



## Ethanol sclerotherapy of ovarian endometrioma: a safe and effective minimal invasive procedure. Preliminary results



Amparo García-Tejedor<sup>a,\*</sup>, Marta Castellarnau<sup>b</sup>, Jordi Ponce<sup>a</sup>, M<sup>a</sup>Eulalia Fernández<sup>a</sup>, Fernando Burdio<sup>c</sup>

<sup>a</sup> Department of Gynecology, Bellvitge University Hospital-IDIBELL, Barcelona, Spain

<sup>b</sup> Universitat Autònoma de Barcelona. Departments of Obstetrics and Gynecology, Hospital General de l'Hospitalet, Barcelona, Spain

<sup>c</sup> Department of Surgery, Hospital del Mar, Barcelona, Spain

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### ABSTRACT

**Objective:** To study if ultrasound-guided aspiration with ethanol sclerosis is a safe and effective treatment for endometriomas.

**Study design:** We conducted a prospective study of 25 women with 27 endometriomas (two bilateral) measuring 4–10 cm in diameter with no suspected malignancy, who underwent ultrasound-guided aspiration and ethanol sclerosis between August 2010 and July 2014. Patients were followed up by ultrasound at 6, 12, 24, and 36 months to identify rates of complication and recurrence. Clinical characteristics of the patients (age, history of infertility, previous surgery, and abdominal pain), the cysts (location, diameter, and volume) and the procedure (duration and complications) were recorded. Kaplan–Meier survival curves were used to analyze the recurrence rates by SPSS statistical software. **Results:** The recurrence rate after sclerosis was 12%. The mean length of follow-up was 17 (SD 9.9) months. Although no major procedure-related complications were recorded, minor complications included three cases of low abdominal pain during the procedure (10.7%) and two cases of abdominal ethanol extravasation (7.1%).

**Conclusion:** Ultrasound-guided aspiration and ethanol sclerotherapy are a safe and effective treatment for endometriomas measuring 4–10 cm in diameter with no evidence of malignancy. This conservative treatment could possibly achieve a symptomatic cure while preserving healthy ovarian tissue, thereby improving fertility outcomes and avoiding early menopause.

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### Introduction

Ovarian endometrioma is a common presentation of endometriosis that occurs in 17–44% of patients with endometriosis [1] and is frequently associated with pelvic pain and infertility. Nowadays, these two clinical manifestations are leading the gynecologists to perform surgical treatments [2,3], although the risk of malignant transformation is just 0.3–0.8% [4]. Laparoscopic cystectomy is the most common surgical option, with a recurrence rate of around 15–30% after 2–5 years of follow-up [5,6] and a high risk of compromised fertility. Incidental excision of normal ovarian tissue along with the wall of the endometrioma has resulted, in some studies, in lower ovarian reserves after the excision of

ovarian endometriomas [7–9]. Endometrioma *per se* seems to have a lower ovarian reserve that decreases even more 6 months after surgery [10]. Similar results were found in a systematic review and meta-analysis by Raffi et al., with a significant postoperative reduction in circulating anti-Müllerian hormone (AMH) which suggested a negative impact on ovarian reserve after the excision of endometriomas [8]. This must be considered with care when surgery is scheduled for patients with no symptoms other than infertility or when patients already have a small ovarian reserve [9].

Other minimally invasive therapies are emerging to avoid surgical complications and to reduce fertility damage. Ultrasound (US)-guided aspiration and sclerosis have proven effective and cost-efficient for benign cysts located in other organs such as the thyroid, parathyroid, liver, kidney, and spleen [11]. Therefore, some authors are beginning to use this procedure in the management of ovarian cysts with low malignant risk, including endometriomas, and have reported recurrence rates between 0%

\* Correspondence to: Bellvitge Hospital, Ave. Feixa Llarga, sn. Hospitalet de Llobregat 08970. Barcelona. Spain. Tel.: +0034 93 260 76 95.

E-mail address: [agarciat@bellvitgehospital.cat](mailto:agarciat@bellvitgehospital.cat) (A. García-Tejedor).

and 56% [12–22]. Tetracycline, methotrexate, and ethanol are the most common agents used for sclerosis. Importantly, sclerosis seems to decrease pelvic pain [21] without affecting the number of terms or aborted pregnancies, extracted oocytes, embryo quality, or hormonal levels when compared to infertile women without ovarian cysts [16,23]. Some authors have even reported better responses to assisted reproduction treatment administered immediately after sclerosis [18].

After our positive previous experience with ethanol sclerotherapy in simple ovarian cysts [22] we decided to use the same agent for ovarian endometriomas. We thought that this minimally invasive procedure, the ethanol sclerosis of endometriomas, could have the same or even better results than the standard therapy (surgery) with lower rate of complications. Before designing a multicenter randomized study with a larger number and a longer follow-up comparing laparoscopy versus sclerosis, we performed a preliminary study to evaluate the new technique. This preliminary study aimed to assess the safety and efficacy of US-guided aspiration and ethanol sclerosis for selected cases of low-risk ovarian endometrioma.

