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ORIGINAL ARTICLE

Analysis of modified ilib therapy in patients submitted to plastic surgery

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Abstract
The sample comprised 44 volunteers who had undergone some surgical procedure and were equally divided into four groups. G1 started the therapy 24 h after the surgical procedure with the device off. G2 followed the same time pattern, 24 h, but with the device turned on. G3 and G4 started therapy three days after the surgical procedure; in G3, the device was turned off, and in G4, the device remained on during therapy; each session lasted 30 min, using 660 nm (red), energy 180 J. For all groups, the therapy started with daily use for seven days and followed the interval use of three times a week until completed 21 days. The revaluation was performed after 7 and 21 days. The results found show changes in HR at rest, systolic and diastolic BP, and in peripheral oxygen saturation, which showed a significant difference in the groups that used on-therapy ($p < 0.05$). In the MCGILL Scale evaluation, the mean total score showed a more accentuated drop in the groups that used ILIB, ($p < 0.05$). ILIB may have prevented a more significant evolution of firosis levels; however, no changes were observed in the evaluation of sleep and anxiety. The application of the ILIB in patients undergoing plastic surgery was supported in terms of hemodynamics and pain; in addition, starting the ILIB application 24 h after the procedure proved to be more advantageous.

Keywords ILIB · Postoperative · Laser · Questionnaires

Introduction

The surgical act constitutes tissue aggression that can lead to the appearance of some complications. When it comes to aesthetic plastic surgery, there is a great expectation in the patient, and it is often seen states of anxiety, stress and changes in synchronization of the waking/sleep cycle, which can be potentiated in the immediate post-surgical period by the presence of oedema, haematomas and scars, leading to a worse and slower recovery, besides interfering in the immune response. For good results, it is necessary to have planning, intervention, and care before and after the procedures. Timely intervention in the trans- and postoperative period can reduce rest time, restore function ability, and accelerate recovery [1–3].

Intravascular Laser Irradiation of Blood (ILIB) emerges as a therapeutic option to act simultaneously with other treatments, accelerating the process of the patient's return to normal activities. Low-level systemic lasers aim to irradiate blood through an optical fibre inserted into a vascular channel. ILIB irradiation lasts about 30 min so that it is enough time for all the blood to receive light, enabling a systemic effect. Thus, blood components such as lipids, platelets, the immune system, and red blood cells are the main targets [4].

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Some benefits demonstrated are systemic healing mechanisms, analgesia, anti-inflammatory effect, antitoxic, vasodilator, antiallergic, immunocorrective, and increase in ATP synthesis and energy formation in cells. According to RANGEL et al. [5], the energy applied by ILIB generates activation of the neurohumoral regulation and synchronization and cell modulation with antioxidant, metabolic, immunological, antispasmodic, sedative, healing, analgesic, anti-inflammatory, and increased blood circulation effects. It has a significant effect by stimulating the limbic system and the hypothalamus, as well as a hormonal effect regulating sleep, mood, and normalizing endorphins and serotonin, generating well-being and improving quality of life.

Non-invasive irradiation (introduced by Brazilian research a few years ago) has been supported by the industry, which has developed a unique device for this modified ILIB technique (MILIB). Irradiation can be performed with an intranasal laser or skin irradiation on the wrist, guided by a bracelet placed at the level of the radial artery. This modification in the irradiation technique allows for more frequent use and broadens its applicability in-home treatment. All these new ILIB techniques need to be further studied and researched. Further investigations on irradiation time, amount of light, and rate of light absorption by irradiated blood vessels should be done [4, 6–8].

Despite the known effects among patients and therapists, the use of ILIB has not yet been quantified in postoperative plastic surgery settings regarding the quality of sleep, pain improvement, presence of fibrosis, anxiety, stress and fatigue at rest, in addition to blood pressure (BP), heart rate (HR) and saturation (SpO2). Thus, the purpose of the present study was to analyse the effects of modified ILIB therapy in patients undergoing plastic surgery.

Methodology

Characterization of the sample

An experimental study was conducted to analyse the effects of modified ILIB therapy in patients undergoing plastic surgery, with approval by the Ethics Committee (code: 5.786.532) and conducted according to the recommendations of the Consolidated Standards of Reporting Trials – CONSORT (CONSORT TRANSPARENT REPORTING OF TRIALS, 2010). Signatures were collected from all volunteers participating in the study using the informed consent form (ICF), and the treatment was conducted in 2021 in Natal, Rio Grande do Norte, Brazil.

