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Is it possible to predict office hysteroscopy failure?

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ABSTRACT

Objective: The purpose of this study was to develop a clinical tool, the HFI (Hysteroscopy Failure Index), which gives criteria to predict hysteroscopic examination failure.
Study design: This was a retrospective diagnostic test study, aimed to validate the HFI, set at the Department of Gynaecology, Obstetric and Reproductive Science of the Second University of Naples, Italy. The HFI was applied to our database of 995 consecutive women, who underwent office based to assess abnormal uterine bleeding (AUB), infertility, cervical polyps, and abnormal sonographic patterns (postmenopausal endometrial thickness of more than 5 mm, endometrial hyperechogenic spots, irregular endometrial line, suspect of uterine septa). Demographic characteristics, previous surgery, recurrent infections, sonographic data, Estro-Progestins, IUD and menopausal status were collected. Receiver operating characteristic (ROC) curve analysis was used to assess the ability of the model to identify patients who were correctly identified (true positives) divided by the total number of failed hysteroscopies (true positives + false negatives). Positive and Negative Likelihood Ratios with 95%CI were calculated.
Results: The HFI score is able to predict office hysteroscopy failure in 76% of cases. Moreover, the Positive likelihood ratio was 11.37 (95% CI: 8.49–15.21), and the Negative likelihood ratio was 0.33 (95% CI: 0.27–0.41).
Conclusion: Hysteroscopy failure index was able to retrospectively predict office hysteroscopy failure.

Introduction

Today hysteroscopy is commonly regarded as the gold standard for the diagnosis and assessment of intrauterine pathology, such as abnormal uterine bleeding, infertility, recurrent pregnancy loss and suspected intrauterine pathology [1,2].

Hysteroscopy can be performed in the office setting (outpatient or office hysteroscopy) or under general or peripheral anaesthesia (inpatient hysteroscopy) [1].

Office hysteroscopy has been shown to be as accurate as inpatient hysteroscopy, but compared to a traditional inpatient procedure, it has the advantage of reduced anaesthetic risks, enhanced time-cost effectiveness and patient preference [1,2].

Cervical stenosis and pain represent the main reasons of failure of office hysteroscopy with a percentage ranging from 86.4% to 100% of attempted procedures [1–4]. The passage through the internal cervical orifice (ICO) usually represents a technical obstacle causing related pain for the patient [1,4].

Main anatomic impediments are represented by the passage through the internal cervical orifice (ICO) and the so called "cervical stenosis" described as a variety of cervical anomalies, from subjective impression of narrowing to a completely obliterated internal or esternal os [5].

About cervical stenosis, some investigators have suggested that post-menopausal women and those on progestin contaceptives are at higher risk, because of a lack of estrogen [5,6]. Moreover, also nulliparity [7,8], curettage [9–11] and cervical surgery [5,12,13] are strictly correlated with cervical stenosis.

The international literature reports hysteroscopy success rates ranging from 44% to 99.5% [1,3,8,14].

The purpose of this study was to develop a clinical tool that gives criteria to predict hysteroscopic examination failure, in order to set in motion strategies to overcome anatomic impediments.

Materials and methods

This retrospective study (Canadian Task Force classification III) was carried out at the Department of Gynaecology, Obstetric and

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Reproductive Science of the Second University of Naples, Italy, between 2009 and 2011 to develop a clinical tool that give criteria for suspecting a "difficult uterus" and that predict hysteroscopic examination failure, in order to set in motion strategies to overcome anatomic impediments.

After the analysis of studies present in the international literature [1–15], the retrospectively detailed data, collected from our electronic medical record database of 995 consecutive patients undergone office hysteroscopy, were used to create a database with 14 variables. These variables are shown in Table 1. The data were analyzed by multiple logistic regression, evaluating the Odds' ratios values and respective covariates significance, to identify those factors most predictive of hysteroscopic failure. Subsequently, to create a simple scoring system, the Hysteroscopy Failure Index (HFI, Fig. 1), the statistically significant variables were assigned a whole number of points, based on the found Odds ratios (Table 1) divided for 2, in order to create more homogeneous numbers.

After obtaining a point for each parameter, the score was developed and analyzed to define possible cut-offs to predict hyteroscopic failure: a score lower than 10 considered a low possibility to find a difficult uterus (20%), a score between 11 and 20, a possibility to find a difficult uterus at 50%, and, finally, a score higher than 20 a high possibility to find a difficult uterus (>90%).

Since the present study aimed to determine Sensitivity and Specificity of the HFI, we needed to calculate the sample size to acquire an appropriate precision for estimating Sensitivity and Specificity. To achieve the precision of 0.05 for Sensitivity, we need a sample size of 808 patients; with this sample size we give a precision for Specificity equal to 0.,27. To achieve the precision of 0.05 for specificity, we need a sample size of 232 patients; with this sample size we give a precision for sensitivity equal to 0.0932.

