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Effect of Pulsed High-Intensity Laser Therapy Combined with Exercise Protocol in Treatment of Primary Dysmenorrhea: A Randomized Controlled Trial

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ABSTRACT

Background: The most common cause of pelvic discomfort is primary dysmenorrhea, which causes lower-abdominal cramping pain during menstruation or just before it.

Purpose: The aim of this study was to determine the effect of a pulsed high-intensity laser (HILT) combined with a protocol of exercise on pain and quality of life in patients with primary dysmenorrhea.

Methods: This randomized control trial was conducted between February and September, 2022 in the Department of Physical Therapy, College of applied Medical Sciences, Umm AL-Qura University, and included 59 female students from Umm AL-Qura University with primary dysmenorrhea who were randomly assigned into four groups. Group 1 (HILT) received two sessions of HILT every menstrual cycle for two cycles, Group 2 (Ex) did an exercise protocol (aerobics, yoga, pelvic floor exercise, and pelvic rocking), Group 3 (HILT+Ex) received HILT combined with the exercise protocol, and group 4 served as a control. All participants were evaluated at the beginning ("pre") and after one month (post-1) and two months (post-2) with a visual analogue scale (VAS), quality of life scale (QoL), and pain relief scale (PR). Data were analyzed using a repeated-measure ANOVA and t-test.

Results: Participants in group 3 showed a significant reduction in pain assessed by VAS and highly significant improvement in their quality of life compared with other groups.

Conclusion: The combination of HILT and an exercise protocol showed effectiveness in decreasing pain and improved quality of life after two months of intervention in patients with dysmenorrhea.

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INTRODUCTION

Dysmenorrhea is defined as severe cramping pain in the lower abdomen during menstruation or just before it. It is considered one of the most frequent complaints and affects more than two-thirds of Saudi female adolescents,[1] although it also affects women of all reproductive ages and has a high burden on their quality of life, work achievement, and activities of daily living.[2] It has two main types. Primary dysmenorrhea is recurring abdominal cramps that develop before or when bleeding actually starts and has no particular reason, while menstrual pain is caused by some reproductive disorders such as adenomyosis, endometriosis, or fibroids known as secondary dysmenorrhea.[3]

Prostaglandin is a chemical mediator responsible for contracting the uterus. On the first day of one's period, the prostaglandin level becomes higher than usual, so the uterus contracts excessively. This phenomenon leads to a decrease of oxygen supply to some tissues due to constriction of blood vessels, which results in pain increasing in severity as prostaglandins and uterine contractions increase.[4] Due

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to pain, dysmenorrhea has bad effects on the lives of women, including physical, social, and psychological aspects. Some common symptoms of menstruation include muscle cramps, diarrhea, or constipation. Other symptoms are nausea, vomiting, bloating, headache, fatigue, stress, chills, and mood swings, which could even reach depression.[5] Pain may also radiate to the upper thigh or lower back, causing cramps and back pain.[6]

According to emerging data, women with primary dysmenorrhea are more prone to experiencing negative attitudes toward illness and have a harder time dealing with the psychological impact of their condition, which significantly increases depression and anxiety levels, thus raising the intensity of dysmenorrhea.[7] Dysmenorrhea is a significant problem for not only the affected individual, but also society as a whole. The reason is that it causes women to stop performing their normal daily functions at work, home, or school in the majority of cases by affecting their functioning, which has been linked to short-term absenteeism and isolation from the environment.[8,9]

For dysmenorrhea management, people usually use non-steroidal anti-inflammatory drugs (NSAIDs) as a medication that has a fast effect in relieving various types of pain.[10] However, taking NSAIDs over a long period of time has many side effects, including bleeding, ulcers, nausea, vomiting, increased blood pressure, kidney problems, and allergic reactions.[11] In contrast to pharmacological therapy, which has long-term side effects, traditional home remedies have low significant effectiveness. Therefore, this study focuses on using non-pharmacological physical therapy techniques that show no adverse effects. These techniques have a great outcome by reducing pain, decreasing inflammation, promoting tissue healing, and decrease prostaglandin levels, which can have a great role in treating dysmenorrhea. These physical therapy modalities include manipulation of the spine, exercises, acupuncture, electrotherapy, massage, yoga, and laser therapy.[12,13]

