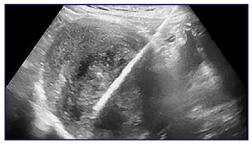
CLINICAL STUDY



An Evaluation of Ultrasound-Guided Percutaneous Microwave Ablation for the Treatment of Symptomatic Uterine Fibroids

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ABSTRACT

Purpose: To evaluate the feasibility and effectiveness of ultrasound-guided percutaneous microwave ablation (MWA) for the treatment of symptomatic uterine fibroids.

Materials and Methods: A single-center retrospective study was conducted on 17 patients, mean age 37.5 years (SD ± 7.3; range 19-47 years) with symptomatic uterine fibroid who underwent MWA between September 2018 and December 2022. Outcomes included volume reduction of uterine fibroids, hemoglobin levels, uterine fibroid symptoms, and health-related quality-of-life questionnaire scores before and 12 months after ablation.

Results: Preoperative fibroid diameter was a mean of 6.7 cm (SD ± 1.1; range 5–9 cm), and volume was a mean of 101.9 cm^3 (SD ± 63.3; range 16.9–264.1 cm^3). The mean ablation time was 12.2 minutes (SD ± 3.1; range, 8–20 minutes). The mean reduction of volume at 12 months after treatment was 70.9% (SD ± 23.8). The hemoglobin level increased significantly from 9.96 g/dL ± 2.33 before treatment to 12.14 g/dL ± 1.34 at 12 months after treatment ($P = .002$). The symptom severity score and health-related quality-of-life scores were significantly improved at follow-up ($P < .001$).

Conclusions: The application of MWA as a standalone treatment method might provide an effective, minimally invasive option for Federation of Gynecology and Obstetrics Types 1–6 symptomatic uterine fibroids with the potential to enhance patients' quality of life.

ABBREVIATIONS

AE = adverse event, FIGO = Federation of Gynecology and Obstetrics, HIFU = high intensity ultrasound, MR = magnetic resonance, MWA = microwave ablation, QoL = quality of life, RF = radiofrequency, UAE = uterine artery embolization, UFS-QoL = uterine fibroids symptom and quality of life, US = ultrasound

Uterine fibroid is the most common benign pelvic tumor in women of childbearing age (1). Considering the high proportion of undiagnosed fibroids, an accurate assessment of fibroid prevalence is difficult. Depending on the population and diagnostic method, the estimated prevalence ranges from 5.4% to 77% (2). Uterine fibroids are generally asymptomatic but can be associated with significant symptoms in approximately 30% of patients (3). These symptoms include menorrhagia, dysmenorrhea, subfertility, secondary anemia symptoms, back pain, and decreased quality of life (QoL) (3).

Currently, treatment choices are surveillance (for asymptomatic fibroids), medical therapy, surgical procedures (myomectomy and hysterectomy), and minimally invasive procedures (3). In recent years, minimally invasive or noninvasive therapies have gained popularity owing to organ preservation, rapid symptom alleviation, and low risk of complication (4). Minimally invasive treatments include uterine artery embolization (UAE), high-intensity focused ultrasound (HIFU) ablation, radiofrequency (RF) ablation, and microwave ablation (MWA) (5). Although UAE is the most widely used minimally invasive alternative, some adverse effects, such as postembolization syndrome, and concerns regarding long-term pregnancy outcomes may prompt consideration of other therapeutic approaches (6).

MWA as an image-guided thermal ablation technique has been advocated to overcome the weaknesses of surgical procedures and UAE (7,8). By using electromagnetic energy, MWA causes adjacent polar water molecules to rotate rapidly, producing heat, coagulation necrosis, and

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RESEARCH HIGHLIGHTS

- Ultrasound-guided percutaneous microwave ablation (MWA) is a feasible, safe, and effective treatment for symptomatic uterine fibroids.
- Percutaneous MWA significantly reduced the size of uterine fibroids and alleviate fibroid-related symptoms.
- Percutaneous MWA improved the health-related quality of life of patients with uterine fibroids. MWA can be considered as a viable treatment option for patients with Federation of Gynecology and Obstetrics Type 1–6 uterine fibroids.

