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Serum CA 19-9 and CA 125 in uterine leiomyoma and their association with lesion characteristics

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Abstract
Background: Most benign female genital tract tumors are uterine leiomyomas, which arise during reproduction. Monoclonal tumors vary in size, frequency, and location. Leiomyomas can cause irregular uterine bleeding, dysmenorrhea, pelvic discomfort, abdominal distention, reproductive issues, and malignancy, however most are asymptomatic. Patient age, tumor size and location, symptom intensity, and uterine preservation need to be considered. Biological molecules called biomarkers indicate normal or abnormal processes. CA 19-9, first utilized in pancreatic cancer, and CA 125, a membrane-bound glycoprotein used in gynecology, are raised in benign and malignant disorders. Uterine leiomyomas have few reliable blood indicators for diagnosis or surveillance.
Aim: To evaluate serum levels of CA 19-9 and CA 125 in women with uterine leiomyomas and assess their association with lesion characteristics.
Study Design and Methods: This case-control study was conducted at Babil Teaching Hospital for Maternity and Children between December 2023 and August 2024. One hundred women aged 19-49 years were enrolled, including 50 patients with ultrasonographically confirmed symptomatic uterine leiomyomas and 50 apparently healthy controls with normal menstrual cycles and no fibroids on ultrasound. Venous blood samples were collected from all participants, and serum CA 19-9 and CA 125 levels were measured and compared.
Results: Serum CA 19-9 levels were significantly higher in the leiomyoma group compared with controls (33 ± 21.4; $p< 0.0001$), with significantly higher levels in intramural fibroids. Serum CA 125 levels were also significantly elevated in patients (29.21 ± 18.87; $p< 0.0001$) and showed a strong association with fibroid size, particularly lesions ≥5 cm.
Conclusion: Serum CA 19-9 and CA 125 may serve as useful prognostic biomarkers in uterine leiomyoma. CA 19-9 is associated with fibroid location, while CA 125 correlates with tumor size.

Keywords: CA 19-9, CA 125, uterine, leiomyoma

Introduction
Uterine fibroids, also known as uterine leiomyomas, are the most common benign tumors affecting women of reproductive age. They are monoclonal tumors arising from uterine smooth muscle cells and represent the most frequent benign neoplasm of the female genital tract. Histologically, leiomyomas are well-circumscribed, round masses composed of smooth muscle cells and fibroblasts, surrounded by a pseudocapsule formed from a fibro-neurovascular layer that separates the lesion from the normal myometrium [1]. Fibroids vary widely in size, number, and composition, not only among different women but also within the same uterus. The incidence of uterine fibroids increases with advancing age during the reproductive period. It has been estimated that fibroids occur in 20-40% of women during their reproductive years and are identified in up to 70% of uteri removed at hysterectomy [2]. Beyond their high prevalence, fibroids impose a substantial socioeconomic burden. In the United States alone, they affect approximately 11 million women and generate an estimated annual cost of 34 billion dollars due to healthcare expenditures and loss of productivity [3]. Multiple risk factors have been implicated in the development of uterine fibroids. Increasing age is a major determinant, with cumulative incidence reaching nearly 70% in white women and more than 80% in Black women by the age of 50 [4]. Race is a well-established risk factor, as women of African ancestry have a threefold higher risk, tend to develop fibroids at a younger age, and often present with larger, more symptomatic tumors [5]. Obesity has also been consistently associated with increased fibroid risk, likely through altered estrogen metabolism and reduced sex hormone-binding globulin levels [6]. Parity appears to be protective, with nulliparous women having a higher risk than multiparous

women, possibly due to postpartum uterine remodeling and ischemic changes leading to fibroid regression [7]. Genetic abnormalities, including chromosomal rearrangements and somatic mutations, as well as hormonal influences of estrogen and progesterone, play central roles in fibroid pathogenesis [8]. Additional factors such as vitamin D deficiency and lifestyle influences have also been linked to fibroid development [9]. Despite being benign, uterine fibroids can cause significant morbidity, including abnormal uterine bleeding, pelvic pain, pressure symptoms, infertility, and adverse pregnancy outcomes, with a marked negative impact on quality of life [10]. Diagnosis relies primarily on imaging, particularly transvaginal ultrasonography, while management is individualized and ranges from expectant and medical therapy to surgical and minimally invasive interventions [11]. Tumor markers such as carbohydrate antigen 19-9 (CA 19-9) and cancer antigen 125 (CA 125) are widely used in the evaluation of various malignant and benign conditions. Although CA 19-9 is classically associated with pancreatic and gastrointestinal malignancies, and CA 125 with ovarian cancer, both markers may be elevated in several benign gynecological disorders [12]. However, their role in uterine leiomyomas remains incompletely defined, with previous studies reporting modest and inconsistent findings. Therefore, evaluating serum levels of CA 19-9 and CA 125 in women with uterine fibroids and exploring their association with lesion characteristics may provide additional insight into their potential diagnostic or prognostic value.

