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Research Article

The Impact of Mineral Water Balneotherapy on Pain and Physical Function in Patients with Knee Osteoarthritis: A Pilot Study

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Abstract: (1) Objectives: This pilot study aimed to evaluate the effectiveness of a 2-week rehabilitation program consisting of electrotherapy, physical therapy, and balneotherapy in patients with knee osteoarthritis (KOA); (2) Methods: A total of 98 patients were enrolled in the study and assigned to either an experimental group or a control group. The primary outcome measures were pain intensity and knee function scores, while secondary outcomes included functional tests such as the 30s chair stand test, stair climbing test, and 40-meter walk test; (3) Results: Results showed significant improvements in pain intensity, knee function scores, and the 30s chair stand test in both groups. However, the experimental group showed more significant improvement in the 40-meter walk test than the control group. Linear Model ANOVA test showed that after the 2-week treatment, participants receiving balneotherapy showed significant progress compared to the control group in pain intensity, knee function scores, and walking test. The results for the stair climbing test did not differ significantly between the two groups, but it improved in both; (4) Conclusions: Study findings suggest that a rehabilitation program consisting of electrotherapy, physical therapy, and balneotherapy can show significant improvement in regards to pain and function in patients with KOA.

Keywords: Mineral water, Băile Tinca, Knee osteoarthritis, Knee function

1. Introduction

Knee osteoarthritis (KOA), the most common disease of the locomotor system, is also amongst the degenerative joint diseases with highest incidence. The incidence of KOA cannot be evaluated only by taking an anamnesis because many patients are asymptomatic and do not consult a doctor. A more realistic assessment is given by epidemiological studies that show that, currently, over 80% of individuals older than 60 years have degen-

erative changes in one or more joints. The impact of KOA is significant, with 60% of rheumatic patients reporting limited mobility, disability, and limited work capacity, a fact that underlines the socio-economic importance of this condition [1, 2].

The prevalence of KOA increases with age, and there are gender-related differences. Thus, after the age of 50, women suffer from KOA much more frequently compared to men of the same age [3].

The incidence of KOA among people over the age of 65 is 70% and 90% in the general population after the age of 30. Early degenerative changes of the knee were detected by MRI before the age of 45 and are commonly observed in younger and asymptomatic healthy adults [4].

The pathogenesis of knee osteoarthritis is complex and includes degradation and repair processes of the cartilage and subchondral bone with synovial inflammation. Hence, OA affects the entire joint, including cartilage, synovia, subchondral bone, ligaments, and muscles.

At present, there is no specific medicine for OA, and several interventions such as education of patient and nonpharmacological and pharmacological modalities are recommended. Over time, several studies investigating the benefits of oral and parenteral drugs in KOA were conducted with unsatisfactory results. Nonsteroidal anti-inflammatory drugs, glucosamine, chondroitin-sulphate, hyaluronic acid (HA) and glucocorticoids have been proposed for pain reduction, mobility improvement, and disability, but the results were controversial [5, 6, 7].

Balneotherapy (BT), a noninvasive treatment procedure, is used in various rheumatic conditions, including knee osteoarthritis [8].

Balneotherapy refers to bathing in thermal or mineral water, and although it is different from hydrotherapy, both terms have been accepted as forms of water-based treatment.

The mineral water from Băile Tinca in Romania has been known since 1884 through the Old Well that still works today, with a depth of 270 meters [9]. Over time, many patients with rheumatic diseases have been treated here with mineral water.

Băile Tinca is a balneo-climatic tourist resort, which has springs with alkaline thermomineral waters rich in calcium, magnesium, sodium, and slightly carbonated, with hypertonic effect (osmotic concentration over 325 mOsm). According to the analysis report from 2021, the chemical composition of the water is varied, having a rich content of active substances necessary for the body [10]. The resort's treatment base has 24 pools for balneotherapy.

The physical properties and chemical effects of mineral water therapy can play an essential role in treating of rheumatic diseases. The most important physical characteristics of mineral water are density, buoyancy, specific gravity, viscosity, hydrostatic pressure, temperature, and dissolved substances of water [11].

Properties mentioned above have made BT an increasingly popular form of physiotherapy treatment with multiple influences on the neuro-immuno-endocrine system [12, 13].

This paper aims to show if 2 weeks of BT is superior to conventional physiotherapy in patients with knee osteoarthritis.