We evaluated 44 volunteers, aged between 30 and 50 years old, who had undergone cosmetic surgery and presented common postoperative conditions (pain, ecchymosis, oedema), chosen in a non-probabilistic manner in the city of Natal/RN. Participants who presented altered sensitivity, and contraindications for the use of the device, such as blood tumours and pregnant women, were excluded.

The sample was divided equally into four groups, as shown in the following diagram (Fig. 1):

Data collection and treatment instrument

After the selection, the volunteers were informed about the procedures and signed the free and informed consent form. Then they were evaluated according to the research criteria and answered the following validated questionnaires: sleep assessment in this period by the EPWORTH sleepiness scale; pain by the pain intensity scales and the McGILL PAIN Questionnaire [9]; fibrosis by the questionnaire adapted from PANFIC [10]; and anxiety and

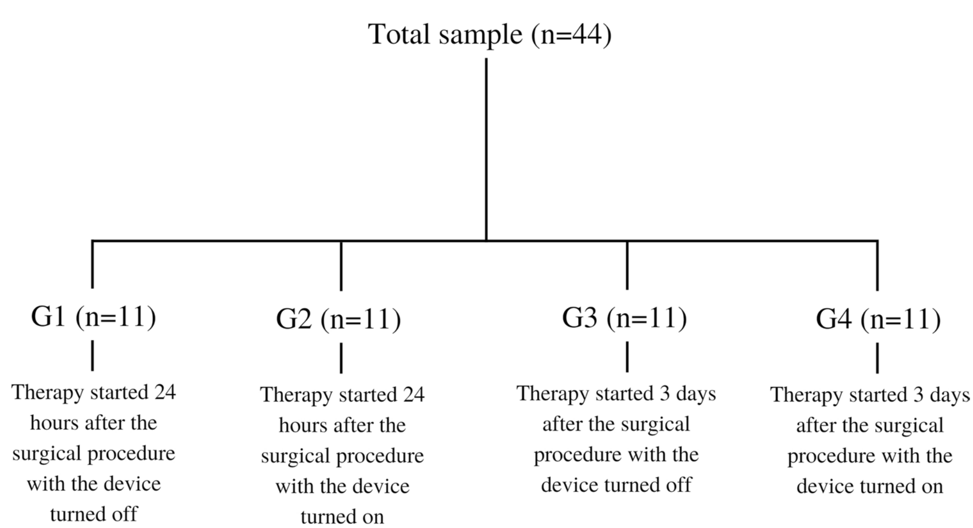


Fig. 1 Diagram of the division of the study groups

well-being by the generalized anxiety disorder questionnaire for DSM-IV [11]. The hemodynamic changes of the volunteers were also evaluated, including resting heart rate (HR), blood pressure (BP) and peripheral oxygen saturation (SpO2).

The treatment was performed using the ILIB equipment of the brand ECCO Fibres™. For all groups (respecting the start time of the application, 24 h or three days), the application of therapy was performed starting with daily use for seven days and following the interval use three times a week until completing 21 days. The application time was 30 min, using 660 nm (red), energy 180 J. For the application, the volunteers lay on a stretcher, and the ILIB bracelet was positioned on the wrist region, allowing the laser light to focus on the radial artery, and then the equipment was attached, and therapy started. The revaluation was performed after 7 and 21 days.

Data analysis

Statistical analysis was performed using the software Statistical Package for the Social Sciences (SPSS) version 24.0 for Windows. First, the Kolmogorov–Smirnov (K-S) test was performed to verify the normality of the data. In the inferential statistics, we used the ANOVA Two-way analysis of variance test with repeated measures to verify differences between the groups before and after the interventions. A 5% significance level and 95% confidence interval (95% CI) were assigned in all statistical analyses.

Results

Based on the physical therapy sheet analysis, the mean values of weight and BMI did not show significant values in the intra- and intergroup comparisons at all times assessed ($p > 0.05$). The averages obtained through the hemodynamic evaluation are in Table 1 and showed that for G1, the averages of all variables showed an upward trend, while G2 showed a reduction in the average HR at rest, and the other variables showed an upward trend. In G3, the HR at rest and SBP means were variable, and there was a reduction in DBP, and saturation means. Finally, in G4, only the mean saturation showed an increase; the other variables presented variable values.

