

# Feasibility of a new system of classification of submucous myomas: a multicenter study

Ricardo Bassil Lasmar, Ph.D., M.D.,<sup>a</sup> Zhang Xinmei, M.D.,<sup>b</sup> Paul D. Indman, M.D.,<sup>c,d</sup> Roger Keller Celeste, C.D., M.Sc., Ph.D.,<sup>e</sup> and Attilio Di Spiezio Sardo, M.D., Ph.D.<sup>f</sup>

<sup>a</sup> Department of Gynecology and Obstetrics, Federal Fluminense University, Rio de Janeiro, Brazil; <sup>b</sup> Department of Gynecology, Women's Hospital School of Medicine, Zhejiang University, Hangzhou, Zhejiang, People's Republic of China; <sup>c</sup> Los Gatos Surgical Center, Los Gatos, California; <sup>d</sup> Good Samaritan Hospital, San Jose, California; <sup>e</sup> Department of Odontology, Federal University, Rio Grande do Sul, Brazil; and <sup>f</sup> Department of Gynecology and Obstetrics and Pathophysiology of Human Reproduction, University of Naples, "Federico II", Naples, Italy

**Objective:** To evaluate the performance of the STEPW (size, topography, extension, penetration, wall) classification system in predicting partial or complete fibroid removal on hysteroscopic myomectomy.

**Design:** Multicenter, prospective study (Canadian Task Force classification II-2).

**Setting:** Four hysteroscopy centers in Brazil, China, Italy, and the United States.

**Patient(s):** Four hundred forty-nine women who underwent hysteroscopic resection of 465 submucous fibroids.

**Intervention(s):** Resection of the submucous fibroids (hysteroscopic myomectomy). Fibroids were scored according to the European Society for Gynaecological Endoscopy (ESGE) and STEPW classifications. The validation of the two classifications was assessed using sensitivity and specificity of each classification, with their best cutoff point. A test of equality of the two areas under the receiver operating characteristic curves was performed for correlated samples.

**Main Outcome Measure(s):** Correlation of ESGE and STEPW classifications with complete or incomplete removal of submucous fibroid.

**Result(s):** Removal of the myoma was complete in 432 (92.9%) of 465 myomectomies and incomplete in 33 (7.1%). All 320 fibroids (100%) with a score  $\leq 4$  in the STEPW classification were completely removed, and 112 of 145 fibroids (77.2%) with a score  $>4$  were removed. All 33 cases of incomplete hysteroscopic myomectomy (100%) had a STEPW score  $>4$ . Using the ESGE classification, 85 of 86 cases (98.9%) of type 0 fibroids, 278 of 298 (93.3%) of type 1, and 69 of 81 (85.2%) of type 2 were completely resected.

**Conclusion(s):** Classifying submucous fibroids using the STEPW classification permits greater correlation with complete or incomplete removal of the myoma by hysteroscopic myomectomy. (Fertil Steril® 2011;95:2073–7. ©2011 by American Society for Reproductive Medicine.)

**Key Words:** Hysteroscopy, myomectomy, myoma, classification, fibroids

Uterine myomas are the most common benign pelvic tumors of the female genital tract. Their incidence is approximately 25%–30% and can be higher depending on race, family history, and genetics (1–3). Submucous fibroids are frequently associated with bleeding and infertility (4, 5).

Hysteroscopic myomectomy is the surgical procedure of choice for the treatment of submucous fibroids (6–9). Hysteroscopic myomectomy is less invasive than other treatment methods, and recovery is rapid. In 1993, faced with the surgical complexity

posed by some deeply penetrating submucous fibroids, Wamsteker et al. (10) proposed a classification system for submucous fibroids to enable prediction of the degree of difficulty of the surgical procedure, based on the degree to which the myoma penetrates the myometrium. With this classification, gynecologists can estimate the likelihood of complete or incomplete removal of the submucosal myoma by hysteroscopic myomectomy and prepare accordingly. The Wamsteker classification was adopted by the European Society for Gynaecological Endoscopy (ESGE). Although the ESGE classification proves effective in separating cases of low complexity (type 0) and high complexity (type 2), it is less effective if fibroid penetration is  $<50\%$  (type 1).