Some scientific research shows that exercise has a highly significant effect on relieving pain from dysmenorrhea as a result of decreasing the level of serum aldosterone. This occurs by reducing the level of renin and increasing estrogen and progesterone, thus reducing undesirable physical symptoms. Moreover, exercising during menstruation boosts levels of endorphins, resulting in a calming effect on the mind and body. It also plays an important role in improving blood circulation by promoting the transfer of waste products and prostaglandins out of the uterus.[14] Previous studies show that a high-intensity laser was effective in relieving symptoms by having a sedative effect that can diminish pain transmission through Aδ and C-fibers along with lowering prostaglandin levels in blood.[15]

To our knowledge, there is no scientific research proving the effect of therapeutic exercises combined with the use of lasers. Some have used only lasers, and others have studied the effect of general exercises. Therefore, this study may be one of the first if not the only one to examine a specific intervention that includes using pulsed high-intensity laser therapy (HILT) in combination with a therapeutic exercises protocol. This study assesses the effect of this combination on the treatment of primary dysmenorrhea.

METHODS

The current study was a single-blind randomized controlled trial (RCT) that assessed the impact of an exercise protocol and pulsed HILT and on dysmenorrhea among students at Umm Al-Qura University. The study was conducted between February and September, 2022 in the Department of Physical Therapy, College of applied Medical Sciences, Umm AL-Qura University. The Umm Al-Qura University Biomedical Research Ethical Committee approved this study and considered it ethically feasible (approval number HAPO-02-K-012-2022-02-941). The study included 59 women aged 18–24 years old with a mean age of 21.017±1.207 years. The women had mild to moderate dysmenorrhea with an average of less than 8 out of 10 on an analogue scale (VAS), regular cycle recurring about every 24–30 days with a mean of 26.552±3.560 days, a body mass index (BMI) of 16–26 kg/m^2 with a mean of 21.189±2.659 kg/m^2, and bleeding time extended for 4–10 days with a mean of 6.690±1.079 days.

Participants were excluded from the study if they had chronic back pain, musculoskeletal problems, genital or hormonal disorders, heart or respiratory diseases, thyroid problems, diabetes, kidney problems, anemia, or neurological disorders. Participants were also excluded if they were using medications that affect dysmenorrhea, on a regular training program, receiving supplemental therapies, or practicing special diets. The study goal was discussed with participants after evaluation, and all of them signed an informed consent form for participation and for publication of the results of this study.

Questionnaire: A total of 59 participants with mild to moderate primary dysmenorrhea were selected as the study sample based on their menstrual history and data obtained from a questionnaire. The questionnaire contained 24 questions, which were distributed into three parts. The first part covered demographic information including the participant's name, age, marital status, physical activity, and chronic diseases. The second part considered menstrual characteristics, including the drugs if any were consumed, volume and rate (quantity and quality) of bleeding, onset and duration of menstruation, and regularity of menstrual cycle. Pain was evaluated in the third part, which asked about menstrual pain on a VAS and about quality of life (QoL).

Randomization: A random systematic method was used to divide the patients into following groups. Group 1 (HILT) received HILT, Group 2 (Ex) performed an exercise protocol, Group 3 (HILT+Ex) received pulsed high intensity laser combined with the exercise protocol, and Group 4 (Cont.) served as a control group. The control group received no treatment and received only instructions to avoid any method than could modulate pain from the menstrual cycle, like pain killers. Randomization was carried out after the initial evaluation of the participants.

Evaluation methods: The main goal of this research was to study the impact of the interventions on dysmenorrhea, so pain level, pain relief, and QoL were evaluated. The VAS is a rating scale with number values placed at equal distance in a line from 0 to 10, where 0 means no pain, 1 to 3 means mild pain, 4 to 6 means moderate pain, 7 to 9 means severe pain, and 10 means unbearable pain. The VAS has proved to be valid and reliable when used to assess different types of pain (especially the acute type).16 In addition, it has high reliability in various health disorders, including abdominal pain which is more

related to our study.17 It was used to measure pain intensity in all groups. Pain was evaluated before treatment ("pre"), after one month (post-1), and after two months (post-2) of intervention for all groups.

