

Original Article

## A National Survey of Umbilical Endometriosis in Japan

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**ABSTRACT** **Study Objective:** To identify the clinical presentation, diagnostic evaluation, operative or medical management, and postoperative recurrence of umbilical endometriosis.

**Design:** A retrospective national survey.

**Setting:** Obstetrics and Gynecology and Plastic Surgery Departments at a teaching hospital in Japan.

**Patients:** Patients with umbilical endometriosis or malignant transformation.

**Interventions:** A national survey was conducted to identify and evaluate cases of umbilical endometriosis or malignant transformation documented between 2006 and 2016.

**Measurements and Main Results:** The following were evaluated for each patient: age at diagnosis, body mass index, medical history, presence of extragenital endometriosis, surgical history, symptoms, imaging modalities, surgical therapy, hormonal therapy, follow-up period, postoperative recurrence, and time to recurrence. Ninety-six patients were identified with pathologically diagnosed benign umbilical endometriosis. The patients frequently had swelling (86.5%), pain (81.3%), or bleeding (44.8%) in the umbilicus. Sensitivity was 87.1% for physical examination, 76.5% for transabdominal ultrasonography, 75.6% for computed tomography, and 81.8% for magnetic resonance imaging. The cumulative recurrence rate was 1.34% at 6 months, 6.35% at 12 months, and 6.35% at 60 months after surgery. Importantly, there was no recurrence after wide resection including of the peritoneum (0 of 37 cases). The efficacy of dienogest (an oral progestin), gonadotropin-releasing hormone agonists, and oral contraceptives was 91.7%, 81.8%, and 57.1%, respectively. Finally, 2 cases of malignant transformation were identified.

**Conclusion:** There was a low recurrence rate following surgery, and hormonal treatment is an option, although the current findings suggest surgical therapy as the first choice of treatment for umbilical endometriosis. *Journal of Minimally Invasive Gynecology* (2019) 00, 1–8. © 2019 AAGL. All rights reserved.

**Keywords:** Hormonal treatment; Nationwide survey; Postoperative recurrence

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Endometriosis is a common disease characterized by the presence of endometrium-like tissue outside the uterus. It occurs in 10% to 15% of women of reproductive age [1,2]. Endometriosis commonly forms peritoneal lesions, ovarian lesions, and deep infiltrating endometriosis that less commonly involves the bowel, bladder, and rarely distant sites, such as the lung and umbilicus.

Umbilical endometriosis is rare, with a reported incidence rate of 0.4% to 4% among all extragenital endometriosis [3]. At our hospital, of the 2530 patients diagnosed with endometriosis between 1999 and 2011, 7 patients (0.28%) presented with umbilical endometriosis [4]. The rarity of the disease makes it difficult to investigate surgical or medical outcomes at a single institution. Indeed, little is known about the postoperative recurrence rate, efficacy of hormonal therapy, and frequency of malignant transformation. Here we present data from a national survey to investigate the clinical presentation, diagnostic evaluation, operative or medical management, and postoperative recurrence in patients with umbilical endometriosis in Japan.

## Materials and Methods

As a primary survey, 637 obstetrics and gynecology departments in teaching hospitals authorized by the Japan Society of Obstetrics and Gynecology and 315 teaching facilities of plastic surgery authorized by the Japan Society of Plastic and Reconstructive Surgery were contacted regarding their experience with cases of umbilical endometriosis and malignant transformation between 2006 and 2016. If the answer was affirmative, the department received a secondary survey requesting that physicians from each facility complete case report forms for each case. The reported cases included those diagnosed by pathological examination, based on physical examination findings, symptoms accompanying menstruation, and imaging results.

For the present study, the pathologically diagnosed cases were extracted and subsequently analyzed. The following information was included in the case report form: age at diagnosis, body mass index, medical history, presence of extragenital endometriosis, surgical history, symptoms, imaging modalities, surgical therapy, hormonal therapy, follow-up period, postoperative recurrence, and time to recurrence. Swelling, pain, and bleeding that disappeared after surgery and subsequently reappeared and worsened was defined as postoperative recurrence. Hormonal therapy was defined as effective when symptoms such as pain and bleeding improved and hormonal therapy could be continued without side effects.

