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Original Article

Surgical correction of T-shaped uteri in women with reproductive failure: Long term anatomical and reproductive outcomes☆

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ABSTRACT

Objective. – To evaluate the long term anatomical and reproductive outcomes of hysteroscopic treatment for T shaped uterus in patients presenting with reproductive failure.
Methods. – This prospective cohort study included 56 patients with a history of long-standing unexplained infertility, recurrent implantation failure (RIF), and/or recurrent pregnancy loss (RPL) who were eligible for metroplasty by office hysteroscopy. Office hysteroscopy under conscious sedation was performed. Anatomical outcomes were assessed with pre- and postoperative measurements of the transostial, isthmic and myometrial diameters and the uterine volume using three-dimensional transvaginal sonography (3D-TVS). Reproductive outcome was assessed after spontaneous or assisted conception.
Results. – Hysteroscopic treatment significantly increased the volume of the uterus from a mean of 2.5 + 1 mL before surgery to 3.2 ± 1 mL by the end of 1 year as measured by 3D-TVS. According to the main indication to perform metroplasty, 20 of 32 (62.5%) patients with long standing unexplained infertility, 9 of 14 (64%) patients with RIF, and 8 of 10 (80%) patients with RPL conceived either spontaneously or with assisted reproduction.
Conclusions. – Office hysteroscopic metroplasty results in a significant long-term expansion of the uterine cavity and improved reproductive outcomes in women presenting with a T shaped uterus and poor reproductive history.

Introduction

The European Society of Human Reproduction and Embryology and the European Society for Gynaecological Endoscopy working group of experts published in 2013, a new classification scheme for uterine anomalies [1]. The major difference between this and the classifications systems that were previously widely used is the introduction of a new category defined as dysmorphic uterus. Dysmorphic uterus incorporates all cases with a normal uterine outline but with an abnormal shape of the uterine cavity excluding septa. *Class U1a or T-shaped uterus* characterized by a narrow uterine cavity due to thickened lateral walls with a correlation 2/3 uterine corpus and 1/3 cervix. *Class U1b or uterus infantilis* characterized also by a narrow uterine cavity without lateral wall thickening and an inverse correlation of 1/3 uterine body and 2/3 cervix. *Class U1c or others* which is added to include all minor deformities of the uterine cavity including those with an inner indentation at the fundal midline level of <50% of the uterine wall thickness. In the American Fertility Society classification, these anomalies are included in Class VII and are mainly related to in utero diethylstilbestrol (DES) exposure [2].

Despite the fact that DES has not been used for over 40 years, dysmorphic uterus is still encountered in women presenting with reproductive failure, i.e. infertility, recurrent miscarriage or recurrent implantation failure (RIF). Dysmorphic appearance may also develop iatrogenically as a result of intrauterine adhesions and constriction of the uterine cavity after curettage. The management of such patients remains controversial due to subjectivity of the diagnostic methods, different operative

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techniques that have been employed, and the lack of studies comparing surgical treatment with expectant management. Hysteroscopic metroplasty is commonly used to treat dysmorphic uteri but anatomical and/or reproductive outcomes have been reported only in a few studies. Small sample size [3,4], retrospective design [5–7] and different surgical techniques (i.e. monopolar vs. bipolar system, 5 Fr vs. 26 Fr hysteroscopes) used [3–6,8] cause elusive results. In a pilot study [8], the anatomical and reproductive outcome of metroplasty was prospectively evaluated, however the mode of conception of patients postoperatively was not reported and the measurement of the uterine volume was performed only once after surgery.

The aim of the current study was to evaluate the long term anatomical and reproductive outcomes of a novel office hysteroscopic treatment for T shaped uteri in patients presenting with reproductive failure.

