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JMIG The Journal of Minimally Invasive Gynecology

Original Article

Hysteroscopic Assessment of Tubal Patency: A Randomized Comparison between the Flow and Parryscope Techniques

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ABSTRACT **Study Objective:** To evaluate the accuracy of the "Parryscope" and "flow" techniques for hysteroscopic assessment of tubal patency.

Design: Prospective randomized clinical trial.

Setting: From May to October 2019, women with subfertility undergoing laparoscopic and hysteroscopic surgery at the Medical University of Vienna were invited to participate in the study. The primary outcome was accuracy of Fallopian tube patency relative to the gold standard of laparoscopic chromopertubation.

Patients: Sixty women with subfertility.

Interventions: Hysteroscopy with either the "Parryscope" or the "flow" techniques for tubal assessment, directly followed by laparoscopy with chromopertubation.

Measurements and Main Results: Hysteroscopic prediction of fallopian tube patency was possible in a statistically significant manner in both study groups (p <0.05). The Parryscope technique achieved higher sensitivity (90.6%, 95% CI: 61.7−98.4) and specificity (100%, 95% CI: 90.0−100.0) than the flow technique (sensitivity: 73.7%, 95% CI: 48.8−90.9 and specificity: 70.7%, 95% CI: 54.5−83.9).

Conclusion: Using the Parryscope technique to determine if air bubbles traverse the ostia can provide valuable additional information during hysteroscopy and is more accurate in predicting fallopian tubal occlusion than the flow method. Journal of Minimally Invasive Gynecology (2020) 27, 1552−1557. © 2020 AAGL. All rights reserved.

Keywords: Fallopian tubes; Chromopertubation; Laparoscopy; Female infertility; Hysteroscopy

Hysteroscopy is the gold standard for intrauterine evaluation in patients with subfertility [1,2] and can be performed in outpatient and office settings [2−4]. Maximizing insight through a single procedure makes for more efficient and effective clinical care [5]. If hysteroscopy inherently has meaningful value for procreative testing, and tubal patency can be concurrently assessed gently, accurately, safely, and economically, then tubal assessment should also be incorporated into the hysteroscopic evaluation of patients with subfertility.

Several approaches to hysteroscopic assessment of fallopian tubal patency exist and have been recently reviewed [6]. The 2 approaches with the highest potential seem to be the Parryscope and flow techniques, based on speed, cost, ease of learning, and gentleness (as they can be performed without an operative channel, allowing for smaller hysteroscopes). The initial crossover trial for the Parryscope technique demonstrated a sensitivity and specificity of 98.3% to 100% and 83.7% [7], whereas sensitivity and specificity for the flow technique were 86.4% and 77.6%, respectively [8]. Although both approaches have been evaluated in crossover trials and compared with the gold standard of laparoscopy, these 2 approaches have never been compared directly; a randomized controlled trial has not been performed, and European data for the Parryscope technique have not been published, where the diversity of practitioners adds value to estimates of true clinical accuracy. Our objective was to

Dr. Parry has a U.S. patent relating to hysteroscopic assessment of fallopian tubal patency.

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Submitted December 12, 2019, Revised January 6, 2020, Accepted for publication January 30, 2020.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ — see front matter
https://doi.org/10.1016/j.jmig.2020.01.014

address these gaps in the literature and add to the limited but growing number of studies with hysteroscopic assessment of fallopian tubal patency.

Methods

Patient Population

In a prospective, monocentral, randomized study, 60 women aged between 18 and 45 years were enrolled between May and October 2019 for combined hysteroscopy and laparoscopy with chromopertubation, as part of their infertility evaluation at the Clinical Division of Gynecologic Endocrinology and Reproductive Medicine of the Medical University of Vienna, Austria. All women provided informed consent in writing. Patients who had already undergone removal of 1 or both fallopian tubes were not eligible for participation. Immediately before commencing the surgery, the senior surgeon opened the patient's study envelope and determined which hysteroscopic tube assessment technique was to be performed (with block randomization, as described subsequently). The study was approved by the institutional review board of the Medical University of Vienna (1341/2019) and was registered in ClinicalTrials.gov (ID NCT04077242, date of trial registration: September 4, 2019; available online: https://clinicaltrials.gov/ct2/show/NCT04077242?id=NCT04077242&draw=2&rank=1&load=cart). The data set is available online (https://data.mendeley.com/datasets/zf3hp5myyg/1).