STUDY DETAILS

Study type: Retrospective, observational, descriptive study

Level of evidence: 4 (SIR-D)

shrinkage of fibroids. Its high efficacy, cost-effectiveness, real-time application, and low adverse event (AE) rates have led to the widespread usage in the treatment of solid tumors in organs other than the uterus (7,9). The present study aimed to evaluate clinical effectiveness, feasibility, and potential AEs of MWA in the treatment of uterine fibroids.

MATERIALS AND METHODS

Research Participants

This retrospective study included patients with symptomatic uterine fibroids who were treated with ultrasound (US)-guided percutaneous MWA at a single center between September 2018 and December 2022.

The inclusion criteria were as follows: (*a*) uterine fibroid diagnosed by US and magnetic resonance (MR) imaging and a fibroid diameter of ≥4 cm and <10 cm with classification of Type 1–6 according to the International Federation of Gynecology and Obstetrics (FIGO); (*b*) fibroid-related symptoms (eg, menorrhagia, secondary anemia, dysmenorrhea, pelvic pressure, and frequent micturition); (*c*) absence of perimenopausal signs; (*d*) failure of medical treatment (nonsteroidal anti-inflammatory drugs, oral contraceptive pills, selective progesterone-receptor modulators, gonadotropin-releasing hormone analogs, and iron supplements) or other conservative therapies (levonorgestrel intrauterine devices); (*e*) a desire to preserve the uterus and contraindications to UAE and voluntarily accepted ablation treatment; and (*f*) an available safe transabdominal puncture path as determined using US by the interventional radiologist (S.A.). The exclusion criteria were as follows: (*a*) FIGO Type 7; (*b*) breastfeeding, pregnant, or postmenopausal women; (*c*) pelvic pathologies identified by history or MR imaging, including endometriosis, and acute or chronic pelvic inflammatory disease; (*d*) cervical, ovarian, uterine, or endometrial malignancy; (*e*) any contraindication for general anesthesia; (*f*) severe and uncorrectable coagulopathy (international normalized ratio, more than or equal to 1.5–1.8; platelets, $<50 \times 10^9$/L); (*g*) body mass index >35 kg/m^2; (*h*) untreated cervical intraepithelial neoplasia III; (*i*) patients with more than 1 fibroid or adenomyosis; (*j*) a history of uterine interventional procedures, such as UAE or HIFU.

Table 1. Demographic Data and Fibroid Characteristics

Data characteristics	Value
Age (y)	37.5 ± 7.3
Marital status	
Married	13 (81)
Single	3 (19)
BMI (kg/m^2)	22.9 ± 3.2
Fibroid classification	
I	1 (6)
II	5 (31)
II–V	6 (38)
III	0 (0)
IV	2 (13)
V	1 (6)
VI	1 (6)
Fibroid location	
AW	8 (50)
PW	7 (44)
Fundal	1 (6)
Preablation fibroid diameter (cm)	6.7 ± 1.1
Ablation time (min)	12.2 ± 3.1
Total procedure time (min)	
Transabdominal US	30.2 ± 4.3
Transvaginal US	45.1 ± 3.5
Adverse events	
Fever	2 (12)
Pain at the surgical site	3 (18)
Vaginal discharge	2 (12)
Pelvic infection	0 (0)
Pelvic organ injuries	0 (0)

Note–Values are reported as n (%) or mean ± SD.
AW = anterior wall; BMI = body mass index; PW = posterior wall; US = ultrasound.

A total of 17 patients were included. The mean age of the patients was 37.5 years (SD ± 7.3; range, 19–47 years). The mean preoperative fibroid diameter was 6.7 cm (SD ± 1.1; range, 5–9 cm) and the mean volume was 101.9 cm–^{3} (SD ± 63.3; range, 16.9–264.1 cm^3). Patient demographic data, location, FIGO classification, and characteristics of fibroids are shown in Table 1.