Patients and methods

Patients

Between January 2015 and January 2017, primary infertile patients with a T-shaped uterus were included in the study. Institutional review board approval was obtained for prospective collection and publication of the data from the Koc University School of Medicine Committee of Human Research. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Study group consisted of patients with a long-standing unexplained infertility (absence of a definable cause for a couple's failure to achieve pregnancy approximately 2 years of attempting conception despite a thorough evaluation), RIF in in vitro fertilization (IVF) (2 or more unsuccessful IVF attempts despite the transfer of good quality embryos and in the absence of other obvious impediments that may potentially be associated with lack of implantation), and history of recurrent pregnancy loss (RPL) (2 or more spontaneous early pregnancy losses with a negative workup including karyotype analysis and antiphospholipid antibody syndrome)).

Exclusion criteria were essentially limited to subjects in whom optimal three-dimensional transvaginal sonography (3D-TVS) measurements could not be obtained due to obesity, uterine position, and other uterine pathology such as fibroids and adenomyosis and subjects who had an acquired T-shaped uterus presumably due to adhesions, or subjects who had a history of curettage.

Preoperative assessment of the uterine cavity

All patients had an initial hysterosalpingography (HSG) performed in the early follicular phase followed by a 2D and 3D-TVS evaluation performed in the mid-luteal phase. Morphology of the uterine cavity was assessed by HSG and 3D-TVS.

All HSG records were individually evaluated by two authors (BU, AB) with a long-standing experience in infertility work-up. Only when both authors were in agreement a diagnosis of T shaped was entertained. 3D-TVS examinations were performed by two expert operators (OD, AB) during the luteal phase of the cycle (days 21 to 25): this is the optimal time to examine patients for the presence of uterine anomalies, because the endometrium increases in volume, and the uterine cavity is stretched in the coronal plane and can be clearly differentiated from the surrounding myometrium [9]. A 7.5-MHz probe was used for 3D-TVS. Analysis of the uterine shape was carried out in a standardized plane using the interstitial portions of the fallopian tubes as reference points. The distance between tubal ostia (transostial: TO), the transverse diameter at the isthmus (isthmic; I), the mean depth of the myometrium up to the serosa (myometrial; M) were also measured (Fig. 1).

Uterine cavity volumes were assessed by the digital platform VOLUSON E8 and E10 System (Iberian Kretztechnik, Inc., Madrid, Spain) using VOCAL program (Virtual Organ Computer Aided Analysis). This equipment is provided with a volumetric multifrequency vaginal probe (3–9 MHz) that has an insonation angle of 146°. The maximum endometrial thickness is obtained from the longitudinal or "A" plane which is defined as the greatest distance between both myo-endometrial interfaces. Through the VOCAL program the endometrial area is manually traced from the coronal or "C" plane. Coronal plane rotates the uterine axis in a longitudinal plane. Applying the rotational technique with 9 steps, 20 endometrial "slices" are obtained outlining the endometrium at the myoendometrial junction from the fundus to the internal cervical os; this was applied because it was previously shown to yield the best intra and inter-observer reproducibility [10,11]. Using the manual mode, EV was calculated by the VOCAL program automatically and given in cubic centimeters.

Hysteroscopic surgery technique

Hysteroscopy was performed immediately after cessation of the menstrual bleeding. A vaginoscopic approach under conscious sedation (midazolam 10 mg and fentanyl 100 g intravenously) was used. A 5-mm diameter continuous-flow hysteroscope with an oval profile, a 30° fore-oblique telescope and a 5 Fr operating channel (Office Continuous Flow Operative Hysteroscopy 'size 5'; Karl Storz, Tuttlingen, Germany) was used with saline solution (NaCl 0.9%) as the distension medium.