Statistical analysis was performed using JMP Pro version 14 (SAS Institute, Cary, NC). Continuous data are reported as mean  $\pm$  SD. The categorical data were analyzed with the  $\chi^2$  and Fisher exact tests and are presented as counts and percentages. The Kaplan-Meier method was used to analyze the postoperative recurrence rate. Comparisons between the groups were performed using the log-rank test. Results were considered statistically significant at  $p < .05$ .

This study was conducted with the approval of the Ethics Committee of the University of Tokyo (October 10, 2015; #11004). The study received ethical approval for the use of an opt-out methodology based on the low risk to the patient, and informed consent was waived owing to the study's retrospective nature. In addition, the data collection protocol was approved by the Ethics Review Committee of each participating facility. This study was carried out as a part of a policy research initiative of the Japanese Ministry of Health, Labor, and Welfare.

## Results

Primary reports were received from 403 of the 952 departments contacted (42.3%), including 240 of 637 clinical obstetrics and gynecology departments (37.7%) and 163 of 315 plastic surgery departments (51.7%). There were 173 cases of umbilical endometriosis without malignant findings, and 5 cases (2.8%) with malignant findings. In the secondary survey, 115 benign umbilical endometriosis case reports were obtained (115 of 173; 66.5%). Among these, 96 were pathologically diagnosed and enrolled in the present analysis. The background and demographic characteristics of these 96 patients are presented in Table 1. The mean age at the time of diagnosis was  $39.2 \pm 5.8$  years, and the median age was 40 years (range, 25–52 years). Regarding surgical history, 11 patients (11.5%) underwent cesarean section, 11 (11.5%) underwent laparotomy surgery other than cesarean section, 9 (9.4%) underwent laparoscopic surgery, and 64 (66.7%) had no history of abdominal surgery. The incidence of concurrent extragenital endometriosis was also investigated; 3 patients (3.1%) showed complications of extragenital endometriosis, including 2 with inguinal endometriosis and 1 with bladder endometriosis.

## Symptoms

Among the patients with umbilical endometriosis, 94 (97.9%) were symptomatic. Of these, 74 (77.1%) experienced symptoms with menstruation and 10 (10.4%) experienced symptoms unrelated to menstruation. In addition, swelling was observed in 83 patients (86.5%), umbilical pain in 78 (81.3%), and umbilical bleeding in 43 (44.8%).

## Imaging

The umbilical lesions were identified through physical examination in 81 patients (87.1%) (Table 2). In addition, transabdominal ultrasonography was performed in 51 patients, and significant findings were found in 39 (76.5%). Similarly, computed tomography (CT) and magnetic resonance imaging (MRI) showed significant findings in 75.6% (39 of 51) and 81.8% (54 of 66) of patients, respectively. In addition, when combining each diagnostic imaging method with physical examination, the probability of no findings was 9.8% for transabdominal ultrasonography, 9.8% for CT, and 3.0% for MRI (Table 2).

