

ORIGINAL ARTICLE

Title: Validation of the ECO System in management of patients with endometriosis: a preliminary study.

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Synopsis: The ECO system is an efficient instrument to help the non-specialized gynecologist in managing patients with endometriosis.

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Abstract

Objective: To validate a new instrument created to suggest treatment of patients with endometriosis for non-specialized gynecologists.

Study Design: A retrospective study of 69 patients with a diagnosis or suspicion of endometriosis, seen at the endometriosis outpatient's clinic, *Hospital Universitário Antônio Pedro*. The management used at the service was compared to the procedures suggested by the ECO system.

Result(s): All patients with a score of 2 were submitted to exclusively medical treatment. In the group with a score of 3, a total of 93.9% were dealt with clinically, while 6.1% were submitted to surgical intervention. In patients with a score of 4, in 59.1% clinical control with drug treatment was indicated, and in 40.9%, the surgical approach was indicated. All other patients with scores of 5 and 6 were treated surgically.

Conclusion(s): Patients with scores ≥ 4 should be referred to centers specialized in endometriosis.

Keywords: Endometriosis, Pain, Infertility, Approach.

Introduction

Endometriosis is a frequent disease in the female population at child-bearing age and there are still significant difficulties in establishing its management [1,2]. There is no consensus in literature as to when to indicate surgical or medical treatment, especially in mild cases of endometriosis with associated symptoms (pain or infertility) [3,4].

It is estimated that it occurs in 10% of women at child-bearing age and it is one of the main causes of pelvic pain and infertility [1,5,6]. It may also be associated with psychological disorders, frequent absenteeism, and marital problems [7,8]. Diagnosis is made based on a detailed medical history and a thorough physical examination. However, it is known that the mean time from onset of symptoms until diagnosis of the disease may be up to 10 years [4,7,9]. From the suspected diagnosis, which is basically clinical, an evaluation is made of the pelvis with imaging tests that aid the gynecologist stage and define the extension of the disease. Treatment may be medical or surgical, depending on the degree of involvement of the disease, and the desire of the patient is fundamental in managing each case [3,4,10]. The approach of the patient with endometriosis is complex, mainly due to the site of the disease, age, desire for pregnancy, and reported complaints. Therefore, the gynecologist needs to know endometriosis well and thoroughly discuss with the patient the objectives and possible results of the treatment chosen. Surgical treatment is well established for cases of large ovarian endometriomas and functional compromise of organs [3,4]. Intense pain, refractory to medical treatments, is also an indication for surgery [11,12].

Recently, an instrument for evaluation of treatment in patients with endometriosis, called the "ECO System" [4] was developed. This system takes into consideration the patient's clinical complaint, findings of the physical examination and/or imaging exams, and the patient's wishes, qualifying and quantifying by means of the score of each one of the parameters.

With these parameters, a total score is obtained, suggesting the management - surgical or clinical treatment, or cases in which one or the other would be appropriate. In the said study, the treatment suggested by the score obtained is: for scores of 0 to 2 – clinical follow-up, for score 3 – clinical follow-up or surgical intervention, and for scores 4 to 6 - surgery.

The objective of this project is to validate the ECO system as a useful instrument to guide management in cases of endometriosis using the database of patients seen at the pelvic pain and endometriosis outpatient's clinic of the *Hospital Universitário Antônio Pedro*, of the *Universidade Federal Fluminense* (HUAP-UFF).

Material and Methods

This is a retrospective study, with data obtained by review of the medical records of patients with endometriosis, seen at the gynecology outpatient's clinic of the *Hospital Universitário Antônio Pedro*, from July 1st, 2012 to July 30th, 2013. This study was approved by the Ethics Committee of the *Hospital Universitário Antônio Pedro*. There was no need for a Consent Form since the project did not interfere with the normal procedures of the organization.

Inclusion criterion was patients with endometriosis diagnosed with surgery and with clinical/laboratorial suspicion of endometriosis, without surgery, seen at the *Hospital Universitário Antônio Pedro* during the period from July 1st, 2012 to July 30th, 2013.

Exclusion criteria were lack of information on the parameters of interest and surgical indication for another cause not exclusively endometriosis.

The following variables were noted: patient's complaint, extension of the disease mapped by the imaging tests and by the physical examination (sites of endometriosis), objective expressed by the patient, and treatment performed (surgery or conservative treatment). To complement this, also adopted were data such as age, parity, use of medication, prior pelvic operations, time of diagnosis, analog pain scale, and histopathological report of the patients who had undergone surgery.

