


Clinical Characterization of Genital Tract Malformations: A Retrospective Cohort Study on Associations with Endometriosis and Pregnancy Outcomes

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Purpose: To characterize the clinical phenotypes of congenital genital tract malformations and evaluate their associations with endometriosis (EM) and fertility outcomes.

Patients and Methods: This retrospective cohort study analyzed 306 women with congenital genital tract anomalies treated at a tertiary hospital (2011–2022). Anatomical classifications (obstructive vs non-obstructive), laparoscopically confirmed EM, and postoperative fertility were assessed. Infertility was defined as failure to achieve a clinical pregnancy after ≥ 12 months of unprotected intercourse.

Results: The overall EM prevalence was 18.3% (56/306), which was significantly higher in the obstructive group than in the non-obstructive group (42.86% vs 16.49%, $P=0.006$). Patients with obstructive malformations developed EM at a younger age (25.22 ± 4.02 vs 28.46 ± 4.49 years, $P=0.049$) and had more severe EM stages ($P=0.027$). Preoperative infertility rates were comparable between the obstructive (38.10%) and non-obstructive (36.84%) groups ($P=1.0$). However, within the non-obstructive group, the infertility rate was significantly higher in women with EM than in those without (53.32% vs 33.19%, $P=0.004$). Surgical intervention significantly reduced infertility rates, with the most substantial benefit observed in the non-obstructive malformation + EM subgroup (Absolute Risk Reduction=48.94%, Number Needed to Treat=2). Vaginal septa and residual uterine horns were associated with the highest infertility risks.

Conclusion: Obstructive malformations are associated with early-onset, severe EM, likely facilitated by retrograde menstruation. Non-obstructive variants are linked to insidious EM progression and diagnostic delay. Timely surgical correction, particularly for septal anomalies, significantly improves fertility. Integrating MRI into diagnostic protocols and maintaining a high index of suspicion for occult malformations in adolescents with EM are crucial.

Keywords: endometriosis, genital tract malformations, infertility, vaginal septum, uterine septum, pregnancy outcomes

Introduction

The estimated prevalence of female genital tract anomalies ranges from approximately 4% to 6.9%.¹ The prevalence rates of specific anomalies, however, vary. For instance, imperforate hymen occurs in about 1 in 1000 to 2000 females, whereas Müllerian agenesis has a prevalence of approximately 1 in 5000 females.² With advances in imaging techniques, these anomalies are increasingly diagnosed and are observed in approximately 7% of the general population, with a notably higher prevalence among infertile individuals.³ The American Society for Reproductive Medicine (ASRM) and other professional bodies have classified these anomalies to aid in diagnosis and management, yet their clinical presentation and impact can be highly variable.⁴

A fundamental distinction lies between obstructive (eg, transverse vaginal septum, obstructed hemivagina) and non-obstructive (eg, uterine septum) malformations, each dictating distinct clinical pathways. Obstructive malformations typically present with symptoms such as cyclic pelvic pain and hematometra shortly after menarche, directly contributing to chronic pelvic pain (CPP) in adolescents.⁵ In contrast, non-obstructive variants frequently remain asymptomatic and undetected until fertility evaluation or investigation for recurrent pregnancy loss.

The pathogenic link between obstructive malformations and endometriosis (EM) is well-established, with retrograde menstruation considered the cornerstone mechanism. However, contemporary research has elucidated that this involves more than mere mechanical reflux; it encompasses the dissemination of endometrial epithelial cells harboring somatic driver mutations (eg, in KRAS), which confer a survival and proliferative advantage, facilitating ectopic implantation and lesion establishment.⁶ This molecular understanding provides a deeper explanation for the accelerated EM pathogenesis observed in these cases. Consequently, the early recognition of obstructive anomalies is paramount not only for pain relief but also for the potential mitigation of severe, early-onset EM.^{7,8}

Despite this knowledge, significant clinical challenges and evidence gaps persist. Comprehensive, large-scale data quantifying the specific risk profile of EM across the diverse phenotypes of genital tract malformations remain limited. Furthermore, the impact of these malformations, both obstructive and non-obstructive, on fertility potential is not fully stratified, and the quantitative benefits of surgical intervention in restoring fertility within these distinct phenotypic groups require more robust evidence.⁴ While recent guidelines, such as those from the ASRM, provide recommendations on diagnosing uterine septa, they also highlight the insufficiency of evidence regarding its association with infertility and call for further research.⁴

Therefore, a pressing need exists for detailed phenotypic characterization in large cohorts to inform clinical decision-making and optimize patient outcomes. Based on our institutional experience with 306 cases, this study seeks to address these gaps by: (1) characterizing phenotype-specific EM risk profiles, (2) assessing the differential effects of obstructive versus non-obstructive malformations on fertility potential, and (3) evaluating the improvements in postoperative reproductive outcomes following surgical correction.