In the statistical evaluation, the intra-group analysis of hemodynamic changes presented in Table 2, it was observed that the resting HR showed a significant difference in the groups that used the on-therapy. In G2, there was a difference when comparing 24 h with 21 days ($p = 0.02$). In the G4 group, a significant difference was observed in two moments, 24 h with 21 days ($p = 0.05$) and seven days versus 21 days ($p = 0.03$). For the blood pressure variable, it was seen that in systolic BP, only G2 showed a significant difference when comparing 24 h with seven days ($p = 0.03$) and 24 h with 21 days ($p = 0.03$). As for diastolic BP, G4 showed a significant difference when comparing seven days with 21 days ($p = 0.008$). The other groups did not show significant differences. The peripheral oxygen saturation showed a significant difference only for G2 compared to 24 h with 21 days ($p = 0.04$).

Table 1 Anthropometric and hemodynamic data of the volunteers

		G1 Mean ± SD	G2 Mean ± SD	G3 Mean ± SD	G4 Mean ± SD
Age		36.5 ± 2.8	39.5 ± 5.9	42.4 ± 6.6	36.7 ± 5.6
Height		1.55 ± 0.02	1.63 ± 0.08	1.65 ± 0.05	1.64 ± 0.07
Rest HR	Home	88.8 ± 4.8	90.8 ± 14.8	87.4 ± 1.5	76.8 ± 9.5
	Average	8.6 ± 5.0	87.8 ± 8.1	77.0 ± 8.0	77.0 ± 8.0
	Final	89.6 ± 5.8	82.6 ± 12.0	86.4 ± 2.9	71.4 ± 8.6
Systolic BP	Home	109.3 ± 15.8	108.1 ± 17.7	112.8 ± 4.8	117.6 ± 12.0
	Average	111.5 ± 5.4	118.1 ± 9.8	107.7 ± 12.7	119.0 ± 5.5
	Final	115.0 ± 5.4	118.1 ± 4.0	110.0 ± 10.0	116.0 ± 5.9
Diastolic BP	Home	77.1 ± 11.1	74.5 ± 10.3	71.4 ± 8.9	72.5 ± 8.5
	Average	76.6 ± 5.1	80.9 ± 8.3	68.5 ± 10.6	77.0 ± 8.0
	Final	76.6 ± 5.1	82.7 ± 6.4	68.5 ± 8.9	71.0 ± 9.6
Saturation	Home	96.5 ± 2.3	95.8 ± 3.0	96.6 ± 5.3	96.6 ± 5.3
	Average	97.5 ± 1.2	97.0 ± 2.8	96.1 ± 2.2	96.9 ± 5.7
	Final	98.2 ± 0.6	98.2 ± 0.6	95 ± 2.1	97.9 ± 1.7

SD: Standard deviation; Rest *HR*: Resting Heart Rate; Systolic *BP*: Systolic Blood Pressure; Diastolic *BP*: Diastolic Blood Pressure

Table 2 Intra-group analysis of hemodynamic changes

		G1 *P* value	G2 *P* value	G3 *P* value	G4 *P* value
Rest HR	AV 1 × AV 2	0,60	0,55	0,99	1,0
	AV 1 × AV 3	0,69	**0,02***	0,99	**0,05***
	AV 2 × AV 3	1,0	0,22	0,99	**0,03***
Systolic BP	AV 1 × AV 2	0,96	**0,03***	0,63	0,95
	AV 1 × AV 3	0,61	**0,03***	0,90	0,91
	AV 2 × AV 3	0,78	1,0	0,91	0,48
Diastolic BP	AV 1 × AV 2	0,99	0,12	0,84	0,15
	AV 1 × AV 3	0,88	0,06	0,88	0,91
	AV 2 × AV 3	0,64	0,85	1,0	**0,008***
Saturation	AV 1 × AV 2	0,50	0,19	0,40	0,93
	AV 1 × AV 3	0,27	**0,04***	1,0	0,24
	AV 2 × AV 3	0,83	0,56	0,78	0,51