In 2005 Lasmar et al. developed of a new classification for submucous myomas using five parameters: size, topography, extension of the base in relation to the uterine wall, and penetration into the myometrium (STEPW). They undertook a preliminary study of 62 hysteroscopic myomectomies, which demonstrated that the STEPW classification had a greater correlation with surgical outcomes than the ESGE system (11). It is important to establish the validity of this

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Reprint requests: Ricardo Bassil Lasmar, Ph.D., M.D., Department of Gynecology and Obstetrics, Federal Fluminense University, Rua Marques do Paraná 303, Niterói, Rio de Janeiro 2270-010, Brazil (E-mail: Ricardo@lasmar.com.br).

classification in different centers, to assess its utility for surgeons performing hysteroscopic myomectomy around the world (12).

The five parameters of STEPW are as follows :

1. Size: the largest diameter found by any of the imaging methods. When the nodule measures  $\leq 2$  cm, it is given a score of 0; if it is 2.1–5 cm, it gets a score of 1; and if it measures  $>5$  cm, it gets a score of 2.
2. Topography: defined by the third of the uterine cavity where the fibroid is situated. If it is in the lower third, the score is 0; if in the middle third, the score is 1; and if in the upper third, the score is 2.
3. Extension of the base of the myoma: when the fibroid covers one third or less of the wall, it is given a score of 0; when the base of the nodule occupies between one and two thirds of the wall, the score is 1; and when it affects more than two thirds of the wall, the score is 2.
4. Penetration of the nodule into the myometrium: when the fibroid is completely within the uterine cavity it is given a score of 0; if it has its larger part in the uterine cavity it is given a score of 1; and when it has its larger part in the myometrium it is given a score of 2.
5. Wall: when the fibroid is on the lateral wall, 1 extra point is added regardless of the third that is affected (Fig. 1).

The objective of this study was to compare the STEPW classification with the ESGE classification in terms of ability to predict whether hysteroscopic removal of a submucous fibroid would be partial or complete. For this comparison to be viewed as applicable in various countries, the Brazilian principal investigator organized an international multicenter study with academic gynecologists from the United States (P.I.), Italy (A.D.S.S.), and the People's Republic of China (Z.X.).

## MATERIALS AND METHODS

### Sampling Procedures

This was a prospective, multicenter study, carried out between January 2007 and December 2009, with 449 patients who underwent 465 hysteroscopic myomectomies at centers in four countries: Brazil, China, Italy, and the United States. Fourteen women presented two or three myomas; such cases were not excluded because sensitivity analysis showed that inclusion/exclusion did not change the results.

The research protocol was approved by the institutional review board of the Pedro Ernesto University Hospital of the State University of Rio de Janeiro, Brazil, and each participant was responsible for it in his country.

Prospective subjects invited to participate in the study were informed before surgery about the risks and benefits of hysteroscopic myomectomy and of their participation in the study. Those who agreed to participate in the study were asked to sign an informed consent form. Subjects received no financial remuneration for their participation.

The inclusion criterion was planned hysteroscopic resection of a submucosal myoma. Exclusion criteria were the presence of severe cardiovascular disease, decompensated diabetes, or severe hematologic disorders.

Eleven patients had multiple myomas and were included in the database additionally for each myoma that was treated. Nine patients had two myomas removed. In two patients three myomas were removed. In the data analysis each myoma was treated as a separate case.

All surgeons who participated in this study have extensive experience with hysteroscopic surgery, recent publications about hysteroscopic myomectomy, and prior experience applying the STEPW classification to cases. Not all of the coauthors submitted cases for the entire study period (2007–2009).

Nearly half (48.1%) of the 465 cases were from China, followed by Brazil with 41.5%, Italy with 8%, and the United States with 2.4%. Caucasian women made up 37.3% of the sample, African American women 13.5%, and Asian women 49.2%. The mean age was 42.6 years (range, 20–76 years). Fifty-eight women (12.6%) reported using combined oral contraceptives, and 12.6% reported using GnRH agonists preoperatively. A total of 373 subjects (80%) reported one or more pregnancies; 92 subjects (20%) had never been pregnant.

