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Hysteroscopic outpatient metroplasty for T-shaped uterus in women with reproductive failure: Results from a large prospective cohort study

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ABSTRACT

Objective: To evaluate the effectiveness of hysteroscopic outpatient metroplasty in women with T-shaped uterus and primary reproductive failure.
Study Design: Prospective cohort study including nulliparous women with primary unexplained infertility, repeated in vitro fertilization (IVF) failure or recurrent spontaneous miscarriage and T-shaped uterus anomaly not diethylstilbestrol-related, diagnosed by 3D ultrasound and diagnostic hysteroscopy. Between January 2015 and December 2017, hysteroscopic metroplasty was performed in outpatient settings with a 5-mm diameter hysteroscope and 5-Fr operative scissors. After 3 months, expectant management was proposed to women with unexplained couple infertility or recurrent spontaneous miscarriages, and IVF treatment was proposed after 6 months without natural conception or immediately to couple with repeated IVF failure. Minimum follow-up was planned for 1 year.
Results: A total of 63 women were included, and only 60 tried to conceive after metroplasty. Hysteroscopic procedures were performed without complications. Clinical pregnancy rate after metroplasty was 83.3% (n = 50/60) ($p < 0.001$), and the live birth rate was 63.3% (n = 38/60) ($p < 0.001$). Cesarean section rate was 26.3%. No pregnancy complications potentially related to uterine surgery were reported. The abortion rate was 12% (n = 6/50) ($p < 0.001$).
Conclusion: In women with primary reproductive failure and T-shaped uterus, hysteroscopic metroplasty seems to be effective to improve reproductive outcomes.

Introduction

The T-shaped uterine malformation is a rare Müllerian anomaly incorporated in the category of dysmorphic uterus (U1), that is characterized by abnormally shaped uterine cavity and normal uterine outline, excluding septa. T-shaped uterus (U1a) has thickened lateral walls with hypoplastic uterine cavity and a correlation 2/3 uterine corpus and 1/3 cervix [1]. The altered uterine cavity shape and volume may play a contributory role in diminishing endometrial receptivity, potentially explaining the increased prevalence of uterine malformations in women with infertility and habitual miscarriages [2,3]. About T-shaped uterus, different studies reported poor reproductive outcomes when this malformation was untreated [4,5]. With the introduction of the minimally invasive treatment by hysteroscopic metroplasty, a limited number of studies reported anatomical and/or reproductive outcomes after this procedure with promising results [6–14]. Nevertheless, small sample size, heterogeneity in the etiology of T-shaped anomaly, retrospective design and different diagnostic and surgical techniques do not allow to draw a definitive conclusion. Moreover, large series include a high prevalence of T-shaped uterus anomaly related to diethylstilbestrol (DES) *in utero* exposure, that is progressively disappearing in the fertile age [9,10].

On that basis, we performed a prospective cohort study on nulliparous women with primary infertility, repeated in vitro fertilization (IVF) failure or recurrent spontaneous miscarriage with T-shaped uterus anomaly not related to DES, who were surgically treated with standardized hysteroscopic technique. The primary aim of the study was to evaluate the effects of hysteroscopic metroplasty for T-shaped uterus not related to DES on the live birth rate. Secondary aims were to assess its impact on clinical pregnancy rate, spontaneous miscarriages rate, and surgical, reproductive, and obstetrics outcomes.

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Materials and methods

We performed a prospective observational cohort study, recruiting patients between January 2015 and December 2017, with a follow-up of at least 1 year after hysteroscopic outpatient metroplasty (until December 2018). The study design was approved by an independent Institutional Review Board (23/2014), and all patients signed an informed consent for all the procedures they underwent and to allow data collection and analysis for research purposes.