Surgical Technique

All surgical procedures were conducted under general anesthesia and either directly performed or supervised by experts in infertility surgery [9]. A forward-oblique 30° hysteroscope (Karl Storz GmbH & Co KG; Tuttlingen, Germany; sheath diameter: 5 m) was used for diagnostic hysteroscopy. A continuous inflow was achieved with an intravenous solution of 0.9% sterile saline, tubing with a drip chamber, and a reusable intravenous pressure bag [5]. As previously described for the Parryscope technique, the minimal amount of inflow resulting in sufficient uterine distention was used, so uterine distension pressures were not quantified [7]. Hysteroscopic assessment of fallopian tube patency was always conducted with the 5-mm Aesculap hysteroscope, so even if subsequent operative hysteroscopy with a larger hysteroscope was performed, there was no variability in hysteroscope size at the time of diagnostic hysteroscopy. Intrauterine length was measured from the uterine fundus to the external os of the cervix.

For subsequent laparoscopy with chromopertubation, a "Spackmann" uterine manipulator with adjustable clamp fixation and an adjustable rubber cone (diameter 18 mm, reference number 1264; WISAP Medical Technology GmbH; Brunnthal/Hofolding, Germany) was placed through the cervix. The uterine manipulator was placed 1 cm from the fundus in all cases [5]. Laparoscopies were performed with a thorough inspection of the pelvis, internal genitalia, and liver region. Chromopertubation was performed using a dilute solution of indigo carmine blue dye (Amino AG; Gebersdorf, Switzerland) through the uterine manipulator with a 50-mL syringe. Patency, the volume of dye used for chromopertubation, and a subjective assessment of the pressure needed to achieve patency were recorded [5].

Hysteroscopic Assessment of Fallopian Tube Patency

For the flow group, a positive flow was defined as the observation of a naturally present substance contrasting with saline that traversed the ostia [5,8]. Examples of these included, but were not limited to, blood, mucus, and displaced endometrial tissue. In the Parryscope group, approximately 0.25 mL of air was introduced into the intravenous tubing by inverting the drip chamber to create air bubbles. When air entered the uterine cavity, a single, large air bubble (extending fully from the anterior to the posterior wall of the uterine cavity) or stream of air bubbles traversing the ostia was considered indicative of tubal patency. Intracavitary evaluation was typically performed for at least 10 seconds before air bubble entry to allow pressure equilibration if a hydrosalpinx was present. At least 30 seconds of observation per ostia was performed if patency was not observed [9]. Examples of these techniques are provided in online videos from related articles [2,5,10].

Parameters Analyzed

Using a prospective case report form for each patient, the following parameters were assessed by the senior surgeon. Tubal patency, as assessed by laparoscopic chromopertubation and separately documented for each side, was considered the main outcome parameter. With fallopian tube occlusion, the site within the tube was documented, as previously defined for proximal and distal occlusion [11]. Additional parameters tracked included hysteroscopic assessment of fallopian tube patency using either the Parryscope or the flow techniques as described above; uterine length as measured in the course of diagnostic hysteroscopy; patients' age and body mass index; the type of infertility (primary vs secondary); the surgical indication; menstrual cycle day at the time of surgery; duration of the hysteroscopic evaluation of tubal patency (in minutes); additional findings/surgical procedures in the course of hysteroscopy/laparoscopy, including intracavitary abnormalities, and the presence of endometriosis, hydrosalpinx, or peritubal adhesions; a subjective assessment of pressure used in demonstrating patency with chromopertubation (low vs high, which affects accuracy and prognosis); and the amount of dilute solution of indigo carmine blue dye used for chromopertubation. Notably, details about hysteroscopy were entered into the case report form

directly after hysteroscopy (i.e., before laparoscopy started). This was necessary to avoid chromopertubation findings potentially biasing hysteroscopic observations. Outcomes were always supervised by a study member who was not part of the surgical team for the respective operation.