All procedures were carried out by a single operator (BU). The surgical technique consisted of making two lateral incisions in the isthmic area of the uterine sidewalls and one incision when necessary to the fundal area with a 5 Fr bipolar electrosurgical system (Versapoint; Gynecare Inc, Menlo Park, CA, USA) (Fig. 2 and video). The extent and depth of lateral and fundal incisions was determined according the indentation of the sidewalls and the

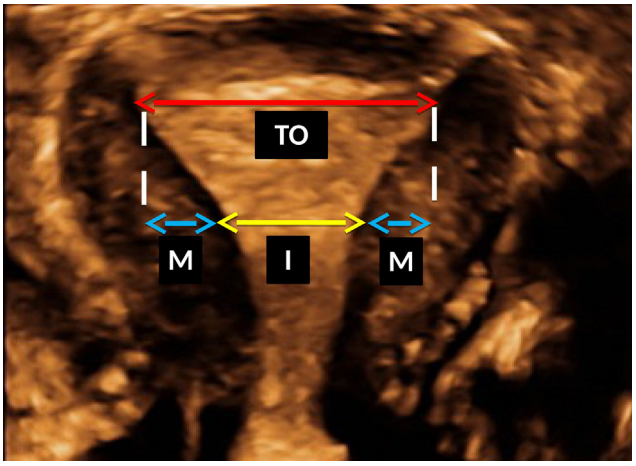

Fig. 1. Three-dimensional transvaginal ultrasound imaging referring to the landmarks of uterine measurements. Trans-ostial (TO) diameter: the distance between tubal ostia; Isthmic (I) diameter: the transverse diameter at the isthmic level; Myometrial (M) diameter: the depth of the myometrium up to the ostial alignment.

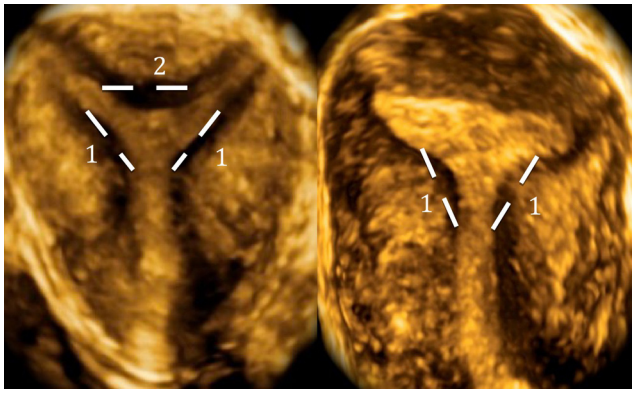

Fig. 2. Hysteroscopic metroplasty incisions on coronal view of a T-shaped uterus. Incisions on lateral side walls (1) and on fundal area (2), if necessary.

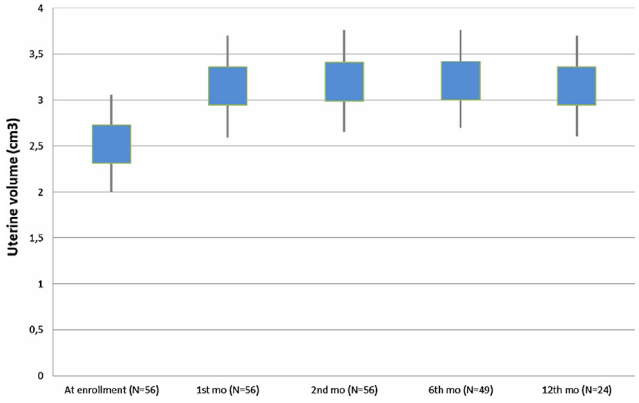

Fig. 3. Changes in uterine volume measured at three-dimensional transvaginal ultrasound before and at 1st, 2nd, 6th and 12th months after metroplasty at ($p < 0.001$).

fundus determined by 3D-TVS. Hyaluronic acid (HA) gel (Materegen Gel, Bilar Medical Company, Istanbul, Turkey) 4–5 mL was instilled into the uterus at the end of the procedure. All patients received 6 g daily oral estradiol tablets from postoperative days 1 to 25 days and 10 mg medroxyprogesterone acetate tablets from days 15 to 25. The patients were advised to use barrier methods of contraception for 2 months following surgery after which spontaneous or IVF pregnancies were allowed.

Assessment of anatomical and reproductive outcomes

Post-surgical anatomical assessment of the uterine cavity was undertaken by 3D-TVS during the luteal phase of the menstrual cycle at 1st, 2nd, 6th and 12th months and by HSG 1 month postoperatively. The measurements at 6 and 12 months were only obtainable from patients who failed to conceive. Measurements (the volumes, TO, I and M diameters) and volume analysis at enrollment were compared with those recorded before surgery.