Clinical indications were abnormal uterine bleeding in 297 cases (63.9%), an alteration on pelvic ultrasound ordered for screening in 84 (18.1%), pelvic pain in 44 (9.5%), infertility in 15 (3.2%), bleeding and infertility in 12 (2.6%), and other complaints in 13 (2.8%).

### Data Collection

A spreadsheet was created so that the necessary parameters could be entered into the database by the medical team that carried out the procedure. The STEPW classification score was automatically calculated within the spreadsheet according to the point system in Figure 1. Procedures to evaluate the internal consistency of the data and for quality control were carried out during the data analysis.

The information provided by the patients and the data about the submucous fibroid(s) were collected before the myomectomy. After the myomectomy, data about the surgical procedure and its results were recorded. The following

**FIGURE 1**

STEPW submucous fibroid classification.

	Size (cm)	Topography	Extension of the base	Penetration	Lateral Wall	Total
0	< 2	Low	< 1/3	0	+ 1	
1	> 2 a 5	Middle	>1/3 - 2/3	< 50%		
2	>5	Upper	> 2/3	> 50%		
Score	+	+	+	+	+	

Score	Group	Complexity and therapeutic options
0 to 4	I	Low complexity hysteroscopic myomectomy.
5 to 6	II	High complexity hysteroscopic myomectomy. Consider GnRH use? Consider Two-step hysteroscopic myomectomy.
7 to 9	III	Consider alternatives to the hysteroscopic technique

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**TABLE 1****Correlation between ESGE and STEPW classifications in complete and incomplete hysteroscopic myomectomies.**

Parameter	Complete (432, 92.9%)			Incomplete (33, 7.1%)			
	Classification	Complete/total	%	Classification	Incomplete/total	%	
ESGE	Type 0	85/86	98.9	Type 0	1/86	1.2	
	Type 1	278/298	93.3	Type 1	20/298	6.7	
	Type 2	69/81	85.2	Type 2	12/81	14.8	
STEPW	Group I	Score ≤4	320/320	100.0	Score ≤4	0/320	0.0
	Groups II and III	Score >4	112/145	77.2	Score >4	33/145	22.8

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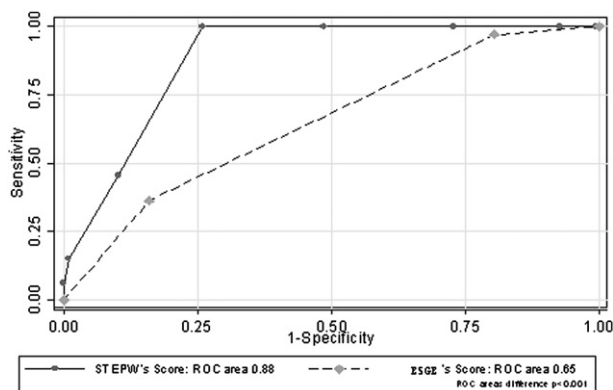
information was recorded in the spreadsheet: patient's initials, age, number of previous pregnancies, deliveries, cesareans, miscarriages, history of tubal ligation, ethnicity, history of hormone replacement therapy use, chief complaint; information about the submucous fibroid: size (dimensions according to measurements obtained by ultrasound or magnetic resonance imaging [MRI]), wall penetration (obtained by hysteroscopy, ultrasound, and/or MRI), topography, extension of the base, and lateral vs. anterior or posterior wall; and information about surgical technique and complications: GnRH analogue use, technique, energy, operative time, distension media, fluid balance, fibroid removal, anesthesia, antibiotic, intra- and postoperative complications, duration of hospital stay, and surgeon's name. The patients were treated according to the surgery protocols of each center, in accordance with the norms of the surgical team.

### Statistical Analysis

Data were described in bivariate tables, with the percentage of cases with complete fibroid removal and trends in the proportion of fibroid removal tested with a  $\chi^2$  test for trends. The validation of the two classifications was assessed according to the sensitivity and specificity of each one using their best cutoff point. Positive and negative predictive values were also calculated. Test of equality of the two areas under the receiver operating characteristic (ROC) curves was performed for correlated samples (13). Agreement between the scales was measured by the  $\kappa$  coefficient (14). Analyses were carried out using Stata version 9.2 (StataCorp, College Station, TX).