The Pain Relief Scale (PR) is a valid scale that was used to indicate whether the intervention resulted in pain reduction after treatment sessions, and if yes, it also determined how much relief there was. It is similar to the VAS but limited to only 5 values ranging from 0 to 4, where 0 means no relief, 1 means slight relief, 2 means good relief, 3 means excellent relief, and 4 means absolutely complete relief. It was measured after one month (post-1) and two months (post-2) of intervention for all groups.

The Spanish version of the EQ-5D scale for quality of life was used to quantify the effect of dysmenorrhea on health condition in dimensions of mobility, self-care, daily activity, depression, and anxiety.[19] Every item is rated on a three-point scale (always = 2, sometimes = 1, never = 0). 0 means there is no effect of dysmenorrhea on the rated dimension. Participants rated their QoL on the scale before, during, and after they finished all their treatment sessions. This scale also shows high validity and reliability.[19] It was evaluated before treatment (pre), after one month (post-1), and after two months (post-2) of intervention for all groups. The total duration of the intervention was two successive menstrual cycles (2 months), and exercises were explained and supervised through video and conducted throughout the Zoom platform.

HILT: Participants received pulsed HILT with a Nd:YAG laser from a HIRO 3 device, which has wavelength of 1,064 nm, high **intensity** (15,000 W/cm^2), high peak power (3 kW), energy density of 810–1,780 mJ/cm, and short pulse durations less than 100 μs. HILT was applied with total energy of 620 J with the participant in a supine position. The laser was applied on the suprapubic area with total energy of 300 J. The application was divided into a first phase (fast; 100 J), a second phase (100 J distributed at 5 points receiving 20 J each), and a third phase (slow; 100 J). It was also applied in a prone lying position on the lumbosacral region (paraspinal) at levels between L4 and S3 with total energy of 320 J in three more phases: a first phase (fast; 100 J divided into 50 J on each side), a second phase (120 J applied at 3 points on each side (6 points on each one) at 20 J each), and a third phase (slow; 100 J). HILT sessions were applied twice a month on the first two days of menstruation, and the duration of each session was about 15 minutes.

Exercise protocol: The training program extended for 2 months and was done on the first 3 days of menstruation and 3 times a week during the rest of the month. It started with a pre-exercise of 5 min of ROM exercises as a warmup and ended with 5 min of stretching as a cooldown. The total time of exercise in the first month took about 30 min per day, and an extra 10 min was added in the second month to reach a total of approximately 40 min per day. It was preferably done at the same time every day, such as every morning or afternoon.

In the first month during the first 3 days of the menstrual cycle, yoga was done. It consisted of cobra, fish, and child poses with 10 s of rest between each pose, 35- 50 s of holding each pose, and 2 repetitions. This was followed by pelvic rocking exercise after resting for 5 min, knee rolling, and cat-cow pose done with 3-5 s of holding each, with 10 repetitions and 2 sets. During the rest of the month, pelvic floor and aerobic exercise of moderate intensity were done three times weekly. The aerobic exercise included running in place for 1 min and 10 s of rest for 2 sets. Marching (with high knees) and lunges were done with 10 repetitions for 2 sets with 10 s of rest between each set and 30-60 s of rest between each exercise. Resting for 5 min was followed by a pelvic floor exercise including bridge and natural supine posterior pelvic tilt done with10 repetitions, holding for 3-5 s, and 2 sets.

In the second month, during the first 3 days of the menstrual cycle, yoga exercises consisted of cobra, fish, and child poses with 10 s of rest between each pose, 45–60-s holds for each one, and 3 repetitions. This was followed by pelvic rocking exercise after resting for 5 min, knee rolling, and cat-cow pose with a 3–5-s hold for each, as well as 15 repetitions and 3 sets. During the rest of the month, pelvic floor and aerobic exercises of moderate intensity were done three times a week. The aerobic exercise included running in place for 1 min, 10 s of rest, and 3 sets. Marching (with high knees), lunge twisting, and lateral shuffling were done with 15 repetitions, 3 sets, 10 s of rest between each set, and 30-60 s of rest between each exercise. Resting for 5 min was followed by pelvic floor exercise including bridge and natural supine posterior pelvic tilt done with 15 repetitions, holding for 3-5 s, and 3 sets.