Study cohort

Nulliparous women with suspected dysmorphic uterus were considered eligible if they had a history of primary unexplained infertility, repeated IVF failure (RIF) or recurrent spontaneous miscarriages (RSM) (Table 1) [15]. We included women with confirmed primary T-shaped uterus by 3D ultrasound and diagnostic hysteroscopy. 3D ultrasound (Fig. 1) was performed transabdominal and transvaginal in the luteal phase of the cycle (day 21–26) by the same expert gynecologist. The primary T-shaped anomaly was subsequently confirmed by diagnostic hysteroscopy (Fig. 2) whether the subcornual stricture was reported associated to hypoplastic uterine cavity [1].

Exclusion criteria were body mass index greater that 30 kg/m^2; pregnancy; previous pregnancy carried to term; malignancies; systemic severe chronic disease; gynecological condition related to infertility such as fibroids and endometriosis; suspected or certain *in utero* exposure to DES; suspected acquired T-shape uterus (Asherman syndrome at hysteroscopic evaluation of uterine cavity); and previous hysteroscopic surgery.

Surgical technique

Hysteroscopic metroplasty was performed after menstrual bleeding cessation in the first part of the cycle (day 6–10). Under conscious sedation, a vaginoscopic approach was used with a 5-mm diameter continuous-flow hysteroscope, with a 30° fore-oblique telescope and a 5-Fr operating channel (Compact Hysteroscope 5 mm, Richard Wolf GmbH, Knittlingen, Germany). Saline solution (NaCl 0.9%) was used as distension medium with an electronic irrigation and aspiration system (Endomat; Karl Storz, Tuttlingen, Germany), which provided a stable intrauterine pressure of 50 mmHg by setting irrigation pressure at 100 mmHg, suction pressure at 0.2 bar and a flow rate at 240–370 mmHg. All the procedures were performed by the same expert endoscopist (L.A.P.).

The hysteroscopic metroplasty consisted in two lateral incisions at the lateral uterine sidewall with a 5-Fr operative scissors, avoiding electrosurgery. The myometrium was incised on each lateral side perpendicular to the uterine sidewall, from the isthmus to the uterine fundus, under visual control. The incision was performed advancing through the same groove several times in order to achieve satisfactory result and a maximum incision depth of 7 mm to avoid perforation. Result was defined satisfactory when both the tubal ostia were visible from the isthmus, and subcornual strictures were interrupted.

No intrauterine silicone sheet or gel were inserted in the uterus at the end of the procedures in order to reduce the risk of

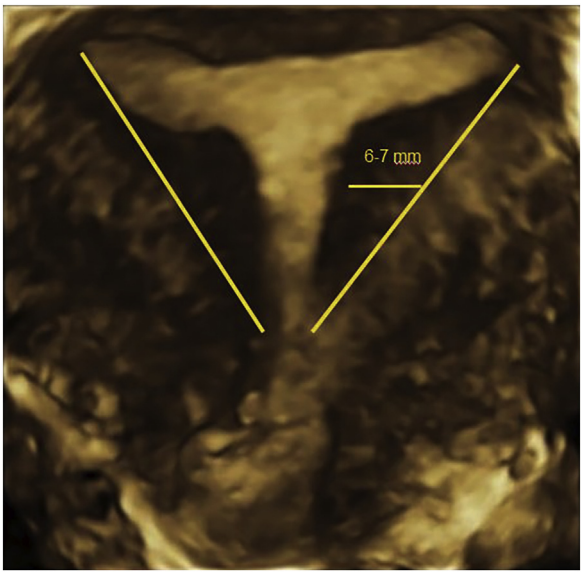

Fig. 1. Measurement of the uterine wall thickness is defined as the distance between the interostial line and external uterine profile at the mid-coronal plane of the uterus obtained with transvaginal 3D ultrasonography; as clearly showed in the Figure, the external uterine contour and the length of any existing internal indentation (defined as the distance between the interostial line and the indentation's edge at the cavity) should be always clearly delineated for a proper diagnosis.