Sample Size Calculation

Two considerations influencing sample size and design should be noted. Although spontaneous air bubbles can be used as part of a flow assessment, it would be difficult to distinguish the Parryscope technique from the flow technique if a crossover study were designed because residual air bubbles in the setting of occlusion would block visualization of the flow of mucus and more. In addition, prolonged hysteroscopy can potentially lead to peritubal edema, potentially biasing toward a false positive toward occlusion with a second hysteroscopic technique if the 2 approaches were studied with an immediate crossover design. Accordingly, a randomized controlled trial with laparoscopic control for separate evaluation of the 2 methods was performed. Because the "flow effect" was considered the less reliable method, the sample size was aligned to this method. An alpha of 5%, a power of 80%, a general disease likelihood of 39%, and a sensitivity of 66% with an odds ratio of approximately 10 for occluded tubes resulted in a total amount of 59 tubes and, accordingly, 30 patients [5]. Thus, the group for the Parryscope technique also had to contain 59 tubes (30 patients). The randomization of the total 60 patients was performed as block randomization into 4 blocks using the free software R (The R Foundation; available online at: https://www.r-project.org/).

Statistical Analysis

Numerical data are reported as means and standard deviations, and nominal variables are reported as number and frequency. Baseline patient characteristics were analyzed using unpaired t tests for numerical parameters and the χ^2 test or Fisher's exact test for categorical variables. Using classic crosstabs, the sensitivity, specificity, and positive and negative predictive values including the 95% confidence intervals (95% CIs) were calculated for hysteroscopic assessment of the tubes, separately for both study groups (evaluated technique vs gold standard laparoscopic chromopertubation). Statistical analyses were performed with the software R. Differences were considered significant if $p < .05$.

Results

Patient characteristics did not significantly differ between the Parryscope and the flow groups and are described in Table 1. A cervical stricture was found in 2 women (6.7%) in the Parryscope group and 3 women (10.0%) in the flow group. (p = .000). After dilatation with successively larger Hegar dilators, hysteroscopic entrance to the uterine cavity was possible in all cases. Details about hysteroscopic findings in the 2 groups are provided in Table 2. After assessment of hysteroscopic fallopian tube patency, an operative hysteroscopy was performed in 4 women (13.3%) in the Parryscope group and 2 women (6.7%) in the flow group (p = .671). All fallopian tubal ostia could be hysteroscopically visualized, and thus, a hysteroscopic assessment of tubal patency was feasible for all 120 tubes.

Table 1

Basic patient characteristics of the "Parryscope" and the "flow" groups

Patient characteristics	"Parryscope" group	"Flow" group	p
Age (yrs)*	33.0 ± 4.8	31.9 ± 5.0	.391
BMI (kg/m^2)*	23.2 ± 3.5	23.5 ± 4.6	.800
Phase of menstrual cycle at the day of surgery†			1.000
Follicular phase	26 (86.7)	26 (86.7)	
Luteal phase	4 (13.3)	4 (13.3)	
Primary sterility†	22 (73.3)	22 (73.3)	1.000
Indication for surgery†,‡			
Endometrial polyp	3 (10.0)	2 (6.7)	1.000
Suspicion of endometriosis	13 (43.3)	13 (43.3)	1.000
Suspicion of tubal factor	6 (20.0)	4 (13.3)	.731
Laparoscopic ovarian drilling	2 (6.7)	4 (13.3)	.671
Uterine malformation	3 (10.0)	3 (10.0)	1.000
Ovarian cyst	8 (26.7)	13 (43.3)	.279
Myoma	5 (16.7)	5 (16.7)	1.000
Otherwise unexplained infertility	1 (3.3)	0 (0)	1.000

BMI = body mass index.
* Data are provided as mean ± standard deviation.
† Data are provided as number (frequency).
‡ Multiple mentions are possible.

Table 2

Hysteroscopic and laparoscopic findings in the "Parryscope" and the "flow" groups

Findings		"Parryscope" group	"Flow" group	p
Hysteroscopic findings	Normal cavity	20 (66.7)	25 (83.3)	.233
	Endometrial polyp	5 (16.7)	3 (10.0)	.706
	Myoma FIGO type 0−II	1 (3.3)	1 (3.3)	1.000
	Uterine malformation	4 (13.3)	1 (3.3)	.353
Laparoscopic findings	Bilateral tubal occlusion	5 (16.7)	4 (13.3)	1.000
	Bilateral tubal patency	20 (66.7)	15 (50.0)	.295
	Endometriosis	13 (43.3)	18 (60.0)	.301
	Hydrosalpinx on one or both sides	1 (3.3)	4 (13.3)	.353
	Polycystic ovary syndrome—laparoscopic ovarian drilling	2 (6.7)	4 (13.3)	.671
	Ovarian cyst	8 (26.7)	13 (43.3)	.279
	Myoma	3 (10.0)	5 (16.7)	.706

FIGO = International Federation of Gynecology and Obstetrics.
Data are provided as number (frequency); multiple mentions are possible.

