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Original Article

Preliminary Results: Ethanol Sclerotherapy After Ultrasound-Guided Fine Needle Aspiration Without Anesthesia in the Management of Simple Ovarian Cysts

Marta Castellarnau Visus, MD*, Jordi Ponce Sebastia, PhD, Ramon Carreras Collado, PhD, Enric Cayuela Font, PhD, and Amparo Garcia Tejedor, PhD

From the Consorci Sanitari Integral, Obstetrics and Gynecology, Hospitalet de Llobregat, Barcelona, Spain (Drs. Visus and Font), Universitat Autonoma de Barcelona, Barcelona, Spain (Drs. Visus and Collado), Bellvitge Teaching Hospital, Gynecology, Avinguda Feixa Llarga, sn. Hospitalet de Llobregat, Barcelona, Spain (Drs. Sebastia and Tejedor), and Parc de Salut Mar, Obstetrics and Gynecology, Barcelona, Spain (Dr. Collado).

ABSTRACT **Study Objective:** To investigate the feasibility of ultrasound-guided, fine-needle aspiration and ethanol sclerotherapy of simple ovarian cysts in an office setting without anesthesia. We also describe the rate of cyst recurrence in patients treated with this technique and explore the associated risk factors.

Design: Prospective follow-up of patients after ethanol sclerotherapy of simple adnexal cysts in a single center trial (Canadian Task Force classification II-1).

Setting: The study was conducted at Bellvitge Teaching Hospital in Barcelona, Spain.

Patients: Ethanol sclerotherapy was performed on 60 simple adnexal cysts between 2009 and 2012.

Interventions: Ultrasound-guided fine-needle aspiration and ethanol sclerotherapy.

Measurements and Main Results: Patient demographics and cyst characteristics were collected for all patients. Potential risk factors for recurrence were analyzed by univariate and multivariate analyses. All the procedures, except 1, were performed without anesthesia. The only major complication was a case of self-limiting hem peritoneum that was managed expectantly. Moderate abdominal pain occurred in 26.7% of patients during the procedure. Fifty-five patients completed at least 6 months of follow-up and were included in the statistical recurrence analyses. Cyst recurrence was recorded in 9.1% of the patients and was managed in the usual manner in all the cases. Univariate analyses indicated that a larger cyst diameter and a higher estimated cyst volume were significantly associated with recurrence. In the multivariate analysis, recurrence was only significantly associated with estimated cyst volume.

Conclusion: Ethanol sclerotherapy of simple ovarian cysts in an office setting without anesthesia is a feasible technique associated with a low rate of complications and recurrence, although larger randomized studies are necessary to assess the predictive factors for cyst recurrence. Journal of Minimally Invasive Gynecology (2015) 22, 475–482 © 2015 AAGL. All rights reserved.

Keywords: Ethanol sclerotherapy; Ovarian cyst; Ultrasound-guided aspiration

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Benign adnexal masses are frequently detected in asymptomatic women during ultrasound scan (US) [1]. In premenopausal women, most of these masses are simple, functional cysts that tend to resolve spontaneously. However, approximately 7% of women, regardless of menopausal status, develop ovarian cysts [2], which are a common source of anxiety, primarily due to the fear of malignancy. The risk of malignancy in simple ovarian cysts is <1% in premenopausal women and between 0.1 and 9.6% in postmenopausal women [2–4].

Although simple cysts of any size are almost certainly benign, there is little evidence in the literature to guide which asymptomatic simple cysts may be ignored versus which cysts need to be followed [5].

Corresponding author: Marta Castellarnau Visus, MD, Consorci Sanitari Integral, Obstetrics and Gynecology, Avinguda Josep Molins, 29-41. Hospitalet de Llobregat, 08906, Barcelona, Spain.
E-mail: Marta.Castellarmau@sanitatintergral.org

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Conservative management of simple cysts can result in ovarian torsion or cyst rupture. Although open or laparoscopic surgery was formerly the gold standard treatment for simple ovarian cysts of >5 cm in postmenopausal women and for persistent adnexal masses in premenopausal women [6], currently, there is a clear tendency for conservative management of ovarian cysts. In a recent consensus of the Society of Radiologists in Ultrasound, it was suggested that surgical evaluation should be considered for cysts >7 cm. They also recommended a yearly follow-up with US in postmenopausal women with cysts >1 and ≤7 cm and in premenopausal women with cysts >5 and ≤7 cm [5].

However, surgical management is associated with an increased risk of complications and morbidity and elevated costs. A less invasive alternative, which has proven to be viable in selected cases, is US-guided fine-needle aspiration [7–9]. However, aspiration of ovarian cysts has generated considerable controversy because the spillage of fluid from an undiagnosed malignant cyst can cause cancer spread [9,10]. Therefore, strict selection criteria are essential for minimizing the risk of missing malignant disease [8,11,12].