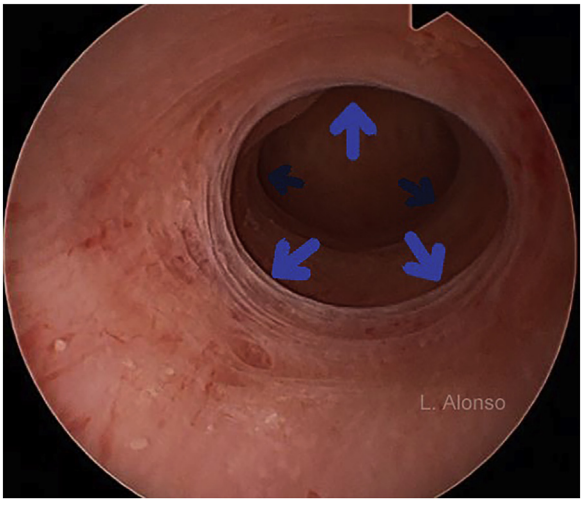

Fig. 2. Hysteroscopic view showing the isthmical and subcornual strictures (arrows), associated with hypoplastic uterine cavity.

Table 1
Definitions of inclusion criteria based on reproductive history.

Criteria	Definition
Primary unexplained infertility	Failure to achieve a clinical pregnancy after 12 months of regular, unprotected sexual intercourse with apparent normal female and male reproductive functions
Repeated IVF failure	2 or more failed IVF despite good quality embryos (egg donation in women older than 43 years) and without other obvious potential factors that may impede implantation
Recurrent spontaneous miscarriages	2 or more spontaneous early pregnancy loss (<24 weeks) with negative workup including karyotype and antiphospholipid antibody analysis

synechiae. All patients were prescribed a sequential estrous-progestin treatment for 3 month in order to avoid pregnancy. Spontaneous or IVF conception was allowed after 3 months.

Data collection and postoperative assessment and reproductive outcomes

Characteristics of the patients were obtained from medical history and collected in a database. After 3 months from hysteroscopic metroplasty, the patients underwent follow-up visit. Expectant management with spontaneous conception was proposed for 6 months to women with unexplained couple infertility or RSM, and IVF treatment was proposed after 6 months without conception. IVF was offered to couple with RIF. In case of expectant management, women were followed up every 2 months and were invited to contact the center in case of spontaneous pregnancy, and a gynecological follow-up was planned at the 6th month. Clinical pregnancy was defined as the ultrasonographic diagnosis of intrauterine pregnancy; miscarriage was defined as the spontaneous loss of a pregnancy before 24 weeks of gestation; live birth was defined as the delivery of viable fetus after 24 weeks of gestation. Follow-up was planned for at least 1 year after metroplasty.

Statistical analysis

Data analyses was performed using SPSS Version 24.0 (IBM Corporation, Armonk, New York). Descriptive statistics were showed for continuous variables as mean and standard deviation (SD) or as median and interquartile range as appropriate, and for the nominal variables as number of cases (n) and percent (%). Proportions were analyzed with Fisher's exact test, and *post hoc* analysis was performed as appropriate. P-values < 0.05 were considered statistically significant in all the tests.

Results

A total of 63 nulliparous women were included. All patients were diagnosed with T-shaped uterus based on 3D ultrasound evaluation and diagnostic hysteroscopy, none had malformation related to DES *in utero* exposure or acquired malformation, and all were caucasian. The characteristics of included patients and the indication for metroplasty are reported in Table 2. All the hysteroscopic metroplasties were successfully performed without any significant complication, with a mean duration of the procedure of 11.2 ± 4.2 min.