**Table 1**

Patient characteristics (N = 96)	
Characteristic	Value
Age at diagnosis, yr, mean $\pm$ SD (range)	39.2 $\pm$ 5.8 (25–52)
Age distribution, n (%)	
<25 yr	0
25–29 yr	6 (6.3)
30–34 yr	13 (13.5)
35–39 yr	29 (30.2)
40–44 yr	29 (30.2)
45–49 yr	17 (17.7)
50+ yr	2 (2.1)
Height, cm, mean $\pm$ SD (range)	158.4 $\pm$ 4.8 (145.6–170)
Weight, kg, mean $\pm$ SD (range)	54.9 $\pm$ 8.8 (40.0–91.8)
Body mass index, kg/m <sup>2</sup> , mean $\pm$ SD (range)	21.9 $\pm$ 3.7 (16.6–35.9)
Parity, mean $\pm$ SD (range)	1.11 $\pm$ 0.94 (0–3)
Nulliparous, n (%)	30 (31.3)
Parous, n (%)	61 (63.5)
No record, n (%)	5 (5.2)
Dysmenorrhea, n (%)	
Yes	47 (49.0)
No	27 (28.1)
No record	22 (22.9)
Surgical history, n (%)	
Cesarean section	11 (11.5)
Laparotomy (excluding cesarean)	11 (11.5)
Laparoscopy	9 (9.4)
No abdominal surgical history	64 (66.7)
No record	1 (1.0)
Other extragenital endometriosis, n (%)	
Inguinal endometriosis	2 (2.1)
Bladder endometriosis	1 (1.0)
Symptoms, n (%)	
Presenting symptoms	94 (97.9)
Symptoms related to menstruation	74 (77.1)
Symptoms not related to menstruation	10 (10.4)
No record	10 (10.4)
No symptoms (incidental findings)	2 (2.1)
Swelling, n (%)	
Yes	83 (86.5)
No	13 (13.5)
Pain, n (%)	
Yes	78 (81.3)
No	18 (18.8)
Bleeding, n (%)	
Yes	43 (44.8)
No	53 (55.2)

## Treatment

The surgical or medical treatments administered were identified (Table 3). Eighty-seven patients (90.6%) underwent surgery and 9 (9.4%) did not. Of the 9 patients who did not undergo surgery, 4 received hormonal therapy and 5 did not.

### Surgical Therapy

Surgical resection including the peritoneum (wide resection) was performed in 37 of the 87 patients who underwent surgery, and excision of the lesion without the peritoneum was performed in the other 50. Umbilical reconstruction was performed in 23 of the 37 patients in whom the lesion

was removed with the peritoneum and in 26 of the 50 who underwent resection without the peritoneum. Among the surgical cases, 19 patients received preoperative hormonal therapy and 60 did not. Twenty-one patients received postoperative hormonal therapy (dienogest [an oral progestin] in 12, oral contraceptives [OC] in 10, gonadotropin-releasing hormone [GnRH] agonists in 2, and aromatase inhibitors in 1), and 66 patients did not.

Recurrence occurred in 3 patients, at 3, 8, and 12 months after surgery. According to the Kaplan-Meier analysis, the cumulative postoperative recurrence rate was 1.34% at 6 months, 6.35% at 12 months, and 6.35% at 60 months after surgery. There was no significant difference in recurrence rate between patients who underwent wide resection including the peritoneum and those who underwent excision without the peritoneum (Fig. 1A). However, there were no recurrences in the patients who underwent wide resection, whereas recurrence was observed in 3 patients who underwent excision without the peritoneum. There also was no significant difference between patients who received and those who did not receive postoperative hormonal therapy in each group (Fig. 1B). One patient developed postoperative recurrence even after postoperative hormonal treatment. Comparing patients who underwent wide resection without postoperative hormonal therapy and those who underwent excision not including the peritoneum without hormonal therapy, none of the patients who underwent wide resection developed recurrence, but there was no significant difference between the 2 groups.

### Hormonal Therapy

The therapeutic effect of hormonal therapy was investigated. In the patients who received hormonal therapy but did not undergo surgery, a GnRH agonist was administered as the first regimen in 2 patients, dienogest in 1 patient, and OC in 1 patient (Fig. 2). Three patients were finally given dienogest for 18, 22, or 44 months as optimal treatment, and 1 patient was given OC for 32 months.

Nineteen patients who received hormonal therapy before surgery were included in our evaluation of hormonal therapy on patient symptoms. Eight patients received a GnRH agonist, 7 received dienogest, and 4 received OC as their initial preoperative regimen (Fig. 2A). For the second preoperative regimen, dienogest, OC, or a GnRH agonist was administered to each patient. When evaluating the therapeutic effects of these medications in patients receiving only medical therapy and those who received preoperative hormonal treatment (Fig. 2B), dienogest was effective in 91.7% of cases (11 of 12), GnRH agonist was effective in 81.8% of cases (9 of 11), and OC was effective in 57.1% of cases (4 of 7).