In subsequent laparoscopic chromopertubation, there were 86 (71.7%) patent fallopian tubes (64 with normal, i.e., low chromopertubation pressure, and 22 with increased chromopertubation pressure) and 34 (28.3%) occluded fallopian tubes (32 proximal and 2 distal occlusions). When fallopian tube patency could be shown with low pressure (n = 64), a significantly lower amount of dilute solution of indigo carmine blue dye was used than with high pressure (n = 34; 42.3 ± 35.3 mL vs 135.0 ± 39.0 mL; p <.001). Of all patent fallopian tubes in chromopertubation, high pressure was necessary in 10 of 45 tubes (22.2%) in the Parryscope group and 12 of 41 (29.3%) in the flow group (p = .471). Notably, 15 of 34 occluded fallopian tubes (44.1%) were associated neither with endometriosis nor with hydrosalpinx. Bilateral tubal occlusion was found in 9 of 60 women (15.0%). Concerning the final laparoscopic findings, there were no significant differences between the 2 study groups (Table 2).

As shown in Table 3, hysteroscopic prediction of fallopian tube patency was possible in a statistically significant manner in both study groups (p <.05). However, the Parryscope technique achieved higher sensitivity (90.6%, 95% CI: 61.7−98.4) and specificity (100%, 95% CI: 90.0−100.0) than the flow technique (sensitivity: 73.7%, 95% CI: 48.8−90.9 and specificity: 70.7%, 95% CI: 54.5−83.9).

One could argue that the presence of hydrosalpinx would increase the risk for a false-normal result as published for the flow technique [5]. Thus, all tubes affected by a hydrosalpinx (Parryscope group: n = 1; flow group: n = 5) were excluded for the following subanalysis. Hysteroscopic prediction of fallopian tube patency was still possible in both study groups (p <.05) with similar sensitivity (Parryscope: 90.0%, 95% CI: 60.5−98.3 vs flow: 70.6%, 95% CI: 44.0−89.7) and specificity (100%, 95% CI: 90.0−100.0 vs flow: 76.3%, 95% CI: 59.8−88.6). Details are provided in the Supplementary Table.

Table 3

Accuracy of hysteroscopic fallopian tube patency testing—comparison of the 2 approaches

"Parryscope" technique		Laparoscopic chromopertubation			p*	<.001
	Occluded	Open	*Sum*	Sensitivity (%)‡	90.6 (61.7−98.4)	
Hysteroscopic tube assessment	Abnormal	14	0	*14*	Specificity (%)‡	100.0 (90.0−100.0)
	Normal	1	45	*46*	PPV (%)‡	100.0 (71.6−100.0)
Sum		*15*	*45*	*60*	NPV (%)‡	96.8 (85.5−99.5)
"Flow" technique		Laparoscopic chromopertubation			p†	.002
	Occluded	Open	*Sum*	Sensitivity (%)‡	73.7 (48.8−90.9)	
Hysteroscopic tube assessment	Abnormal	14	12	*26*	Specificity (%)‡	70.7 (54.5−83.9)
	Normal	5	29	*34*	PPV (%)‡	53.8 (33.4−73.4)
Sum		*19*	*41*	*60*	NPV (%)‡	85.3 (68.9−95.0)

NPV = negative predictive value; PPV = positive predictive value.
* p-values were calculated using Firth logistic regression with a penalized likelihood estimation method because of quasi-complete separation.
† p-values were calculated with a binary logistic regression model.
‡ Results are provided with a 95% confidence interval.

Discussion

Our study shows that in women with subfertility, approximately 15% of patients have bilateral tubal occlusion at chromopertubation and 28% of all fallopian tubes were occluded. Although one could argue that this was because of a high rate of false-positive proximal occlusion, the mentioned data are comparable with those previously found by our group [5] and lie in the middle of the range of recently published reports [7,8]. Although it is possible for this number to be elevated through referral bias for surgery, given that only 17% of the patients who underwent combined hysteroscopy and laparoscopy had preoperative findings specific to potential fallopian tube abnormalities, this is not a particularly high-risk population. Endometriosis was identified in more than 50% of women and 8.3% had hydrosalpinges. Thus, we believe that the proximal blockages were actually true occlusion on chromopertubation rather than false positives.

