagnostic hysteroscopic procedures had very low complication rates, so are safe procedures with which to evaluate intrauterine pathology. Operative hysteroscopic procedures were more risky, but the removal of polyps had a very low complication rate (12 times lower than synechiolysis). Half the complications were entry-related, so attention has to be paid to the method of entry with the hysteroscope (ie, no unnecessary dilation of cervix and introduction of the scope under direct vision). The other half of complications were related to surgeons' experience and type of procedure. (*Obstet Gynecol* 2000;96:266–70. © 2000 by The American College of Obstetricians and Gynecologists.)

The hysteroscope has become a standard part of gynecologists' armamentarium, and hysteroscopy is taught routinely in residency curriculums. In recent years, its

use in gynecology has changed from a diagnostic tool only to an instrument for gynecologic operations. With operative hysteroscopy increasing as a surgical alternative for various gynecologic problems, there is heightened awareness of potential complications associated with it. The adverse effect of fluid overload, caused by excessive absorption of distention medium (eg, glycine, sorbitol), was described as a potentially serious complication of hysteroscopy.¹ Surgical complications from intrauterine manipulation of instruments also are potentially hazardous.

Most reports on complications of hysteroscopy are on retrospective studies,^{1,2} concern diagnostic procedures or case reports,^{3–7} and give incidences from referral centers. Recently, some prospective studies were published on complications and follow-up of endometrial resections.^{8–13} We performed a multicenter study in 1997 to estimate the risk of complications caused by hysteroscopic surgery with respect to procedure, surgeons' experience, and patients' characteristics, and to gain insight into its risks.

Materials and Methods

All 130 gynecologic units in The Netherlands were invited to participate in a prospective study of surgical complications of hysteroscopy. Eighty-two (63%) agreed to participate and received questionnaires to record complications immediately after hysteroscopic procedures. A complication was defined as an unexpected event during hysteroscopy that required further treatment (eg, stopping procedures because of excessive fluid overload, longer postoperative observation, or further laparoscopy or laparotomy). Participants were asked to record all types of hysteroscopic procedures, experiences of gynecologists (general and specific procedures), possible risk factors in medical histories (eg,

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premenopausal or postmenopausal status, uterine surgery, cesarean), and type of hysteroscopic surgery. Postoperative complications also were recorded. Data were collected each month for every hysteroscopic procedure. If no monthly response to the questionnaire was received, participants were contacted by telephone, so all necessary information could be collected from all participating centers for a 100% response rate. The study took place from January 1 to December 31, 1997. Participating gynecologic units also were required to provide information on the total number of hysteroscopic operations.

Complications of hysteroscopy were classified in two categories: those that were caused by hysteroscopic approach or were entry-related (sounding of the uterine cavity, dilation problems, perforation by hysteroscope), and those caused by hysteroscopic technique, related to the operative hysteroscopic procedure itself (instruments, forceps, electro-coagulation, laser). The rates of complications in the study were compared with those in current literature. Statistical analysis was by the χ^2 test and 95% confidence intervals (CIs).¹⁴

Results

Among 82 participating hospitals, 29 (35%) were teaching hospitals and 53 were not. The median number of gynecologists in the participating hospitals was 5.0 (range 1–20). Among 48 hospitals that did not participate, the percentage of teaching hospitals was substantially less (seven of 48, 15%), and they had a lower median number of gynecologists in each hospital (3.5 [range 1–17]). Among responders, the median number of diagnostic procedures done by each gynecologist was 40 (range 5–348). For operative hysteroscopic procedures, the median was 5 (range 0–86). Seven of 82 participating hospitals (8.5%) did no hysteroscopic procedures. In the further calculation, those were not taken into account. Therefore, the response among participants was 100%. In the remaining 75 participant hospitals, 13,600 hysteroscopic procedures were done—11,085 diagnostic and 2515 operative. Among 75 participant hospitals, 52 recorded no complications of hysteroscopy and 23 (31%) recorded one to four complications. A total of 38 complications (rate 0.28 per 100 procedures) was recorded during the study period. Eight (21%) were caused by trainees, and 30 (79%) by board-certified gynecologists.