2. Materials and Methods

2.1. Study Design and Participants

This pilot study took place in two locations at "Băile Tinca Resort" and at "Fiziohelp Med" Clinic in Salonta. This controlled study complied with the rules of good clinical practice; the protocol was approved by the Ethics Committee of "Băile Tinca Resort" in July 2021 (approval no. 85/07.07.2021). All participants provided their written consent before participating in the study. The patients were selected according to inclusion and exclusion criteria.

The inclusion criteria were: patients with unilateral or bilateral primary KOA, according to American College of Rheumatology criteria [14]; KOA grade 2 and 3 according to Kellgren and Lawrence criteria; both genders; aged between 40 and 80 years; participants willing to participate in this study.

We excluded patients with neurological deficits, fibromyalgia, inflammatory arthritis, microcrystalline arthritis, a history of septic arthritis, knee trauma, or surgery. No patient has received arthrocentesis and, or intraarticular steroid injection during the last 3 months.

A total of 110 participants who met the eligibility requirements were enrolled in the study from December 2020 to December 2021. According to each patient's willingness, they were assigned to a control group (CG) or an experimental group (EG).

The study started in "Băile Tinca Resort", and 58 patients with primary KOA were assigned to an experimental group (EG). Following the exclusion criteria, 49 patients remained in this group.

Since there were not enough patients at "Băile Tinca Resort" due to the COVID-19 pandemic, we chose patients with primary OA who expressed their agreement to enter the study and assigned them to "Fiziohelp Med" as a control group (CG). Out of 60 patients, following the exclusion criteria, 49 patients remained in this group.

Patients were assessed before treatment (T1) and after treatment (T2). All assessments were performed simultaneously by two researchers. The study population was examined and was under the supervision of the same doctor in both locations, who is specialized in physical medicine and rehabilitation.

2.2. Assessments

The participants' demographic characteristics, such as age, gender, weight, height, and body mass index (BMI) were recorded. Moreover, somatometric measurements and functional tests were applied (a 40-meters fast-paced walk test, stair-climb test, and self-administered questionnaires). (Figure 1).

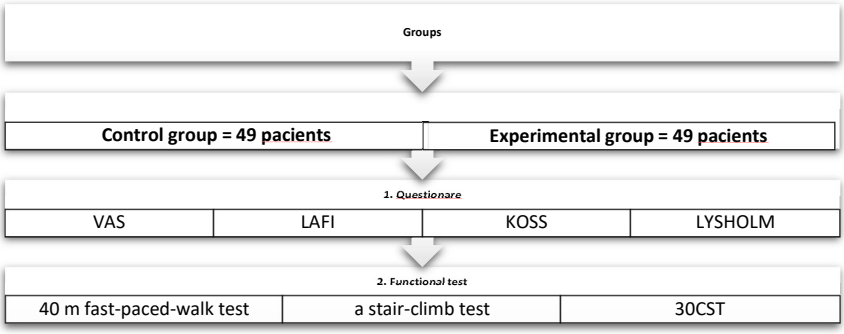

Figure 1. The study flow

The primary outcome was the pain (Visual Analog Scale - VAS) and the knee function (Lequesne Algofunctional Index – LAFI, Lysholm Knee Scoring Scale and Knee Injury and Osteoarthritis Outcome Score - KOSS) [15, 16, 17]. The secondary outcomes included the functional test 30s chair stand test (30CST), stair climbing test (SCT), and 40-meters walk test (40WT) [18, 19, 20].

2.3. Interventions

All subjects received 10 sessions of rehabilitation treatment over a period of two weeks. The rehabilitation treatment consisting of electrotherapy and physical therapy was the same for both groups, and the experimental group also benefited from balneotherapy procedures (Table 1).

TECAR (Transfer of Energy Capacitive and Resistitive) was performed using a BTL-6000 TR-Therapy Elite device, with a capacitive selection time of 5 min and resistive section time of 15 min, at an intensity ranging from 30 to 100 % depending on the pain intensity threshold. Continuous ultrasound was applied using a BTL 5000 device at an intensity of 1.2 W/cm2 and 3MHz, for 5 min. (Table 1)

The physical therapy program aimed at strengthening the muscles, acquiring joint mobility, restoring the stability of the lower limb, and gaining a controlled walking mobility.