This study was approved by the ethics review committee of the Pardis Noor Medical Imaging Center. Written informed consent was obtained from all patients prior to procedure. All procedures performed in study involving human participants were in accordance with the ethical standards of the institutional and/or national research

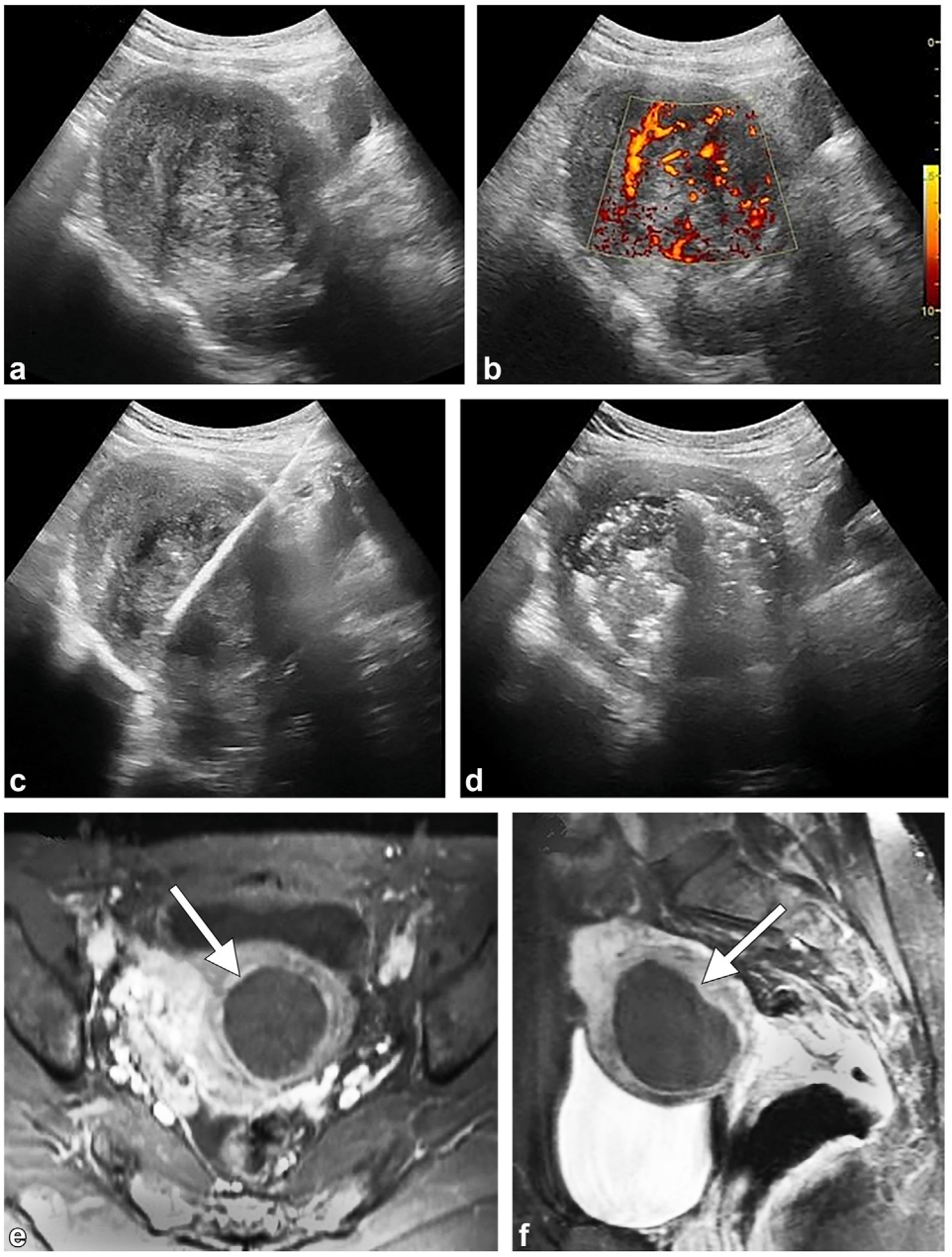

Figure 1. Ultrasound imaging of the ablation procedure and pelvic magnetic resonance imaging 6 months after ablation in a 40-year-old woman with menorrhagia and pelvic pain. **(a)** The preablation 2-dimensional grayscale abdominal ultrasound image of the fibroid and the **(b)** preablation color Doppler flow image showed the fibroid with hyperperfusion. **(c)** The antenna was placed in the center of the fibroid. **(d)** The postablation 2-dimensional grayscale ultrasound image after 14 minutes of ablation with 100 W energy showed interval appearance of shadowing gas bubbles throughout the fibroid. **(e)** Axial and **(f)** sagittal sections of gadolinium-enhanced T1-weighted magnetic resonance images showed an unenhancing (necrotic) center of the fibroid (white arrows).

committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Instruments and Materials

An US was performed using a color Doppler US diagnostic instrument (Logiq 9; GE Healthcare, Chicago, Illinois) equipped with a convex array probe (C5-1) and a vaginal US probe (C10-3V) (Fig 1a, b). Ablation was performed using an Emprint Microwave Ablation System with Thermosphere Technology (Medtronic, Minneapolis, Minnesota), which was connected to a 14-gauge Emprint percutaneous ablation antenna, with a 2.7-cm radiating section by coaxial cable.

Procedure

The ablations were performed under general anesthesia through intravenous injection of propofol (0.5–2.0 mg/kg/h), fentanyl (1–2 μg/kg), and midazolam (0.07–0.08 mg/kg). An anesthesiologist was present during the entire procedure. A

local anesthetic (10 mL solution of lidocaine 2%) was injected at the entrance site of the antenna. All patients received antibiotic prophylaxis with a preprocedural intravenous injection of 1 g of cefazolin. Patients were placed in a supine position for the treatment. An interventional radiologist (S.A.) with 25 years of experience (10 years of experience in ablation) inserted the microwave antenna into the targeted fibroid using the most suitable US probe (transabdominal for anterior wall fibroid/anteverted uterus or transvaginal for posterior wall fibroid/retroverted uterus). The output energy of 100 W for a total time between 8 and 20 minutes was set to induce ablation. The entire ablation process was monitored via real-time ultrasonography (Fig 1c). MWA was stopped when the hyperechogenic signal covered the entire lesion or extended to 3–5 mm from the margin of the serosa or uterine endometrium (Fig 1d). If the fibroid exceeded 5 cm in diameter, the antenna was partially withdrawn and repositioned to treat the entire mass. The patients were observed in the clinic overnight to monitor for any acute AEs.

Outcomes

Technical success was defined by the ability to target the fibroid and create the expected hyperechoic ablation effects on US monitoring. Clinical success was determined by the improvement of symptoms during follow-up of one year. The uterine fibroids symptom and quality of life (UFS-QoL) questionnaire was used to assess symptom severity and QoL (10). The patients completed the questionnaire before and 12 months after treatment. In addition, hemoglobin levels before and 12 months after treatment were evaluated. AEs were registered using the Society of Interventional Radiology classification system both during and after the procedure (11). Contrast-enhanced MR imaging was performed 6 months after the ablation to assess the extent of fibroid necrosis (Fig 1e, f). The MR images were interpreted by a diagnostic radiologist (20 years of experience) who was blinded to the objectives and results of the study. The part of the fibroid that was not enhancing was considered to be necrotic tissue (12).

Statistical Analysis

SPSS v26.0 (IBM, Armonk, New York) was used for all statistical analyses. A *P* value of .05 was considered to indicate statistical significance. *T* test was used to compare data with normal distributions, whereas the Wilcoxon signed-rank test was used to compare data with skewed distributions. The chi-square test was used to compare discrete variables between the 2 groups.

RESULTS

Effectiveness of the Ablation

Technical success was achieved in all participants. The mean ablation time was 12.2 minutes (SD ± 3.1; range, 8–20 minutes). One patient was lost to follow-up.

Table 2. Fibroid Volumes, Hemoglobin Levels, and Uterine Fibroid Symptom and Health-Related Quality-of-Life Questionnaire Scores before and after Ablation

	Time			*P* value
	Before ablation	6 mo after ablation	12 mo after ablation	
Uterus volume (cm^3)	232.3 ± 89.2	166.5 ± 64.5	—	.014
Fibroid volume (cm^3)	101.9 ± 63.3	32.1 ± 43.4	—	.006
Hb level (g/dL)	9.96 ± 2.33	—	12.14 ± 1.34	.002
UFS score	51.1 ± 22.2	—	11.5 ± 4.7	.000
HRQoL score	61.0 ± 21.7	—	95.4 ± 6.5	.000

Note–Values are reported as mean ± SD.
Hb = hemoglobin; HRQoL = health-related quality-of-life; UFS = uterine fibroid symptom.