The 2515 surgical procedures were categorized as follows: 798 removals of myomas, 784 removals of polyps, 494 endometrial ablations, 180 removals of corpora aliena, 134 adhesiolyses, 81 sterilizations, 40 uterine septum resections, and four other procedures. All operative hysteroscopic procedures were done with

Table 1. Complications During Hysteroscopic Procedures

Complication	Diagnostic procedures (<i>n</i> = 11,085)	Operative procedures (<i>n</i> = 2515)
	No. complications (%)	No. complications (%)
Total	14 (0.13)	24 (0.95)
Fluid overload	0 (0)	5 (0.2)
Perforation	14 (0.13)	19* (0.76)
Cause of perforation		
Dilation	10 (0.09)	0 (0)
Hysteroscope	4 (0.04)	4 (0.16)
Instrumental	0 (0)	15 (0.60)

* Four of which (0.16) were accompanied by bleeding.

patients under general or regional anesthesia (peridural or spinal), whereas 35% of diagnostic procedures were done under local anesthetics (paracervical block) and the remaining 65% under general anesthesia. Sorbitol 3% was used most frequently as distention medium in surgeries.

Table 1 shows the incidence of complications during various procedures. Significantly more complications occurred during the operative hysteroscopic procedures (rate 0.95%) than during diagnostic procedures (rate 0.13%; $P < .01$; 95% CI 0.44, 1.21). In five cases, we recorded fluid overload (defined as the absorption of more than 1500 mL of distention medium) with clinical consequences for the patient (rate 0.2%). Four of those were during myomectomy procedures, and one was during an endometrial resection. Thirty-three perforations were recorded, four with bleeding. Fourteen of the perforations (42%) occurred during diagnostic procedures, ten during dilations of the cervical os, and four during introductions of hysteroscopes. Two of those procedures were diagnostic and were done just before the start of operations (both endometrial resections). Those complications caused the resections to be abandoned. In the operative hysteroscopy group, 19 perforations occurred (rate 0.76%), four during the introduction of the hysteroscope and 15 caused by technique (eg, by another instrument). Dividing all 33 perforations into approach and technique groups showed that 18 (55%, 95% CI 36, 72) were entry-related and 15 (45%) were technique-related. The analysis showed no statistically significant difference between incidence of entry-related and technique-related surgical complications. The consequences of perforations ($n = 33$), were four cases with severe bleeding in which hysterectomy ($n = 1$), laparotomy ($n = 1$), or laparoscopy ($n = 2$) was done to stop it. In one case, a small bowel was perforated by the resectoscope; a laparotomy was done, and the lesion was repaired. During one other procedure, a fallopian tube was drawn into the uterine cavity by a forceps at the end of the procedure. After the tube was reposi-

tioned through the perforation and conservative treatment (observation and antibiotics), there were no further adverse effects. Among 12 diagnostic hysteroscopies, 11 had to be stopped. In one case, it was possible to continue. Among 15 operative procedures, ten were stopped because of perforations, three were finished, and in two cases, the procedure was completed after perforation. No further intervention was necessary in those 27 cases.

The incidence of complications for the several operative hysteroscopic procedures is given in Table 2. Adhesiolysis had the highest complication rate (4.5%), whereas polypectomy had the lowest rate (0.4%). Among endometrial ablations ($n = 494$), one complication (fluid overload) occurred during a resection procedure (155, rate 0.65%), two complications (perforations) during rollerball procedures (116, rate 1.7%), and one (also a perforation) during a combined resection and rollerball procedure (223, rate 0.45%). For procedures such as hysteroscopic sterilization, resection of uterine septum, and removal of corpus alienum, no complications were reported. There were no deaths during the study. Adhesiolysis had a statistically significantly higher complication rate than other procedures. However, no statistically significant difference could be found for endometrial resection versus myomectomy or polypectomy.