The physical therapy program consisted of 30 minutes of daily sessions and included passive range of motion exercises, glide mobilization techniques, and stretching exercises. Further, as the pain decreased, active range of motion exercises, isometric, and resistive exercises were added to the therapeutic program. The exercises included slow reversal and slow opposition reversal PNF techniques, repeated contractions, and sequencing for strengthening.

The active exercises were performed from joint unloading positions, from sitting and lying down, respecting the principle of progressivity, and aimed mainly at strengthening the quadriceps and lower limb muscles as well as improving joint mobility of the lower limb.

Active resistance exercises were performed using sandbags, elastic bands, and physiotherapy balls. The ergometric bicycle was also used both for active free exercises, deactivating its resistance, and for active exercises with resistance, progressively activating its resistance.

Table 1. Rehabilitation treatment procedures

Treatment procedures	Băile Tinca (EG)	Fiziohelp Med Salonta (CG)	Dosage	Frequency	Intensity
Balneotherapy in mineral water at 37,5 °C	✓		20 min	1/day	
Physical Therapy	✓	✓	30 min	1/day	
Ultrasound	✓	✓	5 min	3 MHz	1.2 W/cm²
TECAR	✓	✓	20 min	1/day	30-100 %

The individual balneotherapy procedure was as follows: the bathtub was filled with 200 liters of mineral thermal water, and the patients had baths (immersion up to the armpits) for 20 minutes, monitored by a therapist. The mineral water used comes from the "Old Well" that still exists today, with a depth of 270 meters discovered in 1884. The outlet temperature of the mineral water of the spring from Băile Tinca is 14°C, and the total concentration of minerals is 4090.5mg/lt.

Table 2. Hydrochemical analysis of the mineral water spring from Băile Tinca

Temperature (°C)	**14**
Conductivity (µS/cm)	4090
Salinity	2.1
pH	7.4
Mineralization	4090.5
Component	
Ca^{2+} (mg/L)	25.6
Mg^{2+} (mg/L)	25.3
K^{+} (mg/L)	19.0
Na^{+} (mg/L)	1105.8
Cl^{-} (mg/L)	404.3
Br^{-} (mg/L)	1
I^{-} (mg/L)	≤ 0.1

NO^{-}_{3} (mg/L)	5.0
NO^{-}_{2} (mg/L)	≤ 0.06
SO_4^{2-} (mg/L)	5.1
HCO_3^{-} (mg/L)	2470.5
NH^{+}_{4} (mg/L)	2.8
Fe^{2+} (mg/L)	0.1
H_2SiO_3 (mg/L)	16.4
HBO_2 (mg/L)	6.9
O_2 (mg/L)	2.1
CO_2 (mg/L)	440.0

Before conducting the study, a power sample size calculation was performed to ensure at least 80% power to detect the expected effect size, taking into account factors such as the level of significance and variability in the data. This is a crucial step to ensure that the study is adequately powered to achieve meaningful results and reduce the risk of type II errors.

2.4. Statistical Analysis

Continuous data are presented as a mean (M) with standard deviation (SD) where data has a normal distributed and as a median with the 25th and 75th centiles for non-parametric data.

Categorical data are summarized as frequencies and percentages. Differences between groups for continuous normally distributed data were tested using Welch's t-test for two groups or ANOVA when there were more than two groups. Post hoc tests were conducted using the Bonferroni correction to adjust for multiple comparisons when appropriate. Non-parametric continuous data were tested using a Mann–Whitney U test for two groups or the Kruskal–Wallis test for three or more groups. Differences across categorical data were tested using the $\chi 2$ or Fisher's exact test when expected cell counts were less than five.

The selection of the statistical tests was guided by the nature of our data and the specific requirements of our study design. Each test was chosen for its ability to accurately analyze the type of data (parametric or non-parametric) and the number of groups involved in each comparison. This careful selection ensures the validity and reliability of our statistical analyses.

We employed the Linear Model ANOVA to compare means across the different groups in our study. This test is particularly apt for our design as it allows for the comparison of more than two groups simultaneously, which is essential for analyzing the effects of our intervention across the Control and Experimental groups, both pre- and post-treatment.

For comparisons involving two independent groups, we used Welch's t-test for normally distributed data and the Mann–Whitney U test for non-parametric data. These tests are appropriate for our study, given the different data distributions present and the need to compare two groups at a time, such as pre-treatment vs. post-treatment within each group.

