

## SUBMUCOUS FIBROID: DIFFERENT PRESURGICAL CLASSIFICATION METHODS AND THEIR EFFECT ON HYSTEROSCOPIC SURGICAL MANAGEMENT

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### ABSTRACT

**Objective:** To compare the degree of difficulty and outcome measures of hysteroscopic myomectomy of submucous fibroid according to 2 classification systems.

**Methods:** This prospective study conducted in the Cytogenetic & Endoscopy unit, Zagazig University Hospitals during the period from July 2009 to July 2012, included 100 patients candidates for hysteroscopic resection of submucous fibroids. All fibroids were diagnosed and assessed by saline infusion sonohysterography and diagnostic hysteroscopy. Presurgical classification was performed according to the two classification systems; the European Society of Endoscopic Surgery (ESES)–considering only the penetration of the fibroid into the myometrium – and STEPW considering size, topography, extension, penetration and wall affected. Primary outcome measure was incomplete resection of the fibroid. Secondary outcome measures were operating time (in minutes), the fluid deficit (in milliliters) and any intraoperative complications. Sensitivity, specificity and kappa measure of agreement were calculated for each classification at their best cut off. P value less than 0.05 is considered significant.

**Results:** Myomectomy was considered incomplete in 8 out of 104 fibroids (7.7%) According to **ESES**, 2 belonged to type 0 and 6 belonged to type I. Risk ratio and 95% confidence interval (CI) was **0.56 (0.07-3.3)** and the difference was not significant ( $p=0.7$ ); whereas according to the **STEPW** classification, the incomplete myomectomies were one in group I (1/8, 12.5%) and seven in group II (7/8, 87.5%). The risk ratio (95% CI) was **0.02 (0.0-0.18)** and the difference was significant ( $p= 0.000$ ). Considering the area under the ROC curve, the dichotomized STEPW scores performed better than the dichotomized ESES scores ( $P<.001$ ).

**Conclusion:** The application of STEPW classification of submucous fibroid gives better prediction of myoma removal than ESES classification.

**Key words:** submucous fibroid classification, hysteroscopic myomectomy, ESES, STEPW.

### INTRODUCTION

Uterine myomas- the most common solid pelvic tumors in women- occur in 20–40% of women in the reproductive years and form the most common indication for hysterectomy<sup>(1)</sup>. Only 5–10% of fibroids are estimated to be submucosal, but they are often symptomatic. Common symptoms include menorrhagia, intermenstrual bleeding and subfertility<sup>(2)</sup>.

Hysteroscopic myomectomy currently represents the standard minimally invasive surgical procedure for treating submucous fibroids, with abnormal uterine bleeding and reproductive issues being the most common indications<sup>(3)</sup>. The complication rate for hysteroscopy, however, was reported as approximately 3%. The most frequent complications of hysteroscopic myomectomy are uterine perforation (14/1000) followed by postoperative bleeding (2.5/1000) and water intoxication (2/1000)<sup>(4)</sup>.

Therefore, a thorough pre-surgical evaluation and classification of different types of submucous fibroids is essential in order to establish a surgical prognosis and weight the limits of the surgical technique.

The European Society of Endoscopic Surgery proposed a classification, originally developed by **Wamsteker et al (1993)**, which considers only the degree of myometrial penetration of the submucous fibroid<sup>(5)</sup>. According to this classification, a myomata type 0 is completely

within the uterine cavity and appears only jointed to the cavity wall by a thin pedicle; a myomata type I is sessile myomata with less than 50% of the mass in the myometrium, or more than 50% in the uterine cavity ; and a myomata type II has more than 50% of the mass in the myometrium.

**Lasmar et., al ( 2005)** proposed a new classification system that took into consideration not only the degree of penetration, but also other parameters including the extension of the base of the myoma with respect to the wall of the uterus, the size of the nodule (cm) by any of the imaging methods, the topography which is defined by the third of the uterine cavity where the myoma is situated and the wall of the uterus affected (**STEPW** classification) to evaluate the viability of hysteroscopic myomectomy in predicting partial or complete fibroid removal<sup>(6)</sup>. They reported that **STEPW** classification had a greater correlation with surgical outcomes as compared to ESES system.

Since then, only few studies have been conducted comparing the 2 classification systems. One study included only Brazilian women<sup>(7)</sup> and the other was a multicenter study conducted in China, Italy and United States as well as Brazil<sup>(8)</sup>. Both studies reached the same conclusion that **STEPW** classification allows better prediction of myoma removal, fluid balance, surgical complications and operative time in hysteroscopic myomectomy than ESES classification.