Notably, 44% of all occluded fallopian tubes were associated neither with endometriosis nor the presence of hydrosalpinx. The ability to detect bilateral tubal occlusion has obvious implications for patients desiring conception through oral medication and/or insemination. Unilateral occlusion may also matter, even though some studies have shown reasonable success rates when the dominant follicle is present contralateral to a patent tube, although most studies on intrauterine insemination (IUI) in women with unilateral tubal blockage did not report the side of the dominant follicle. Nevertheless, they performed several consecutive IUI cycles irrespective of the side of the dominant follicle and showed pregnancy rates similar to the rates after IUI for unexplained infertility [12]. However, some patients are intuitively reluctant to follow through on therapy in months where the dominant follicle is on an occluded side, particularly if using donor sperm that may cost $1000 per vial. If almost half of tubal occlusion is without endometriosis or hydrosalpinges, using just risk factors and simple sonography to decide who needs tubal patency assessment will likely result in missing many patients with underlying disease. Moreover, even if a patient has no procreative goals, hysteroscopic assessment of tubal patency may have value in estimating true fluid deficits because approximately 40% of hysteroscopic deficit can be from transtubal flow accumulating in the posterior cul de sac for patients with bilaterally patent tubes [13].

Using the flow technique, a sensitivity of 74% and specificity of 71% for tubal occlusion was observed (Table 3). Coupled with our previous prospective study for the flow technique (85% and 66%, respectively) [5], this demonstrates suboptimal reliability in assessing fallopian tubal patency. Accounting for the positive and negative predictive values (53.8% and 85.3%, respectively) and acknowledging that senior surgeons with considerable expertise in the flow method assessed the fallopian tube ostia during hysteroscopy, these estimates for accuracy may be higher than those seen with typical use or for surgeons new to the technique. However, these positive and negative predictive values are still comparable with those generally accepted for hysterosalpingography (HSG; 38 and 94% respectively) [14]. Conversely, the Parryscope technique was more accurate in assessing fallopian tubal patency in this prospective randomized study, and these were among the first procedures using the technique performed by the Austrian surgeons; therefore, the technique does not appear to have a steep learning curve. The sensitivity, specificity, and positive and negative predictive values for the Parryscope technique were 90.6%, 100%, 100%, and 96.8%, respectively. We consider these results comparable with those from the initial study for the accuracy of the Parryscope technique (sensitivity: 98.3%, specificity: 83.7%) [7]. The 1 tube that was assessed as patent using the Parryscope technique but was centrally occluded at chromopertubation was also surrounded by adhesions and found in a 33-year-old woman with peritoneal endometriosis (r-American Society of Reproductive Medicine stage II).

One might argue that the presence of a hydrosalpinx would increase the likelihood of a false-normal result, a fact that has already been demonstrated for the flow technique [5]. This could even be the case for the Parryscope technique, wherein one could expect bubbles to travel from the uterus into the tube, despite distal tubal occlusion. However, the subanalysis on tubes without hydrosalpinx (Supplementary Table) demonstrated similar predictive reliability for both techniques. In particular, the Parryscope technique's accuracy remained unaltered. We believe that the latter is because of 2 core steps that help prevent false positives even with large hydrosalpinges. The first is to have steady-state infusion pressures using 1 L of saline and intravenous tubing. When performing syringe-based infusion, the surges in pressure can drive air in to a tube with distal occlusion, going from decompressed to expanded. The second was to allow adequate filling time before air infusion, so that by the time air is introduced, if a hydrosalpinx was present, it had already distended so that there was no pressure gradient that would have allowed air bubbles to enter.

