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ORIGINAL ARTICLE

Comparison of the effect of whole-body vibration therapy versus conventional therapy on functional balance of patients with Parkinson's disease: adding a mixed group

Eduardo Guadarrama-Molina[1] · Carlos Enrique Barrón-Gámez[1] · Ingrid Estrada-Bellmann[2] · Jesús D. Meléndez-Flores[2,3] · Paola Ramírez-Castañeda[1] · Rosa María Gisela Hernández-Suárez[1] · Minerva Menchaca-Pérez[1] · Oscar Salas-Fraire[1]

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Abstract

Objective Assess the effect of Whole-Body Vibration (WBV) therapy in functional balance status of Parkinson's disease (PD) patients and compare this to conventional and combined therapy.

Introduction PD patients experience a decreased mobility, inactivity, and loss of independence as consequence of disturbances in gait, posture, and balance. Rehabilitation therapy is a non-pharmacological way of improving functionality. One of the most studied modalities is WBV, with multiple studies showing improvement in motor function. However, results in this manner are inconsistent.

Methods Forty-five patients were enrolled in a non-randomized controlled trial and divided into three groups. Group 1 received conventional therapy (thermotherapy, stretching, strengthening, coordination and balance). Group 2 received WBV therapy, and group 3 patients underwent a combined therapy protocol. A total of 20 sessions (3 per week) were conducted, assessing Berg Balance Scale (BBS) before initial and after final session.

Results The 3 intervention groups showed significant improvement in BBS scores after concluding the 20-session trial compared to initial assessment. When comparing mean change in BBS score from initial to final assessment, the combined therapy group had a greater increase compared to conventional therapy, but no significant differences were observed comparing to WBV group. Mean change in BBS score showed no significant difference between conventional therapy and WBV therapy group.

Conclusions WBV therapy is a useful tool as co-adjuvant in conventional therapy. The combination of both therapies is a significant therapeutic alternative for the improvement of functional balance status in PD patients compared to conventional therapy alone.

Keywords Whole body vibration · Parkinson disease · Postural instability · Balance

Introduction

A range of 40–70% of patients with Parkinson's disease (PD) suffer multiple falls that may predispose to injury and dependency, arising from postural instability [1–3]. Factors such as parkinsonian symptoms, postural deformities, loss of postural reflexes, sensorial changes related to age and the ability of integrating proprioceptive, vestibular, and visual stimuli may contribute to this instability [4, 5]. Moreover, among other causes of falls in this population are gait abnormalities [6]. One common is freezing of gait, characterized by an episodic incapacity of generating effective forward progression [7]. This affects patients' mobility

✉ Ingrid Estrada-Bellmann
ingridestmann@hotmail.com

1 Sports Medicine and Rehabilitation Department, University Hospital "Dr. José E. González", Universidad Autónoma de Nuevo León, Monterrey, México

2 Neurology Division, Internal Medicine Department, University Hospital "Dr. José E. González", Universidad Autónoma de Nuevo León, Madero y Gonzalitos S/N, Monterrey, Nuevo León 64700, México

3 Faculty of Medicine, Universidad Autónoma de Nuevo León, Monterrey, México

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greatly, reducing quality of life [8–10]. The appearance of this gait disturbance varies by disease severity, being present in more than 80% of the patients in advanced stages [11, 12]. A study investigated predictors for gait disturbance and reduced mobility and found poor postural balance to be the major predictor [13], eliciting how interrelated these are. Moreover, interventions addressing balance proved beneficial to gait enhancement in mildly to moderately affected patients [14].

Rehabilitation therapy's role in Parkinson's disease involves improving joint range of motion, chest expansion, postural stability, posture, and re-educating gait [15, 16]. One particular type is whole body vibration (WBV), which consists of vibrations emerging from a platform that stimulate proprioceptive receptors and produce involuntary muscle contractions [17]. These types of vibrations provide beneficial effects for the organism, with moderate frequencies, small amplitudes, and short exposures [17, 18].