### Malignant Transformation

Five of the 178 patients (2.8%) in the primary survey had malignant transformation of umbilical endometriosis.

**Table 2**

Sensitivity of and agreement between physical examination and imaging modalities

Parameter	Patients, n	Sensitivity, %	Physical examination, n (%)		
			Positive	Negative	No record
Physical examination					
Positive	81	87.1	N/A	N/A	
Negative	12		N/A	N/A	
No records	3				
Ultrasound					
Positive	39	76.5	34	3	2
Negative	12		7	5 (9.8)	
Not performed	39				
No records	6				
CT					
Positive	31	75.6	28	1	2
Negative	10		6	4 (9.8)	
Not performed	50				
No records	5				
MRI					
Positive	54	81.8	46	6	2
Negative	12		10	2 (3.0)	
Not performed	24				
No records	6				

CT = computed tomography; MRI = magnetic resonance imaging, N/A = not applicable.

In the secondary survey, 2 cases of malignant transformation were noted among the 5 patients (Table 4). The case report forms of these 2 patients revealed that 1 patient had endometrioid adenocarcinoma and the other had adenocarcinoma, identical to an already published case study

[5]. In the other 3 patients, whether the malignant transformation of the umbilical endometriosis occurred was not determined.

## Discussion

Approximately 70% of the 96 patients with benign umbilical endometriosis diagnosed by pathological examination and 2 cases of malignant transformation had no history of abdominal surgery. The sensitivity of transabdominal ultrasonography, CT, or MRI was positive; the cumulative recurrence rates at 6, 12, and 60 months after surgery were low. Importantly, compared with patients who underwent excision without the peritoneum, there were no recurrences in patients who underwent wide resection including the peritoneum. Dienogest, GnRH agonist, and OC were found to be effective. To our knowledge, this is the largest survey on umbilical endometriosis and the most detailed study on the efficacy of operative and hormonal therapy and postoperative recurrence reported to date.

The fact that most patients had no history of abdominal surgery indicates that these lesions were associated with spontaneous umbilical endometriosis rather than secondary implants associated with surgical history and scars. These results are in line with a previous study, in which a 75% rate of spontaneous occurrence was reported among 28 patients with umbilical endometriosis [6]. Therefore, the pathogenesis of umbilical endometriosis may differ from that of other types of abdominal wall endometriosis, given that other abdominal wall endometrioses are strongly

**Table 3**

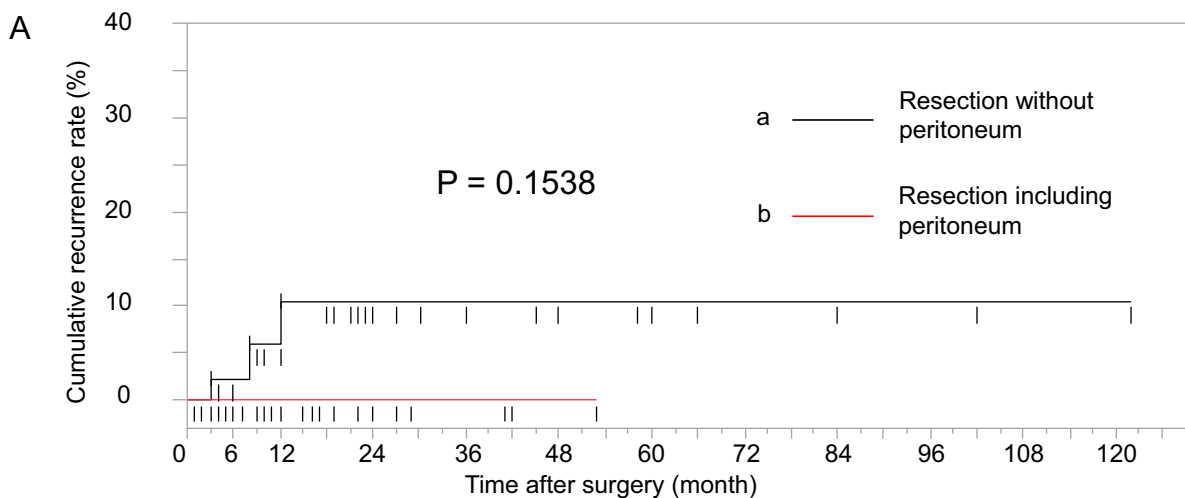
Surgical procedures and medical treatment (N = 87 evaluable patients)