Method

This cross-sectional study was conducted at Babil Teaching Hospital for Maternity and Children over a nine-month period from 1 December 2023 to 31 August 2024.

Ethical considerations: Ethical approval was obtained from the Scientific Board and Ethical Committee of the Iraqi Board of Medical Specialties, as well as from the Scientific Board of Obstetrics and Gynaecology at Babil Teaching Hospital for Maternity and Children. Verbal informed consent was obtained from all participants after a clear explanation of the study objectives and procedures. A total of 100 married, non-pregnant women aged 19-49 years were enrolled and divided into two equal groups. The case group included 50 women with symptomatic uterine leiomyoma confirmed by abdominal and/or transvaginal ultrasonography. The control group consisted of 50 apparently healthy women with regular menstrual cycles and no fibroids detected on ultrasound.

Inclusion criteria: For the case group were women aged 19-49 years presenting with abnormal uterine bleeding, dysmenorrhea, abdominal pain, or abdominal distension and having ultrasonographic confirmation of leiomyoma. Controls were asymptomatic women of the same age range with normal ultrasound findings.

Exclusion criteria: Included age <19 or >49 years, menopausal status, pregnancy, unmarried status, refusal to consent, and the presence of medical conditions known to elevate serum CA 19-9 or CA 125 levels.

Clinical assessment: All participants underwent detailed history taking, including demographic data, gynecological and obstetric history, contraceptive use, medical and surgical history, and family and social history. Physical examination included general assessment, vital signs, abdominal examination, and pelvic examination. Height and weight were measured, and body mass index (BMI) was calculated and classified as normal, overweight, or obese.

Ultrasound examination: Abdominal and/or transvaginal ultrasound was performed by an experienced radiologist using a Samsung ultrasound system (5-9 Hz). Leiomyoma characteristics were recorded, including number, location (intramural, subserosal, or submucosal), and largest diameter. Lesions were categorized as <5 cm or ≥5 cm.

Laboratory investigations: Venous blood samples (3-5 mL) were collected, centrifuged, and serum stored at −20°C until analysis. Serum CA 19-9 and CA 125 levels were measured using electrochemiluminescence immunoassay (ECLIA) on Roche Cobas analyzers. Reference ranges were <37 U/mL for CA 19-9 and <35 U/mL for CA 125.

Statistical analysis: Data were analyzed using Microsoft Excel 2010 and SPSS version 26. Quantitative data were expressed as mean ± standard deviation, while categorical data were presented as frequencies and percentages. Student's *t*-test was used to compare means between groups, with $p<0.05$ considered statistically significant.

Results

Table (1) show that the mean age for leiomyoma patient was (39.5 ± 5.3) year and for control participants was (37.7 ± 4.7) year with no statistically significant difference between case and control groups (p value = 0.0755). BMI groups show higher percentage of patients with overweight in leiomyoma group 27 (54%). parity groups show no significant between case and control groups, displaying more finding in para 0 in leiomyoma group 20 (40%) and close result for para 1-3 control group 19 (38%). At last family history showed 28 (56%) at leiomyoma group.

Table 1: Distribution of demographic data between the studied groups

	Case group N=50	Control group N=50	P value
Age (year)	(19-49) years	(19-49) years	
mean ± SD	39.5 ± 5.3	37.7 ± 4.7	0.0755
BMI (Kg/M^2)			
Normal weight (18.5-24.9)	14 (28%)	25 (50%)	0.08
Overweight (25-29.9)	27 (54%)	19 (38%)	0.24
obese >30	9 (18%)	6 (12%)	0.45
Parity			
Para 0	20 (40%)	10 (20%)	0.07
Para 1-3	19 (38%)	20 (40%)	0.87
Para 4 and more	11 (22%)	22 (44%)	
Family history of leiomyoma			
Yes	28 (56%)	0 (0.00)	
No	22 (44%)	50 (100%)	

P value >0.05: Not significant, P value <0.05 is statistically significant, p<0.001 is highly significant. t: Unpaired T-test

Figure (1), show analysis of clinical presentation of leiomyoma in the patients group. We found that 38 (76%) had abnormal uterine bleeding, 30(60%) had abdominal pain, 18(36%) had dysmenorrhea, 6(12%) had abdominal distention.