The average follow-up period was 16 months (range: 12–44 months). Three out of 63 women were not looking for pregnancy after surgery: 1 had colon cancer diagnosis after hysteroscopy, 1 had peritonitis due to diverticulitis, and 1 has psychological problems and avoided to try again IVF. Fifty women became pregnant, with an overall clinical pregnancy rate after metroplasty of 83.3% (n = 50/60), that was statistically significant increased after metroplasty ($p < 0.001$). Thirty-eight out of 50 pregnant women delivered a viable fetus, with a live birth rate of 76% (n = 38/50), that increased from 0% before to 63.3% (n = 38/60) after the metroplasty ($p < 0.001$). Ten out of 38 women delivered by cesarean section, with a rate of 26.3% (n = 10/38). Uterine rupture, adherent placenta, cervical incompetence, and other pregnancy complications related to uterine surgery were not reported. Considering the other 12 clinical pregnancies, six pregnancies are ongoing, and 6 were miscarriages, with a spontaneous abortion rate of 12% (n = 6/50). The abortion rate decreased from 100% of pregnancies before to 12% (n = 6/50) after the metroplasty ($p < 0.001$).

Among 25 women with primary infertility, 21 became pregnant, with a clinical pregnancy rate after metroplasty of 84% (n = 21/25), and 16 pregnant women delivered a viable fetus, with a live birth rate of 76.2% (n = 16/21), that increased from 0% before to 64% (n = 16/25) after the metroplasty ($p < 0.001$). Two spontaneous abortion (9.5%; n = 2/21) and 3 ongoing pregnancies were reported, actually at 13, 24 and 34 weeks of pregnancy. Seven out of 21 (31.3%) clinical pregnancies were spontaneously conceived between 3 and 9 months after metroplasty, 18 out of 25 women underwent IVF cycles (1 egg donation) with a clinical pregnancy rate of 77.8% (n = 14/18) and a median of 1 IVF cycle (range: 1–3).

Among 20 women with RSM, 18 women became pregnant with a clinical pregnancy rate after metroplasty of 90% (n = 18/20), and 13 pregnant women delivered a viable fetus, with a live birth rate of 72.2% (n = 13/18), that increased from 0% before to 65% (n = 13/20) after the metroplasty ($p < 0.001$). Three spontaneous miscarriages (16.7%; n = 3/18) and 2 ongoing pregnancies were reported, actually at 7 and 12 weeks of gestation. The abortion rate decreased from 100% of pregnancies before to 16.7% (n = 3/18) after metroplasty ($p < 0.001$). Seven out of 18 (38.9%) clinical pregnancies were spontaneously conceived between 3 and 9 months after metroplasty, 13 out of 20 women underwent IVF cycles (3 egg donation) with a clinical pregnancy rate of 84.6% (n = 11/13) and a median of 1 IVF cycle (range: 1–3).

Among 45 women managed expectantly with primary unexplained infertility and RSM, the clinical pregnancy rate was 86.7% (n = 39/45) and 14 pregnancies were spontaneously conceived (35.9%; n = 14/39).

Among 15 women with RIF, 11 women became pregnant with a clinical pregnancy rate after metroplasty of 73.3% (n = 11/15), and 9 pregnant women delivered a viable fetus with a live birth rate of 81.8% (n = 9/11), that increased from 0% before to 60% (n = 9/15) after the metroplasty ($p < 0.001$). One spontaneous miscarriage (9.1%; n = 1/11) was reported. One out of 15 (6.7%) clinical pregnancies were spontaneously conceived during follow-up after metroplasty and before IVF, 14 out of 15 women underwent IVF cycles (3 egg donation) with a clinical pregnancy rate of 71.4% (n = 10/14) and a median of 1 IVF cycle (range: 1–3). Detailed reproductive outcomes with comparison between groups based on eligible criteria for metroplasty are reported in Table 3.

Biopsies of lateral sidewall were performed in 43 out of 63 women (71.6%). Histopathological analysis of biopsies performed at the site of lateral sidewall incisions reported myometrial tissue in all patients (no fibroid tissue or atypical histological architecture were reported).

Fig. 3 shows study design and flow of patients, summarizing results for clinical pregnancies and type of conception.