Procedure	Patients, n
Local resection including peritoneum	37
With umbilical reconstruction	23
Without umbilical reconstruction	14
Local resection without peritoneum	50
With umbilical reconstruction	26
Without umbilical reconstruction	24
Preoperative treatment	
Without preoperative hormonal treatment	67
With preoperative hormonal treatment	19
Dienogest	9
GnRH agonist	9
OC	5
Not documented	1
Postoperative treatment	
Without postoperative treatment	66
With postoperative treatment	21
Dienogest	12
OC	10
GnRH agonist	2
Aromatase inhibitor	1

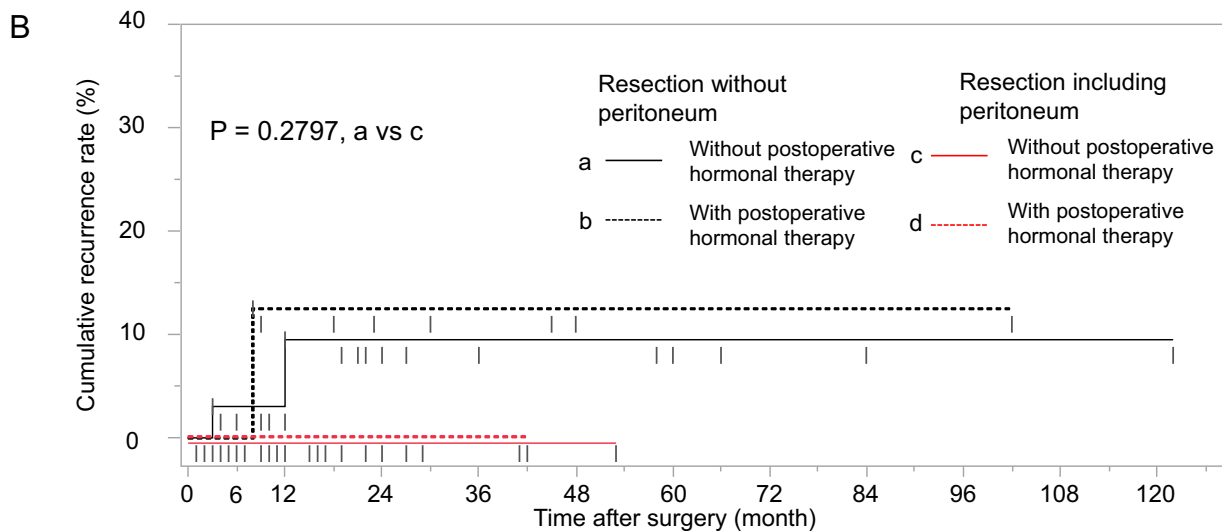
GnRH = gonadotropin-releasing hormone; OC = oral contraceptive.

**Fig. 1**

Cumulative recurrence rate after resection of umbilical endometriosis. The comparison of cumulative recurrence rate between resection without the peritoneum and resection including the peritoneum (A), and with or without postoperative hormonal treatment (B). Tables below the graphs show the number of patients at risk for developing postoperative recurrence.



Number	a, 50	35	21	13	8	4	2
at risk	b, 37	24	14	6	1		



Number at risk	a, 39	25	15	9	7	4	3	1
	b, 11	10	7	5	3	2	2	1
	c, 27	16	8	5	2			
	d, 10	9	6	4	1			

related to surgical history and scars, particularly cesarean section [7].