The reproductive outcomes were evaluated prospectively. Patients were managed expectantly or underwent IVF depending upon the etiology of their infertility. Patients who were thought to be infertile due to the abnormal uterine shape (i.e. patients with long-standing unexplained infertility, patients who had RIF attributed to a uterine factor rather than embryo quality and patients with a history of RPL) were offered natural conception for a period of 6 months. IVF treatment was offered to patients who had other factors precluding natural conception (i.e. mild male factor, ovulatory PCOS) or after 6 months without natural conception.

Clinical pregnancy was defined as a pregnancy diagnosed by ultrasonographic visualization of an intrauterine gestational sac; live birth rate (LBR) was defined as a delivery of a live fetus after 24 completed weeks of gestational age; spontaneous abortion was defined as the spontaneous loss of a clinical pregnancy before 20 completed weeks of gestation.

Statistical analysis

Descriptive variables were presented using percentages, means and standard deviations. Friedman tests were conducted to test whether there is a significant change in the uterine volumes. Mean differences between measures and its standard deviation were used as indicators of inter-observer agreement. The inter-observer agreement in determining the uterine volume was investigated using Kappa-test.

Results

A total of 56 patients were included in the study. All were diagnosed with a T shaped uterus after a careful review of their HSG and 3D-TVS records by two independent observers. In case of disagreement, a third observer was invited to review the records. Consensus was achieved for all patients that were included in the study. Individual characteristics of the included patients are shown in Table 1. Mean age was 36 ± 4.5 with a mean BMI of 23.6. All patients had primary infertility with a mean duration of 36 ± 19 months. RIF was present in 25% and RPL in 18% of the patients.

There were no complications associated with the surgery. Metroplasty significantly increased the volume of the uterus from a mean of 2.5 + 1 mL before surgery to 3.2 ± 1 mL by the end of 1 year as measured by 3D-TVS ($p < 0.001$). Uterine cavity volume at different time points throughout the 1 year follow-up period is shown in Fig. 3. Fundal incision was performed in 13 of 56 patients (23%). The changes in transostial, isthmic and myometrial diameters at enrollment and after surgery are shown in Fig. 4. Isthmic diameter increased significantly whereas the myometrial diameter decreased significantly, thus rendering the cavity shape resembling more like a triangle as opposed to T-shaped. We did not observe any intrauterine adhesions on HSG that was performed 1 month after surgery and 3D-TVS at different time points.

Inter-assessor agreement for the uterine volume measurement was substantial to almost perfect during follow up period (Kappa values for 1st, 2nd, 6th and 12th months were 0.78, 0.82, 0.79 and 0.88, respectively, $p < 0.001$).

The uterine volume of patients who did not become pregnant spontaneously or with IVF was similar to patients who got pregnant (3.8 ± 1 mL vs. 3.6 ± 1.5 mL by the end of 1st year, respectively). Of the 19 patients who did not conceive, six were over 41 years of age; three had a history of RIF and two discontinued further treatment.

Of the 32 patients with long standing unexplained infertility, 9 conceived spontaneously and 11 with IVF (62.5%). Of the 14 patients with RIF, 4 conceived spontaneously and 5 with IVF (64%). Of the 10 patients with RPL, 4 conceived spontaneously and 4 with IVF (80%) (Table 2). Pregnancy related complications such as abnormally adhered placenta, cervical insufficiency, or uterine rupture were not encountered. LBR rate increased from 0% before to 51.8% after the metroplasty. Among patients with live birth ($N = 29$), three had preterm delivery at 34 weeks of gestation.

Table 1
Main characteristics of patients with T-shaped uterus ($N = 56$).