Materials and Methods

Study Design and Population

This retrospective study analyzed women diagnosed with genital tract malformations at Nanjing Drum Tower Hospital between 2011 and 2022. Inclusion criteria required laparoscopic/histopathological confirmation of EM (when present), preoperative pelvic ultrasound, and intraoperative anatomical classification. The detailed clinical characteristics of the included patients, stratified by obstructive and non-obstructive malformations, are summarized in ([Supplementary Table S1](#)). Histopathological verification of EM was performed using laparoscopy or laparotomy. A total of 306 women were divided into groups as follows: women with EM and obstructive malformations, women without EM with obstructive malformations, women with EM with non-obstructive malformations, women without EM with non-obstructive malformations. A detailed flowchart outlining patient selection process is presented in [Figure 1](#). The median follow-up period was 72 months (range 17 to 144 months), concluding with the last outpatient visit or telephone contact post-surgery.

Definitions

Infertility was defined as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse, consistent with standard definitions in the field.

Statistical Analysis

Statistical analyses were conducted using SPSS version 20.0 (IBM). Group comparisons for categorical variables were made using the chi-squared test or Fisher's exact test, as appropriate. For continuous variables, the independent *t*-test or Mann-Whitney *U*-test was used based on data distribution. Effect sizes for categorical data were calculated as Phi (ϕ) for 2×2 tables or Cramér's *V* for larger tables to complement the *p*-values. And specific malformation subtypes. Data are presented as mean ± SD or n (%), with 95% confidence intervals (CI) reported for key proportions. A significance level of $P < 0.05$ was considered statistically significant for all analyses.

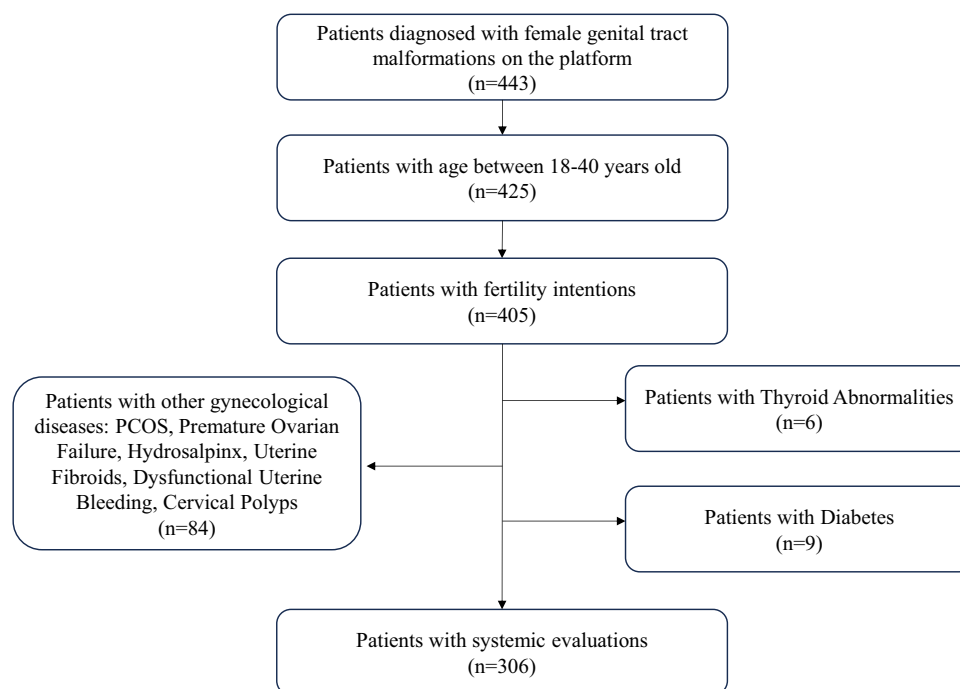


Figure 1 Flowchart of patient selection for the study cohort. The diagram illustrates the stepwise identification and exclusion of patients from the initial platform dataset to form the final analytical cohort of 306 women with congenital genital tract malformations. Exclusion criteria were applied sequentially to focus the analysis on reproductive-aged women (18–40 years) with fertility intentions and without other significant gynecological or systemic conditions known to confound fertility outcomes.

Abbreviation: PCOS, polycystic ovary syndrome.