WBV programs have been implemented in PD patients in various studies with varying results. A study assessing balance after application of WBV showed an improvement in Berg Balance Scale (BBS), which assesses functional balance status [19]. However, main limitation of this study was the small sample size, as it only included three patients. A doubled blind, placebo control study assessed WBV in PD patients and found no difference in any outcomes compared to placebo, stating a possible placebo mechanism for WBV benefits [20]. Another study found a significant improvement in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) motor score in patients treated with WBV [21]. Nonetheless, results of WBV effect in PD are inconsistent [22].

We conducted a non-randomized clinical trial assessing the effect of WBV alone compared to conventional therapy and to a combined protocol of conventional therapy + WBV on functional balance status in PD patients via evaluation of BBS.

Materials and methods

Patients

We recruited patients from the neurology outpatient clinic of the University Hospital Dr. José Eleuterio González with prior PD diagnosis, without age or sex restrictions, that manifest gait, balance, or postural disorders as consequence of the disease. Inclusion criteria for eligibility were prior PD diagnosis made by a neurologist with competence in movement disorders according to the UK PD Brain Bank Criteria, having anti-parkinsonian treatment, Hoehn and Yahr (HY) grade I–III, clinically assessed gait and postural disturbances that allowed patients to stand on the vibration plate. Exclusion criteria included (1) patients without PD and without any anti-parkinsonian treatment, (2) patients with HY grade ≥ IV, (3) patients having deep brain stimulation therapy, (4) having any contraindication for vibratory platform use, (5) having maximum score in BBS at initial evaluation, (6) having aggregated diseases such as chronic heart failure, pacemaker use, valvular heart disease, thrombosis, aneurisms, spondylolysis, and recent surgical operations, and (7) any disorder in lower extremities that impede patients stand at the vibration plate (fractures, ulcers, acute injuries, etc.). Elimination criteria included patient discontinuing protocol sessions, intolerance to intervention, and experiencing side effects of the latter, such as first-grade burns, falls or pain in any corporal region.

Study design

Participants were enrolled in a 20-session non-randomized clinical trial that compared 3 interventions: conventional rehabilitation therapy (control), WBV therapy, and combined therapy protocol. For sample size calculation, we conducted a pilot test with five patients using BBS as primary outcome, and then performed a formula for means equivalence, with a $z\alpha$ of 1.96 and a two-tailed significance level of 95%, a $z\beta$ of 0.84 with power of 80% and BBS scores as primary outcome, obtaining a sample size of 14 participants per group (3), with a suggested total of 42 participants. One day prior to the first session, BBS was applied to patients at the Sports Medicine and Rehabilitation department of the University Hospital. Patients then underwent 3 sessions per week until completing 20 sessions. BBS was then applied again after concluding all 20 sessions.

Primary outcome

Balance functional status was evaluated using BBS, as this is typically used as quantitative measure of this status in the elderly. This scale has been used in studies evaluating balance in the PD population [23–25]. This consists of 14 items that contain multiple functional activities which involve dynamic and static balance. Item-level scores range from 0–4, with a total maximum of 56 (excellent balance) and minimum of 0 (balance severely affected). Primary outcome involved pre- and post-intervention BBS scores, and change in score for each intervention group.

Procedures and intervention

First selection filter was conducted at the neurology outpatient clinic, where potential participants were screened to determine eligibility. Those potentially eligible, were referred to the Sports Medicine and Rehabilitation department, where a semi-structured interview was used to obtain

information on disease history and other sociodemographic data. Time with diagnosis was defined as the years from diagnosis to the time of this semi structured interview, whereas time since symptom onset was defined as the years elapsed from first symptomatology to the time of this evaluation. In clinical evaluation, gait, balance, and postural disturbances were corroborated by the specialist in sports medicine. Once fulfilling eligible criteria, participants signed an institutional approved consent form. Later, patients were non-randomly assigned to one of the three experimental groups previously named.

Conventional therapy (control) consisted of a set of activities that belong to a basic rehabilitation therapy program to correct deficits of a PD patient with gait, balance, and posture disturbances. This involved application of infrared on the posterior compartment of lower limbs (including glutes, hamstrings, and triceps surae) for 15 min. The patient laid in prone position on a physical therapy table, and a sheet covered the infrared exposing area as protection. Subsequently, a facilitated stretching technique for lower limbs was applied, consisting of ten cycles of 5 s (s) of contraction, and 5 s of stretching for quadriceps, hamstrings and triceps surae. Next, on the gym area, gait re-education was performed, where the therapist taught the correct gait technique, and then the patient performed it on parallel bars in front of a mirror for a time of 10 min. Balance exercises were performed for 15 min under therapist monitoring with Bobath-type ball and exercises with help of a Swedish ladder. Lastly, coordination exercises for upper limbs fine and gross motor were performed on the coordination table for 10 min. This therapy had been previously instructed to all therapists of the Sports Medicine and Rehabilitation department.