Analysis of risk factors found that among 38 women with complications, 25 were premenopausal and 13 postmenopausal. However, many premenopausal women were treated preoperatively with GnRH-analogues, therefore had postmenopausal status of the uterus. The total number of premenopausal or postmenopausal women in the uncomplicated procedures is unknown. The number of complications, related to the experience of the surgeon, gave results that were difficult to interpret, especially because of lack of knowl-

Table 2. Surgical Complications During Operative Hysteroscopic Procedures

Procedure	<i>n</i>	Complication	Rate (per 100)
Adhesiolysis	134	6	4.5
Endometrial ablation*	494	4	0.8
Myomectomy	798	6	0.8
Polypectomy	784	3	0.4
Rest†	305	0	0
Total	2515	19	0.8

Comparison of rates showed statistical significance for adhesiolysis ($P < .001$) versus other procedures. No statistical significance was found for resection versus myomectomy versus polypectomy ($P = .39$).

* Ablation included procedures of endometrium resection ($n = 155$), rollerball ($n = 116$), and combination ($n = 223$).

† Removal corpus alienum ($n = 180$), sterilization ($n = 81$), septum resection ($n = 40$), rest ($n = 4$).

Table 3. Reported Complications of Operative Hysteroscopic Procedures

Year	Author	<i>n</i>	Perforation	Bleeding	Fluid
1991	Magos et al ⁸	234	2.0	0.4	3.0
1992	Hill et al ⁹	850	0.8	0.8	0
1994	Pinion et al ¹⁰	105	1.0	6.0	11.0
1995	Scottish Hysteroscopy Audit Group ¹¹	978	1.1	3.6	6.0
1996	O'Connor and Magos ¹²	525	2.0	0.6	4.0
1997	O'Connor et al ¹³	116	3.0	0	3.0
1997	Nicoloso et al ¹⁶	2,757	1.5	0.11	0.11
Present study		2,515	1.3	0.16	0.2

The first six quoted studies were prospective, and complications occurred only during endometrial ablations. The last two studies represent all types of operative hysteroscopies.

edge of the number of procedures done by each gynecologist. For diagnostic hysteroscopies, there was no substantial difference in number of complications and experience. However, for operative procedures, most complications occurred when surgeons had more experience; nine of 24 (37%) of all complications occurred in the group in which surgeons had done more than 50 of the specific procedures. Probably more advanced operations were done by more experienced surgeons; therefore, more complications occurred because of the difficulty of the surgery.

Discussion

The development of hysteroscopy came relatively late compared with other endoscopic procedures, possibly because of particular difficulties peculiar to the uterus, including narrowness of the uterine cervix, fragility of the endometrium, and the practical problem of ensuring thorough cleansing of the uterine cavity by a distending medium to allow clear viewing.¹⁵ Although hysteroscopy is an important diagnostic tool in gynecology, a small percentage (rate 0.13%) ends in undesirable events and even death.^{3,4,11} Since the slow diffusion of more complex hysteroscopic operations, more has become known about their complications. However, only a few studies of them were prospective.

We compared our study with the literature in Table 3. The first six studies (from 1991–1997) give the results of endometrium resection and present less data.^{2–7} The study of Nicoloso et al¹⁶ gives the results of a multicenter prospective registration study of complications with hysteroscopy in France. They found similar complication rates to ours; however, they did not calculate procedure risks. Our rate of fluid overload (0.2%) was lower than those in the average literature (up to 6.0%), but was similar to that in Nicoloso's study.¹⁶ Probably because of our definition, the number reported is lower.

Only women with intravasation of distension medium with clinical consequences were counted in our study. At present, much is known about the cause of fluid overload.¹⁷ Factors related to it are intrauterine pressure and degree of damage to endometrium and myometrium, as well as time, preparation of the uterus, depth of resection of tissue into the uterine wall, and opening of sinuses while resecting. It is not always possible to explain why overload appears.¹ As reported in later studies (Table 3), endometrium resection might have a better chance of excessive absorption than other procedures (eg, myomectomy, polypectomy, and synchiolysis).

