Effects of Home Exercise and Manual Therapy or Supervised Exercise on Nonspecific Chronic Low Back Pain and Disability

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Featured Application: In this study, we describe a specific exercise program for individuals with nonspecific chronic low back pain. The exercises can be performed by individuals at home as a home exercise program. Physicians, physiotherapists, and researchers can apply the results and conclusions of this study in their therapeutic and scientific practice.

Abstract: In this study, we aimed to evaluate the effects of two therapeutic methods: home-based exercise and manual therapy (MT) or supervised exercise on pain and functional status in individuals with chronic nonspecific low back pain. In total, 60 individuals with LBP were included in this randomized study. All participants were treated for 6 weeks in one of two groups: the manual therapy group or the exercise therapy group. In addition, all participants were asked to perform an exercise program at home independently. Levels of pain, spinal mobility, disability, and abdominal and back muscle endurance were measured before and after 6 weeks of intervention. Results: After MT, disability was reduced by 70% (F = 42.2; p < 0.00; η²p = 0.99) and pain was reduced by 78% (F = 4.9; p < 0.00; η²p = 0.51). After exercise therapy, disability and pain were reduced by 78% (F = 11.5; p < 0.00; η²p = 0.78) and 68% (F = 9.4; p < 0.00; η²p = 0.41), respectively. Muscle endurance and lumbar spine mobility values were significantly higher in both groups after 6 weeks of intervention (p < 0.00). After 12 MT interventions, lumbar spine mobility increased by 40% (F = 1.9; p < 0.00; η²p = 0.24) and after exercise therapy by 38% (F = 28.4; p < 0.00; η²p = 0.82). Abdominal muscle endurance improved by 29% (F = 24.2; p < 0.00; η²p = 0.79) after MT and by 34% (F = 57.6; p < 0.00; η²p = 0.67) after exercise therapy; back muscle endurance improved by 18% (F = 48.6; p < 0.00; η²p = 0.78) after MT and by 20% (F = 14.2; p < 0.00; η²p = 0.76) after exercise therapy. After 6 weeks of intervention, there was no statistically significant difference between the pain, disability, and spinal mobility groups (p > 0.05). However, differences between groups in kinesiophobia (p = 0.02), back (p < 0.02) and abdominal (p < 0.03) muscle endurance values were statistically significant. Following the home exercise program and manual therapy, or the home exercise program and supervised exercise, LBP and disability had clinically significant reductions and functional status showed improvement.

Keywords: chronic low back pain; musculoskeletal pain; disability; exercise therapy; manual therapy

1. Introduction

Low back pain (LBP) is one of the most common musculoskeletal disorders leading to disability. It is the main cause of activity limitations and absence from work worldwide [1,2]. People who experience chronic and recurrent LBP have long-term disabilities, which result in a significant economic burden [3]. About 85% of the population complain of nonspecific low back pain at some point in their lives [4].

Pain, limited mobility, stiffness, or increased muscle tension below the costal margin and above the inferior gluteal folds, which may or may not convey pain to the leg, are collectively referred to as low back pain [4,5]. LBP can be divided into specific and nonspecific LBP according to established etiology. The most common LBP is nonspecific, lacks a clear pathologic cause, and is not attributable to a recognizable, specific pathology such as...
fracture, ankylosing spondylitis, spondyloarthritis, infection, neoplasm, or metastasis [4,5]. Chronic LBP occurs when symptoms persist beyond 12 weeks [4–7]. Low back pain can be episodic for certain people, marked by remissions, relapses, and periodic flare-ups; this type of pain is referred to as persistent low back pain [7].

Research results have provided a variety of treatment options for LBP. Treatment options for LBP include acupuncture, educational tools, behavioral therapy, cognitive behavioral therapy, medication, Kinesiology tape, mechanical and manual traction, manual therapy, and exercise therapy [1,6,8,9].

Strength-building, spinal stabilization, stretching, and aerobic and McKenzie method exercises are known to help patients with chronic LBP, and these exercise therapies have been shown to reduce pain and disability in the short and long term [7,10,11]. Research evidence does not indicate which type of exercise therapy is best for reducing LBP and improving functional ability [1]. For chronic LBP without serious pathology, the recommended primary conservative physical treatment options include exercise, yoga, biofeedback, progressive relaxation, massage, manual therapy, and interdisciplinary rehabilitation [7,10–12].