We utilized Kruskal–Wallis test to compare three or more groups where data did not follow a normal distribution. This non-parametric method is suitable for analyzing outcomes where the assumption of normality is not met.

For categorical data analysis, we used $\chi 2$ test and Fisher's exact test depending on the sample size. The $\chi 2$ test was used for larger samples; while Fisher's exact test was more suitable for smaller samples or when expected frequencies were low, ensuring accuracy in our results.

All statistical analyses were performed using R (version 3.6.3). We used various packages like tidyverse, finalfit, mcgv, survival, stringdist, janitor, and Hmisc, which provided robust tools for our data analysis and enhanced the accuracy of our results.

3. Results

Demographic characteristics of the experimental and control groups are summarized in Table 3.

There was no significant difference between the two groups. Data are presented as mean ± SD.

Table 3. Demographic characteristics of the participants

	Total (n = 98)	**EG Pre Evaluation (n = 49)**	**CG Pre Evaluation (n = 49)**	**p - value**
Age (years)	M = 69.0, SD = 6.9	M = 68.7, SD = 7.1	M = 69.4, SD = 6.6	0.522
Female, n (%)	52.00 (53%)	26.00 (53%)	26.00 (53%)	1.000
Male, n (%)	46.00 (47%)	23.00 (47%)	23.00 (47%)	
Education (years)	M = 11.6, SD = 2.5	M = 11,26, SD = 2,51	M = 11.3, SD = 2.6	0.450
BMI (kg/cm2)	M = 31.6, SD = 4.1	M = 32.6, SD = 4.3	M = 30.6, SD = 3.6	0.001

The experimental group had a significantly higher BMI than the control group (p = 0.001). Still, there was no significant difference in years of education, gender distribution, or age between the two groups (p > 0.05).

The results show significant improvements in both groups for VAS (p = 0.001), LAFI (p = 0.001) and the 30CST (p = 0.001). However the mean differences were higher in the experimental group than the control group for these parameters (Table 4). The 40WT results were significantly better in the experimental group (p = 0.001), while in the control group, it did not improve (p = 0.688).

The SCT, KOOS, and LYSHOLM did not show significant improvements in either of the two groups.

Table 4. Effects of an intervention on physical and functional outcomes in patients with KOA

Variables	**EG Pre-test and Post-test (n = 49)**				**CG Pre-test and Post-test (n = 49)**			
	Mean difference	SD	t	Sig. (2-tailed)	Mean difference	SD	t	Sig. (2-tailed)
VAS	1.388	2.008	4.837	0.001	1.082	1.525	4.964	0.001
LAFI	1,551	3,042	3,569	0,001	1,245	2,385	3,654	0,001
KOOS	-4,204	24,072	1,223	0,227	-2,796	19,119	-1,02	0,311
LYSHOLM	-3,49	24,454	0,999	0,323	-2,878	14,867	-1,36	0,182
30CST	-1,469	1,101	9,341	0,001	-1,102	1,327	-5,82	0,001
40WT	4,1731	1,624	17,99	0,001	0,85	14,731	0,404	0,688
SCT	1,714	10,494	1,143	0,259	1,861	21,069	0,618	0,539

Legend: VAS = Visual Analogue Scale; LAFI = Lequesne Algofunctional Index; KOOS = Knee Injury and Osteoarthritis Outcome Score; LYSHOLM = Lysholm Knee Scoring Scale; 30CST = 30s chair stand test; 40WT = 40 meters walk test; SCT = stair climbing test

The intervention appears to have a significant impact on 30CST scores in the EG and a large effect size. Also significantly impacted were 40WT scores in the EG, with a considerable effect size. The CG showed substantial improvements in VAS and LAFI scores, but the effect sizes were generally smaller than in the EG. The intervention did not have a significant impact on KOOS scores, LYSOLHM scores, and SCT scores in either group (Figure 2).