WBV therapy consisted of a rehabilitation therapy protocol designed specifically for this purpose, with the aim of working lower limbs and, in a lower extent, upper limbs with tolerable and beneficial frequencies. The Fitvibe Excel Pro Vibration Trainer was used for this therapy. The patient was placed on the vibration plate and the therapist monitored the entire procedure. The protocol used was: eight postures at a frequency of 20 Hz, with a duration of 20 s, at a low level (amplitude of 2 mm) and rest between postures of 30–60 s. The postures that PD patients underwent were easy and uncomplicated to execute, and involved gluteus muscles, hamstrings, quadriceps, and triceps sural, which are important for stability and posture.

The combined therapy protocol group consisted of applying the conventional rehabilitation therapy, and later performing the WBV therapy protocol. No blinding was conducted during the interventions nor BBS assessments.

This study was approved by the ethics committee of our institution and all patients signed informed consent for inclusion in this study, all in compliance with the Declaration of Helsinki.

Statistical analysis

All statistical analyses were assessed using the SPSS computer program (SPSS version 20.0, IBM, Armonk, NY, USA). Data were tested for normality using the Shapiro–Wilk test, and continuous variables were thus expressed as mean ± standard deviation (SD) or as median (Interquartile range, IQR), and categorical variables as percentages. Quantitative data were analyzed by one-way ANOVA test or Mann–Whitney *U* test and Kruskall–Wallis where appropriate. Bonferroni correction was performed with an alpha value of 0.05 for multiple comparisons. Categorical variables were analyzed using Pearson's Chi-Square test. A value of $p < 0.05$ was considered statistically significant. Graphics were created using Microsoft Office Word program.

Results

Participant characteristics

A total of 63 participants were screened for the study. Of these, 11 patients were eliminated by exclusion criteria. From these, one (9%) patient had deep brain stimulation therapy, one (9%) was unable to sustain therapy, and nine (82%) had maximum BBS score at initial evaluation. Seven patients were eliminated by elimination criteria, as they discontinued the protocol after the first session was conducted, stating lack of time and disinterest. From these, two patients belonged to conventional therapy group, four patients to WBV therapy group, and one patient to the combined therapy group. In the end, 45 patients were assigned to the conventional therapy group ($n = 15$), the WBV therapy group ($n = 15$), or the mixed protocol group ($n = 15$), concluding the 20-session protocol.

The mean age of the included population was 63.5 ± 9.9 years, with 40% ($n = 18$) of the patients being female and 60% male ($n = 27$). Considering HY scale, most of the participants belonged to stage 2 (78%). In relation to clinical type, 80% of the population had a motor subtype rigid/akinetic, and the rest had a motor subtype tremor. Median time with diagnosis was 2 (3) years, whereas median time since symptom onset was 5 (4) years. The mean score on the BBS was 46.84 ± 4.03. Conventional therapy group had a mean of 48.00 ± 2.9, WBV therapy group of 47.27 ± 4.1 and combined therapy group of 45.27 ± 4.5. No significant differences were observed in sociodemographic data and BBS scores between groups (Table 1).

Pre- and post- intervention BBS scores

Comparing initial versus final BBS scores for each intervention group, greater scores were obtained after the 20 sessions for each therapy, showing significant differences (Table 2).