The aim of this study was to correlate **ESES** and **STEPW** classifications with complete or incomplete removal of submucous myoma, length of surgery, fluid balance, and surgical complications in Egyptian women undergoing hysteroscopic myomectomy.

#### PATIENTS AND METHODS

##### Participants

This prospective study was conducted during the period from July 2009 to July 2012 in the Cytogenetic & Endoscopy unit, Zagazig University Hospitals. The protocol of this study was approved by our institutional review board. Fully informed consent was obtained from all women participating in the study.

A total of 100 women, candidate for hysteroscopic myomectomy, were included in the study. They were in the child-bearing age- with mean age of 34.2±4.6 y- complaining of abnormal uterine bleeding &/ or infertility. All women had to have submucous myoma either type 0 (completely intracavitary) or type 1 (less than 50% penetration into the myometrium), diagnosed by saline infusion sonohystrography (SIS) and confirmed by diagnostic hystroscope. Cases with type 2 submucous fibroid according to ESES classification or those having score >6 according to STEPW classification were excluded due to expected technical difficulties (**table 1**).

Pregnant women, cases with severe cardiovascular disease, uncontrolled diabetes, gross abdominal or pelvic pathology, severe hematologic disorders, or pelvic inflammatory disease were also excluded.

##### Management protocol

After counseling the patients and explaining the procedures, all the included cases were subjected to the following: 1) Transvaginal ultrasound (Voluson730 Pro V unit, GE healthcare, Zipf, Austria) and SIS to detect number, size, degree of penetration of submucous fibroid into the myometrium, the extension of the base of the nodule in relation to the wall affected and the location with respect to the third of the cavity

where the fibroid was found. 2) Diagnostic hysteroscopy to confirm the diagnosis and the classification of the fibroids according to the two scoring systems (ESES & STEPW) (**tables 1 & 2**). 3) In another setting, and after preoperative evaluation for the patient fitness, operative hysteroscopy was performed in the immediate post menstrual period without premedication. Operative hysteroscopy was performed -using resectoscope 9mm in diameter-the telescope used is (**Karl Storz GMBH, Hopkins II 27005BA, Tuttlingen, Germany**) which has angle of view 0° and diameter of **4.0mm with** inflow and outflow channels to keep continuous irrigation of the uterus by the distension medium which is saline 0.9%).

The electrosurgical unit used was bipolar (**Versapoint of Gynecare ®**). Myomectomy was performed by slicing technique. Intrauterine pressure was adjusted via the (**Wiest Hysteromat 3700, Germany**) and fluid deficit was calculated. Primary outcome measure was complete or incomplete resection of the fibroid. Secondary outcome measures were operating time (in minutes), the fluid deficit (in milliliters) and any intraoperative complications.

##### Statistical analysis

Data were coded, entered and checked to Statistical Package for Social Science (SPSS) version 20.0 soft ware. Quantitative data were summarized as mean and standard deviation, comparison between 2 means was calculated by independent t test. Qualitative data were presented as number and percentage and testing association was conducted by Chi-square test and Fisher Exact was recommended when expected cell is less than 5.

Validity of the score for prediction of incomplete removal was done by Receiver Operating Characteristic (ROC) curve and the best cut off was chosen. Sensitivity, specificity and kappa measure of agreement were calculated. P value less than 0.05 is considered significant.

**Table (1) ESES classification system of submucous fibroid** <sup>(5)</sup>

Score	Penetration into myometrium
0	0
1	<50%
2	>50% **

**Table (2) STEPW classification scoring system of submucous fibroid <sup>(6)</sup>**

Points	Size	Topography	Extension of the base	Penetration	Lateral wall	Total score
0	≤ 2cm	Lower third	<1/3	0	+1	
1	>2to 5 cm	Middle third	>1/3 to 2/3	<50%	+1	
2	>5cm	Upper third	>2/3	>50% **	+1	
Score		+	+	++		+ =

- The patient can have more than one submucous fibroid. Each fibroid has its own score.
- To decide which group (I, II or III) a patient belongs; only the fibroid with the highest score must be taken into consideration.
- The maximum total score is 9 points <sup>(6)</sup>, but in this study, the maximum total score is 8 as the cases with penetration more than 50% of the fibroid into the myometrium were excluded \*\* (1+2+2+2+1) table 3.
- If the lateral wall is affected, extra 1 point is added.