Table 2
Baseline characteristics of the included women (n = 60).

Age mean, SD	36.4 (4.52)
BMI mean, SD	24.0 (2.83)
History of diethylstilbestrol exposure n, %	0 (0)
History of oral estroprogestins contraceptive use n, %	42 (66.7)
Indication for surgery n, %	
Primary infertility	27 (42.9)
Repeated spontaneous abortions	20 (31.7)
In vitro fertilization failure	16 (25.4)

Nominal variables are described with number of cases (n) and percent (%).
Body Mass Index (BMI).
Standard deviation (SD).

Comment

The main outcome was to evaluate the impact of hysteroscopic metroplasty on live birth rate in nulliparous infertile women with T-shaped uterus, that resulted significantly improved up to 65%

Table 3
Overall and based on eligible criteria for metroplasty postoperative reproductive outcomes.

	Total	Primary infertility	Recurrent spontaneous miscarriages	Repeated IVF failure	p*
N	60	25	20	15	
Age mean, SD	36.07 (4.31)	34.68 (3.22)[a]	36.20 (5.25)	38.20 (3.84)	0.04
Clinical pregnancy	50/60 (83.3)	21/25 (84.0)	18/20 (90.0)	11/15 (73.3)	0.420
Live birth	38/50 (76.0)	16/21 (76.2)	13/18 (72.2)	9/11 (81.8)	0.915
Before 37 GW	4/38 (10.5)	2/16 (12.5)	2/13 (15.4)	0/9 (0)	0.658
After 37 GW	34/38 (89.5)	14/16 (87.5)	11/13 (84.6)	9/9 (100)	0.658
Spontaneous abortion	6/50 (12.0)	2/21 (9.5)	3/18 (16.7)	1/11 (9.1)	0.859
Ongoing pregnancy	6/50	3/21	2/18	1/11	
Overall live birth rate	38/60 (63.3)	16/25 (64.0)	13/20 (65.0)	9/15 (60.0)	1.000
Clinical pregnancies with spontaneous conception	15/50 (30.0)	7/21 (33.3)	7/18 (38.9)	1/11 (9.1)	0.203
Live birth after spontaneous conception	11/15 (73.3)	6/7 (85.7)	4/7 (57.1)	1/1 (100)	0.677
Clinical pregnancies with IVF conception	35/50 (70.0)	14/21 (66.7)	11/18 (61.1)	10/11 (90.9)	0.201
Clinical pregnancy after IVF	35/45 (77.8)	14/18 (77.8)	11/13 (84.6)	10/14 (71.4)	0.824
Live birth after IVF	27/45 (60.0)	10/18 (55.6)	9/13 (69.2)	8/14 (57.1)	0.743

Nominal variables are described with number of cases (n) and percent (%). Standard deviation (SD). Gestational week (GW). In vitro fertilization (IVF).
* evaluated among the three subgroups based on eligible criteria for metroplasty.
[a] $p < 0.05$ Primary infertility group versus Repeated IVF failure group.