Ethics

This study received approval from the Ethics Committee of Nanjing Drum Tower Hospital (Ethics number: 2023–376-03). This study was performed in line with the principles of the Declaration of Helsinki. All participants provided informed consent for the chart review and follow-up procedures.

Results

Demographic and Clinical Characteristics

Women with obstructive malformations were diagnosed at a significantly younger age (mean 25.09 ± 4.17 years, range: 13–31, $n = 21$) compared to those with non-obstructive malformations (mean 27.43 ± 3.63 years, range: 20–37, $n = 285$, $P = 0.005$, mean difference = 2.34 years, 95% CI[0.70–3.97], Cohen's $d = 0.64$). The interval between diagnosis and surgical intervention was shorter in obstructive cases (mean 1.85 ± 3.18 years, range: 0–14) than in non-obstructive cases (mean 2.11 ± 1.43 , range: 0–10; $P = 0.006$, $r = 0.16$) (Table 1).

Table 1 Clinical Characteristics of Patients with Female Genital Tract Malformations That Had Obstructive Genital Tract Malformations or Non-Obstructive Genital Tract Malformations

	n	Obstructed	Non-Obstructed
Numbers of female genital tract malformation cases	306	$n = 21$	$n = 285$
Numbers of EM cases	56	9	47
Numbers of non-EM cases	250	12	238
Numbers of infertility cases	113	8	105
Numbers of fertility cases	193	13	180
Age at diagnosis of genital tract malformations (y)	306	$25.09 \pm 4.17^*$	27.43 ± 3.63
Time from diagnosis to surgical intervention of genital tract malformations	306	$1.85 \pm 3.18^*$	2.11 ± 1.43

Note: * $P < 0.05$.

Endometriosis Burden

Among 306 women with genital tract malformations, 56 (18.30%) were diagnosed with EM via laparoscopy/laparotomy. EM phenotypes included ovarian cysts ($n = 18$), scattered pelvic lesions ($n = 32$), and peritoneal cysts ($n = 6$). The incidence of EM was significantly higher in obstructive malformations (42.86%, 9/21) compared to non-obstructive cases (16.49%, 47/285; $P = 0.006$, $\phi = 0.17$). Women with obstructive malformations were diagnosed with EM at a younger age (mean 25.22 ± 4.02 years, range: 19–30) than those with non-obstructive malformations (mean 28.46 ± 4.49 years, range: 16–39; $P = 0.049$, mean difference = 3.35 years, 95% CI[0.10–6.47], Cohen's $d = 0.74$). The interval between menarche and EM diagnosis was shorter in obstructive cases (mean 11.33 ± 4.35 years, range: 6–18) compared to non-obstructive cases (mean 14.68 ± 4.41 years, range: 2–31; $P = 0.042$, mean difference = 3.35 years, 95% CI[0.13–6.56], Cohen's $d = 0.76$). The distribution of EM stages differed significantly between the groups ($p = 0.027$, $r = 0.30$). Specifically, patients with non-obstructive malformations presented with significantly lower EM stages than those with obstructive malformations. (Table 2).

Subgroup Analysis

In non-obstructive malformations, vaginal septa were associated with higher infertility rates (39.22%, 20/51) compared to uterine septa (34.11%, 73/214). Conversely, obstructive malformations showed elevated infertility risks in residual horn uterus cases, warranting clinical vigilance (Table 3).

Table 2 Clinical Characteristics of Patients with EM That Had Obstructive Genital Tract Malformations or Non-Obstructive Genital Tract Malformations

	Obstructed	Non-Obstructed
n = 56	n = 9	n = 47
EM occurrence rate, %	42.86% (9/21)*	16.49% (47/285)
Age at diagnosis of EM (y)	25.22 \pm 4.02*	28.46 \pm 4.49
Time between menarche and EM diagnosis (y)	11.33 \pm 4.35*	14.68 \pm 4.41
Stage I	n = 2 (22.22%)	n = 30 (63.83%)
Stage II	n = 5 (55.56%)	n = 12 (25.53%)
Stage III	n = 1 (11.11%)	n = 3 (6.38%)
Stage IV	n = 1 (11.11%)	n = 2 (4.26%)

Note: * $P < 0.05$.