With the data collected, an "ECO SYSTEM" score was obtained for each patient, as is shown on Table 1 [4]. The ECO System is formed by the following parameters: **Extension of the Disease**, which represents the site and extension of endometriosis (the score is 0 when the endometriosis is peritoneal; it is 1 when it affects the uterus and/or uterine ligaments (uterosacral and parametric) and/or endometrioma ≤ 3 cm, and is 2 when there is involvement of an intestinal loop and/or bladder and/or ureter and/or ovarian endometrioma > 3 cm); **Clinical status of the patient** represents the complaint of the patient (the score is 0 when the patient is asymptomatic; it is 1 when there is complaint of non-incapacitating pain and/or infertility, and it is 2 when the pain is incapacitating); **Objective of the patient** represents the desire of the

patient (the score is 0 when the patient does not express a desire for a change in the situation; it is 1 when she desires to get pregnant or get relief of pain, and it is 2 when the patient desires to get pregnant and get relief of pain). Figure 1. Incapacitating pain was defined as cases of pain that keep the patient from performing her regular daily activities.

Statistical analysis

The results of the continuous variables are presented as means and standard deviations, and the categorical variables as frequencies. Associations between the surgical outcome and the variables studied were tested using a logistic regression model. The predictive power of the ECO score was evaluated using the ROC curve. The SPSS software, version 18.0 for Windows (IBM, Chicago, IL, USA), was used for statistical analysis.

Results

Data from 94 medical records were collected on patients with endometriosis at *Hospital Universitário Antônio Pedro*. Of the 94 patients, 10 were excluded for having, besides endometriosis, symptomatic uterine myomas, seven had no histopathology of endometriosis, and eight had incomplete medical records. Sixty-nine patients were enrolled in the study, and their general characteristics are shown on Table 2.

Age ranged from 18 to 48 years (mean 34.9, SD 7.32 years). Twenty-eight (40.6%) patients never had children, 35 (50.7%) had one or two, and six (8.7%) had three or more. A total of 54 (78.3%) patients never had an

abortion/miscarriage, whereas 12 (17.4%) referred one abortion and three (4.3%) had had two abortions.

No case had a score of 0 or 1. The total score varied from 2 to 6.

Out of 69 patients included in the study, 47 (68.1%) were followed clinically against 22 (31.9%) who were submitted to therapeutic laparoscopy, Table 3.

All patients with a score of 2 were submitted to exclusively medical treatment. In the group of 33 patients with score 3, 31 (93.9%) of them were followed clinically and two (6.1%) were submitted to surgical intervention.

Of 22 patients with score 4, in 13 cases (59.1%) clinical control with medications was indicated, and in nine (40.9%), a surgical approach was used. All other patients with score 5 (10) and score 6 (1) were treated surgically.

In a multivariate model, the ECO scoring was strongly associated with a decision in favor of a surgical approach (OR 31.365, $P < 0.001$) even after adjustment for age, parity, and number of abortions, Table 4. The number of abortions was also found to be independently associated with a decision in favor of surgery (OR 5.776, $P = 0.048$).

The predictive power of the ECO scoring was tested in a receiver operating characteristic (ROC) curve, Figure 1. The area under the curve was 0.89. The cutoff point favoring a surgical approach was a score >3 .

Discussion

Management of patients with endometriosis is still controversial [4]. We aimed to validate the use of a tool to help in making decisions in these cases. To compare the predictive power of the ECO score, we resort to the ROC curve, which is considered very accurate in this regard and allows calculation of the cutoff points of the index.

When the 36 patients with a score ≤ 3 were evaluated, representing 52.2% of all the cases studied, it was noted that in only 5% of cases there was indication for surgery. As the proposal is to find markers to help the non-specialized gynecologist in treating patients with endometriosis, it seems that a score ≤ 3 is the limit for safe follow-up, with a great possibility for a conservative approach. In contrast, 100% of patients with a score ≥ 5 were submitted to surgery for treatment of endometriosis. This group with 11 cases represented 16% of the population studied.

Of the 69 patients accompanied, in almost 1/3 of them (22) the score was 4. In the group with this score, the management at the gynecology service was divided - in that, 59.1% for surgery against 40.9% for conservative treatment. Therefore, it was evident that it was with score 4 and not 3, as initially proposed, that the cases of endometriosis were found in which the treatment decision depends on more detailed information about the patient or the couple.

With the application of the ECO system, almost half (49.3%) of the patients with endometriosis could be accompanied by non-specialized gynecologists, decreasing referral to specialized centers.

From this preliminary study, we reinforce the usefulness of the ECO system, which proved efficient in predicting the management suggested by the

endometriosis outpatient's clinic at the HUAP-UFF. Therefore, we propose a new scoring and treatment table for the ECO system (Table 5). This system has its main indication for the non-specialized gynecologist, guiding the professional as to the possibility of conservative treatment for scores ≤ 3 and referral to specialists in endometriosis when the score is equal to or greater than 4. This last group would encompass all cases with doubts as to treatment and those with a clear indication for surgery.