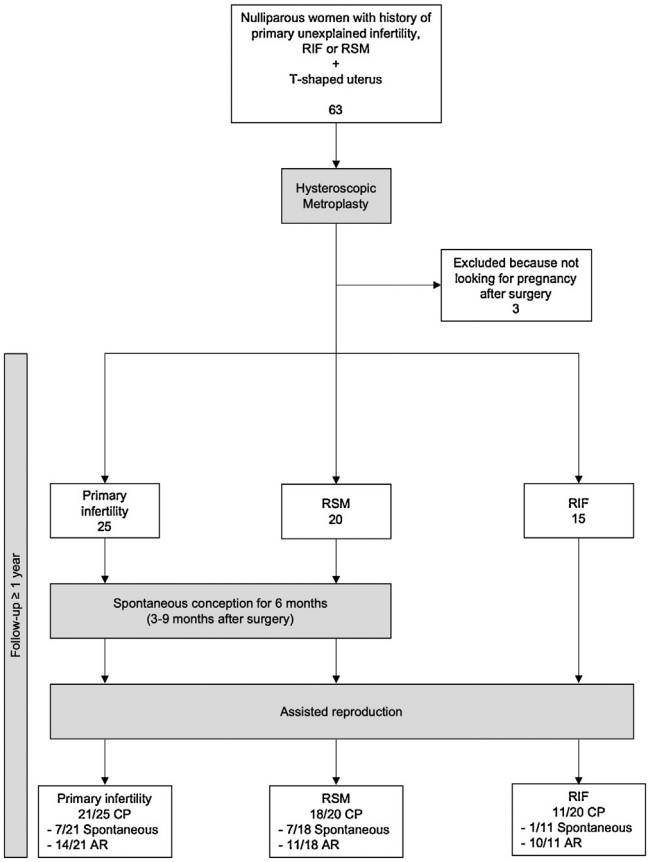

Fig. 3. Study design flow-chart, with results of clinical pregnancies and type of conception. Repeated IVF failure (RIF); Recurrent spontaneous miscarriages (RSM); Clinical pregnancy (CP); Assisted reproduction (AR).

($p < 0.001$), regardless of reproductive history. Pregnancy complications related to uterine surgery were not reported, with an 89.5% of fetus delivered at term and a prevalence of cesarean section of 26.3%. Similar to live birth rate, the clinical pregnancy rate was increased up to 90% ($p < 0.001$) regardless of reproductive history, and in the 35.9% of couple underwent expectant management the pregnancies were spontaneously conceived. In RSM subgroup, the miscarriages rate was statistically significant reduced to 16.7% ($p < 0.001$). Overall, our results confirm that hysteroscopic metroplasty is able to improve the reproductive prognosis and fertility outcomes in nulliparous infertile women with T-shaped uterus not exposed to DES *in utero*.

Because DES use was prohibited about 40 years ago, T-shaped uterine malformation is now encountered in young infertile patients not exposed to DES [16]. On that basis, two prospective [10,14] and one retrospective [13] recent studies investigated the role of hysteroscopic metroplasty in women with dysmorphic uterus in patients not exposed to DES. Sükür et al. [13] retrospectively evaluated the reproductive outcome of 62 women with a T shaped uterus, who underwent a lateral metroplasty performed with conventional 26-Fr resectoscope, reporting a clinical pregnancy rate of 59.7% and a live birth rate of 75.6% after surgery. Di Spiezio Sardo et al. [14] prospectively evaluated 30 women with dysmorphic uteri, including 12 T-shaped uteri, who underwent hysteroscopic metroplasty performed with the Hysteroscopic Outpatient Metroplasty to Expand Dysmorphic Uteri (HOME-DU) technique, characterized by lateral and anteroposterior incisions on the constriction ring. Among patients with primary infertility and repeated spontaneous abortion, the live birth rate increased up to the 71%. Boza et al. [12] performed a prospective study on 56 patients with primary T-shaped uterus and primary infertility, IVF failure or recurrent miscarriages. Hysteroscopic metroplasty was performed with vaginoscopic approach under conscious sedation by 5-mm diameter hysteroscope and a bipolar electrosurgical system. They reported a significant increased clinical pregnancy rate (66.1%), live birth rate (78.4%), and decreased spontaneous abortion rate (21.6%).

Our prospective study is one of the largest homogeneous series. The significant improvement of clinical pregnancy and live birth rates and the decreased spontaneous abortion rate are consistent with those previously reported. Our results strength the effectiveness of hysteroscopic metroplasty in nulliparous women with T-shaped uterus due to the prospective design and the strict diagnostic criteria based on 3D ultrasound and hysteroscopic diagnosis, that represent the gold standards of diagnosis and allowed a clear and certain identification of the anomaly [1]. Moreover, the choice to exclude T-shaped uterus related to DES reduces biases and is in line with the actual clinical practice. In addition, we excluded women with previous live birth that could potentially influence post-surgical reproductive outcomes.