Manual therapy (MT) involves treatment of the spine with the hands, including spinal manipulation and mobilization [13]. Both methods are equivalent and recommended as single interventions in guidelines [12]. Research evidence suggests that both mobilization and manipulation are safe methods [14]. MT is recommended in evidence-based clinical practice and other guidelines because of its use of non-pharmacological interventions for LBP [6,12,13,15]. According to a systematic review of the literature, there is considerable evidence that manual therapy is no less effective than other treatments (exercise, conventional medical care, or physiotherapy) at reducing back pain and promoting healing [15,16,17]. One systematic review suggests sufficient evidence for MT’s effectiveness in treating LBP [17,18]. Another systematic review reported that MT is widely used in treating back pain. Several studies of different methodological quality and size were investigated, and mixed results were found [13]. Moreover, other studies found that treating LBP with MT showed no improvement [19]. There is still a lack of evidence regarding MT effectiveness, including manipulation and mobilization, with or without treatment, for pain or disability [14].

Thus, these studies do not clearly support the superiority of one type of intervention for treating chronic nonspecific LBP. Although the above treatments have been widely used, they show limited efficacy at best, with a recurrence rate of approximately 70% for LBP [9]. Despite a significant amount of scientific research in this area, there is still uncertainty about the most effective treatment. Thus, there are insufficient studies to demonstrate the greater or lesser effects of different therapeutic approaches in treating chronic nonspecific LBP. In this study, we aimed to evaluate the effects of spinal manual therapy and home-based exercises or supervised exercises on pain and functional status in individuals with chronic nonspecific low back pain.

2. Materials and Methods
2.1. Study Design

The study was conducted from July to October 2022 after receiving permission from the Lithuanian Sports University Biomedical Research Ethics Committee for Research Compliance. All participants signed written informed consent prior to the start of the study. The study was registered on clinicaltrials.gov (NCT05784168).

Our study included 60 subjects with chronic non-specific LBP who had a sedentary job and lifestyle. In total, 60 subjects were randomly divided into two groups: the manual therapy group (MTG, n = 30), and the exercise therapy group (ETG, n = 30). For 6 weeks, all patients were asked to perform a therapeutic exercise program at home.

2.2. Participants

Inclusion criteria for the study were men and women between the ages of 18 and 60 who experienced daily nonspecific (with no identifiable etiology) low back pain or almost
daily for at least 12 weeks. Participants evaluated baseline pain intensity of $\geq 3$ points on a numerical rating scale from 0 to 10. For 8 h/day, participants performed sedentary work, and lived a sedentary lifestyle. Exclusion criteria for the study included subjects taking pain medication, pregnant women, and those who had spinal operations, specific causes of back pain (spinal tumor, spinal fracture, spinal stenosis, radiculopathy), or infections, severe comorbidities (cardiovascular disease, respiratory problems, advanced rheumatoid arthritis, and uncontrolled diabetes) and contraindications to exercise or manual therapy.

2.3. Interventions

All participants were treated twice per week for 6 weeks in either the manual therapy group or the exercise therapy group. In addition, all participants were asked to independently perform an exercise program at home on days with no intervention (a physical therapist discussed the exercise program and training in detail with participants). Participants were asked to refrain from any additional treatment (including pharmacological treatment such as muscle relaxants, analgesics, or psychotropic drugs) for back pain during the study period. Before starting the intervention and after the intervention, the following tests were conducted: pain, disability, kinesiophobia, muscle endurance, and spine mobility.

2.3.1. Manual Therapy

MT procedures were performed by a physiotherapist and a manual therapy specialist with more than 10 years of experience. The intervention duration was 6 weeks (twice a week). We applied an optimal duration MT treatment scheme for chronic LBP [20]. Before performing MT, hypomobility or hypermobility of the lumbar spine was checked. Hypomobile vertebrae were manipulated. In each individual case, appropriate manipulation or manipulations were applied (Supplementary Figure S1).