The HFI was applied to our electronic medical record database of 995 patients undergone office hysteroscopy (all of them performed by L. C. and P. D. F.) and subsequently analyzed for the aforementioned criteria. A total of 995 consecutive women underwent office based hysteroscopy to assess infertility, abnormal uterine bleeding (AUB), cervical polyps, and abnormal sonographic patterns (postmenopausal endometrial thickness of more than 5 mm, endometrial hyperechogenic spots, irregular endometrial line, suspect of uterine septa). Patients were divided, according to the indication for the execution of hysteroscopy in two groups. In Group A, 590 women were sent to office hysteroscopy for primary (A1 = 480) and secondary (A2 = 110) sterility, while in Group B were included 405 women undergone hysteroscopy for AUB anomalies at TV ultrasound examination and cervical polyp.

Demographic characteristics, previous surgery, recurrent infections, sonographic data, estro-progestins, IUD and menopausal status were collected.

All the procedures were performed in an office setting using the vaginoscopic approach (without tenaculum and speculum) to avoid patient discomfort or pain not directly related to uterine examination. Neither analgesia nor local anesthesia were administered to any patient. A saline distension medium and a 3.6 mm continuous flow office Hysteroscope with a 30 degree—2.0 mm rod lens (BettocchiOffice Hysteroscope size 5; Karl. Storz GmbH & Co., Tuttlingen, Germany).

Data distribution was assessed by the Shapiro–Wilks test and showed a non parametric distribution. No patients had missing data. Statistical significance was set at $P < 0.05$.

Positive and Negative Likelihood ratios were calculated for each HFI of 0 through 100. Positive likelihood ratio was defined as sensitivity (number of failed hysteroscopies who were correctly identified -true positive- divided by the total number of failed hysteroscopies -true positive + false negative-)/100- specificity (number of managed hysteroscopies who were correctly identified -true negatives- divided by the total number of managed hysteroscopies -true negatives + false positives-). Negative Likelihood ratio was defined as 100-sensitivity/specificity. 95%CI for positive and negative likelihood ratios were calculated.

Receiver operating characteristic (ROC) curve analysis was used to assess the ability of the model to identify patients who were correctly identified (true positives) divided by the total number of failed hysteroscopies (true positives + false negatives).

Table 1
Statistical calculation to develop the Hysteroscopic Failure Index (HFI) by multiple logistic regression, evaluating the Odds' ratios values and respective covariates significance. Subsequently, the statistically significant variables were assigned a whole number of points, based on the found Odds ratios divided for 2, in order to create more homogeneous numbers.

Multiple logistic regression analysis					
	Odds	95% CI Odds		Odds/2	*P* value*
		Inferior	Superior		
Previous surgery					
Cesarean section	20,014	1,435	422,109	**10**	<0.05
Interventions on cervix	19,917	1,288	407,821	**10**	<0.05
Abdominal surgery	6,175	1,342	111,638	**3**	<0.05
Miomectomy	10,730	1,211	113,565	**5**	<0.05
Infections					
Recurrent vaginitis	16,372	1,792	426,083	**8**	<0.05
Cistitis	6,161	1,653	58,165	**3**	<0.05
Vaginitis	10,187	1,473	233,650	**5**	<0.05
Pelvic TV scan					
Ventrofixed uterus	14,035	1,579	293,563	**7**	<0.05
Retroverted uterus	6,424	1,228	248,091	**3**	<0.05
Anteverted uterus	0,720	0,090	32,815	**0**	NS**
IUD	10,499	1,586	266,660	**5**	<0.05
Estro-progestins	10,104	1,541	270,627	**5**	<0.05
Menopause	16,831	1,095	316,660	**8**	<0.05
NONE§	0,460	0,125	1,694	**0**	NS**

IUD: intrauterine device.
* $P < 0.05$ was considered significant.
** NS: non significant.
§ NONE: we grouped the absence of risk factors identified for possible hysteroscopic failure in this single variable.

Results

The present work refers to 995 women, who underwent diagnostic Hysteroscopy. The patients, divided according to the indication, were homogeneous for weight, height, BMI, and previous surgery, while for age and parity the groups resulted statistically different (Table 2).

Table 3 reports global data detected by the HFI score: statistical analysis to verify the validity of retrospective predictive value of the HFI score revealed that this score in 76% of cases is able to detect the presence of a uterus where hysteroscopy is impractical.

Moreover, the positive likelihood ratio was 11.37 (95% CI: 8.49–15.21), and the negative likelihood ratio was 0.33 (95% CI: 0.27–0.41).

ROC analysis showed an area under the curve of 0.958, (95% CI = 0.947–0.970, $P < 001$). The chosen cut-off of 20 showed a sensitivity of 90% and a specificity of 94% (Fig. 2).

In Group A1 ($n = 480$) 245 patients had a HFI score <10 and in 18 of them hysteroscopy was not possible (7%); 148 women had a score between 11 and 20, and only in 19 of them hysteroscopy was not possible (13%); finally in 87 patients the HFI score resulted >20 and in 58 of them it was not possible to complete hysteroscopic examination (78%) (Table 4).

In Group A2 ($n = 110$) 71 patients had a score <10, and in 5 of them hysteroscopy failed (7%); 28 women had a score between 11