Figure 1. Evaluating the mean difference impact of an intervention on various metrics in Experimental and Control Groups

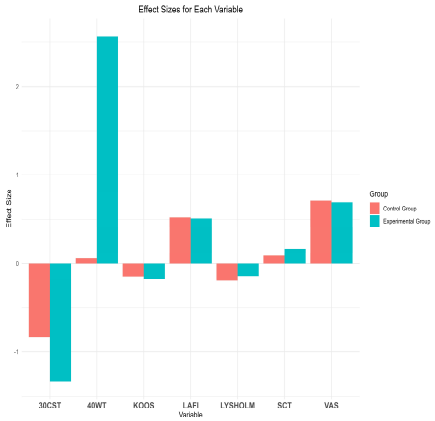

Figure 2. Evaluating the effect size impact of an intervention on various metrics in Experimental and Control Groups

VAS showed a significant correlation between pretest and posttest in the control group, and LYSHOLM showed a significant correlation between pretest and posttest in both the control and experimental groups. The 30CST, 40WT, and SCT showed significantly stronger correlations between pretest and posttest in the experimental group compared to the control group.

Table 5. Pearson Correlation between Pre and Post-Test Scores in Control and Experimental Groups for Various Variables

	CG (n = 49)		EG (n = 49)	
Variables	R	p-value	R	p-value
VAS	,318*	0.025	,279	0.052
LAFI	,177	0.221	,354*	0.012
KOOS	,165	0.255	,034	0.812
LYSHOLM	,517**	0.0001	,351*	0.013
30CST	,800**	0.000	,886**	0.000
40WT	,929**	0.000	,999**	0.000
SCT	,887**	0.000	,973**	0.000

Legend: VAS = Visual Analogue Scale; LAFI = Lequesne Algofunctional Index; KOOS = Knee Injury and Osteoarthritis Outcome Score; LYSHOLM = Lysholm Knee Scoring Scale; 30CST = 30s chair stand test; 40WT = 40 meters walk test; SCT = stair climbing test

Linear Model ANOVA test shows that after 2-week treatment (Table 4), participants receiving balneotherapy (bath in mineral water) showed significant outcomes compared to the control group in terms of pain intensity ($p < 0.001$, knee function scores ($p < 0.001$ for LAFI, LYSHOLM and $p < 0,05$ for KOOS) and walking test ($p < 0.001$). The results of the stair climbing test did not differ significantly between the two groups, the performance on this test improved in both groups.

4. Discussion

Osteoarthritis is one of the leading causes of pain and disability worldwide, affecting millions of people. In the quest for effective and noninvasive treatments, BT has emerged as a promising option. In this pilot study, we explore the potential benefits of balneotherapy in KOA patients in regard to pain and knee function. Findings showed the superiority of adding BT in the experimental group over the other group in which only the conventional physiotherapy was given. In 2013, the International Osteoarthritis Research Society International (OARSI) published the guidelines for the non-surgical management of KOA.

Among these recommendations, balneotherapy is considered a noninvasive treatment method with a beneficial effect on knee pain and functionality [21].

As we delve further into the study, it's essential to understand the context of balneotherapy and its potential benefits. Balneotherapy is a non-invasive treatment method that involves bathing in mineral-rich water, which is believed to have therapeutic effects on various ailments, including osteoarthritis.

Recently, many clinical trials, meta-analyses, and systematic reviews show the beneficial effect of BT alone or in combination with other therapeutic modalities on pain, function, and quality of life of patients with KOA [22-25].

Thus, Yurtkuran and colleagues investigated, in a randomized placebo-controlled trial, if BT shows better results compared to tap water (TW) in relieving pain and improving mobility, strength, function, and life quality of patients with KOA. All patients followed a home-based standardized exercise program. Only pain, tenderness score, and the Nottingham Health Profile improved significantly better with BT in 12 weeks [26].

In another multicenter randomized clinical trial conducted by Forestier et al. (2010) patients with KOA were given BT treatment for 3-weeks together with home exercises and usual pharmacological treatments. The group of patients treated with BT compared to the control group registered better outcomes in pain and function, and the benefits persisted after 6 months [27].

Fioravanti et al. (2012) applied balneotherapy with mineral water for three weeks with good results in osteoarthritis symptoms reduction, a fact confirmed by the significant decrease of medication intake. The significant improvement in parameters persisted throughout the 12-week follow-up period. [28]

In another study Kulisch et al. (2014) evaluates how Lake Hévíz thermal mineral water influences pain, knee function and quality of life in patients with knee osteoarthritis even after 15 weeks. [29]

Morer et al. (2017) carries out a systematic review of specialized literature with reference to balneotherapy, highlighting the specific therapeutic role of mineral elements and other chemical compounds of mineral waters and derived peloids/sludges, compared to tap water. [30]

Similarly, in our study, after 2-weeks of balneotherapy (bath in mineral water), the participants registered significant outcomes in pain intensity and knee function.

