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Short Communication

Long-term follow-up of severely symptomatic women with adenomyoma treated with combination therapy

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Abstract

Objective: The aim of our study was to assess the long-term efficacy of conservative surgery combined with gonadotropin-releasing hormone agonist therapy for uterine adenomyoma.
Materials and Methods: We carried out an uncontrolled descriptive study of 285 women who had symptomatic uterine adenomyoma. A total of 186 women with pathologically proven adenomyoma underwent ultramini-laparoscopic adenomyomectomy and a 6-month course of goserelin acetate treatment, and were evaluated semi-annually during a follow-up period of at least 3 years.
Results: Patient scores for dysmenorrhea using a self-reported six-point verbal numeric rating scale significantly declined compared with the baseline assessment, from 3.84 ± 0.65 to 0.33 ± 0.57, 0.52 ± 0.86, and 0.88 ± 1.29 at the end of the 1-, 2-, and 3-year follow-up visits, respectively ($p < 0.001$). Similar reductions were observed for analgesic usage scores. Menorrhagia scores significantly decreased compared with the baseline assessment, from 3.45 ± 1.46 to 0.42 ± 0.59, 0.65 ± 0.83, and 1.1 ± 1.34 at the end of the 1-, 2-, and 3-year follow-up visits, respectively ($p < 0.001$).
Conclusion: Combination therapy for adenomyoma provides an effective treatment option for long-term symptom control and uterine preservation in severely symptomatic women for whom previous long-term drug therapy has failed or proven to be intolerable.

Keywords: adenomyoma; conservative surgery; gonadotropin-releasing hormone agonist

Introduction

Uterine adenomyoma is a gynecologic condition with a diagnosis and a clinical significance that remain somewhat enigmatic, and is most often associated with extensive-type adenomyosis and endometriosis [1–6]. Hysterectomy is a common surgical therapy for treating symptomatic adenomyoma. Various noninvasive diagnostic techniques, such as ultrasonography and magnetic resonance imaging, allow accurate diagnosis of adenomyosis in most cases [7,8]. The recent advent of high-resolution transvaginal ultrasound (TVUS) has markedly improved the accuracy of uterine adenomyoma diagnosis, with sensitivity ranging from 53% to 89%and specificity ranging from 65% to 98% [9–12]. However, the accuracy of TVUS in differentiating between leiomyomas and adenomyoma may occasionally be limited [7,10,13,14].

Conservative drug therapy for uterine adenomyoma includes the use of prostaglandin inhibitors, oral contraceptives, progestogens, danocrine, and gonadotropin-releasing hormone (GnRH) agonists [3,14–24]. However, the effects of these medical treatments are often transient and the symptoms of uterine adenomyoma, pain in particular, nearly always reappear following cessation of the medication [1]. Surgical treatments for uterine adenomyosis are effective in up to 50% of patients [8,25–28]. However, follow-up assessments have been of short duration, and the long-term effects of surgical treatments are unclear [25–34].

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We investigated the use of a combination of surgery and drug therapy for the treatment of uterine adenomyoma by combining ultramini-laparotomy with postoperative goserelin acetate therapy. Our results show significant long-term improvement in symptoms and preservation of the uterus in patients with adenomyoma.

Methods

Participants

Our study was approved by the Institutional Review Board of Taipei Medical University Hospital. We reviewed female patients between the ages of 18 and 55 years. Patients with severe dysmenorrhea and/or menorrhagia were given a tentative diagnosis of uterine adenomyoma based on clinical and TVUS findings. Patients were preoperatively excluded for other diseases of the pelvic organs and illnesses that may result in anemia to avoid confounding follow-up assessments. Patients were excluded postoperatively on the following basis: (1) negative pathological findings of adenomyoma; (2) extensive uterine adenomyosis; (3) concurrent endometriosis; or (4) other pelvic pathologies.

Combined surgical–drug treatment

Ultramini-laparotomy was used for all the surgical procedures in our study [35–38]. The principles of reproductive surgery were strictly followed, minimizing trauma to normal uterine tissues at all times. The microsurgical technique was applied using magnification, intermittent irrigation, and fine-scale instrumentation to minimize blood loss and prevent postoperative adhesion formation [39]. The adenomyotic lesions were resected and removal of all nonmicroscopic lesions was assured by systematic and thorough palpation of the uterus. The surgical margins were electrocauterized to destroy all residual lesions and pelvic adhesions were excised. To reduce bleeding, 10 mL of dilute vasopressin solution (20 U in 80 mL of isotonic sodium chloride solution) was administered at the site of the adenomyoma.