Patient	Age	Duration of infertility (months)	No of previous abortions	No of previous implantation failures	Additional infertility factors
1	33	28	0	0	–
2	34	15	2	0	–
3	27	24	3	0	–
4	27	34	0	0	Ovulatory factor
5	30	36	0	0	Ovulatory factor
6	33	36	0	2	–
7	40	50	0	3	–
8	41	20	1	0	–
9	38	36	0	1	–
10	35	30	0	3	–
11	40	36	2	0	–
12	35	60	1	2	–
13	33	60	2	0	–
14	43	24	0	0	–
15	41	36	0	1	–
16	35	28	0	2	Male factor
17	39	48	1	5	–
18	29	30	2	1	–
19	39	36	0	0	–
20	35	36	0	0	Male factor
21	42	48	1	0	–
22	43	15	0	0	–
23	40	30	0	1	–
24	31	36	0	0	Ovulatory factor
25	36	36	0	0	–
26	39	90	0	1	Male factor
27	34	22	0	3	–
28	30	60	1	0	–
29	34	48	1	0	–
30	42	18	3	0	–
31	43	72	0	0	–
32	33	28	0	0	–
33	38	18	1	2	–
34	28	13	1	3	–
35	35	48	0	0	–
36	37	26	0	0	–
37	35	16	3	0	–
38	41	16	2	0	–
39	41	120	0	4	–
40	32	24	1	2	–
41	33	28	0	0	–
42	40	36	2	0	–
43	30	36	0	0	Ovulatory factor
44	33	36	0	0	–
45	31	36	0	3	Ovulatory factor
46	36	36	0	0	–
47	39	48	1	0	–
48	42	48	0	4	–
49	33	48	1	0	Male factor
50	42	18	3	0	–
51	43	72	0	0	–
52	33	25	0	0	–
53	38	30	0	0	–
54	28	23	1	0	–
55	35	48	0	3	–
56	37	32	0	0	Male factor

Discussion

Our study shows that hysteroscopic treatment of T-shaped uterus is associated with an increased postoperative uterine volume as assessed by 3D-TVS. The technique used in this study offers the advantages inherent to office HS that is the ability to perform the procedure in the office setting under conscious sedation without the need for cervical dilatation. The efficacy of this technique was confirmed by 3D-TVS showing that hystero-

Table 2
Reproductive outcomes after metroplasty according to the main indication to perform surgery.

Indication	No pregnancy	Clinical pregnancy		Spontaneous abortion	Live birth
		Spontaneous	IVF		
Long standing unexplained infertility ($N = 32$)	12 (38)	9 (28)	11 (34)	3 (9)	17 (53)
Recurrent implantation failure ($N = 14$)	5 (36)	4 (28)	5 (36)	3 (21)	6 (43)
Recurrent pregnancy loss ($N = 10$)	2 (20)	4 (40)	4 (40)	2 (20)	6 (60)

Data were given as numbers (%).

