



Original Article

Accuracy of Hysteroscopic Metroplasty With the Combination of Presurgical 3-Dimensional Ultrasonography and a Novel Graduated Intrauterine Palpator: A Randomized Controlled Trial

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ABSTRACT **Study Objective:** To assess whether the use of a novel graduated intrauterine palpator can improve the accuracy of hysteroscopic metroplasty, introducing objective intraoperative criteria.

Design: A prospective randomized study (Canadian Task Force I, evidence obtained from a properly design, randomized, controlled trial).

Setting: University Federico II hysteroscopic clinic.

Patients: Ninety women with a uterine septum diagnosed during office hysteroscopy and 3-dimensional transvaginal ultrasound (3D-TVS) were randomized into 2 groups: group T (metroplasty with intrauterine palpator) ($n = 45$) and group C (metroplasty without intrauterine palpator) ($n = 45$).

Interventions: Outpatient hysteroscopic metroplasty under conscious sedation using a 5-mm hysteroscope and miniaturized 5F instruments including a bipolar electrode for the removal of three quarters of the septum, blunt scissors to refine the base of the septum, and an intrauterine palpator to measure the portion of the removed septum (only group T). 3D-TVS and second-look hysteroscopy were used to identify the number of optimal (residual septum <5 mm), suboptimal (residual septum 5–10 mm), and incomplete resections (residual septum >10 mm). In group T, metroplasty was stopped when the intrauterine palpator showed that the resected septum corresponded to presurgical ultrasonographic measurements in order to obtain a fundal notch of 1.0 cm. In group C, metroplasty was interrupted once the tubal ostia were clearly visible on the same line and/or hemorrhage from small myometrial vessels of the fundus was observed.

Measurements and Main Results: No differences were observed in baseline characteristics between the 2 groups. The proportion of patients with complete septum resection was significantly higher in group T (71.5% vs 41%, χ^2 : $p = .006$; relative risk: 1.684; 95% confidence interval, 1.116–2.506). Suboptimal resection was achieved in 13 cases (28.5%) in group T and 14 cases (20%) in group C, whereas incomplete resection was observed in only 12 patients in group C (27%).

Conclusion: Presurgical evaluation with 3D-TVS together with the use of a graduate intrauterine palpator improves the accuracy of hysteroscopic metroplasty, allowing complete removal of a uterine septum in 1 surgical step. *Journal of Minimally Invasive Gynecology* (2016) ■, ■–■ © 2016 AAGL. All rights reserved.

Keywords: 3-Dimensional ultrasonography; Hysteroscopy; Residual septum; Uterine septa

The authors declare that they have no conflict of interest.

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Submitted December 28, 2015. Accepted for publication January 24, 2016.
Available at www.sciencedirect.com and www.jmig.org

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<http://dx.doi.org/10.1016/j.jmig.2016.01.020>

A septate uterus is the most frequent müllerian anomaly encountered by gynecologists, with an incidence of 2% to 3% in the general population [1,2]. According to the European Society of Human Reproduction and Embryology/European Society for Gynaecological Endoscopy (ESHRE/ESGE) classification [3], a total or partial septate uterus corresponds to classes IIa and IIb, respectively, which are equivalent to type Va (total septum)

and Vb (partial) in the American Fertility Society classification [4]. This müllerian anomaly is associated with the highest rate of pregnancy complications compared with other congenital malformations [5,6] and attracts the greatest surgical interest because, at the same time, it is the most easily corrected by hysteroscopy.

The endoscopic technique for the treatment of a septate uterus, proposed as early as 1974 by Edström [7], has slowly but radically changed the surgical technique of metroplasty involving an abdominal surgery setting and has now become a minimally invasive surgical procedure performed via the transcervical route. Over time, various hysteroscopic procedures have been developed that, on the whole, give results that are significantly better than those yielded via laparotomy.

Currently, there are 2 main hysteroscopic treatment options available for a septate uterus: resectoscopic surgery and operative minihysteroscopy with miniaturized instruments. The rationale underlying these treatment options is hysteroscopic visualization of the septum and subsequent removal, which aims at correcting and restoring the physiological morphology and functionality of the uterine cavity while at the same time maintaining an adequate fundal thickness [8].