Outcome measures and statistical analysis: The VAS and QoL were evaluated on the first day of the menstrual cycle, and PR was evaluated after one and two months of interventions. Data were collected from 59 female students from Umm Al-Qura University, who were randomly assigned into the groups. The study flow diagram shows all the study's steps (Figure 1). To assess participant's demographic data, a one-way ANOVA was used by in SPSS version 16 for Windows (RRID:SCR_019096). ANOVA was used to compare measurement intervals between treatment groups and to measure pre, post-1, and post-2 results in every group. The level of significance was fixed at 0.05.

RESULTS

A total of 307 participants were selected as potential participants for this study, but 248 were excluded (32 did not satisfy the inclusion criteria, 7 had incomplete data, 81 refused to participate, and there was no response from 28 participants). This left only 59 participants for the study, and they were divided into 4 groups (Figure 1). All 59 participants met the inclusion criteria with no significant differences among all groups in mean age, weight, height, or BMI (Table 1). Two patients withdrew from the HILT group, there were 4 total withdrawals from combined group, and there were no withdrawals in both the exercise-only and control groups. This resulted in a total of 53 participants. Participants who dropped out of the study after assigning them to their groups either from the beginning or at follow-up were marked as "participants wo did not complete the study."

Visual analogue scale. The results showed a statistically significant reduction in pain severity in all intervention groups between pre and post-2 ($p < 0.05$) (Table 2). No significant difference was found when comparing pre and post-1 for the same groups. Furthermore, no significant differences were found when comparing different treatment groups for the same intervals in VAS assessment (Table 3). In the control group, no