* significant *P* value; Rest *HR*: Resting Heart Rate; Systolic *BP*: Systolic Blood Pressure; Diastolic *BP*: Diastolic Blood Pressure

For heart rate at rest, significant differences were present in the three times analysed ($p < 0.05$), with G4 showing lower means in this parameter. For SBP, there was a significant difference only at the time "7 days" when comparing G3 versus G4, with higher means for G4 ($p = 0.02$). For DBP, there was a significant difference at "7 days" for groups G2 versus G3 ($p = 0.02$) and "21 days" for groups G2 versus G3 ($p = 0.006$) and G2 versus G4 ($p = 0.003$). For this parameter, the elevation of the averages occurred in G2. For saturation, there was a significant difference only at "21 days" when comparing G2 versus G3 ($p = 0.001$) and G3 versus G4 ($p = 0.001$).

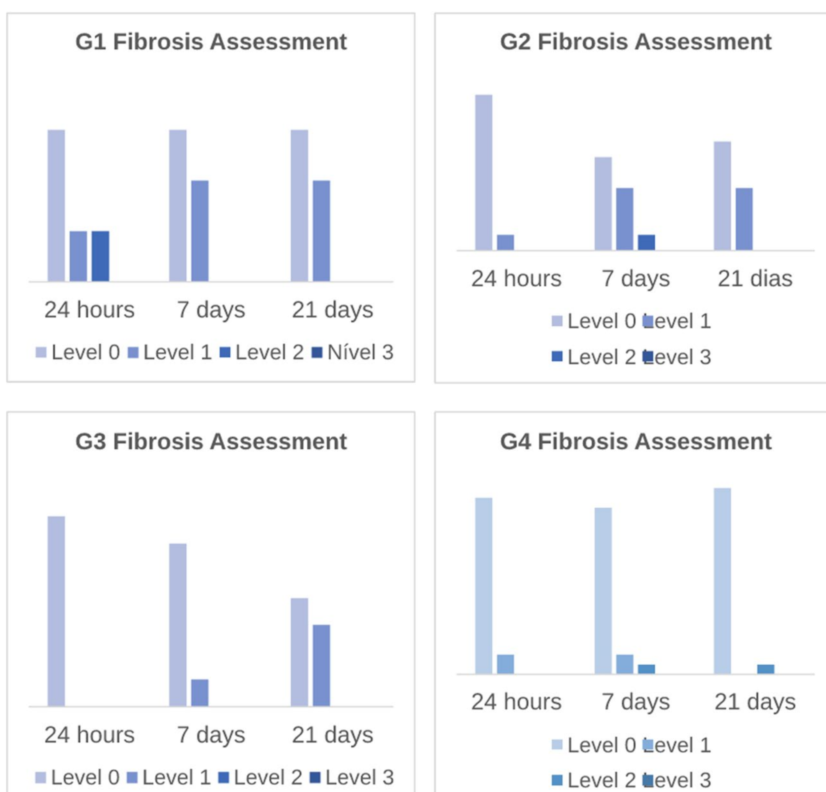
In the evaluation of pain (Fig. 2), the groups were quite heterogeneous; however, in the two scales applied, there was a reduction in the mean value and in the categories evaluated in all groups, even in those that did not use the ILIB; furthermore, no statistically significant differences were observed in the comparison between the groups ($p > 0.05$).

However, in the evaluation of the MCGILL Scale, the mean total score fell more sharply in the groups that used ILIB, with a p-value < 0.05 when comparing the initial versus final time in groups G2 and G4. Moreover, in the intra-group analysis, significant differences were found in the times "7 days" and "21 days" ($p < 0.05$), being favourable to the groups that used the ligated therapy.

In the sleep evaluation, most of the volunteers in this study had no change in sleep, and even the G3 group (most of whom had altered sleep) managed to evolve to normal sleep without using ILIB. These results may be related to the low sensitivity of the scale for this population or to the type of surgical procedure, which did not cause significant changes in sleep.

Over time, the increase in fibrosis levels follows in consonance with the postoperative time. ILIB may have prevented

Fig. 2 Fibrosis analysis



further evolution of levels, as seen in the comparison of G3 with G4 at 21 days (Fig. 3). There was an improvement in anxiety in all groups, considering the action of the placebo effect in health care.