Our results are similar with the findings of previous studies, where patients have reported significant improvement in their levels of pain and mobility after bathing in mineral waters [31-36].

The therapeutic effects of the mineral natural waters depend on their chemical compositions being able to produce analgesic benefits, anti-inflammatory and antioxidant effects, cartilage protection, and immunosuppression [37, 38].

Silva et al (2023) evaluates in his study whether a period of 14 days of balneotherapy influences the inflammatory state, quality of life and quality of sleep, general health and clinically relevant benefits of patients with musculoskeletal pathologies. [39]

In a systematic review of 17 studies, Protano et al. (2023) reported the effects of mineral water balneotherapy in the management of osteoarthritis symptoms and signs. Pain and quality of life were the main symptoms assessed and both improved after spa therapy with mineral water, an improvement that can be attributed to the physical and chemical-physical properties of mineral water. [40]

Macarone (2023) demonstrated in his study the short-term effects of spa therapy on pain, mood and quality of life in patients diagnosed with degenerative rheumatism through an observational study in Italy. [41]

The mineral-rich water used in balneotherapy often contains bicarbonate, calcium, and magnesium ions, which are believed to contribute to the treatment's analgesic, anti-inflammatory, and antioxidant effects. Furthermore, the low cost and easy accessibility of

mineral water therapy make it an appealing adjunctive therapy for the conservative treatment of knee osteoarthritis. The mineral water from Băile Tinca is alkaline, rich in minerals (calcium, magnesium, sodium), and bicarbonate.

Despite the promising results, this pilot study has limitations, including the lack of long-term follow-up and the relatively short treatment period of two weeks.

The limitations of our study were inherent to the research and we start from the small sample size due to the coronavirus epidemic. These would be: the patient's refusal to enter the study, giving up the study for voluntary or involuntary reasons determined by the state of health or for personal reasons; lack of real data refers to self-administered questionnaires that could be irrelevant due to subjective interpretation, exaggeration or underscoring of symptoms; the patient's inability to understand the items and the feedback provided inconsistent with reality, due to either speaking another language or the level of education; insufficient data collection by not applying several tests or limited questions in the evaluation to obtain and analyze as many aspects as possible of balneotherapy in osteoarthritis of the knee on the quality of life of patients; the interruption of collaboration with the patient once he has left the treatment base for various reasons, either he is dependent on third parties due to age, cognitive capacity or health, or he refuses collaboration due to personal, social, economic barriers, etc.; financial impossibility of returning to the treatment base, at least annually, in the conditions where the treatment is not subsidized by the Health Insurance National Agency or the National Pension Agency; conducting the study in two locations, is another limitation of our study, we could not monitor the two groups simultaneously.

The control group received physical therapy and electrotherapy, which may have influenced the study results and limited the ability to conclude about the specific effects of balneotherapy.

Further research is needed to explore the long-term effects of BT on knee osteoarthritis and to identify the optimal duration and frequency of treatment for maximum benefits.

It would be interesting in the future to carry out studies in which joint mobilization techniques are applied in offices / clinics where it is not possible to apply balneotherapy.

5. Conclusions

Our pilot study suggests that balneotherapy may offer a valuable addition to traditional physical therapy and electrotherapy in treating knee osteoarthritis. Combining of these treatment modalities could represent a powerful, multimodal strategy for alleviating pain and improving knee function in osteoarthritis patients. However, more extensive research is necessary to confirm these findings and establish the most effective treatment protocols for this debilitating condition.

Author Contributions: Conceptualization, A.P.C., I.H. and D.I.; methodology, E.S., F.M. and D.I.; software, A.C.M. and I.C.B.; validation, G.A.G., E.S. and I.C.B.; formal analysis, A.C.M., E.S. and G.A.G.; investigation, A.P.C. and I.H.; resources, I.H. and E.S.; data curation, A.P.C. and G.A.G.; writing—original draft preparation, A.P.C. and D.I.; writing—review and editing, F.M. and I.C.B.; visualization, A.C.M. and F.M.; supervision, I.H., F.M. and A.C.M.; project administration, A.P.C., I.H. and G.A.G.; funding acquisition, I.C.B. and D.I. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors declare no conflict of interest.

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