For cases in which it was necessary to enter the uterine cavity, 2-0 chromic sutures were used for closure. The tubal ostia were visualized by inserting splints in both the uterine cavity and the fimbriae to maintain patency [40] and a retrograde dye (methylene blue in saline solution) was injected to demonstrate the os and prevent iatrogenic injury. Horizontal sutures followed by locking sutures were used to close the myometrium, leaving as little dead space as possible. The serosa was closed with a continuous inverting suture of 5-0 poliglecaprone 25 (Monocryl) to minimize raw surfaces on the uterus. Finally, copious peritoneal irrigation with 1:10,000 heparin in lactate Ringer solution was used to remove debris and blood clots from within the abdominal cavity [41].

All patients received a postoperative six-course monthly regimen of 3.6 mg of goserelin acetate intramuscularly for GnRH agonist therapy. The first dose was given to all participants at the beginning of the first postoperative menstrual cycle. The GnRH agonist was administered postoperatively to ensure intraoperative identification of adenomyotic lesions and to suppress the postoperative progression of residual lesions.

Assessment of treatment response

Dysmenorrhea was defined as pelvic pain during, shortly before, or after menstruation. Assessments of dysmenorrhea were performed for the two menstrual periods immediately preceding the time of the visit only. To evaluate variation in pelvic pain, we used a self-reported six-point verbal numeric rating scale (VNRS-6). Patients were asked to rate their pain on a scale from 0 to 5, with 0 representing no pain and 5 representing the worst pain possible. The analgesic usage score (AUS) was also recorded for analgesic use associated with menstrual periods according to the following criteria: 0, no analgesics needed; 1, occasional need for one or two doses of analgesic for less than 1 day; 2, need for more than three doses of analgesic for less than 3 days; 3, need for analgesic drugs during the entire menstrual period; 4, need for analgesic drugs during the entire menstrual period and occasionally on inter-menstruation days; and 5, need for analgesic drugs on nearly every day.

Menorrhagia was defined as a persistent bleeding for more than 7 days during each menstrual period combined with hemoglobin of <10 g/dL in the absence of other causes of anemia. Menorrhagia was graded on a five-point scale according to menses duration and the degree of anemia as follows: 0, no anemia and menses for <4 days; 1, no anemia and menses for 4–7 days; 2, no anemia and menses for >1 week; 3, anemia and menses for <4 days; 4, anemia and menses for 4–7 days; and 5, anemia and menses for >7 days.

Major complications were defined as any condition that required further surgery or prolonged hospitalization. Patients requiring additional procedures, such as blood transfusion, were excluded regardless of whether the hospital stay was compromised or additional surgery was required [42–45]. Patient satisfaction was scored on a three-point scale, with 1 representing dissatisfied, 2 representing satisfied, and 3 representing very satisfied. Recurrence was defined as any VNRS-6, AUS, or menorrhagia score ≥ 2 during follow-up.

Follow-up procedures

For a period of at least 3 years following completion of GnRH agonist therapy, the participants' menstrual symptoms, including dysmenorrhea and menorrhagia, were assessed at 6-month intervals. Satisfaction scores were also recorded at each follow-up visit.

Statistical analysis

Statistical analysis was performed using SPSS software for Windows, version 11.5 (SPSS Inc., Chicago, IL, USA). The nonparametric paired sign test was used to evaluate changes in scores compared with baseline data. The proportion of patients suffering recurrence was determined by Kaplan–Meier analysis using the log-rank test and stratified according to baseline

VNRS-6, AUS, and menorrhagia scores. A p value < 0.05 was considered to represent a statistically significant result.

Results

A total of 285 patients diagnosed with clinical symptoms and TVUS findings associated with adenomyoma were reviewed in our study. All patients underwent adenomyomectomy without major complications or death following surgery, and were followed up for as long as 77 months. We excluded 92 patients because of the coexistence of other pelvic diseases, including 29 patients with extensive uterine adenomyosis and 63 patients with endometriosis. An additional seven patients (3.8%) who suffered from recurrent symptoms were excluded because they underwent hysterectomy during the follow-up period. The remaining 186 women (65.3%), aged 21–51 years (mean 43.4 years), were included as participants in our study.