The criticism of this study is the small number of cases and having been carried out at a single university service, whereas multicenter studies with a larger sample are recommended to confirm the validity of the ECO system.

Conclusion

The ECO system is an instrument to help the non-specialized gynecologist in managing patients with endometriosis, who should refer to specialized centers patients with scores ≥ 4 .

Conflict of interest

Ricardo B Lasmar, Bernardo P Lasmar, Jocemir R Lugon declare that they have no conflict of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). There was no need for a Consent Form since the project did not interfere with the normal procedures of the organization.

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Table 1 - ECO SYSTEM for approach of patients with endometriosis

Parameters	Score	Findings
Extension	0	Peritoneum
	1	Uterus and/or uterine ligaments, ovarian endometrioma \leq 3 cm
	2	Bowel and/or bladder, ureter, ovarian endometrioma $>$ 3 cm
Complaints	0	Asymptomatic
	1	Infertility or no incapacitating pain
	2	Incapacitating pain relating to the affected organs (dyschezia, dyspareunia, dysuria, dysmenorrhea)
Objective	0	No change wanted, accepting the situation
	1	Desiring pregnancy or pain relieve
	2	Desiring pregnancy and pain relieve

Table 2. General characteristics of the study population (N=69)

	n	%
Age (years)		
< 30	21	30.4
30 to 40	30	43.5
> 40	18	26.1
Parity		
Nulligesta	28	40.6
≤ 2 deliveries	35	50.7
≥ 3 deliveries	6	8.7
Abortion		
0	54	78.3
1	12	17.4
2	3	4.3
ECO Score		
2	03	4.4
3	33	47.8
4	22	31.9
5	10	14.5
6	01	1.4

Table 3. ECO score and approach of patients with endometriosis (N = 69)

ECO Score	Conservative (%)	Surgery (%)	Total (%)
2	3 (100.0)	0 (0.0)	3 (100.0)
3	31 (93.9)	2 (6.1)	33 (100.0)
4	13 (59.1)	9 (40.9)	22 (100.0)
5	0 (0.0)	10 (100.0)	10 (100.0)
6	0 (0.0)	1 (100.0)	1 (100.0)
Total	47 (68.1)	22 (31.9)	69 (100.0)

Table 4. Multivariate model of logistic regression to test for association of the ECO scoring with the surgical treatment

	O.R. (95% C.I.)	P
Total ECO score	31.365 (5.098 – 192.986)	<0.001
Age, years	1.057 (0.926 – 1.206)	0.412
Parity, N	0.403 (0.146 – 1.109)	0.078
Abortion, N	5.776 (1.015 – 32.860)	0.048

Table 5: Modified ECO Score

Score	Approach suggested	Specialized gynecological care
0, 1, 2,3	Conservative (medical treatment)	No
4	Conservative or surgical treatment	Yes
5, 6	Operative laparoscopic surgery	Yes

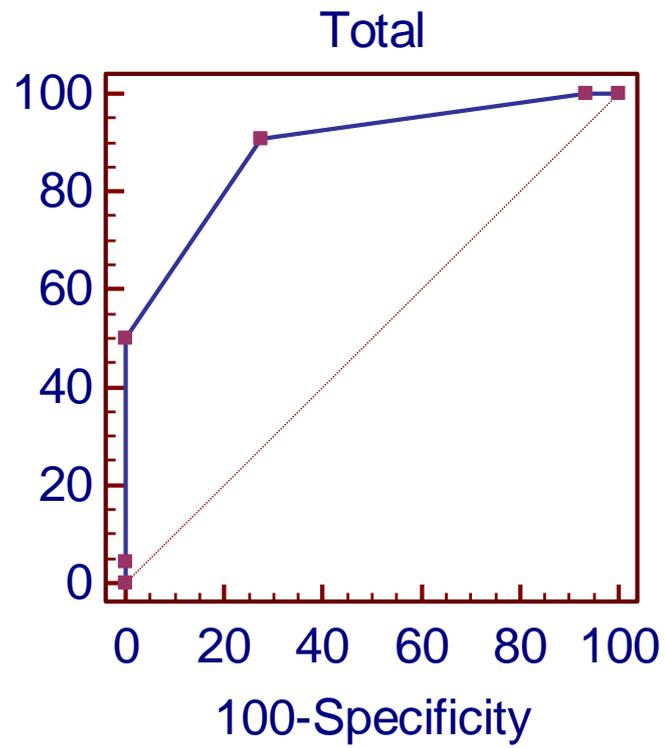


Figure 1: ROC curve to assess the predictive value of the ECO scoring in favor of a surgical approach