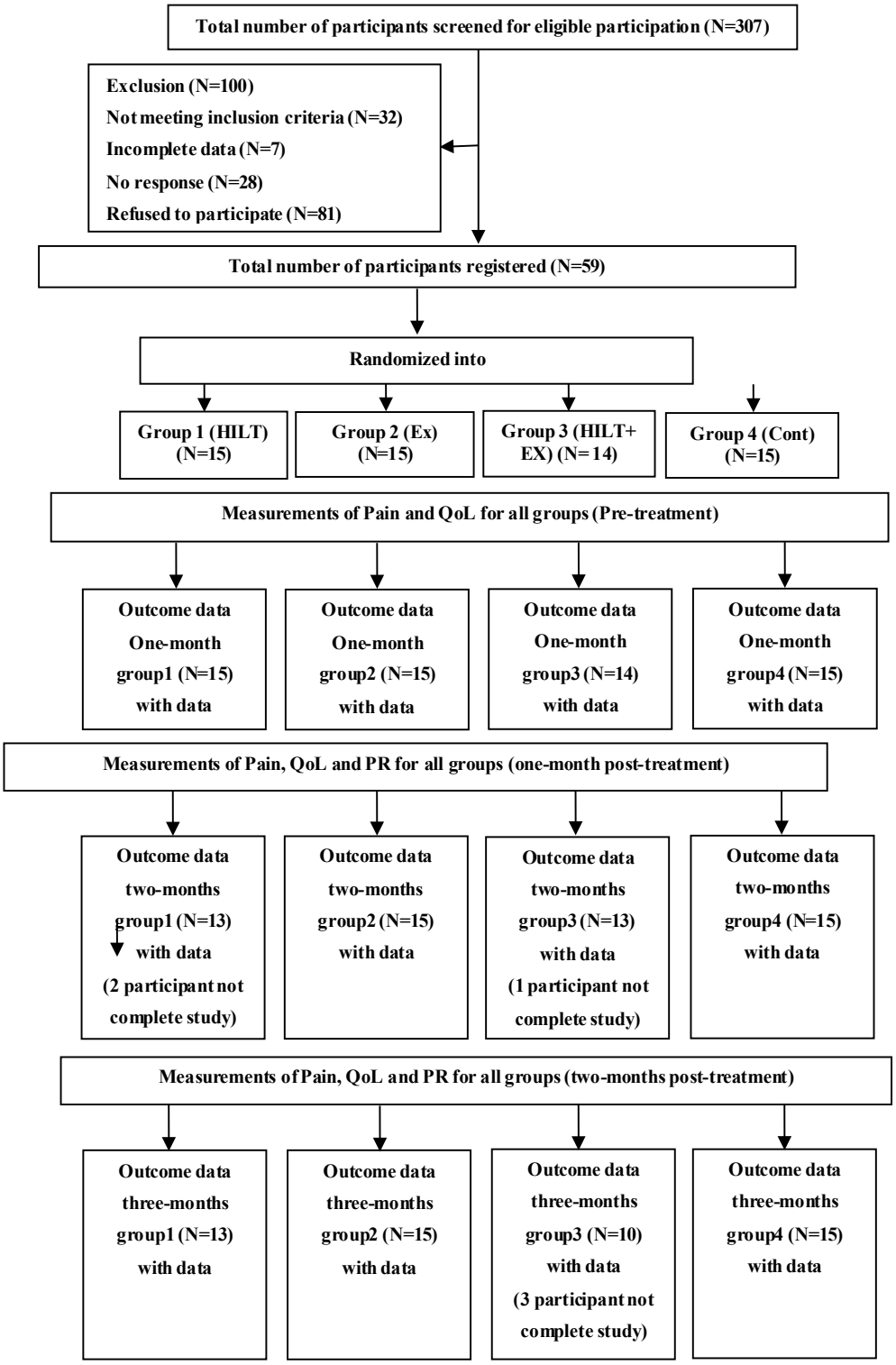

Fig. 1: The study flow diagram according to CONSORT checklist.

Table 1: Baseline values among all groups.

	Group 1 (HILT)	*Group 2 (Exercise)*	*Group 3 (Combined)*	*Group 3 (Control)*	*F value*	*P value*
Age (years)	21.47±1.06	20.93±1.03	21.57±1.02	20.88±1.21	1.576	0.2058**
Weight (kg)	51.53±9.49	52.90±6.29	54.57±8.38	53.07±8.53	0.3290	0.8044**
Height (cm)	157.07±6.61	158.43±3.99	158.82±4.32	158.71±8.42	0.2600	0.8538**
BMI (kg/cm2)	20.84±2.88	21.16±2.89	21.47±2.94	21.31±2.05	0.1417	0.9345**
Number of patients	15	15	14	14		

**Non-significant.
HILT, high intensity laser therapy: BMI, body-mass index

Table 2: Comparison between VAS assessment in each treatment group

	Visual Analog Scale		
	Pre vs Post1	*Pre vs Post2*	*Post1 vs Post2*
	P value		
HILT	0.2998**	0.0077*	0.4277**
Exercise	0.3586**	0.0076*	0.1128**
Combined	0.0669**	0.0051*	0.2922**
Control	0.8116**	0.7832**	0.9452**

*Significant difference.
**Non-significant differences.

Table 4: Comparison between QoL assessment in each treatment group

	Quality of Life		
	Pre vs Post1	*Pre vs Post2*	*Post1 vs Post2*
	P value		
HILT	0.0374*	0.2331**	0.4427**
Exercise	0.1794**	0.001*	0.1253**
Combined	0.0910**	0.0015*	0.2342**
Control	0.4051**	0.5664**	0.8688**

*Significant difference.
**Non-significant differences.

Table 6: Comparison between PR assessment in each treatment group

	Pain Relief
	Post1 vs Post2
	P value
HILT	0.3171**
Exercise	0.0200*
Combined	0.1290**
Control	0.5569**

*Significant difference.
**Non-significant differences.

statistically significant differences were found in all interval measurements ($p > 0.05$) .

Quality of life and pain relief. Regarding QoL, the exercise and combined groups showed a highly significant improvement in their QoL when comparing pre and post-2 ($p<0.005$), but there was no improvement in the pre and post-1 comparison. In contrast, the HILT group showed a marked and significant improvement between pre and post-1, but there was no significant difference between pre and post-2, as shown in Table 4. The control group showed insignificant differences in all interval measurements for QoL. However, when comparing different intervals between treatment groups, there was an insignificant difference in all groups except for HILT versus the combined groups, which showed a clearly significant difference in pre and post-1 assessment (Table 5).