Discussion

The trauma caused by plastic surgery disrupts the transport function of vessels, which can compromise the supply of oxygen, cells, hormones, and nutrients to their targets. Besides interrupting the drainage function of the blood and lymphatic vessels, it leads to inefficient drainage of impurities, residues and toxins in the organs and tissues, and consequently, a dysfunction occurs [12, 13]. This article aimed to clarify the use of ILIB, a non-invasive technique, to reverse or minimize the effects previously described caused by plastic surgery procedures.

Previous studies have indicated that intravascular and modified ILIB present analgesic, spasmolytic, and sedative effects besides stimulating blood circulation, making its effects generalized in almost all systems. It is believed that the technique promotes modulation of redox signalling in the respiratory chain, leading to stimulation of mitochondrial components, being able to cause positive effects on the expression of immunoglobulins, interferons and interleukins [14, 15]. The results found in this study show changes in several hemodynamic components altered by surgery. In addition, it was seen that the early start (after 24 h) showed more positive effects when compared to the group that started therapy after three days.

The use of intravascular ILIB to improve blood oxygen delivery can be justified due to the change in haemoglobin affinity for oxygen caused by the technique. An increase in O2 concentrations and a decrease in the CO2 particle rate have been observed, proving the elimination of tissue hypoxia with concomitant improvement in tissue oxygenation [12]. In this study, the group that used the ligand therapy 24 h after the surgical procedure showed significant differences in comparing the initial and final moment concerning peripheral oxygen saturation. Significant values were also observed in the comparison (at 21 days) between the groups under on-therapy versus the ones on off-therapy.

A study conducted with 18 volunteers diagnosed with ALS evaluated the treatment with intravascular ILIB, performed four times a week for two weeks. The effects were assessed using capnography and oximetry and demonstrated that peripheral oxygen saturation (SpO2) and pulse rate increased significantly during ILIB application. The authors believe the technique can stimulate the sympathetic nervous system and modulate hyperkinetic haemodynamics. However, further studies are needed to clarify these results [16].

In the analysis of the resting heart rate variable, the groups that used the ligated therapy presented a lower mean

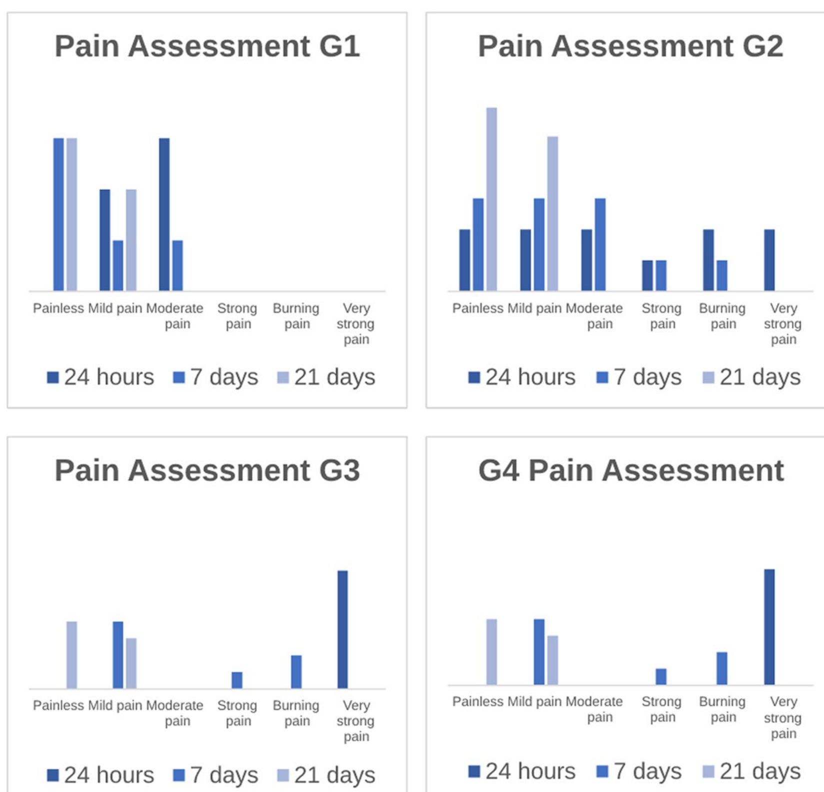


Fig. 3 Pain analysis

value in their final evaluation; however, the group that started the treatment at 24 h obtained a more constant reduction, showing the results already in the first revaluation. The reduction in these values may indicate a cardioprotective factor for these patients who used the modified ILIB [17]. A case study demonstrated the difference in heart performance during stress tests before and after blood irradiation with intravenous laser (conventional ILIB). After performing the exercise program, an increase in blood oxygenation (SpO2 96% to 99%) and a 17.4% improvement in mean heart rate recovery (86.25 s to 71.25 s) were observed [18].