Table 1 Baseline characteristics of patients in each intervention group

Variable	Conventional therapy group ($n=15$)	WBV therapy group ($n=15$)	Combined therapy group ($n=15$)	*P*
Age, mean ± SD	61.1 ± 11.3	67.2 ± 8.7	62.2 ± 9.2	0.209
Sex, male (%)	10 (66)	10 (66)	7 (46.7)	0.435
Time with diagnosis, years (IQR)	2.0 (2.5)	2.0 (5.7)	2.0 (2.0)	0.993
Time since symptom onset, years (IQR)	4.0 (5.0)	6.0 (5.0)	5.0 (3.0)	0.787
Motor subtype of onset (%)				
Rigid/Akinetic	11 (73)	13 (87)	12 (80)	0.287
Tremor	4 (27)	2 (13)	3 (20)	
Hoehn and Yahr (%)				0.126
1	2 (13)	2 (13)	3 (20)	
2	13 (87)	13 (87)	9 (60)	
3	0 (0)	0 (0)	3 (20)	
Berg Balance Scale (BBS), mean ± SD	48.0 ± 2.9	47.3 ± 4.1	45.3 ± 4.5	0.159

SD Standard deviation, *IQR* Interquartile Range, *WBV* Whole body vibration

Table 2 Pre- and post-interventional BBS scores per group

Group	Pre-intervention BBS score, mean ± SD	Post-intervention BBS score, mean ± SD	*P*
Conventional therapy group	48.0 ± 2.9	51.3 ± 3.4	0.001
WBV therapy group	47.3 ± 4.1	51.3 ± 2.6	0.012
Combined therapy group	45.3 ± 4.5	51.13 ± 3.4	0.001

BBS Berg Balance Scale, *SD* Standard Deviation, *WBV* Whole body vibration

Table 3 Mean value change in BBS scores per group

Variable	Conventional therapy group ($n=15$)	WBV therapy group ($n=15$)	Combined therapy group ($n=15$)	*P*
Mean value change ± SD	3.40 ± 2.4	4.1 ± 1.5	5.9 ± 3.1	0.022

BBS Berg Balance Scale, *SD* Standard deviation, *WBV* Whole body vibration

Mean change in BBS score between groups

As there were significant differences in each group pre- and post-intervention, we proceeded to compare changes in BBS score after intervention therapies, to assess potential differences between groups (Table 3). Patients who underwent conventional therapy had a change in BBS score of 3.4 ± 2.4, WBV therapy group of 4.1 ± 1.5, whereas combined therapy had a change in BBS score of 5.9 ± 3.1, having these differences significance ($p=0.022$). Post hoc analysis was carried out to analyze groups that differed significantly, showing that differences were significant between conventional therapy and combined therapy group ($p=0.021$), but not between conventional and WBV therapy ($p=0.370$), nor WBV therapy and combined therapy group ($p=0.052$).

Responder analysis of BBS score threshold

We conducted a responder analysis of patients that reached the threshold of four points change in BBS score after intervention, as with this we are 95% confident that a significant change occurred when being in the range of 45–56 BBS score (five points change when BBS score lies within 35–44 range) [26]. Combined therapy group had the greatest percentage of patients that reached this threshold, followed by WBV therapy group, and at last, conventional therapy with the least percentage of patients (shown in Fig. 1). A significantly higher percentage of responders were found in combined therapy group when compared to conventional therapy group ($p=0.025$), but not when compared to WBV therapy group ($p=0.232$). No significant differences were observed when comparing conventional therapy to WBV therapy group ($p=0.273$).