Nevertheless, some limitations should be addressed. First of all, our analysis lacks a control group. To date, there are neither prospective studies nor randomized controlled trials evaluating the outcomes after expectant management versus surgical treatment. In this scenario, a control group managed expectantly

or with a minimal surgery, such as endometrial scratching procedure [17,18], could be considered in future research. As second point, the limited sample size impedes to achieve definitive conclusion about a possible different effect on the reproductive outcomes of hysteroscopic metroplasty for T-shaped uterus in the three subgroups.

The improvement of reproductive outcomes may be explained by the remodeling of uterine morphology, the enhancement of uterine compliance, and the improvement of uterine vascularization, as well as microscopic changes such as endometrial receptivity. Nevertheless, the exact mechanism was not well established so far, considering the numerous mechanisms involved in the endometrial receptivity, such immunological factors [19].

Similar to other studies [6–14], pregnancy complications related to uterine surgery were not reported in our series, and 89.5% of the fetuses was delivered at term. On that basis, hysteroscopic metroplasty seems to have limited impact on uterine integrity and function during subsequent pregnancy. About delivery, the prevalence of cesarean section was 26.3%, that was lower compared to previous studies [9,10,12,14]. Theoretically, vaginal delivery is not contraindicated [9], although it should be taken into account that hysteroscopy metroplasty likely determines uterine fragility and theoretically increases the risk of uterine rupture. Nevertheless, only one case of uterine rupture was reported at 26 weeks of gestation (not during labor) [20]. Therefore, this risk could be considered low, if incisions are limited to myometrial hypertrophy, restoring normal wall thickness without lessening it [10].

Our prospective study provides data about a homogeneous group of nulliparous women with reproductive failure affected by T-shaped uterus diagnosed and surgically treated with standardized approach. The strict inclusion criteria allowed to identify T-shaped uterus as the only known potential infertility factor, and hysteroscopic metroplasty provided a significant improvement of reproductive outcomes, independently by the reproductive history. Based on our results comparable with previous studies, hysteroscopic metroplasty with vaginoscopy approach and conscious sedation seems to be effective to improve reproductive outcomes without significant obstetrics complications, although larger controlled studies are needed to confirm such promising results.

Authors' contribution

All the authors conform the International Committee of Medical Journal Editors (ICMJE) criteria for authorship, contributed to the intellectual content of the study and gave approval for the final version of the article. The authors alone are responsible for the content and writing of the paper.

L.A.P., A.S.L., and F.G.: study conceptualization and protocol planning and design, supervision. L.A.P.: surgical procedures. A.P. G., A.F.G., and S.G.: clinical data search, collection and analysis. S.G., A.S.L., and F.G.: manuscript writing/editing.

Ethics and methodological standards

The design, analysis, interpretation of data, drafting and revisions conform the Helsinki Declaration, the Committee on Publication Ethics (COPE) guidelines (http://publicationethics.org/), and the RECORD (REporting of studies Conducted using Observational Routinely-collected health Data) statements, available through the EQUATOR (enhancing the quality and transparency of health research) network (www.equator-network.org). The study design was approved by an independent Institutional Review Board (23/2014), taking into account the observational nature of the study and the standardized approaches for the usual management of the patients (routinely-collected health data), without any collection of personal data that could lead to the identification of the patients. Each patient enrolled in this study signed an informed consent for all the procedures and to allow data collection and analysis for research purpose. The study was non-advertised, and no remuneration was offered to encourage patients to give consent.

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Declaration of Competing Interest

The authors have no proprietary, financial, professional or other personal interest of any nature in any product, service or company. The authors alone are responsible for the content and writing of the paper.

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