Some hysteroscopic operations seem to be more risky than others. In our study, intrauterine adhesiolysis had a 12 times higher complication rate than removal of a polyp, and a five to six times higher complication rate than endometrium resection or myomectomy, respectively. Those findings underline the necessity of surgeon experience to do more difficult procedures, and the need for careful supervision, as other studies also indicate.^{18,19} The Royal College of Obstetricians and Gynaecologists,¹⁹ and recently, the International Society for Gynecologic Endoscopy,¹⁹ implemented and suggested skill levels for certification and issuance of credentials of surgeons doing operative hysteroscopy. Our study and that of Nicoloso et al¹⁶ involved gynecologists of varying experience and expertise, so those data are applicable to the average gynecologist and not just experts in this surgery. However, a statistical analysis of surgeons' experience in hysteroscopic procedures and the occurrence of complications was not possible in our study because of lack of knowledge of experience of gynecologists performing each specific procedure. The extent of adhesions were not documented in this study, so it was not possible to analyze the relationship between complication rates and severity of adhesions. We believe that more experienced surgeons did the more difficult operations, therefore faced the most complications. Comparable with laparoscopic surgeries, a large group of surgeons who currently do endoscopic procedures (hysteroscopic and laparoscopic) acquired their experience outside an approved resident training program.²⁰ Those surgeons usually develop their skills under poor supervision, often without access to senior surgeons, whose greater experience could be helpful. There is enough evidence that hysteroscopy is superior to dilation and curettage,^{21,22} and we can postulate from our study and from the findings of Nicoloso et al¹⁶ that diagnostic hysteroscopy has such a low complication incidence (0.13% and 0.1%, respectively), that it must be part of resident training in gynecology. We also have to consider that in a training program a start has to be made to do surgery;

the removal of a polyp seems to be the best procedure to start with because of the low complication rate. Severe adhesiolysis is an advanced hysteroscopic operation for better-skilled surgeons. This also had been suggested in the Royal College of Obstetricians and Gynaecologists report of training in Gynaecological Endoscopic Surgery.¹⁸

Outpatient hysteroscopy under local anesthesia for diagnosis is now an established technique.^{23,24} In our study, 65% of diagnostic procedures were done under general anesthesia. All perforations occurred in that group. Choosing to do suspected difficult hysteroscopic procedures under general anesthesia beforehand explains that phenomenon, but dilating the cervical os before introducing the scope and instruments also might have an effect. Dilation of the cervix for diagnostic procedures is not recommended,^{2,24,25} although others dilated the cervix during all diagnostic procedures without complications.²³ Our experience in an outpatient clinic setting is that dilation is seldom necessary and has to be done very delicately to avoid bleeding, pain, and perforation. Introduction of the hysteroscope under direct vision reduces the risk of perforation even more. The same is true for a diagnostic hysteroscopy under general anesthesia. After perforation of the uterine wall, distention of the uterus is difficult. Depending on the location of perforation (fundus or near cervical os) the procedure does not always have to be abandoned. In this study, it was possible to complete the procedure in three of 33 cases (9%). Patients at risk (premenopausal or postmenopausal status) could not be detected in our study. Future studies should pay special attention to that subject.

Preventing hysteroscopy complications starts by raising awareness of risks and precautions. Our study showed that hysteroscopy carries small risks that cannot be eliminated completely. About half of the complications (18 of 33) were caused by hysteroscopic approach and were related to entry of the uterine cavity. Dilation of the cervix and introduction of the hysteroscope are to blame for those complications. The incidence of complications of all hysteroscopic procedures (0.3%) is low, and increasing experience of hysteroscopic surgeons will probably reduce the incidence of complications further. Adaptation to standard techniques of introducing the hysteroscope and technical improvement of instruments will probably reduce entry-related complications as well.

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