**FIGURE 2**

Areas under the ROC curves of two scores predicting partial removal of uterine fibroids during hysteroscopic surgery.

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### RESULTS

Of the 465 submucous fibroids, 199 were ≤2 cm, 252 were 2.1–5 cm, and 14 were >5 cm. Using the STEPW classification, 320 (68.8%) of the submucous fibroids were assigned to group I, 136 (29.2%) to group II, and 9 (2.0%) to group III. When separated according to STEPW score, 320 fibroids had scores ≤4 and 145 had

**TABLE 2**

**Validation assessment of classification system for predicting hysteroscopic uterine fibroid removal among women in Brazil, China, the United States, and Italy (N = 465).**

Classification system	Fibroid removal	
	Complete	Partial
<b>STEPW</b>		
Classification		
Score ≤4 (group I)	320 (74.1)	0
Score >4 (groups II and III)	112 (25.9)	33 (100.0)
Total	432 (100.0)	33 (100.0)
Sensitivity	100.0 (89.4–100.0)	
Specificity	74.1 (69.7–78.1)	
ROC area <sup>a</sup>	87.0 (85.0–89.1)	
Positive predictive value	22.8 (16.2–30.5)	
Negative predictive value	100.0 (98.9–100.0)	
<b>ESGE</b>		
Classification		
Type ≤1 (level 0–1)	362 (84.0)	21 (63.6)
Type >1 (level 2)	69 (16.0)	12 (36.4)
Total	432 (100.0)	33 (100.0)
Sensitivity	36.4 (20.4–54.9)	
Specificity	84.0 (80.2–87.3)	
ROC area <sup>a</sup>	60.2 (51.7–68.7)	
Positive predictive value	14.8 (7.9–24.4)	
Negative predictive value	94.5 (91.7–96.6)	

Note: Values are number (percentage) or percentage (95% CI).  
<sup>a</sup> ROC area = (sensitivity + specificity)/2.

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scores >4. In 232 cases the fibroid occupied less than one third of the wall, in 174 between one and two thirds, and in 59 more than two thirds. One hundred ten fibroids were located in the lower third of uterus, 162 in the middle third, and 193 in the upper third. Three hundred forty-two fibroids were located in the anterior or posterior wall and 123 in the lateral wall.

The extent of penetration into the myometrium was stratified according to the ESGE classification: 86 (18.5%) were type 0, 298 (64.1%) type 1, and 81 (17.4%) type 2.

Operative time was calculated as the interval from the beginning of surgery to the end of the procedure. Operative times ranged from 1 to 155 minutes; the mean was 32 minutes.

Complications occurred in 15 cases (3.2%). No deaths were reported. Seven complications occurred in fibroids with STEPW scores  $\leq 4$ , including two cases of fever, two cases with pain, and three cases with bleeding. Eight complications occurred in fibroids with STEPW scores >4: six cases with bleeding, one perforation of the uterus, and one case (STEPW score 8) with fluid overload. Using the ESGE, bleeding occurred in two cases of myoma type 0, five type 1, and two type 2; perforation in one type 1; fever in two type 0; pain in two type 1; and overload in one type 2.

In 432 (92.9%) of the 465 myomectomies removal of the fibroid was complete, whereas in 33 (7.1%) the myomectomy was incomplete. Fibroids were completely removed in all 320 fibroids (100%) with a STEPW score  $\leq 4$  (group I) and in 112 (77.2%) of the 145 fibroids with a score >4.

Using the ESGE classification we observed that 85 of 86 (98.8%) cases of type 0 fibroids, 278 of 298 (93.3%) type 1, and 69 of 81 (85.2%) type 2 were completely resected (Table 1). Of the 33 incompletely resected myomas, 21 (63.6%) of the fibroids were classified according to the ESGE classification as type 0 or 1, and 12 fibroids (36.4%) were assigned to type 2. In contrast, using the STEPW classification, all fibroids classified into group I were completely resected, whereas all fibroids that were incompletely resected were in group II or III, corresponding to STEPW scores >4.