Table 3 Infertility Rates by Genital Tract Malformation Subtype

Malformation Subtype	n	Infertility Occurrence Rate % (n)
Non-obstructed	285	36.84 (105)
Septate uterus	214	34.11 (73)
Septate vagina	51	39.22 (20)
Double uterus	4	50.00 (2)
Bicornuate and Didelphys uterus	10	60.00 (6)
Arcuate uterus	3	100.00 (3)
HWWS (type II)	3	33.33 (1)
Obstructed	21	38.10 (8)
Residual horn uterus	13	38.46 (5)
Transverse vaginal septum	3	33.33 (1)
Imperforate hymen	5	40.00 (2)

Fertility Outcomes

Preoperative infertility rates were comparable between obstructive (38.10%, 8/21) and non-obstructive groups (36.84%, 105/285; $P = 1.0$, $\phi = 0.07$). Within the non-obstructive group, women with EM exhibited higher infertility rates than those without EM (53.32% vs 33.19%, $P=0.004$, $\phi = 0.17$). Postoperatively, infertility rates decreased significantly both in patients with non-obstructive malformations and endometriosis (EM) (from 53.32% to 6.38%, $P < 0.001$) and in those with non-obstructive malformations but without EM (from 33.19% to 2.94%, $P < 0.001$) 93.14%, 285/306 (Table 4). Among obstructive cases, infertility was most prevalent in residual horn uterus subtypes. The therapeutic efficacy of surgery, measured by Absolute Risk Reduction (ARR), Relative Risk Reduction (RRR), and Number Needed to Treat (NNT), is detailed below: In patients with obstructive malformations and EM, surgery yielded an ARR of 33.33% and an RRR of 75.0%, corresponding to an NNT of 3. In patients with obstructive malformations without EM, an ARR of 25.00% and an RRR of 75.0% were observed, with an NNT of 4. The most substantial benefit was identified in patients with non-obstructive malformations and EM, who demonstrated a remarkable ARR of 48.94%, an RRR of 88.5%, and an NNT of 2. For patients with non-obstructive malformations without EM, the procedure resulted in an ARR of 30.25%, an RRR of 91.1%, and an NNT of 3. In summary, the consistently low NNT values, ranging from 2 to 4 across all subgroups, robustly demonstrate that the surgical intervention is a highly efficient and effective strategy for restoring fertility in patients with Müllerian malformations, irrespective of their obstruction or EM status. (Table 4).

Discussion

Pathogenetic Link Between Genital Tract Malformations and EM

This study confirms a significant comorbidity between genital tract malformations and endometriosis (EM). Among the 306 women included, the overall prevalence of EM was 18.30% (56/306), and 36.93% (113/306) had concurrent infertility. Further analysis showed that the prevalence of EM in patients with obstructive malformations was 42.86%, significantly higher than the 16.49% (47/285) in those with non-obstructive malformations. This finding is highly consistent with a recent systematic review and meta-analysis, which reported EM prevalence rates of approximately 47% in obstructive malformations and 19% in non-obstructive malformations, both of which are significantly higher than the prevalence of EM in women of reproductive age (6–10%).⁹ These results collectively support the hypothesis that anatomical abnormalities, particularly obstructive malformations (EM prevalence: 42.86%), are associated with the development of EM through retrograde menstruation mechanisms.¹⁰ Moreover, the significantly shorter interval from menarche to EM diagnosis in the obstructive group (mean 11.33 years vs 14.68 years, $P = 0.042$, mean difference = 3.35 years, 95% CI [0.13–6.56], Cohen's $d = 0.76$) further suggests that mechanical obstruction may accelerate the pathological process of EM.

Phenotypic Heterogeneity in Obstructive Malformations

Residual horn uterus, a complex obstructive variant, exemplified distinct clinical risks.^{11–14} Among 13 cases, 46.15% (6/13) were associated with EM, predominantly types IIa/b (endometrium-containing subtypes). Type IIc (endometrium-absent) cases carried elevated risks of ectopic pregnancy due to implantation in the unicornuate uterus. The anatomical continuity between residual and unicornuate uteri in IIa/b subtypes facilitates hematometra retention,¹⁵ exacerbating EM progression and infertility risks. These findings underscore the necessity for pre-pregnancy imaging to detect occult residual uterine structures.

Clinical Challenges in Non-Obstructive Malformations

Non-obstructive malformations (93.14%, 285/306), primarily septal anomalies, exhibited delayed diagnosis (mean age 27.43 years) and prolonged surgical intervals (2.11 years). Despite preserved menstrual outflow, 16.49% (47/285) developed EM, predominantly stage I lesions localized to the uterorectal fossa and pelvic ligaments. Diagnostic delays, attributable to subtle symptoms and limited ultrasound sensitivity for superficial EM.¹⁶ Highlight the imperative for MRI integration in evaluating non-obstructive anomalies.