US-guided aspiration of simple ovarian cysts is also associated with highly variable recurrence rates, ranging from 20% to 70% [7,10,13]. One promising technique for reducing the high recurrence rates often associated with this procedure is sclerotherapy, which consists of injecting a sclerosing agent into the cyst to induce fusion of the walls. The cellular mechanisms involved are not yet fully known, but the sclerosing agent appears to destroy the epithelial lining of the fluid-secreting walls, thereby obliterating the cyst cavity and preventing the re-accumulation of fluid. Adequate contact between the sclerosing agent and the cyst walls [8,14] seems to activate the coagulation cascade and the production of mediators for inflammation and fibrosis by epithelial lining cells [8,15]. Several agents have been used for sclerotherapy of ovarian cysts, including ethanol, erythromycin, tetracycline, and methotrexate, but to date, none have emerged as being clearly superior [8,10,12,16–19].

At our hospital, simple ovarian cysts are treated using ethanol, a hydrosoluble dehydrating antiseptic substance that denatures micro-organism proteins and dissolves germen lipids. We chose ethanol over other sclerosing agents because of its good results in the management of simple renal and hepatic cysts [14,20,21]. The effect of concentrated ethanol on healthy ovarian tissue has been evaluated by Kukura et al [17], who showed preservation of ovarian function and ovarian tissue after ethanol sclerotherapy of ovarian cysts.

Usually, sclerotherapy is performed under general or local anesthesia. The ease of scheduling, reduced costs, and rapid recovery after procedures performed in an office setting without anesthesia suggest that it can be a first-line treatment for well-tolerated minimally invasive procedures, such as ethanol sclerotherapy of simple ovarian cysts.

The primary aim of our study was to investigate the feasibility of US-guided, fine-needle aspiration and ethanol sclerotherapy of simple primary and recurrent ovarian cysts in an office setting without anesthesia. We also describe the rate of cyst recurrence in patients treated with this technique and explore the associated risk factors.

Patients and Methods

This prospective study was conducted at Bellvitge Teaching Hospital in Barcelona, Spain. Sample size included all the patients referred to our department between March 2009 and May 2012 who matched the inclusion criteria. All the patients enrolled had been referred to our department following the detection of a low-risk adnexal mass in an imaging study. We included women ages older than 18 years with a US diagnosis of a simple ovarian or paraovarian cyst and normal blood coagulation tests. The inclusion criteria for cysts were the presence of a thin wall without septations or papillary projections, a diameter of between 3.5 and 10 cm, and anechoic content. In premenopausal women, the cyst had to have been present for at least 6 months since its detection to avoid sclerosing functional cysts [22]. This criterion was not applied to postmenopausal women, because functional cysts are very unusual in these patients. Written informed consent was obtained from all the patients included in the study, which was approved by the hospital's ethics committee (reference PR157/07).

Exclusion criteria were a personal history of ovarian cancer, self-reported moderate pelvic pain, and elevated serum levels of cancer antigen (CA) 125 (>35 IU/mL) and CA 19.9 (>35 IU/mL). US exclusion criteria following international definitions [23] were as follows: detection of an endometriosis cyst, defined as an echoic ovarian cyst with a low level of internal echoes; features suggestive of a dermoid cyst (fat-fluid levels, globular calcifications, or hyperechoic mural plug); cystic internal echoes; papillary structures; hyperechoic content or solid component; internal flow on color Doppler; and the presence of ascites.

The following data were collected for all patients: age, clinical history, menopausal status, associated symptoms, history of a cyst treated by US-guided aspiration or surgery, cyst location (ovary or paraovary) and laterality, largest cyst diameter, and estimated cyst volume based on US measurements.

The procedures were performed in an office setting by gynecologists trained in US-guided aspiration or by obstetrics and gynecology residents under close supervision by experienced gynecologists. Oral analgesics (ibuprofen or paracetamol) and oral sedation with diazepam were given 20 minutes before the procedure. Anesthesia was used in just 1 case. The vagina or abdominal wall was routinely sterilized with povidone-iodine antiseptic solution, and the procedure was performed using an Acuson Antares (Siemens Sonoline AG, Berlin, Germany) US system and a 22- or 17-gauge needle. In the vaginal approach, the single light and 30-cm-length needle was inserted through the vaginal lateral fornix into the cyst, guided by US. In the abdominal approach, the needle was inserted through the skin to the cyst without any abdominal incision. In both cases, Doppler color was used to avoid vessel interposition. The needle was connected to a vacuum bottle for suction using a 3-way stop cock.

Cystic fluid was drained almost completely (but not totally to avoid needle displacement), measured, and sent for cytological examination. The results of cytological examination were received 1 week after the procedure. The volume of 100% ethanol injected was calculated as two-thirds of the volume of the cystic fluid extracted

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