2.3.2. Exercise Therapy

An exercise program supervised by a physiotherapist was applied for 6 weeks (twice a week). Before the exercises, each subject performed a light aerobic warm-up on stationary equipment. The exercise program consisted of spine stabilization, abdominal and back muscle strengthening, stretching, mobilization, and coordination training exercises (Supplementary Figure S2).

2.4. Outcomes

Back pain was assessed using the Numerical Rating Scale (NRS). Subjects evaluated their current pain intensity in numbers, with 0 indicating “no pain”, and 10 indicating “worst pain possible” [21]. The Oswestry Disability Index (ODI) was used to assess the impact of back pain on functional status and disability (the total percentage from 0 to 100) [22,23]. The Kinesiophobia Assessment Questionnaire (TAMPA) was used to assess fear of movement or repetitive injury in patients with pain (total scores ranged from 17 to 68) [24]. The Kraus–Weber abdominal and Ito back muscle static endurance tests were also conducted [25,26]. Schober’s test was used to assess lumbar spine mobility [27].

2.5. Statistics Analysis

In this study, subjects were divided into two groups using a simple random method (the 1:1 random ratio of the two groups). The sample size was selected using G*Power software version 3.1, as recommended by Hyun Kuang [28]. Following data collection, including the first five subjects who completed the study, the number of participants was determined based on the calculated sample effect size. At a mean effect size of $d = 0.8$, a significance level of alpha 0.05, and a power of 80%, our power analysis indicated that we would need 15 participants per group, accounting for a 10% loss to follow-up and 10% treatment non-adherence.

All data analyses were performed using IBM SPSS Statistics 23.0 software. Data were tested for normality using the Shapiro–Wilk test. Since the distributions were significantly
different from the normal distributions, the normality assumption was not met; therefore, statistical analysis of non-parametric criteria was used. The Mann–Whitney U test was used as a non-parametric statistical test for independent samples.

To investigate the effects of home-based exercises and manual therapy or supervised exercises on pain and functional status, a two-by-two (group: ETG, MTG; time: before, post) mixed ANOVA (main effect of time) model was calculated. The data were interpreted using the Greenhouse–Geisser correction, where the sphericity assumption was violated. Statistically significant comparisons were determined by post hoc testing with Bonferroni corrections, provided that the main effect of time attained a significant level. The effect size was measured using the partial eta squared ($\eta^2_p$) obtained from the mixed ANOVA output.

Statistical analysis results were significant at $p < 0.05$.

Minimal clinically important difference scores were determined according to the following formula [29,30]: $((\text{ODI raw score initial} - \text{ODI raw score final})/\text{ODI raw score initial} \times 100\%) \geq 30\%$. A minimal clinically relevant difference is the smallest difference that would concern patients or physicians. A minimal clinically important difference score reflects a patient’s sense of improvement or recovery, which correlates with minimal changes in their outcome score [31].

3. Results

A total of 60 participants (41 men and 19 women) were included in the study. Demographic data are shown in Table 1.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group MTG ($n = 30$)</th>
<th>Group ETG ($n = 30$)</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>44.2 ± 11</td>
<td>41 ± 8.4</td>
<td>0.07</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>24.2 ± 1.3</td>
<td>25 ± 3</td>
<td>0.78</td>
</tr>
<tr>
<td>Gender (no.)</td>
<td>18</td>
<td>23</td>
<td>0.44</td>
</tr>
<tr>
<td>men</td>
<td>12</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>women</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MTG—manual therapy group; ETG—exercise therapy group; BMI—body mass index; $p$—data compared between groups, $p > 0.05$.

The groups showed no significant differences in terms of pain, disability, kinesiophobia, abdominal and back muscle endurance, and spinal mobility at the initial evaluation ($p > 0.05$).

The data showed statistically significant differences between the results before the intervention and after 6 weeks of intervention (intra-group) (Table 2).

After the intervention, kinesiophobia values significantly decreased by 7% in ETG ($F = 42.2; p < 0.00; \eta^2_p = 0.71$) and 14% in MTG ($F = 15.1; p < 0.00; \eta^2_p = 0.79$).