Table 4 Clinical Characteristics of Patients with Infertility That Had Genital Tract Malformations and EM

Group	Number of Patients (n)	Numbers of Patients with Infertility (n)		Numbers of Patients with Fertility (n)		Infertility Occurrence Rate, %		Absolute Risk Reduction (ARR)	Relative Risk Reduction (RRR)	Number Needed to Treat (NNT)
		Before surgery	After surgery	Before surgery	After surgery	Before surgery	After surgery			
Obstructive malformations with EM	9	4	1	5	8	44.44%	11.11%	33.33%	75.00%	3
Obstructive malformations combined non-EM	12	4	1	8	11	33.33%	8.33%	25.00%	75.00%	4
Non-obstructive malformations with EM	47	26	3	21	44	55.32%	6.38%	48.94%	88.50%	2
Non-obstructive malformations combined non-EM	238	79	7	159	231	33.19%	2.94%	30.25%	91.10%	3

Notes: The Number Needed to Treat (NNT) ranged from 2 to 4 across all subgroups, indicating high therapeutic efficiency. Specifically, an NNT of 2 in the non-obstructive malformations with EM subgroup signifies that only two patients need to be surgically treated for one additional patient to achieve fertility.

Surgical Outcomes and Fertility Implications

Surgical correction significantly reduced the infertility rate in cases of non-obstructive endometriosis (EM) (from 53.3% to 6.4%, $P < 0.001$), confirming its therapeutic efficacy. This finding strongly resonates with the results reported by Chang et al, who demonstrated that hysteroscopic metroplasty led to a significant increase in the live birth rate (84.6% vs 3.7%) and a decrease in the early miscarriage rate (8.8% vs 80.6%) in women with a septate uterus.¹⁷ The consistency between these independent studies provides compelling evidence supporting the therapeutic value of anatomical restoration.

Vaginal septa were associated with a higher risk of infertility than uterine septa (39.22% vs 34.11%), potentially due to the altered cervicovaginal anatomy impeding sperm migration. The septal tissue itself may contain functionally deficient endometrium, with studies indicating molecular abnormalities such as altered expression of HOXA10 and VEGF receptor genes, which could impair embryo implantation.⁶ These inherent molecular deficiencies may underlie, at least in part, the persistent postoperative infertility observed in a subset of patients, suggesting a multifactorial etiology that extends beyond anatomical correction alone and necessitates longitudinal follow-up.

Secondary Findings and Embryological Insights

Four excluded cases of Herlyn-Werner-Wunderlich syndrome (HWWS) were complicated by renal agenesis and EM, underscoring the embryological interplay between Müllerian and mesonephric (Wolffian) duct derivatives^{18,19}. MRI identified 100% of these complex anomalies, outperforming ultrasound in detecting genitourinary comorbidities.^{20,21} The diagnostic challenges posed by non-obstructive anomalies, often manifesting as delayed diagnosis and subtle symptoms, highlight the necessity of employing advanced imaging modalities. As reviewed by Smith et al, MRI provides superior soft-tissue contrast resolution compared to ultrasound alone, making it an indispensable tool for the precise classification of Müllerian anomalies and the detection of associated deep infiltrating endometriosis.²² Adolescent-onset EM (within 1–3 years post-menarche) serves as a clinical warning sign for occult obstructive anomalies, warranting prompt anatomical evaluation.

Limitations and Future Directions

While this large cohort ($n=306$) provides novel insights, several limitations should be considered. First, the retrospective design precludes causal inference, and we were unable to systematically control for all potential confounders, such as male factor infertility or differences in EM treatment history. Second, single-center recruitment may introduce selection bias, particularly towards more complex cases. Third, and importantly, the small sample size of the obstructive group ($n=21$) limits the statistical power for robust subgroup analyses within this category; these findings should therefore be considered exploratory and require validation in larger cohorts. Finally, extended follow-up is required to assess long-term fertility outcomes. Future prospective multicenter studies incorporating molecular profiling are warranted to elucidate residual infertility mechanisms.

Conclusion

Obstructive genital tract malformations are associated with early-onset severe EM, likely via retrograde menstruation, whereas non-obstructive variants are linked to an increased risk of insidious EM progression. MRI-enhanced diagnostic protocols and timely surgical intervention mitigate fertility impairment, particularly in septal anomalies. Clinicians should prioritize anatomical evaluation in adolescents with EM to unmask occult malformations. We propose that pelvic MRI should be considered in adolescents with early-onset EM to screen for occult malformations, and that surgical correction is strongly indicated for septate anomalies in women with impaired fertility.

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Disclosure

The authors report no conflicts of interest in this work.

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