The hysteroscopic approach to a septate uterus raises the major issue of deciding where to end the incision to avoid intrauterine complications (i.e., perforation and significant bleeding) and abnormal anatomic results. Abnormal anatomic results occur with a wide variation [9–12] and may include a residual septum at the uterine fundus and isolated intrauterine adhesions in other locations [12]. The risk of a residual septum is mainly caused by the surgeon's subjective assessment of the completeness of resection and a lack of standardized pre- and postoperative evaluation of the uterine cavity [13].

The aim of this study was to assess whether the use of presurgical 3-dimensional transvaginal ultrasonography (3D-TVS) in combination with a novel, graduated intrauterine palpator could improve the accuracy of hysteroscopic metroplasty, introducing objective intraoperative criteria.

Materials and Methods

Our randomized study was conducted between January 2014 and April 2015 in the hysteroscopy unit of the Department of Gynecology and Obstetrics, University of Naples Federico II, Naples, Italy. Ninety patients with a partial or complete uterine septum (classes U2a and U2b according to the ESHRE/ESGE classification system) [3] diagnosed by hysteroscopy and 3D-TVS were enrolled.

Primary care physicians or hospital consultants referred the women because of repeated abortion, preterm birth, dysmenorrhea, or infertility workup. Exclusion criteria were body mass index greater than 30 kg/m²; pregnancy (positive beta-human chorionic gonadotropin test) and severe urinary symptoms; malignancy; other severe comorbidities (coagulation disorders, systemic disease, and severe cardiac disease), alone or in combination with any of the previously

described conditions; and presence of other intrauterine pathologies (i.e., myomas, polyps, and intrauterine adhesions [IUAs]). Complete uterine septa with associated cervical septum or double cervix were also excluded. In these latter cases, a different surgical approach is required, and we believed that it could have affected the results of our study.

These 90 patients were randomized into 2 groups: group T (metroplasty with intrauterine palpator) (n = 45) and group C (metroplasty without intrauterine palpator) (n = 45). To prevent selection bias, the allocation sequence was concealed from the researchers who enrolled and assessed the participants, and a sequentially numbered, opaque, sealed, and stapled envelope containing the allocated treatment with a 1:1 ratio was attached to the clinical record of the patient after she had signed the informed consent. The envelope was opened on the morning of the procedure. Randomization was performed with blocks of 4. The investigators performing the procedures and evaluating the patients during the follow-up were not involved in the randomization process.

The local institutional review boards of the University of Naples approved the study protocol. Before enrollment, the purpose of the study was explained to all patients, and a written consent form was obtained.

Presurgical Assessment of the Uterine Cavity

An evaluation of the morphology of the uterine cavity was performed by using both office hysteroscopy and 3D-TVS assessment. At the office hysteroscopy, in the presence of an extensive septum of the uterine cavity, the endoscopic image encountered is that of a finger-shaped cavity whose apex reveals a tubal ostium found bilaterally. When the septum is incomplete, the hysteroscopic aspect is that of a bifid cavity presenting with an interposed central projection of variable thickness lined with a normal endometrium. At the level of both hemicavities, the tubal ostium comes into view. In the case of a small subseptum, a hysteroscopic image confirms the presence of a minor, saddle-shaped structure modifying the fundal profile. In such cases, a panoramic view, offered by all modern hysteroscopes, should permit quantification of the dimensions of the septum by comparing its length with the longitudinal diameter of the uterus (e.g., estimated as less than 0.5 cm or equal to about one third, two thirds, or the whole cavity). This information is appropriately integrated into an overall diagnostic scheme with a meticulous ultrasound examination.

3D-TVS was performed by 2 expert operators (CE and GN) during the luteal phase of the cycle (days 21–25), which is considered the optimal time to examine patients for the presence of uterine anomalies because the endometrium appears thick and echogenic and the uterine cavity can be clearly differentiated from the surrounding myometrium. A 7.5-MHz probe was used to perform 3D-TVS. The uterus was visualized in the longitudinal plane, and the 3-dimensional volume was acquired using the automatic

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