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JMIG The Journal of Minimally Invasive Gynecology

Original Article

Ultrasound-Guided Aspiration With and Without Ethanol Sclerotherapy in the Management of Simple Adnexal Cysts: A Single-Center Experience

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ABSTRACT **Study Objectives:** To compare the efficacy of ultrasound-guided aspiration versus aspiration with ethanol sclerotherapy in the management of simple adnexal cysts measuring 3 to 10 cm, and to explore the risk factors for recurrence associated with each approach.

Design: A prospective follow-up of patients after cyst aspiration with and without ethanol sclerotherapy in simple adnexal cysts in a single-center trial (Canadian Task Force classification II-1).

Setting: Bellvitge Teaching Hospital, Barcelona, Spain.

Patients: Cyst aspiration and ethanol sclerotherapy were performed in 66 and 75 patients, respectively, between 2002 and 2014. Women enrolled before March 2009 underwent simple aspiration (group 1), and those enrolled after March 2009 underwent ethanol sclerotherapy (group 2).

Interventions: Ultrasound-guided fine-needle aspiration with and without ethanol sclerotherapy.

Measurements and Main Results: Potential risk factors for recurrence—age, menopausal status, symptoms, cyst diameter, laterality, aspirated volume, simple US-guided aspiration or alcohol sclerotherapy, and complications—were analyzed by logistic regression. The recurrence rates were analyzed by the Kaplan–Meier and Mantel–Haenszel methods. The overall recurrence rates were 72.7% (48 of 66) in group 1 and 22.7% (17 of 75) in group 2 ($p < .0001$). Risk factors significantly associated with recurrence were simple aspiration without ethanol sclerotherapy (odds ratio [OR], 19.7; 95% confidence interval [CI], 6.756–57.714), postmenopausal status (OR, 9.3; 95% CI, 1.720–50.956), and cyst size (OR, 1.04; 95% CI, 1.005–1.093).

Conclusion: Based on the lower recurrence rate, ethanol sclerotherapy was more efficacious than simple aspiration in the management of simple adnexal cysts measuring <10 cm. Journal of Minimally Invasive Gynecology (2015) ■, ■–■

Keywords: Ethanol sclerotherapy; Fine-needle aspiration; Management; Simple adnexal cyst; Ultrasound

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Benign ovarian cysts are the most frequently detected ovarian masses, regardless of menopausal status [1–4]. The overall malignancy risk of simple ovarian cysts is <1% [2,4–8], with several studies showing that benign epithelial ovarian cysts do not increase the risk for ovarian cancer [9–12]. Furthermore, large observational studies have found no evidence that simple ovarian cysts smaller than 10 cm undergo malignant transformation, and

The authors declare that they have no conflict of interest.

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Submitted July 7, 2015. Accepted for publication October 14, 2015.
Available at www.sciencedirect.com and www.jmig.org

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http://dx.doi.org/10.1016/j.jmig.2015.10.006

have concluded that they require only routine follow-up [2,4–7,13,14]. In line with this evidence, the Society of Radiologists in Ultrasound recommends annual follow-up for postmenopausal women with cysts smaller than 7 cm and for premenopausal women with cysts between 5 and 7 cm; however, they would consider surgery for cysts larger than 7 cm [15].

Traditionally, benign cysts have been managed by open or laparoscopic surgery, which may represent overtreatment, with costs and risks outweighing the benefits. Consequently, several authors have suggested that conservative management may be appropriate for simple ovarian cysts [13,15,16]. This approach could reduce the risks of complications and morbidity, favor rapid recovery, and decrease costs. One such approach is ultrasound (US)-guided aspiration of ovarian cysts. Although this procedure is effective, it has variable recurrence rates, ranging from 27.5% to 75% [17–22]; however, those recurrence rates decrease to 4.76% to 41.6% when used in combination with ethanol sclerotherapy [23–26].

Controversies associated with the aspiration of adnexal cysts include the potential for spreading malignant cells if present and the questionable accuracy of cytological examination of cystic fluid. Strict selection criteria and exhaustive US evaluation are essential to minimize the risk of missing malignant disease [8,20,23,27]. The reported sensitivity of aspiration cytology from ovarian cyst fluid ranges from 25% to 50%, but the specificity ranges from 97% to 100% [28–31].