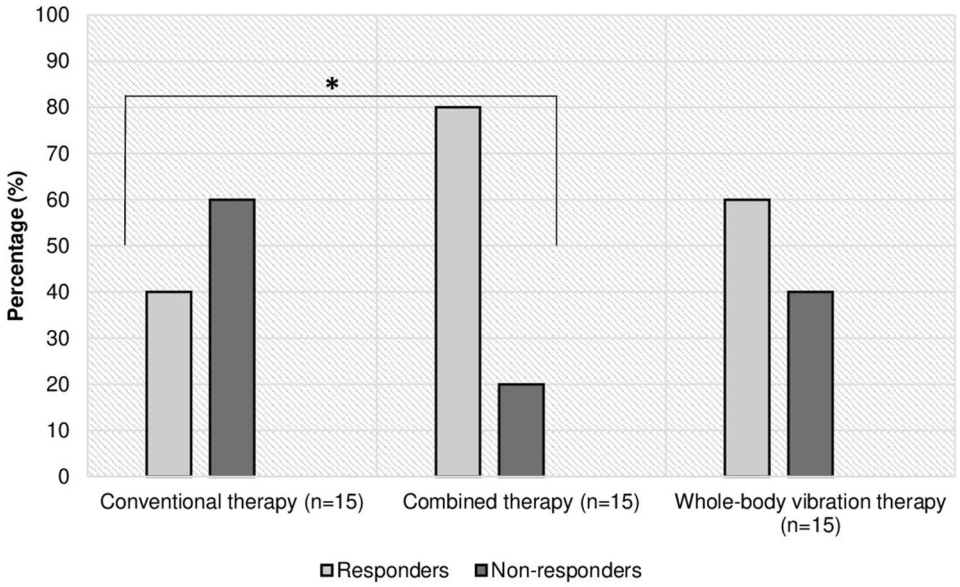

Fig. 1 Percentage of patients in each therapy group that reached the threshold for significant change in BBS score. * = $p < 0.05$, comparing combined to conventional therapy group. *BBS* Berg Balance Scale

Discussion

In this study, we compared the effect of conventional therapy to WBV therapy in functional balance status, adding a third group of a combined therapy. The 3 groups showed a significant improvement in BBS scores after concluding 20 sessions of each intervention. This highlights the need of including a rehabilitation program on PD patients to address gait, balance, or posture disturbances, either with conventional, WBV therapy or combined. Moreover, comparing the change in BBS scores, patients who underwent combined therapy had a greater increase in BBS compared to patients in the conventional therapy, but no differences were observed when comparing WBV group to combined therapy or WBV to conventional therapy. These results suggest that a combined therapy could be more beneficial in patients receiving only conventional therapy.

Vibration frequency is an important aspect to consider in WBV therapy. We used a frequency of 20 Hz, whereas other studies used one of 6 Hz [20, 27], not stating reasons for this use. A systematic review assumed frequencies of 15–30 Hz could have greatest effect, as beta oscillations of the basal ganglia causing abnormal functioning such as tremor or bradykinesia have a frequency of 15–30 Hz [22, 27, 28]. Moreover, another study comparing WBV therapy to conventional therapy at a frequency of 25 Hz showed both therapies to improve intra-group outcomes, not showing, however, significant differences among groups [29].

Considering sample size, our study included more patients than other studies evaluating WBV therapy, where their sample ranged from 21 to 36 patients [20, 27, 29]. However, we still considered our sample to be small, considering this a limitation. A strength of this study is the inclusion of a third group combining conventional and WBV therapies. We hypothesize that patients in the combined therapy benefited more than conventional therapy as with the latter patients' balance, gait and postural deficits are stimulated, and subsequently the WBV therapy supports this stimulation, and improves patients' functional outcomes.

Considering the population of study, we considered patients with mild-to-moderate severity (HY I–III) to benefit the most from the therapy, as these could execute correctly the postures needed in each therapy. Choosing this range of disease severity is important, as studies have shown that even in early stages of PD, high falls incidence is reported [1, 30–32], which might be early targeted with therapy as WBV therapy, increasing muscle strength necessary for posture stability and gait. Moreover, a study evaluating proprioceptive deficits in PD patients in mild to moderate severity showed these impairments may manifest even in early stages of the disease [33]. Another study supporting this idea showed that early stage PD patients have an infraclinical postural instability [34], highlighting the importance of assessing and potentially treating gait and posture disturbances even in early stages of the disease. In addition, a study focused on proprioceptive function in PD patients concluded that this is treatable even in mild stages, improving after somatosensory training [35]. Most studies assessing WBV therapy in PD patients involved mild-to-moderate stages [20, 21, 27, 29], furthermore, one of these used BBS as outcome and had similar scores pre intervention as our study [20], supporting with the latter the inclusion of this severity range.

Ultimately, 12% in the conventional therapy group, 21% in the WBV therapy group, and 6% in the combined therapy group, of patients were lost to follow-up as they discontinued

the therapy protocol from the first session. As this loss could lead to bias in the result analysis, we conducted a worst-case scenario analysis, were no change was observed in BBS score after concluding 20 sessions in each patient lost to follow-up of each therapy group. Greater scores in the BBS were still observed in the post-intervention evaluation in each therapy group. Mean change in score was 3.0 ± 2.5 in conventional therapy, 3.21 ± 2.1 in WBV therapy, and 5.5 ± 3.3 in the combined therapy. Significant differences were still observed between groups ($p = 0.017$). Moreover, post hoc analysis showed significant differences in BBS scores comparing combined therapy group to conventional therapy ($p = 0.030$), and to WBV therapy group ($p = 0.045$), whereas no difference was observed between conventional and WBV group.