After MT, clinically important differences in disability (ODI) and pain (NRA) were reduced by 70% ($F = 15.1; p < 0.00; \eta^2_p = 0.99$) and 14% in MTG ($F = 15.1; p < 0.00; \eta^2_p = 0.79$), respectively. After exercise therapy, clinically important differences in disability (ODI) and pain (NRS) were reduced by 78% ($F = 11.5; p < 0.00; \eta^2_p = 0.78$) and 68% ($F = 9.4; p < 0.00; \eta^2_p = 0.41$), respectively. There was no statistically significant difference between the groups ($p > 0.05$).

Muscle endurance and lumbar spine mobility values were significantly higher in both groups after 6 weeks of intervention ($p < 0.00$). After 12 MT interventions, lumbar spine mobility (Schrober’s test) increased by 40% ($F = 1.9; p < 0.00; \eta^2_p = 0.24$) and after exercise therapy by 38% ($F = 28.4; p < 0.00; \eta^2_p = 0.82$), which were clinically important differences.

Abdominal muscle endurance (Kraus–Weber test) improved by 29% ($F = 24.2; p < 0.00; \eta^2_p = 0.79$) after MT and 34% ($F = 57.6; p < 0.00; \eta^2_p = 0.67$) after exercise therapy, which were clinically important differences. Back muscle endurance (Ito test) improved by 18% ($F = 48.6; p < 0.00; \eta^2_p = 0.78$) after MT and 20% ($F = 14.2; p < 0.00; \eta^2_p = 0.76$) after exercise therapy.
Our results showed that time had a significant main effect on kinesiophobia (F = 193.6; 
$p < 0.00; \eta^2_p = 0.77$), spine mobility (F = 240.4; 
$p < 0.00; \eta^2_p = 0.81$), pain (F = 386.2; 
$p < 0.00; \eta^2_p = 0.87$), disability (F = 453.4; 
$p < 0.00; \eta^2_p = 0.89$), abdominal muscle endurance (F = 199.9; 
$p < 0.00; \eta^2_p = 0.77$) and back muscle endurance (F = 77.2; 
$p < 0.00; \eta^2_p = 0.57$) (Table 2).

After 6 weeks of intervention, no statistically significant differences between the 
groups were detected in pain, disability, and spinal mobility (p > 0.05). However, the 
groups showed statistically significant differences in kinesiophobia (p = 0.02), back muscle 
en endurance (p < 0.02), and abdominal muscle endurance (p < 0.03) (Table 2).

**Table 2.** Effects of intervention on variables in pain intensity, disability level, kinesiophobia, spine 
 mobility, and abdominal and back muscle endurance.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group</th>
<th>Before</th>
<th>Post</th>
<th>Within Group</th>
<th>Main Effect of Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinesiophobia (scores)</td>
<td>ETG</td>
<td>42 ± 3.2</td>
<td>39 ± 3.4</td>
<td>0.02</td>
<td>15.1</td>
</tr>
<tr>
<td></td>
<td>MTG</td>
<td>42 ± 5</td>
<td>36.2 ± 4.2</td>
<td></td>
<td>15.1</td>
</tr>
<tr>
<td>Spine mobility (cm)</td>
<td>ETG</td>
<td>5.2 ± 1.3</td>
<td>7.2 ± 1</td>
<td>0.53</td>
<td>28.4</td>
</tr>
<tr>
<td></td>
<td>MTG</td>
<td>5.2 ± 1</td>
<td>7.3 ± 0.5</td>
<td></td>
<td>1.9</td>
</tr>
<tr>
<td>Pain (scores)</td>
<td>ETG</td>
<td>6.3 ± 1.2</td>
<td>2 ± 2.1</td>
<td>0.23</td>
<td>9.4</td>
</tr>
<tr>
<td></td>
<td>MTG</td>
<td>6.3 ± 1.5</td>
<td>1.4 ± 1.4</td>
<td></td>
<td>4.9</td>
</tr>
<tr>
<td>Disability (%)</td>
<td>ETG</td>
<td>48 ± 8.4</td>
<td>10.5 ± 9.4</td>
<td>0.15</td>
<td>11.5</td>
</tr>
<tr>
<td></td>
<td>MTG</td>
<td>47 ± 10.5</td>
<td>14 ± 14.4</td>
<td></td>
<td>42.2</td>
</tr>
<tr>
<td>Abdominal muscle</td>
<td>ETG</td>
<td>218 ± 33.2</td>
<td>293 ± 17.3</td>
<td>0.03</td>
<td>57.6</td>
</tr>
</tbody>
</table>
enurance (s)                 | MTG     | 218 ± 68       | 282 ± 24.5     |              | 24.2               | 0.00              | 0.79         |               |               |
| Back muscle                | ETG     | 250 ± 37.1     | 300 ± 0.0 x    | 0.02         | 14.2               | 0.00              | 0.76         | 77.2          | 0.00              | 0.57         |
enurance (s)                 | MTG     | 250 ± 56       | 294 ± 14       |              | 48.6               | 0.00              | 0.78         |               |               |