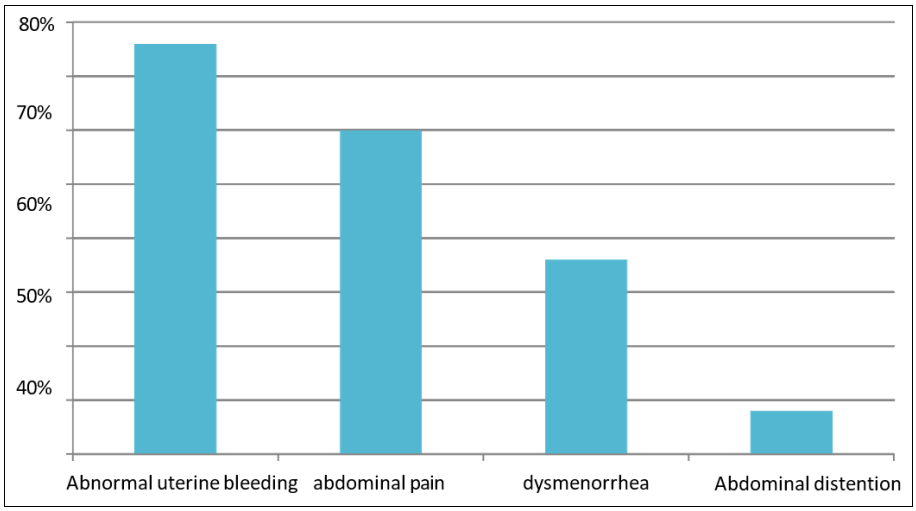

Fig 1: Clinical presentation of leiomyoma group

Table (2) showed that, the most of patients (58%) had intramural localization of fibroid and more than half of patients had Single lesion. While the largest diameter of leiomyoma detected by transvaginal and/or transabdominal ultrasound ranged between (2-14)cm, those with largest diameter < 5 cm were found to be (28%), and those with largest diameter ≥ 5 cm were found to be (72%).

Table 2: Distribution of lesion characteristics in case group

Characteristics	Case group N=50 N (%)
Localization	
Intramural	29 (58%)
Subserosal	12 (24%)
Submucosal	9 (18%)
Number	
Single	23 (46%)
Multiple	27 (54%)
Lesion largest diameter	Range (2-14) cm
< 5 cm	14 (28%)
≥ 5 cm	36 (72%)

Table (3) show that mean serum CA19-9 in case group (33.5 ± 21.4) with high statistically significant difference compared to control group p value (<0.0001). The mean serum CA 125 in case group was (29.21 ± 18.87) with high statistically significant difference compared to control group p value (<0.0001).

Table 3: Comparison of Serum CA19-9 levels and CA 125 between the studied groups

	Case group N=50	Control group N=50	P value
Serum CA19-9 levels (U/ml)			
mean ± SD	33.5 ± 21.4	10.5 ± 5.1	<0.0001
Serum CA 125 levels (U/ml)			
mean ± SD	29.21 ± 18.87	11.3 ± 4.3	<0.0001

P value >0.05: Not significant, P value <0.05 is statistically significant, *p*<0.001 is highly significant. t: Unpaired T-test

This Table (4), show that CA 19-9 levels were significantly affected by the localization of the lesion, with significant higher levels of CA 19-9 in intramural myoma than Submucosal and Subserosal (29.89 ±17.1 vs 10.5± 7.5 and 8.02±8.3) p value (0.03), while Serum CA 125 levels were highly significantly affected by lesion size as p value (0.0016), with significant higher levels of CA 125 in Lesion size ≥ 5 cm than < 5 cm (34.6±18.2 vs 25.8±6.0). No significant association was seen in both CA19-9 and CA 125 regarding weather the leiomyoma was single or multiple.