**Table (3) the distribution of the submucous fibroids according to the study scoring systems**

Points	Penetration	Size	Extension of the base	Topography	Lateral wall +1
0	38 (36.5%)	56 (35.9%)	52 (50%)	24 (23.1%)	77* (74%)
1	66 (63.5%)	46 (44.2%)	38 (36.5%)	36 (34.6%)	27 (26%)
2	**	2 (1.9%)	14(13.5%)	44 (42.3%)	0

\* Anterior or posterior wall involved

## RESULTS

**Out of the 100 studied cases;** 21 (21%) complained of infertility or concerned about the reproductive future and 79 (79%) complained of abnormal uterine bleeding.

Of the 100 studied women, a total of 104 submucous fibroids was found as 97 cases had one, two cases had 2 and 1 case had 3 submucous fibroids.

Using the **STEPW** classification, 82.7% (86/104) of the submucous fibroids were assigned to group I (score 0-4), and 17.3% (18/104) to group II (score 5-6).

Of the 104 submucous fibroids, 56 (53.9%) were ≤ 2 cm, 46 (44.2%) were 2.1–5 cm, and 2 (1.9%) were >5 cm. Fifty two (50%) fibroids occupied less than one third of the wall, 38 (36.5%) occupied between one and two thirds, and 14 (13.5%) occupied more than two thirds.

Twenty four fibroids (23.1%) were located in the lower third of uterus, 36 (34.6%) in the middle third, and 44 (42.3%) in the upper third.

Seventy seven (74%) fibroids were located in the anterior or posterior wall and 27 (26%) in the lateral wall (**table 3**).

The extent of penetration into the myometrium was stratified according to the **ESES** classification: 36.5% (38/104) of the fibroids were type 0 and 63.5% (66/104) were type 1 (**table 3**).

Saline infusion sonohysterography, as a method of diagnosing submucous fibroid, when compared to the diagnostic hysteroscopy gave sensitivity of 97.8% , specificity of 83.3%, and accuracy of 96.15% with Kappa coefficient= 0.81± 0.09 and (p= 0.0015) which ensures significant degree of agreement.

Myomectomy was considered complete in 92.3% (96/104) of the fibroids, whereas in 7.7% (8/ 104) of the fibroids the myomectomy was incomplete. According to **ESES** classification, myomectomies were incomplete in two fibroids belonged to type 0 (2/8; 25%) and six belonged to type 1 (6/8; 75%) with risk ratio and 95% confidence interval of **0.56 (0.07-3.3)** and the difference was not significant (p=0.7); whereas according to the **STEPW** classification, the incomplete myomectomies were one fibroid in group I (1/8, 12.5%) and seven in group II (7/8, 87.5%). The risk ratio and 95% confidence interval was **0.02 (0.0-0.18)** and the difference was statistically significant (p= 0.000) (**table 4**).

According to **ESES** classification, the mean operation time in type 0 myomas (16± 3.4 minutes, range 11.2 to 36.3 ) was significantly shorter than that spent in type 1 myomas (30.7± 5.3 minutes; range 23.3 to 40.2 , p =0.0048) (**table 5**). The mean fluid deficit was 96.9±26.3 ml for type 0, 117.4±29.2 ml for type 1 and the difference was not significant (p=0.08) (**table 5**).

According to **STEPW** classification, the time spent in operations in group I ranged from 9.3 to 21.3 minutes with a mean of  $15.4 \pm 3.1$ . While in group II, it ranged from 33.2 to 48.4 minutes with a mean of  $42.1 \pm 1.4$ , and the difference was significant ( $p=0.000$ ) (**table 5**). The mean fluid deficit was  $130.2 \pm 13.2$  ml for group I, and  $518.4 \pm 49.3$  ml for group II, and the difference was also significant ( $p=0.000$ ) (**table 5**).

The procedure related complications were reported in 2 patients. In the first case, the fibroid was situated in the left lateral uterine wall and it was classified as type 0 according to **ESES** classification (1/38, 2.6%). It was accidentally perforated and the procedure was stopped at once and immediate laparoscopy was performed that revealed no trauma of abdominal organs with securing the bleeding vessel, and then she was kept under observation and discharged on the second day. The other patient had a large based fibroid that belonged to type 1 according to **ESES** classification (1/66, 1.5%) and she suffered from postoperative bleeding. She was treated and managed successfully by insertion of Foley's catheter and inflating its balloon with saline; which was left for 6 hours. There was no significant difference in the incidence of complications between the 2 types of myoma according to **ESES** classification ( $p=0.73$ ).

According to **STEPW** Classification, the 2 complicated procedures occurred in patients belonging to group II (score 5-6) (2/18, 11.1%) and the difference was just above the significant level ( $p= 0.05$ ) when compared with group I (score 0-4) (**table 5**).