The mean follow-up was 29.7 months (range, 12–48 months). During follow-up, the mean UFS value was 11.4 (SD ± 4.7; range, 0–21.8) at 12 months. The mean QoL value was 95.4 (SD ± 6.5; range, 77.6–100) at 12 months (Table 2) (Fig 2a, b). At follow-up evaluation, the mean uterus volume was 166.5 cm^3 (SD ± 64.5) and mean fibroid volume was 32.1 cm^3 (SD ± 43.4; range, 2–144.3 cm^3). Shrinkage of the fibroids was observed in all patients (mean, 59.5 cm^3; range, 7.6–140.5 cm^3). The mean volume reduction rate was 70.9% (SD ± 23.8%; range 44.3%–100%). In the participant with FIGO Type I fibroid, a necrotic mass was expelled during the fifth menstruation period after ablation. Two patients underwent caesarian delivery without any complications during the follow-up period.

Clinical Effectiveness

A comparison of baseline and postablative fibroid diameter and volumes, hemoglobin levels, and UFS and HRQoL scores are presented in Table 2. The differences in these parameters were statistically significant ($P < .05$).

Adverse Events

There were no severe AEs during the procedures, such as uterine perforation or pelvic organ injury. All patients were discharged the day after the procedure. All post-procedural AEs were classified as mild. Two patients developed low-grade fever and 3 patients reported mild surgical site pain that was treated with nonsteroidal anti-inflammatory medications. At routine follow-up visits, 2 patients reported brown vaginal discharge, which gradually decreased and resolved spontaneously within 20 days of the procedure (Table 1).

DISCUSSION

After the first report of uterine fibroids treated with percutaneous MWA in 2009 in Japan (13), a series of studies demonstrated that MWA provides a safe, effective, and

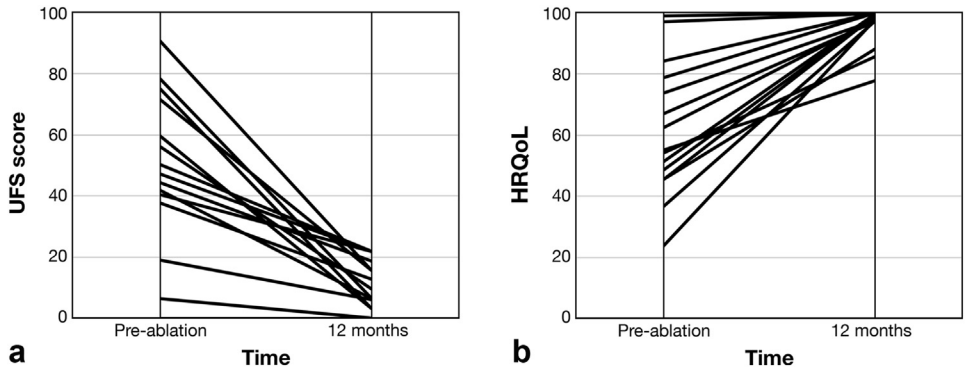

Figure 2. Line plot of **(a)** uterine fibroids symptom (UFS) and **(b)** health-related quality-of-life (HRQoL) scores before and 12 months after treatment.

feasible treatment option (14–16). This study demonstrated that percutaneous MWA led to a reduction of fibroid volume, symptom relief, and a significant improvement in clinical symptoms and QoL. Additionally, no severe AEs occurred in any of the patients.

Considering the benign nature of uterine fibroids, the primary objective of treatment is to alleviate clinical symptoms and improve the QoL of patients. There is, however, no consensus among interventional radiologists and surgeons regarding the most appropriate treatment. Although hysterectomy and myomectomy are the most common treatments for uterine fibroids, these procedures are least preferred by women regardless of whether they intend to have further children (17). Surgical complications range from bleeding, infection, visceral injury, thromboembolism, and vaginal cuff dehiscence after a hysterectomy to a uterine rupture in pregnancies after a myomectomy (18). UAE has long been the nonsurgical and minimally invasive choice for symptomatic fibroids. It has been shown to be both safe and effective. However, the risk of incomplete infarction, abdominal pain, and pelvic radiation in young women and the possible impact on ovarian reserve and fertility render it less suitable for all applications (19). According to an Italian study in 2015, desire for future pregnancy is a relative contraindication to UAE due to insufficient evidence to justify pregnancy success (20).