## Materials and methods

This was a prospective study of 25 women with a total of 27 endometriomas at the Gynecology Department of Bellvitge Teaching Hospital in Barcelona, Spain, between August 2010 and July 2014. We performed US-guided aspiration and ethanol sclerosis of endometriomas in 13% of 202 ovarian cysts referred as a low-risk adnexal mass, previously detected by pelvic US. The study was approved by the ethics committee of our hospital (PR 157/07 Record 21/11).

### Inclusion and exclusion criteria

Patients had to meet all of the following criteria to be eligible: (1) age > 18 years old; (2) US features predictive of endometrioma: homogeneous appearance involving diffuse internal echoes on a hypoechoic background according to the International Ovarian Tumor Analysis (IOTA) group criteria [24] with a maximum diameter between 40 and 100 mm; (3) unilocular cyst; (4) cyst persistence  $\geq 6$  months from diagnosis; (5) tumor marker CA125 <200 IU/mL and CA19.9 <35 IU/mL); (6) no suspected extra-ovarian endometriosis; and (7) written informed consent.

We excluded patients with US features suggestive of dermoid cysts (fat-fluid levels, globular calcifications, or hyperechoic mural plug), as well as anechoic cysts, those with a solid component, internal septation, a fluid–fluid level, or any sign indicating a high risk of malignancy according to the IOTA criteria. Additional exclusion criteria included the following: serum CA125 or CA19-9

levels greater than 200 IU/mL and 35 IU/mL, respectively; abnormal coagulation test results; a personal history of gynecologic cancer; and refusal to participate. When extra-ovarian endometriosis was suspected, magnetic resonance imaging (MRI) was performed to determine whether or not these patients should be excluded.

### Procedure

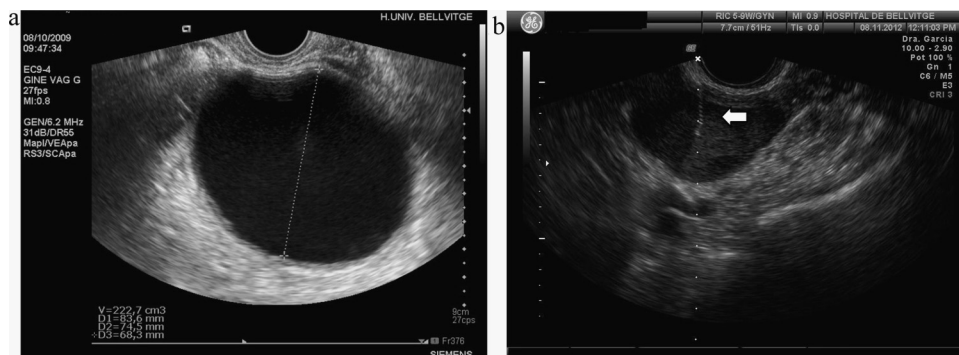
A gynecologist (A.G), trained in interventional procedures, supervised US-guided aspiration using Acuson Antares Sonoline (Siemens AG, Erlangen, Germany). Twenty-five transvaginal and three transabdominal US-guided aspirations were performed. Trans-abdominal aspiration was performed when the patient had had no previous sexual intercourse and when we observed US evidence of high vascularization through the potential vaginal puncture to avoid vessel injury.

The abdominal wall or the vagina was disinfected with povidone solution and we used a sterilized 17 gauge needle (BD Medical, Franklin Lakes, NJ, USA) for the procedure. Under direct US guidance, the needle was aimed toward the center of the cyst (Fig. 1) and the endometrioma was aspirated (if thick intracystic fluid was present, saline dilution was used). Next, we performed several intracystic saline washes before instilling ethanol as the sclerosing agent. The volume of ethanol instilled was equal to two-thirds of the volume aspirated from the endometrioma and always less than 100 mL. Ethanol remained within the cyst for 15 min, and then was removed to allow further washing with a saline solution, until completely dry if possible. We routinely collected the drained fluid, measured it using a syringe, and sent it for cytological examination to confirm the absence of atypical cells.

Patients were followed up by US every 6 months in the first year and annually thereafter. Recurrence was defined as the presence of an adnexal cyst suggestive of endometrioma with a maximum diameter  $\geq 30$  mm in the same ovary on examination by US, to rule out the formation of a new functional cyst [25]. We recorded the clinical characteristics of the patients (age, previous surgery for endometriosis, history of infertility, symptomatology, hormonal therapy after the procedure with contraceptive pills) and the characteristics of the cysts (US size, volume, and localization). None of the patients was menopausal. All procedures took place on an outpatient basis, without anesthesia, sedation, or prophylactic antibiotics.

### Statistical analyses

We performed descriptive analyses of the characteristics of the patients, the cysts, and the procedures using percentages for categorical data (previous surgery, cyst location, symptoms) and



**Fig. 1.** Transvaginal ultrasound-guided aspiration of an endometrioma. a. Endometrioma measured before aspiration. b. Ultrasound-guided endometrioma aspiration. The arrow indicates the end of the needle inside the cyst.

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