#### Validation Comparison

Analysis of the areas under the ROC curve (**Fig. 1**) showed that the best cutoff point for the **STEPW** classification was 4, and the best cutoff point for the **ESES** classification was 1. These cutoff points were used to predict whether the removal of the fibroids would be incomplete.

Sensitivity and specificity of the **STEPW** score were, respectively, 87.5% (95% CI 46.7%–99.3%) and 88.5% (95% CI 80.0%–93.9%) for the prediction of incomplete myomectomy (**Table 6**), whereas the values for the **ESES** classification were, respectively, 75.0% (95% CI 35.5%–95.5%) and 37.5% (95% CI 28.0%–48.0%).

After dichotomizing both scales, the observed agreement between them was 50.96%, with a k value of  $0.061 \pm 0.07$  and  $p=0.18$ . That level is considered a poor agreement.

Considering the area under the ROC curve, the dichotomized **STEPW** scores performed better than the dichotomized **ESES** scores ( $P<.001$ ).

**Table (4): Distribution of myomectomy according to the 2 classification systems**

Myomectomy	ESES classification		STEPW classification	
	Type 0	Type 1	Group I	Group II
Incomplete	2/8 (25%)	6/8 (75%)	1/8 (12.5%)	7/8 (87.5)
Complete	36/96 (37.5%)	60/96 (62.5%)	85/96 (88.5%)	11/96 (11.5%)
Risk ratio (95% CI)	0.56 (0.07-3.3)		0.02 (0.0-0.16)*	

CI = confidence interval, \*  $p=0.000$

**Table (5): Operation time, fluid deficit, and complications of myoma removal according to the classification systems of submucous fibroids.**

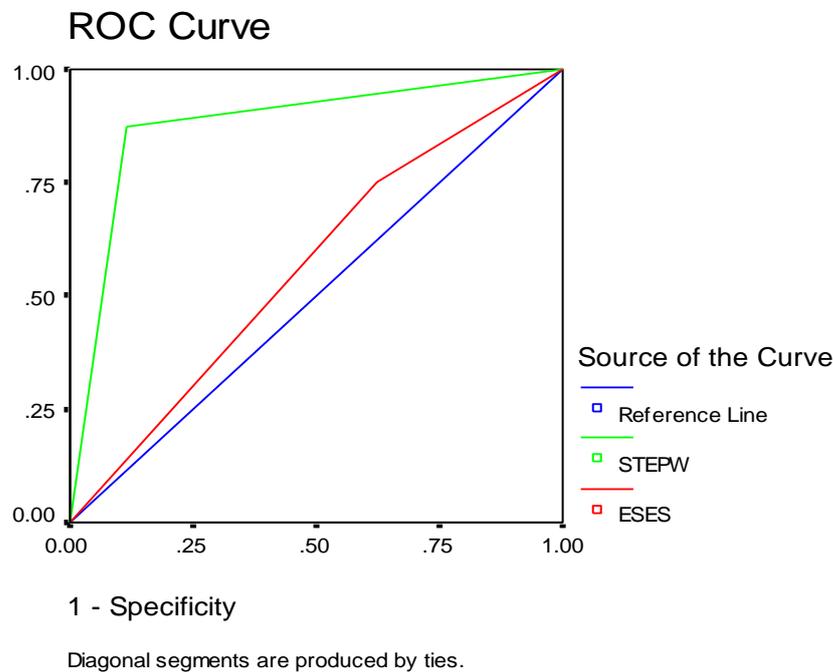
Item	ESES classification		STEPW Classification	
	Type 0	Type 1	Group I	Group II
Operation time mean±SD (minutes)	$16 \pm 3.4$	$30.7 \pm 5.3$	$15.4 \pm 3.1$	$42.1 \pm 1.4$
P	0.0048		0.000	
Fluid deficit (ml) mean±SD(ml)	$96.9 \pm 26.3$	$117.4 \pm 29.2$	$130.2 \pm 13.2$	$518.4 \pm 49.3$
P	0.08		0.000	
Complications	1/38 (2.6%)	1/66 (1.5%)	0/86 (0%)	2/18 (11.1%)
P	0.73		0.05	

P value less than 0.05 is considered significant.