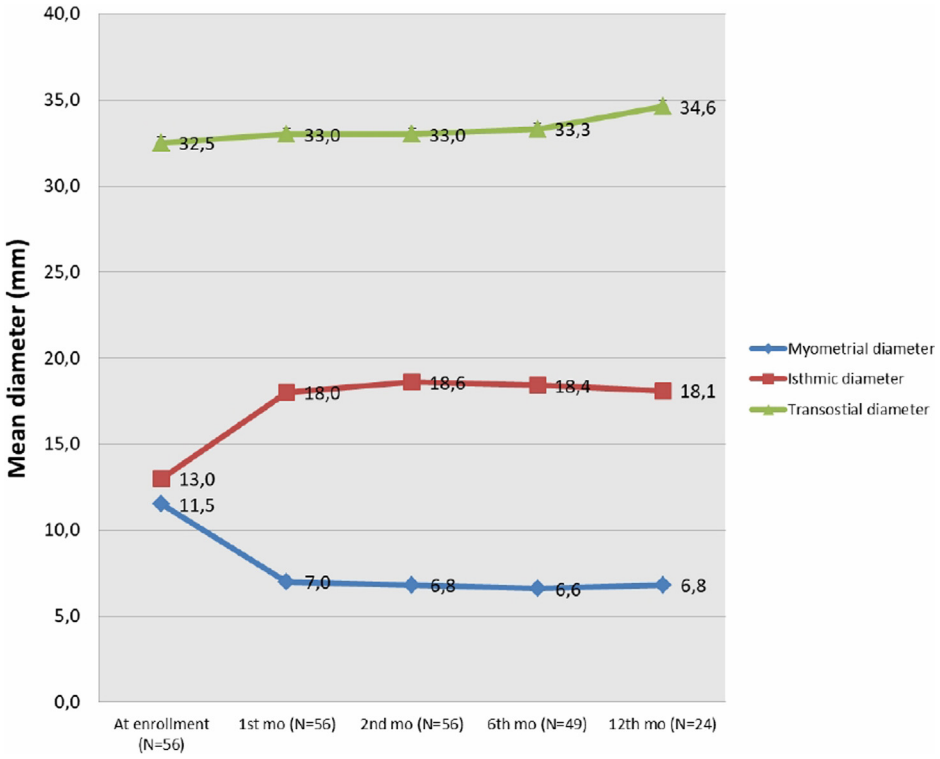

Fig. 4. Transostial, isthmic and myometrial diameter at three-dimensional transvaginal ultrasound at enrollment and after metroplasty (number of patients are given in parenthesis).

scopic metroplasty significantly expanded the volume and improved the morphology of the uterine cavity. The improvement was persistent throughout the 1 year follow-up period. In a group of 56 poor prognosis patients presenting with longstanding reproductive failure, 66% (37/56) conceived postoperatively either spontaneously or with IVF. Due to the nonrandomized design of the study it is difficult to ascertain whether these pregnancies were due to the surgical intervention that was carried out. The conceptions thus achieved may have been unrelated to the intervention or benefit of the intervention may have been due to an endometrial trauma effect.

Dysmorphic uterus is a recently described entity. Previously this uterine anomaly was defined as T-shaped uterus related to DES exposure. Reproductive outcome in patients with a T shaped uterus has been considered to be dismal owing to early reports. Golan et al. reported a very low delivery rate of 21% in women harboring this anomaly [12]. Nagel and Malo reported on 8 patients with infertility and/or RPL who had a T shaped uterus related to DES [4]. Although pregnancies were achieved in patients with pregnancy loss and secondary infertility, none of the patients with primary infertility conceived. Katz et al. incised the sidewalls of the uterus with the guidance of fiberoptic HS in 8 women with a T shaped uterus presenting with RPL. The postoperative performance was available for 7 women of whom 3 conceived 4 term pregnancies. There was one ectopic pregnancy, and no abortions [3].

In large group of patients undergoing ART, Jayaprakasan showed the presence of uterine anomalies in 13.3% (184/1385) as assessed by 3D TVS. Only 1 subject with a T-shaped uterus was identified [13]. However, this was prior to the ESHRE/ESGE consensus report on female genital tract congenital anomalies with the classification of dysmorphic uterus as a distinct entity [1].

More recently Fernandez et al. retrospectively evaluated the reproductive outcome of 97 women with a T shaped uterus, who underwent a lateral metroplasty. The procedure entailed making two incisions 5–7 mm deep on each side of the cavity starting from the fundus and extending into the isthmus. In patients presenting with primary infertility, 55% achieved a live birth. Corresponding LBR in patients with secondary infertility and/or pregnancy loss was 73% [5]. The study reported the reproductive outcome in a heterogeneous group of patients (i.e. patients with history of DES exposure, congenital malformation attributable to another cause or acquired T-shaped uteri) diagnosed by various methods including HSG, diagnostic HS, 2D or 3D-TVS, and or magnetic resonance imaging. Patients were treated with different techniques (26 F monopolar resectoscope requiring cervical dilatation or 5 F bipolar system). Despite high success rate of metroplasty, when the above drawbacks are taken into account, it is difficult to ascertain which group of patients would benefit from different techniques that were employed. In our study, inclusion criteria were stricter and none of the patients had an acquired T-shaped malformation. All patients were diagnosed using the same techniques (HSG and 3D-TVS) and treated similarly (5 F bipolar system). In the detection of uterine anomalies, 3D-TVS is the recommended diagnostic tool with an almost perfect accuracy rate of 97.4% [14].