The patient characteristics and baseline data for dysmenorrhea, AUS, and menorrhagia assessments are listed in Table 1. Patient pain scores for dysmenorrhea significantly declined compared with the baseline assessment (Fig. 1) from 3.84 ± 0.65 to 0.33 ± 0.57 at the end of the 1st year ($p < 0.001$), to 0.52 ± 0.86 at the end of the 2nd year ($p < 0.001$), and to 0.88 ± 1.29 at the end of the 3rd year ($p < 0.001$). The AUS assessment results also decreased compared with baseline measurements (Fig. 1) from 2.39 ± 1.16 to 0.22 ± 0.46 at the end of the first year ($p < 0.001$), to 0.31 ± 0.62 at the end of the second year ($p < 0.001$), and to 0.65 ± 1.12 at the end of the third year ($p < 0.001$). Menorrhagia also improved significantly compared with baseline scores (Fig. 1) from 3.45 ± 1.46 to 0.42 ± 0.59 at the end of the first year ($p < 0.001$), to 0.65 ± 0.83 at the end of the second year ($p < 0.001$), and to 1.1 ± 1.34 at the end of the third year ($p < 0.001$).

Consistent with the significant improvements in VNRS-6, AUS, and menorrhagia assessments, no patients expressed dissatisfaction with the treatment modality at the 1-year follow-up visit (Table 2). At the 2-year follow-up visit, more than 90% of the patients ($n = 168$) were very satisfied (Table 2). However, two patients requested and subsequently underwent hysterectomy because of the recurrence of symptoms. At the 3-year follow-up visit, 83.3% of the patients ($n = 155$) were still very satisfied and 8.1% were dissatisfied, which included the two patients who had requested hysterectomy at the second-year follow-up (Table 2). An additional four patients requested hysterectomy at the 3-year follow-up because of exacerbation of their dysmenorrhea and menorrhagia.

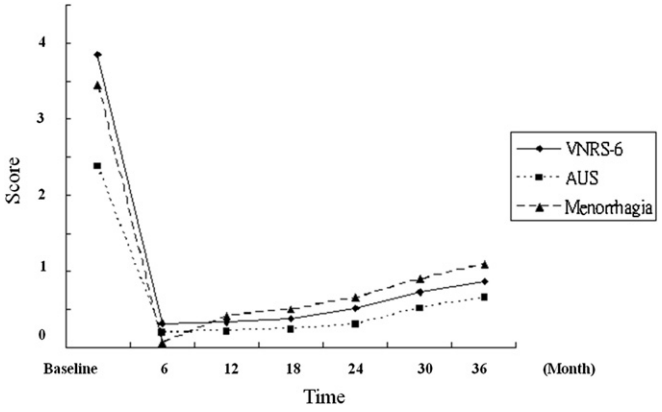

Fig. 1. Self-reported means for the six-point verbal numeric rating scale (VNRS-6), the analgesic usage score (AUS), and menorrhagia grade assessments significantly decreased during the follow-up period according to nonparametric paired sign tests ($p < 0.001$).

There were no recurrences before the 18-month follow-up visit. The cumulative proportion of patients with recurrence during follow-up reached 1.8% at 36 months. The recurrence rate at 36-month follow-up was 9% among patients with baseline VNRS-6 scores of 3 or 4 and 66% for those with a baseline VNRS-6 score of 5. The baseline AUS and menorrhagia grades showed a similar pattern. The rate of recurrence at 36-month follow-up was 70% among patients with a baseline AUS score of 5, which was significantly higher than for patients with baseline AUS scores of 0, 1, 2, 3, or 4, which were 50%, 15%, 1%, 25%, and 33%, respectively, according to the log rank test ($p < 0.001$). Patients with a grade of 5 for menorrhagia had a higher recurrence rate at 36-month follow-up month (49%) compared to those with menorrhagia grades of 1, 2, or 4, who had recurrence rates of 0%, 14%, and 10%, respectively, according to the log rank test ($p < 0.001$).

Table 1
Clinical characteristics of the patients ($n = 186$).

Parameter	Result
Age (y)	43.4 ± 8.3
Body mass index (kg/m^2)	21.0 ± 2.5
Parity	
0	45 (24.2)
1	120 (64.5)
2	21 (11.3)
Baseline VNRS-6	3.8 ± 0.7
Baseline analgesic usage score	2.4 ± 1.2
Baseline menorrhagia scores	3.5 ± 1.5
Anemia	133 (71.5)
Adenomyoma localization during surgery	
Anterior	72 (38.7)
Posterior	98 (52.7)
Fundal	16 (8.6)
Adenomyoma entry into the uterine cavity	49 (26.3)

Data are expressed as mean ± SD or n (%).
VNRS-6 = self-reported six-point verbal numeric rating scale.