Regarding pain relief, the comparison between post-1 and post-2 measurements showed a significant difference in only the exercise group,s as indicated in Table 6 . No significant difference was found in all other groups (Table 7).

Table 3: Comparison between VAS assessment in each treatment group

	Visual Analog Scale		
	Pre	*Post1*	*Post2*
	P value		
HILT vs Exercise	0.3513**	0.4466**	0.1160**
HILT vs Combined	0.4237**	0.7259**	0.5457**
Exercise vs Combined	0.1531**	0.6795**	0.3471**

*Significant difference.
**Non-significant differences.

Table 5: Comparison between QoL assessment in each treatment group

	Quality of Life		
	Pre	*Post1*	*Post2*
	P value		
HILT vs Exercise	0.2058**	0.3204**	0.2193**
HILT vs Combined	0.0138*	0.0272*	0.6672**
Exercise vs Combined	0.3236**	0.4795**	0.0654**

*Significant difference.
**Non-significant differences.

Table 7. Comparison betwen QoL assessment in each treatment group

	Pain Relief	
	Post1	*Post2*
	P value	
HILT vs Exercise	0.9355**	0.3383**
HILT vs Combined	0.8543**	0.7324**
Exercise vs Combined	0.8976**	0.5746**

*Significant difference.
**Non-significant differences.

DISCUSSION

Participants who underwent HILT treatment reported significant improvement in pain and QoL. This result agrees with those of Thabet[15-21] and Abdelbasset.[22] They said that the pulsed HILT effect on dysmenorrhea in relieving pain is accompanied by a rise in the pain threshold and a decrease of the A-δ and C fiber transmission, in addition to lowering prostaglandin levels in the blood. As a result of this effect, the QoL of participants slightly improved.

According to the findings, the exercise protocol effectively decreased the pain in participants with dysmenorrhea, which agreed with results from Carroquino-Garcia.[23] They suggested that the use of exercise for dysmenorrhea was effective in reducing pain. The result of this group also agrees with that of Dehnavi,[14] who reported that pain in dysmenorrhea can be reduced by aerobic exercise. The pain reduction occurred as a result of renin levels decreasing and estrogen and progesterone levels increasing, resulting in the serum aldosterone level decreasing and leading to reduced symptoms. Moreover, exercising during menstruation boosts levels of endorphins, resulting in a calming effect on the mind and body. It also plays an important role in improving blood circulation and promoting the transfer of waste products and prostaglandins out of the uterus.

Nag[20] stated that pain and stress from dysmenorrhea were reduced with yoga exercises, showing the value of yoga in primary dysmenorrhea. Yoga should be practiced by university female students to improve their health and wellbeing as it decreases the level of psychosocial stress. After the intervention sessions, the results showed that the most improvement in reducing menstrual pain was in the group that received HILT with exercise, which proves the hypothesis of the study. The control group showed no improvement in pain and QoL.

Study strength and limitations. Previous research assessed the effect of exercise or HILT alone in management of dysmenorrhea, but there is a lack of research that evaluates a combined exercise program and HILT's effects on dysmenorrhea. Our study helps to evaluate these combined methods. The study's limitations include that the time of assessment was only two months, which could have limited the HILT exercise program's efficacy on the level of pain and QoL.

In conclusion, the study findings show that the combination of HILT and the exercise protocol (aerobic, yoga, pelvic floor, and pelvic rocking) was effective for decreasing pain and improving QoL after two months of intervention in participants with dysmenorrhea.

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***Availability of data and materials*:** The data sets generated and analyzed during the current study are available on request due to privacy/ethical restrictions.

Declaration of interest statement: The authors declare that they have no competing interests.

Compliance with ethical standards

All procedures performed in study were in accordance with the ethical standards of the institutional and/or national research committee

Ethical approval: This study protocol reviewed and received approval from the "Biomedical Ethics Committee at Umm Al Qura University, Makkah, Saudi Arabia with approval number (HAPO-02-K- 012-2022-02-941).

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