The aforementioned AEs might be avoided through the use of less invasive procedures. One such option is image-guided thermal ablation, which involves a rapid rise in temperature causing tissue destruction. Thermal energy sources include HIFU, RF ablation, and MWA (5). HIFU is a Food and Drug Administration (FDA)–approved acceptable alternative method for fibroid treatment. The large published HIFU results show that thermal ablation is an effective type of treatment for fibroid management. To this concept, other thermal ablation sources should provide the same or better results. Although HIFU is noninvasive and effective, its indication is limited by the size, location, and vascularity of the lesion. Furthermore, it is more time-consuming and has a higher cost (21). The shortcoming of HIFU is eliminated in RF ablation and MWA by inserting heat-generating electrodes into the fibroids under US guidance. This results in direct tissue destruction during ablation (5,22). As for RF ablation, the significant limitation is the requirement to conduct electricity into the body. Increasing temperature causes the impedance of the tissue to increase, which prevents the further deposition of electricity in the tissue. This effect is accentuated by charring (17,22). The MWA does not depend on the conduction of electricity into tissues and, therefore, is not limited by charring. MWA is also less susceptible to the heat-sink effect than RF ablation, which is an important factor in hypervascular fibroids. This results in a greater radius of heating for MWA (7,22).

According to the present study, targeted MWA resulted in significant reductions in fibroid volume and fibroid-related symptoms as well as an improvement in QoL score. The volume reduction after 6 months was 71%, which was similar to that observed in previous studies (23). Partial ablation of inherently unsafe fibroids, such as those adjacent to the bowel or bladder, was used to alleviate symptoms and reduce AEs. The transabdominal probe can be used to push away the bowel or mesentery to insert the antenna further. However, the transabdominal route may result in AEs or incomplete ablation if repositioning is mandatory. Therefore, the shortest and safest route should be chosen based on the position of the fibroid (13). According to Lin et al (24), the postoperative volume reduction was significantly higher in patients treated with combined transvaginal and transabdominal US-guided MWA than in the group treated with transabdominal US-guided MWA. However, the frequency and mobility angle of vaginal probes limit the depth and range of the scan and the ability to display multiple or large fibroids, thus reducing the image quality (25). The volume reduction in the current study was lower than the 93.1% reported by Zhang et al (16) at 12 months after treatment. The difference could be partially explained by the 10% complete expulsion rate, as compared to 6% in this study. FIGO Type 1 and 2 fibroids have a higher volume reduction rate than other types because necrotic tissue can be discharged through the cervix (15).

In accordance with the Society of Interventional Radiology classification system, no severe AEs occurred during the 12 months after ablation. Vaginal secretions may result from the liquefaction of necrotic tissue and irritation or inflammation of the endometrium. However, it is essential to consider the AEs associated with thermal ablations. Jeong et al (26) reported a case of uterine-rectal fistula after a laparoscopic and transvaginal US-guided RF ablation of a uterine fibroid. Furthermore, Tan et al (27) reported 3 cases of ileal fistula after percutaneous MWA procedures for adenomyosis and fibroids.

This study was conducted using an Emprint Ablation Generator equipped with Thermosphere Technology that has received FDA approval (28). In previous studies, several different types of ablation generators have been used, each with a different frequency and technology, producing ablation zones of different sizes and shapes (29). The ablation generator used in this study was designed to create large, spherical ablation zones regardless of the tissue environment for improved accuracy and reproducibility (28).

Possible limitations inherent to this retrospective study were the small sample size and single-center design. Additional comparative and prospective studies with larger sample sizes and longer clinical and radiological follow-ups are required to determine the optimal treatment and management of uterine fibroids.

In conclusion, MWA can offer a convenient, effective, and minimally invasive treatment option for FIGO Type 1–6 uterine fibroids. The method has the advantage of rapid recovery and a marked improvement in patient QoL. Nevertheless, without a matched comparator group, definitive conclusions cannot be drawn about the effectiveness of different treatment methods. Longer follow-up is needed before the practice can be widely adopted.

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None of the authors have identified a conflict of interest.

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