Table 4: Serum CA19-9 levels and Serum CA 125 in uterine leiomyoma and their association with lesion characteristics

	Serum CA19-9 levels (U/ml)		Serum CA 125 levels (U/ml)	
	Mean	**±SD**	**Mean**	**±SD**
Localization				
Intramural	29.89	17.1	27.0	18.4
Subserosal	8.02	8.3	22.7	12.4
Submucosal	10.5	7.5	19.1	10.0
P value	0.03		0.41	
Number				
Single	28.6	14.1	30.9	15.9
Multiple	32.8	15.0	29.1	12.7
P value	0.15		0.53	
Lesion size				
< 5 cm	32.5	18.3	25.8	6.0
≥ 5 cm	31.7	16.0	34.6	18.2
P value	0.81		0.0016	

P value >0.05: Not significant, P value <0.05 is statistically significant, *p*<0.001 is highly significant. t: Unpaired T-test.

Discussion

In the present study, the mean age of participants was comparable between the leiomyoma and control groups (39.5 ± 5.3 vs 37.7 ± 4.7 years), with no statistically significant difference, reflecting appropriate matching to minimize age-related bias. The observed mean age among fibroid patients aligns with the established epidemiological pattern that leiomyomas commonly present in the late thirties and early forties. This finding is consistent with population-based evidence indicating that fibroid incidence rises notably among women aged 35-39 years, as reported by Yang Q *et al.* [1]. Regarding body mass index, no statistically significant difference was demonstrated between cases and controls, although a higher proportion of overweight women was observed in the leiomyoma group. This trend supports the biological plausibility linking excess adiposity to fibroid risk through inflammatory pathways and increased bioavailability of estrogen and androgens due to reduced sex hormone-binding globulin levels [13]. Similar findings were described by Quaker E Harmon *et al*., who reported increased fibroid incidence among overweight and obese women compared with normal-weight individuals [14]. Parity showed no statistically significant difference between groups; however, leiomyomas were more

frequent among nulliparous women and less frequent among women with parity ≥4. This pattern is consistent with the protective association of childbirth, potentially mediated by hormonal changes during pregnancy and postpartum uterine involution and remodeling, which may promote regression of smaller lesions [15, 16]. Stewart *et al*. reported a marked reduction in leiomyoma requiring surgery among multiparous women compared with nulliparous women [15], and Song *et al*. similarly demonstrated a decreasing fibroid risk with increasing number of births [16]. A strong association was identified between leiomyoma and family history ($p< 0.0001$), with more than half of cases reporting a positive family history, whereas none of the controls did. This supports a genetic contribution and shared familial factors, consistent with Langton *et al*., who found increased fibroid risk and larger tumor size among women with maternal history of fibroids, particularly when maternal diagnosis occurred early [17]. Clinically, abnormal uterine bleeding and abdominal pain were the predominant symptoms, reflecting their role as major drivers of healthcare seeking. The relationship between fibroids and abnormal bleeding has been attributed to altered angiogenesis and irregular vasculature within the pseudocapsule, mediated by local growth factors [18]. Intramural fibroids were most frequent in this cohort, consistent with Olotu *et al*., who reported intramural lesions as the commonest subtype [19]. Although mean CA 19-9 and CA 125 levels in the leiomyoma group remained within manufacturer-defined reference ranges, both markers were significantly higher than controls, supporting their potential clinical utility [20]. Prior studies have shown variable results: modest CA 125 elevations were reported by Babacan A *et al*. and Moore *et al*. in a subset of patients [21, 22], whereas Dawood *et al*. and Dingiloglu *et al*. found no significant differences versus controls [23, 24]. In the current study, CA 19-9 was significantly associated with intramural location, and CA 125 correlated with larger fibroids (≥5 cm), findings comparable to Babacan *et al*. [21]. Collectively, these results suggest that CA 19-9 and CA 125 may reflect certain leiomyoma characteristics, though inconsistencies across studies indicate that broader validation is needed before routine clinical adoption.

Conclusion

CA19-9 and CA125 serve as valuable prognostic markers in uterine leiomyoma. Serum CA 19-9 levels are markedly influenced by the anatomical location of the fibroid, demonstrating greater importance in individuals with intramural uterine leiomyoma. Serum CA125 is impacted by lesion size being more significant in individuals with fibroid's greatest diameter ≥5 cm.

Conflict of Interest

Not available.

Financial Support

Not available.

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