In another case series of 352 patients presenting with RPL, hysteroscopic metroplasty resulted in a very impressive term delivery rate of 66.7% in the subgroup with a T-shaped uterus [6]. The diagnosis of uterine anomalies was established with HS and metroplasty was performed with conventional 26 F resectoscope. In this study, only patients who tried to get pregnant ($N = 170$) were considered. Reduction in the number of denominators can result in the overestimation of the real effect of the metroplasty. Utilization of HS for the diagnosis of a T shaped uterus may have some limitations as well such as failure to assess the thickness of uterine sidewalls and fundal indentation.

Di Spiezio Sardo et al. prospectively evaluated 30 women with a dysmorphic uterus (including T-shaped and infantilis uteri) who underwent hysteroscopic metroplasty [8]. The technique that was

named HOME-DU involved making lateral and anteroposterior incisions on the lower segment constriction ring. This is different from our technique where we did not make anterior and posterior incisions. Anatomically uterus is compressed antero-posteriorly and is not a cylindrical organ. Antero-posterior incisions may thus extend into the muscular layer of the uterus beyond that of the constricting fibrous tissue. In this study, among patients with primary infertility, term delivery rate was 75%. The study has certain drawbacks that included the lack of information regarding the mode of conception postoperatively and measurement of the uterine volume only once after surgery. Inter-assessor variability for uterine measurements was not taken into account as well. In our study by recording uterine measurements at certain time points after the metroplasty, we showed that increased uterine diameters and cavity volume was persistent throughout the follow-up period. Inter-assessor agreement for the uterine volume measurement was substantial to almost perfect as well.

Management of patients with a T-shaped uterus is controversial and the beneficial effect of hysteroscopic metroplasty is questionable. There are neither prospective follow-up studies nor randomized controlled trials to evaluate the outcome of expectant management versus surgical treatment. Different HS techniques have been proposed, however, there are no comparative studies [15]. Our technique offers the advantages of simplicity due to the use of vaginoscopic approach without cervical dilatation and general anesthesia. Avoiding cervical dilatation may reduce the risk of complication and may provide better identification of lateral uterine walls. Office HS is better tolerated in terms of pain when compared with the conventional approach [16]. This system enables the use of bipolar energy with saline as the distension media. Systems that employ bipolar energy are safer than systems that employ monopolar energy as complications attributable to the distension media are decreased [15]. Adhesion prevention is an integral part of operative hysteroscopy [17]. We advocate the instillation of HA gel into the uterine cavity postoperatively to reduce the formation of postoperative adhesions. Compared to other means, HA gel has been showed to reduce the extent of intrauterine adhesions in randomized studies [18,19]. All of our patients received HA gel at the end of the procedure. We did not observe any adhesion formation on HSG that was performed one month after the surgery.

It is inconceivable that only a well-designed randomized study will properly address the question of whether hysteroscopic metroplasty is beneficial in patients with a T shaped uterus presenting with an unfavorable reproductive history. However, such as study will prove to be very difficult to perform, as has been the case with the septate uterus. Despite being well known for years and acknowledged in the etiology of RPL, an RCT for treatment of the septate uterus has not been performed up to date. Our study, despite being small involves a very homogenous group of patients diagnosed with strict criteria, treated by a single surgeon, and assessed over time with 3D-TVS, shows that in a group of poor prognosis patients presenting with a T-shaped uterus and reproductive failure, office hysteroscopic metroplasty increases the uterine volume and results in a favorable reproductive outcome. However, due to small sample size it was not possible to delineate a specific subset of patients with a T-shaped uterus who would benefit from hysteroscopic metroplasty.

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Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jogoh.2018.10.013.

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