Although patients with HY stage III were not conveniently assigned to the combined therapy group, only this group involved patients with this severity stage (3, 20%). As these could have benefited more from the therapy and have a higher BBS score change, we conducted an exclusion analysis, excluding patients in this severity stage. Greater BBS scores were still observed in the combined therapy group after intervention. However, when comparing mean change in score between groups, no differences were observed ($p = 0.080$), suggesting a greater benefit of the therapy in more severe stages. Furthermore, when excluding these patients in the responder analysis, the greatest percentage of responders were still observed in combined therapy group ($n = 9$, 75%), but without any significant differences between groups. This must be acknowledged as a limitation in our study, as more patients in HY stage III who underwent conventional or WBV therapy would have been useful in clarifying the possible differences between interventions in this severity stage. Nonetheless, when grouping patients based on HY stage and comparing mean change in score between groups, differences were observed in patients in HY stage II ($p = 0.016$). Post hoc analysis showed patients in combined therapy group differed significantly from conventional therapy ($p = 0.014$), however, no differences when comparing to WBV therapy ($p = 0.113$), or comparing the latter to conventional therapy were observed. Similar results were observed in the responder analysis, as a significantly higher percentage of patients in HY stage II who underwent combined therapy reached the threshold when compared to conventional therapy ($p = 0.018$), but not to WBV therapy group ($p = 0.083$).

Limitations

This study assessed functional balance in PD patients after concluding 20 sessions (6.5 weeks) of conventional, WBV or combined therapy, however, long-term outcomes after concluding interventions were not assessed, and this could be important to determine the duration effect of the different therapies. Another limitation might be that we did not include a placebo group, as a study argued that beneficial effects of WBV therapy might be due to placebo effect [20], and thus should be reasonable to add a placebo group with same conditions as the WBV group. Considering levodopa medication status, some studies conducted WBV therapy in patients in ON status [29, 36], while others conducted this in an OFF status [21, 37]. This is important as this ON–OFF status could influence outcomes, and as we conducted therapies in an ON status, we cannot exclude levodopa effect as a potential bias for our results.

Moreover, as this was a non-randomized trial, selection bias must be taken into consideration. However, when comparing participants' baseline characteristics, no difference in sociodemographics, or motor subtype of onset, which could bias interpretation of results, was observed. Nonetheless, an important limitation arises as only the combined therapy group involved patients in HY stage III. To limit this, an exclusion analysis was carried out, where patients in this stage were omitted, showing no differences between groups. However, considering grouping patients based on HY, PD patients in HY stage II who underwent combined therapy had significantly greater mean change in BBS scores compared to conventional but not to WBV therapy groups. In this manner, a greater sample size, particularly of PD patients in HY stage III, is needed to clarify differences between interventions. Lastly, as no blinding was conducted during BBS assessment, detection and performance bias must be taken into consideration. However, this study contributes to knowledge on combined interventions to improve functional balance in PD patients, which might be further confirmed in a greater sample size, randomly allocated to interventions and with blinding of outcome assessment.

Conclusion

Rehabilitation therapy, either conventional, WBV or combined, improved functional balance in patients with PD. Comparing these, combined therapy had a greater improvement compared to conventional therapy, whereas no difference was observed between conventional and WBV therapy. When considering patients lost to follow up in a worst-case scenario analysis, combined therapy showed greater improvement compared to WBV and conventional therapy. However, when excluding patients in HY stage III from combined therapy group in analysis, no differences were observed among groups. This study suggests that a combination of conventional and WBV therapies might benefit PD patients the most regarding functional balance, however, a greater sample size of PD

patients with a HY stage III is needed to fully confirm and compare differences among group interventions.

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Data availability The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants All procedures performed in the study were in accordance with the ethical standards in compliance of the 1964 Helsinki Declaration and its later amendments and received approval by the ethics committee of our institution.

Informed consent Informed consent was obtained from all individual participants included in the study.

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