Several sclerosing agents, including erythromycin, ethanol, methotrexate and tetracycline, have been used in the treatment of ovarian cysts [23–26,32–34]. In this study, we chose ethanol because it is widely used with good results in the conservative management of renal cysts [35], hepatic cysts [36], vascular malformations [37], and lymphoceles [38]. Moreover, we already have experience in ethanol sclerotherapy for ovarian cysts in our institution, with promising results [26,39].

The main aim of this study was to compare efficacies of US-guided fine-needle aspiration with and without ethanol sclerotherapy in the management of simple adnexal cysts. In addition, we aimed to explore the risk factors for ovarian cyst recurrence in the 2 study groups.

Materials and Methods

This was a prospective cohort study comparing sequentially simple US-guided aspiration with aspiration plus ethanol sclerotherapy for the management of simple adnexal cysts. The study was carried out at the Gynecology Department of Bellvitge Teaching Hospital, Barcelona, Spain between March 2002 and June 2014. We compared the results of 2 previous prospective cohort studies. Initially, from 2002 to 2009, we performed a prospective study involving simple aspiration of adnexal cysts with local Ethics Committee approval (reference PR281/11). Next, in 2009, we started a new prospective study of ethanol sclerotherapy in adnexal cysts, also with local Ethics Committee approval (reference PR157/07). Subsequently, we performed a comparative study of simple aspiration and ethanol sclerotherapy in adnexal cysts, comparing data of both cohorts sequentially.

In total, 164 patients diagnosed with simple adnexal cyst (ovarian or paraovarian) in an imaging study were referred to our department. To be eligible for study enrolment, a patient had to meet all of the following criteria: (1) age >18 years; (2) not pregnant; (3) US-detected cyst features predictive of a low risk of malignancy according to the International Ovarian Tumor Analysis criteria [40], including a thin-walled adnexal cyst without septations or papillary projections or solid components, with a diameter of 3 to 10 cm, anechoic contents, and no internal flow seen on color Doppler imaging; (4) cyst persistence from diagnosis ≥6 months in premenopausal women, to avoid treating functional cysts; (5) negative tumor markers (CA-125, <35 IU/mL; CA-19.9, <37 IU/mL); and (6) written informed consent. Cysts with features suggestive of dermoid cysts (fat–fluid levels, globular calcifications, or hyperechoic mural plugs) and endometriomas (echoic ovarian cysts with low-level internal echo) were excluded, to homogenize results. Other exclusion criteria were the presence of ascites, an abnormal coagulation test, personal history of gynecologic cancer, self-reported moderate pelvic pain, refusal to enroll in the study, and loss to follow-up.

All patients with adnexal cysts who met the inclusion criteria were recruited into parallel cohorts, as follows: patients recruited between March 2002 and March 2009 were treated by simple US-guided aspiration, and patients recruited between March 2009 and June 2014 were treated by aspiration plus ethanol sclerotherapy.

We collected clinical data, including age, gynecologic history, menopausal status, history of previously treated cysts, associated symptoms (low abdominal pain or an increase in cyst size ≥1 cm from the previous exploration), cyst location (ovarian or paraovarian), laterality, largest cyst diameter, and aspirated fluid volume.

Both procedures were performed under oral sedation with diazepam and oral analgesia with ibuprofen or paracetamol. The abdomen or vagina was disinfected with povidone solution before the procedure was performed by an interventional gynecologist using an Acuson Antares ultrasound system (Siemens, Munich, Germany) and a 22- or 17-gauge single-lumen needle. The needle diameter was changed from 22 to 17 gauge during the study period to shorten the duration of the procedure. Under direct US guidance, the needle was inserted through the vaginal fornix into the center of the cyst, and the fluid was aspirated. In the simple aspiration group (group 1), the cyst was completely drained where possible. In the sclerotherapy group (group 2), 100% ethanol was injected after aspiration and left in place for 15 minutes, followed by 2 intracystic lavages with saline solution before complete aspiration of the