The pilot study by Lizarelli et al. (2021) [15] observed the effects of transcutaneous and transmucosal laser irradiation on blood pressure (BP) in 36 volunteers. The results demonstrated that, regardless of the irradiation route (transcutaneous or transmucosal), therapy with wavelengths within the visible spectrum can facilitate patient homeostasis and be safely used as an adjunctive method to regulate blood pressure (systolic and diastolic). In another study performed with the application of sublingual laser in hypertensive pregnant women, it was seen that systemic vascular resistance and, consequently, systolic, diastolic and mean arterial pressure suffered a statistically significant decrease after photobiomodulation [19]. In this study, it was not possible to observe a homogeneous pattern in the evaluations performed for both systolic and diastolic blood pressure values. However, the groups that used the therapy presented significant values in the individual and intergroup analyses compared to those that used the device.

The assessment of pain may have suffered interference from some factors, including the use of analgesics recommended in the postoperative period. Thus, our values behaved heterogeneously. However, in the evaluation of the MCGILL Scale, the mean of the total score showed a more accentuated drop in the groups that used ILIB, presenting significant values in the analyses performed. Several studies indicate that laser therapy can effectively relieve pain in nervous system diseases due to the absorption of photons by chromophores, especially haemoglobin and melanin, which have high absorption bands during shorter waves [20].

Leal et al. (2020) [21] evaluated the effects of modified ILIB to relieve pain and improve the quality of life in patients with diabetic neuropathy in 30 volunteers. The treated group received 30 applications of the ILIB, divided into three stages of 10 applications, 30 min each, daily, with a 20-day interval between each step. In the end, it was seen that the treated group had significantly lower levels of pain and better quality of life compared to the control group, which received conventional treatment, and to the group that received the ILIB turned off.

Although there are few studies, the ILIB technique positively affects sleep quality. For Wu et al. (2018) [22], patients who were treated with conventional ILIB had marked improvements in quality of life, sleep, and mood disturbances. The authors believe these changes may have been influenced by soluble mediators such as endorphins and serotonin. In another case study, Chang and Chang (2022) [23], using the Pittsburgh Sleep Quality Index before and after intravascular ILIB, observed a marked improvement in sleep duration, efficiency, and overall sleep quality through increased scores on the scale. In our study, many volunteers had no change in sleep, so the effects of the modified ILIB could not be observed. There was also an improvement in anxiety in all groups.

ILIB in the postoperative aesthetic volunteers may have prevented further evolution of fibrosis levels. Previous studies have indicated that ILIB can promote the modulation of inflammation and reduce the levels of pro-inflammatory cytokines, such as pro-inflammatory interleukin one and interleukin 6 and increase the levels of anti-inflammatory interleukin 10 [24]. In the study by Silva et al. (2022) [25], despite using animals, modified ILIB promoted a statistically significant reduction in inflammatory parameters and showed better results regarding the tissue healing process.

Conclusion

The presented results confirmed the beneficial effects of ILIB and support its application in patients who underwent plastic surgery regarding haemodynamics (resting HR, blood pressure and peripheral O2 saturation) and pain; furthermore, some results suggested starting the application of ILIB 24 h after the procedure was more advantageous. New studies need to be conducted with more sensitive instruments for this population to elucidate the effects of ILIB on sleep and anxiety, as well as other quantitative methods for fibrosis.

Authors contribution R.R.M. and R.M.V.S. analyzed the data and wrote the article. E.M.C., S.L.Q.F., C.E.L.M., D.M.P.S., L.P.S., V.S.R. and D.S.S.B. performed the experiments. F.P. and P.F.M. designed the study, revised the article, and supervised the study.

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Declarations

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