Table 2
Satisfaction of women treated with combined surgical–medical therapy during follow-up after completion of gonadotropin-releasing hormone agonist therapy.

	Very satisfied	Satisfied	Dissatisfied
At the end of the first year	173 (93)	13 (7.0)	0 (0.0)
At the end of the second year	168 (90.3)	14 (7.5)	4 (2.2)
At the end of the third year	155 (83.3)	16 (8.6)	15 (8.1)

Data are presented as n (%).

Discussion

Strong evidence of decidual reactions in adenomyotic foci combined with estrogen, progesterone, and androgen receptors implies that ectopic endometrium is hormone-responsive, suggesting a possible role for hormonal manipulation in the treatment of adenomyoma [14]. Two studies used a progestin levonorgestrel-releasing intrauterine device for management of adenomyosis in women with menorrhagia [3,24,25]. Although high efficacy was reported, the authors acknowledged that the side effects of prolonged exposure to progestin treatment, such as headache, breast tenderness, seborrhea, acne, and weight gain, may diminish long-term patient satisfaction [24,25]. GnRH agonists may be better tolerated in women receiving treatment for adenomyoma [14]. Treatment with GnRH agonists results in both a reduction in uterine size and symptomatic improvement. However, the effects of GnRH agonist treatment are often transient, and treatment for longer than 2 years is not recommended without adding hormone therapy [19–22]. In addition, symptoms and signs will persist in nearly all patients following cessation of therapy.

Relatively promising results for laparoscopic electrosurgical myolysis in patients with adenomyosis were described in a small cohort by Phillips et al [29], in which seven of 10 women treated with three courses of GnRH agonist following myolysis continued to have complete resolution or significantly reduced symptoms at 12 months following surgery [29]. Wood et al reported that four of seven women treated experienced prolonged symptom relief [28], and that seven of eight women who underwent myometrial resection for localized adenomyosis experienced long-term reductions in both menorrhagia and dysmenorrhea [1,28].

Conservative surgical approaches, such as laparoscopic excision of myometrial adenomyomas, have had variable results [5,6,8,31,32]. These surgical approaches produced short-term relief of symptoms in only 64% of patients, and only 55% of patients were symptom-free at 24 months following surgery [1,3], suggesting that the efficacy of these methods is limited. Thus, combinations of surgery and drug therapy are worthy of evaluation. Our data show that combination therapy resulted in dramatically improved efficacy, with more than 90% of our study patients reporting that they were very satisfied at the 2-year follow-up visit and over 83% reporting that they were very satisfied at the 3-year follow-up visit.

Because conservative surgical approaches are often ineffective for the treatment of uterine adenomyomas, hysterectomy may represent the only feasible solution in many cases [46]. A total of seven of our patients (3.8%) suffered recurrent symptoms and underwent hysterectomy during follow-up. However, previous studies of surgery alone reported a less than 70% improvement in symptoms at 24 months following surgery, and drug therapy alone did not result in permanent symptom improvement [1,3]. By contrast, more than 80% of the patients in our study reported being very satisfied with their level of symptom improvement at 36 months following treatment with combination surgery–drug therapy for the management of adenomyoma.

One limitation to the findings of our study is that TVUS was not used to evaluate patients at every visit. Thus, our assessment of the recurrence of adenomyoma was not clinically definitive. However, the final diagnosis of uterine adenomyoma is always retrospective, and our use of the VNRS-6, AUS, and menorrhagia grade assessments as indicators of the symptoms of recurrence during follow-up provide substantial clinically relevant information.

In conclusion, our results indicate that conservative surgery combined with adjuvant GnRH agonist drug therapy in the treatment of adenomyoma is efficacious in controlling symptoms, resulting in a high satisfaction rate among patients and a high success rate for preservation of the uterus for at least 3 years. Because the surgery component is an invasive procedure, this combination therapy may not be appropriate for all patients and should be limited to preserving the uterus in severely symptomatic women with adenomyosis for whom long-term drug therapy has failed or has proven to be intolerable. Additional long-term studies of similar surgery–drug combination treatment for adenomyoma are warranted to verify our findings.

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