One of the important differences in this study relative to the initial publication for the Parryscope technique was instrumentation and analgesia. In the first study, a 2.9-mm flexible hysteroscope was used in conscious patients where oral analgesia was infrequently used [7]. The original choice of instrumentation by the authors stemmed from pretrial experience that suggested that higher caliber hysteroscopes caused more discomfort (consistent with pre-existing research [1,15]), which would detract from the patient experience, as well as potentially induce tubal spasm when pain occurred. They had also avoided exploring the efficacy of the technique in operating room settings because of the concern that if the bed had to be tilted to bring an air bubble adjacent to the ostia through gravity, then a patient may roll off the bed. The present study, which used vacuum mattresses intraoperatively, shows that there are approaches where testing can be done accurately and safely within the operating room.

The ability to perform the Parryscope technique under anesthesia solves 1 of the core limitations to tubal patency assessment in conscious patients, where low pressure (so as to avoid pain) allows for higher sensitivity to occlusion at the expense of specificity, when higher pressure could demonstrate a tube to be patent instead of false-positive occlusion, and thereby improve specificity. Although screening tests generally favor sensitivity at the expense of specificity, the differences in accuracy between the 2 trials may relate to a still-to-be-determined ideal infusion pressure through a receiver operator curve that best balances sensitivity and specificity. Wider use may allow for refinement that determines this pressure as well as other improvements, but, for now, accuracy appears comparable with, if not better than, that for HSG and sonosalpingography [14,16,17].

Uptake of hysteroscopic flow and the Parryscope technique relative to HSG and sonosalpingography will, in part, depend on the setting. For the office, broader use of small caliber flexible hysteroscopes will improve the accuracy of intracavitary evaluation [2] and reduce discomfort relative to HSGs that generate greater patient pain [10]. In operating room settings, when hysteroscopy is independently indicated, tubal patency assessment can quickly provide additional information at minimal additional costs because surgery was already being performed. Moreover, operating room settings offer greater opportunity to see and treat through hysteroscopic tubal cannulation when occlusion is identified.

Trials incorporating the Parryscope technique to date offer several advantages, including high accuracy even with early experience (relative to some techniques with a steep learning curve) and crossover design. Although the present study has the advantage of diversity of setting by being performed in the operating room, if the paradigm shifts to office hysteroscopy, the economic disadvantages associated with the operating room can be largely eliminated. As previously described for the office [7,10], combining disposable supplies with equipment depreciation amounted to $25 per procedure, which is comparable with the cost of catheters used for sonosalpingography and HSG. Another limitation to the present study relates to not precisely quantifying the laparoscopic pressures necessary to achieve tubal patency, particularly given that high-pressure patency is associated with lower fecundity than when it is observed with lower pressure [6,18]. However, this constraint is common to almost all publications on tubal patency. As nanotechnology evolves, we may be able to better assess tubal function and not just patency. However, for now, it is simply a step forward to increase options beyond HSG techniques that have not radically evolved since their introduction in 1911.

Conclusion

The Parryscope technique is more accurate for predicting fallopian tubal occlusion than the flow method. Incorporating air infusion into standard hysteroscopy and observing whether air bubbles traverse or do not traverse the tubal ostia can provide valuable additional information for patients who desire fertility.

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Supplementary Table

Subanalysis on the a*ccuracy of hysteroscopic Fallopian tube patency testing after exclusion of all hydrosalpinges*

"Parryscope" technique		Laparoscopic chromopertubation			p*	<0.001
		Occluded	Open	*Sum*	Sensitivity (%)[#]	90.0 (60.5;98.3)
Hysteroscopic tube assessment	Abnormal	13	0	*13*	Specificity (%)[#]	100.0 (90.0;100.0)
	Normal	1	45	*46*	PPV (%)[#]	100.0 (69.8;100.0)
Sum		*14*	*45*	*59*	NPV (%)[#]	96.8 (85.5;99.5)
"Flow" technique		Laparoscopic chromopertubation			p[+]	0.002
		Occluded	Open	*Sum*	Sensitivity (%)[#]	70.6 (44.0;89.7)
Hysteroscopic tube assessment	Abnormal	12	9	*21*	Specificity (%)[#]	76.3 (59.8;88.6)
	Normal	5	29	*34*	PPV (%)[#]	57.1 (34.0;78.2)
Sum		*17*	*38*	*55*	NPV (%)[#]	85.3 (68.9;95.0)

P-values were calculated either using a *Firth logistic regression with a penalized likelihood estimation method due to quasi-complete separation or a [+]binary logistic regression model. [#]Results are provided with the 95% confidence interval; Abbreviations used: PPV, positive predictive value; NPV, negative predictive value.