## Validation Comparison

Analysis of the areas under the ROC curve (Fig. 2) showed that the best cutoff point for the STEPW classification was 4, and the best cutoff point for the ESGE classification was 1. These cutoff points were used to predict whether the removal of the fibroids would be incomplete. After dichotomizing both scales, the agreement between them was 69.8%, with a  $\kappa$  value of 0.20 (95% confidence interval [CI] 0.11–0.29). That level is considered a poor agreement (14). The percentage of complete fibroid removal in the sample was 92.9%. The sensitivity and specificity of the STEPW score were, respectively, 100% (95% CI 89.4%–100.0%) and 74.1% (95% CI 69.7%–78.1%) (Table 2), whereas the values for the ESGE classification were, respectively, 36.4% (95% CI 20.4%–54.9%) and 84.0% (95% CI 80.2%–87.3%). Considering the area under the ROC curve, the dichotomized STEPW scores performed better than the dichotomized ESGE scores ( $P < .001$ ).

## DISCUSSION

There was a correlation between the STEPW classification and the probability of complete removal of the fibroids. All fibroids (100%) classified as group I—with scores from 1 to 4—were completely removed. The complete removal rate dropped to 0 with a score of 8. Four of the five variables used to calculate the STEPW score were statistically associated with the outcome under analysis

( $P < .05$ ); the exception was location of the fibroid in the lateral wall ( $P = .91$ ). However, the elimination of this variable from the STEPW score reduced the area under the ROC curve; therefore, we decided to retain it in the STEPW score. Furthermore, the original STEPW score includes this variable, on the basis of clinical grounds. We tested whether the area under the ROC curve varied according to a set of variables in the database that could modify the performance of the predictions: country of origin of the patients; number of pregnancies; whether the woman had ever had a caesarean; age; and whether she was taking hormone replacement therapy. Results showed that for both scores, the area under the ROC curve did not change significantly ( $P > .05$ ).

Complications occurred in all the groups; however, the major complications occurred in group II (perforation) and in group III (overload).

The publication in 2005 of the Lasmar classification, now called the STEPW classification, and the findings from the pilot study raised the question of whether group III fibroids (those with a score  $\geq 7$ ) should be resected hysteroscopically. There were only nine group III fibroids (seven with a score of 7 and two with a score of 8) in the present study, suggesting that experienced surgeons limit their hysteroscopic myomectomies of group III fibroids. In these nine cases, only four fibroids (44.4%) were completely removed, and the only case of overload was in this group (15).

As with any international multicenter study, there were some challenges. The study organizers sought to involve coinvestigators with extensive experience in hysteroscopic myomectomy who have published studies about the two classification systems. Although designed as a 3-year prospective study, some of the coinvestigators, for reasons specific to their institutions, were only able to contribute data for 1 year.

There may be limitations to the applicability of the STEPW score and groups. The surgical teams that participated in this study were all quite experienced. Less-experienced surgeons may have higher rates of incomplete removal of fibroids and higher rates of complications, especially in group III. A major advantage of the STEPW classification is its ability to more accurately predict the difficulty of hysteroscopic resection and the likelihood of complete resection. This will permit the surgeon to determine which fibroids are amenable to hysteroscopic resection and to plan and better prepare for the surgery.

In conclusion, the STEPW classification was helpful in predicting which submucous fibroids would be incompletely removed by hysteroscopic myomectomy. All the fibroids whose removal was incomplete were classified with scores >4 (groups II and III). All the fibroids with a score  $\leq 4$  (group I) that underwent hysteroscopic myomectomy were completely removed.

The STEPW classification also demonstrated good specificity: 74.1% of the fibroids that were completely removed had scores  $\leq 4$  (group I).

Unlike the findings of the 2005 pilot study, some submucous fibroids with a score  $\geq 7$ , and thus classified as group III, can be treated hysteroscopically provided that the gynecologist is highly experienced. Even in experienced hands, fewer than half of the fibroids so classified were completely removed, and complications were more likely to occur.

Classifying submucous fibroids using the STEPW classification permits greater correlation with incomplete or complete removed of the fibroid by hysteroscopic myomectomy than does use of the ESGE system; its growing use in clinical practice will further establish the efficacy of this tool.

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