Among the total population, most patients were symptomatic, and nearly all symptoms were associated with menstruation—important clues to the clinical diagnosis of umbilical endometriosis and similar to symptoms reported previously [3].

Many patients were clinically diagnosed by physical examination and imaging, as reported previously [8–11]. Even in the 8 patients with no findings on physical

examination, 6 were diagnosed via MRI, and CT and MRI have been reported to be useful for assessing lesion depth [8,12–15]. A recent paper emphasized that MRI can be the best choice for diagnosis and useful for determining the size and extent of disease [16], making CT or MRI desirable for predetermining the range of surgical resection [8,17–19].

Previous studies have recommended surgery to treat umbilical endometriosis [3,20], reporting that nearly 70% of patients required surgical treatment [3] to suppress



this study, more than one-half of all surgical operations were followed by umbilical reconstruction. When wide resection of the umbilical endometriosis is required, reconstruction of the umbilicus should be offered [26]. Regarding postoperative hormonal therapy, no significant improvement in postoperative recurrence was seen in the present study. One reason for this is that a large number of patients may be needed to evaluate the effect of postoperative hormonal therapy. In addition, 1 patient had postoperative recurrence during postoperative dienogest treatment. According to the operative notes, the endometriotic lesion could not be completely resected; thus, postoperative administration of dienogest was initiated. Accordingly, the usefulness of postoperative hormonal therapy could not be proven in this study. In addition, our findings support the importance of performing complete resection of lesions so that endometriotic lesions do not remain.

Although some studies have reported the efficacy of surgery for umbilical endometriosis [4], there have been few reports on the effectiveness of hormonal therapy. In our previous report, OC was effective in 3 patients, and hormonal therapy was suggested for patients not wishing to undergo surgical therapy [5]. In addition, estrogen and progesterone receptors in umbilical endometriosis lesions have been reported previously [4,8,27,28], supporting the idea that OC or dienogest can be effective options for umbilical endometriosis. In the present study, dienogest and GnRH agonists effectively ameliorated symptoms in 91.7% and 81.8% of patients, respectively. Thus, these treatments can be options for patients who do not want to undergo surgery. The response rate to OC was approximately 60%, and thus OC can also be considered as a treatment option, particularly because it can be used over the long term, if effective. Although GnRH agonists were effective in more than 80% of patients, it is not suitable for long-term administration owing to hypoestrogenic effects.

Regarding the malignant transformation of umbilical endometriosis, 1 of our patients had endometrioid adenocarcinoma and 1 had adenocarcinoma, identical to an earlier case report [5]. Two case reports on the malignant transformation of umbilical endometriosis have been published previously [29,30]. Histopathological examination revealed that 1 of these cases was a clear cell adenocarcinoma [30] and the other was an adenocarcinoma arising from umbilical endometriosis. In these cases, positron emission tomography revealed abnormal fludeoxyglucose accumulation only at the site of the umbilical lesion [5,30], suggesting its usefulness in facilitating preoperative diagnosis of malignant transformation.

Several limitations of this study should be acknowledged. First, this was a retrospective study, and some data might have not been validated as well as data in planned prospective studies. Second, collecting data might be more difficult from outpatients who were never hospitalized compared with inpatients. Third, the response rates were 42.3% to the primary survey and 66.5% to the secondary survey.

Although these response rates were not low, they could be a potential source of bias. Fourth, only a small number of patients received hormone therapy alone; therefore, we could not derive definitive conclusions on the effect of hormonal therapy. Further studies are needed, including prospective studies, to examine the effects of surgery compared with medical therapy—although this may be challenging, considering the rarity of umbilical endometriosis.

## Conclusion

In conclusion, our present findings indicate a low recurrence rate following surgery and support medical treatment as an option to treat umbilical endometriosis. To the best of our knowledge, this is the largest study examining umbilical endometriosis reported to date, and we believe that these findings will provide useful information for the management of this patient population.

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