**Table (6): Validation assessment of the two classification systems for hysteroscopic myomectomy prediction (N= 104)**

Classification system	ESES classification			STEPW classification		
	Fibroid removal	Type 0	Type 1	Total	Group I	Group II
<b>Complete</b>	<b>36</b> (37.5%)	<b>60</b> (62.5%)	<b>96</b> (100%)	<b>85</b> (88.5%)	<b>11</b> (11.5%)	<b>96 (100%)</b>
<b>Incomplete</b>	<b>2 (25%)</b>	<b>6 (75%)</b>	<b>8 (100%)</b>	<b>1 (12.5%)</b>	<b>7 (87.5%)</b>	<b>8 (100%)</b>
<b>Sensitivity</b>	<b>75.0 (35.5-95.5)</b>			<b>87.5 (46.7-99.3)</b>		
<b>Specificity</b>	<b>37.5 (28.0-48.0)</b>			<b>88.5 (80.0-93.9)</b>		
<b>ROC area</b>	<b>56.3 (36.3-76.2)</b>			<b>88.0 (74.2-100.0)</b>		

**Figure (1): areas under the ROC curves of the two scores predicting partial myomectomy during hysteroscopy**



**DISSCUSION**

Transcervical hysteroscopic resection of submucous myomas is safe and is the method of choice for patients with a normal-sized uterus<sup>(9)</sup>. With the objective of establishing a surgical prognosis and enabling a valid comparison of the results of the hysteroscopic myomectomy, it is essential to have a wide-ranging classification system that can correctly group together procedures of the same level of difficulty, however the classification system of the European Society of Endoscopic Surgery (**ESES**) considers only the degree of penetration of the submucous fibroid in the myometrium and so it was claimed to be inefficient at discriminating the complexity of hysteroscopic myomectomies<sup>(6)</sup>.

In 2005 **Lasmar et al.** developed 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 and wall affected (**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 **ESES** classification<sup>(6)</sup>. In the current work, according to **ESES** classification, the risk ratio (95% CI) of incomplete myomectomies for type 0 as compared to type 1 was 0.56 (0.07-3.3) with no significant difference between the 2 types (p=0.7), whereas; according to the **STEPW** classification, group I had a risk ratio (95% CI) of 0.02 (0.0-0.18) for

incomplete myomectomies as compared to group II and the difference was statistically significant ( $p=0.00$ ). For prediction of incomplete removal, there were poor agreement between the 2 classification systems; furthermore, STEPW classification was found to be more sensitive and specific (**87.5 and 88.5%; respectively**) than ESES classification (**75 and 37.5; respectively**).

In addition, it can be speculated that STEPW classification gives a better indication of difficulties in hysteroscopic myomectomies than the ESES classification which is currently being used. There were significant differences when group II was compared to group I as regards time spent in surgery ( $p=0.000$ ) and fluid deficit ( $p=0.000$ ), but as regards incidence of complications, the difference was just above the significant level ( $p=0.05$ ); while, on using ESES, the differences in the same parameters were not significant when type 0 was compared to type 1 except for the time spent in operation ( $p=0.0048$ ).

It was noticed that the average operation time was nearly doubled in type 1 when compared to type 0 using ESES classification, and almost tripled when going from group I to group II when using STEPW classification. Furthermore, the average fluid balance has no significant difference when type 0 and type 1 fibroids according to ESES classification was compared ( $p=0.08$ ) and almost quadrupled when group I was compared to group II using STEPW classification.

In this study there were 2 patients with complicated procedures, one in each type according to ESES classification, whereas; the 2 complications occurred only in group II according to STEPW classification (score 5-6). Both complications were due to criteria not considered in ESES classification; uterine perforation during resection of a laterally situated fibroid and postoperative uterine bleeding following resection of a large based fibroid.

There were 2 studies conducted to compare the 2 classification systems. The first was a multicenter and prospective study in six hysteroscopy centers in Brazil (205 submucous fibroids removal) and concluded that classifying submucous myomas with the STEPW classification allows better prediction of myoma removal, fluid balance, length of surgery and surgical complications in hysteroscopic myomectomy than ESES classification.<sup>(7)</sup>

The second was multicenter, prospective study conducted in four hysteroscopy centers in Brazil, China, Italy, and the United States (465

submucous myomas removed hysteroscopically) and also it concluded that the STEPW classification was helpful in predicting which submucous fibroids would be incompletely removed by hysteroscopic myomectomy.<sup>(8)</sup>

In this study, correlation of the 2 system classification was done with complete or incomplete myomectomy, length of surgery, fluid balance and surgical complication in Egyptian women undergoing hysteroscopic myomectomy and it agreed with the results and conclusion of the previous 2 multicenter studies.

To sum up, STEPW classification of submucous fibroids- considering size, topography, extension, penetration and wall affected- seems to be a more reliable predictor of myoma removal and other outcome measures of hysteroscopic myomectomy than ESES classification which only considers the penetration of the fibroid into the myometrium.

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