Abbreviations: MTG—manual therapy group; ETG—exercise therapy group; \( \eta^2_p \)—partial eta-squared. Note: 

x—All subjects in this group passed the maximum (300 s) Ito test time.

4. Discussion

Our study results showed reduced LBP and disability and improved functional status 
after 12 MT sessions and a 6-week home-based therapeutic exercise program, as well as 
12 sessions of physical therapy exercises supervised by a physiotherapist and 6 weeks of 
home-based therapeutic exercises.

A previous study showed that eight MT sessions combined with core stabilization 
or aerobic exercise significantly reduced disability in individuals with LBP [32]. At the 
beginning of this study, the subjects described LBP as moderate pain and functional 
disability (ODI) as severe disability. After the intervention, they described LBP as mild 
pain and ODI as minimal disability. Therefore, after 12 MT sessions, pain reduced by 78% 
and ODI by 70%. After exercise therapy, the pain reduced 68% and ODI by 78%.

Similar results with minor variation were also obtained by other researchers, who 
found a clinically and statistically significant reduction in pain and functional disability 
after 12 MT sessions [20,33]. Several studies investigating the effects of therapy on chronic 
LBP have based their findings on the statistical significance of the results rather than clinical 
relevance [34]. As defined by the practice guidelines for minimal clinically important 
difference (MCID), a clinically significant improvement occurs if, when comparing the pre-
and post-treatment effects of individual treatment measures, LBP and functional disability 
are reduced by 30% compared to the initial level [29], or if the final ODI score is equal to or 
less than 20% [30]. In our study, the reduction in initial pain intensity levels and disability 
significantly exceeded the recommended MCID reduction of 30%. The positive results of 
our study may have been influenced by the optimal number of 12 MT and exercise therapy 
interventions over 6 weeks. These findings support the results of a previous study, where 
the best treatment effect was determined to be 12 MT interventions over 6 weeks for chronic 
nonspecific LBP and functional disability [20].

The reduction in disability may have been influenced by increased spine mobility after 
the intervention. Similar results have been reported by other researchers, who observed 
a decrease in spinal stiffness and mobility after MT in individuals with LBP [33,35–37].
Spinal mobility and stiffness are influenced by the active contraction of the spinal muscles and normal lumbar neuromuscular control; in other words, when the trunk is fully flexed, the paraspinal muscles relax [33,38]. However, in individuals with LBP, increased lumbar paraspinal muscle activity persists after full lumbar flexion, resulting in either an absent or delayed flexion-relaxation phenomenon [33,38,39]. Due to impaired lumbar neuromuscular control, the paraspinal muscles redistribute activity to meet movement demands and control the spine during lumbar flexion. Stiff lumbar spines and impaired flexion-relaxation are associated with greater disability in individuals with LBP [33].

In this study, abdominal muscle endurance improved by 29% after MT and 34% after exercise therapy, respectively. Back muscle endurance improved by 18% after MT and 20% after exercise therapy, respectively. Since the most effective exercise components for patients with chronic back pain have not been determined, our study participants underwent different types of exercises: abdominal and back muscle strengthening, stretching, and core stabilization exercises. Patients with LBP had decreased abdominal muscle strength, core flexor and extensor muscle imbalance, and decreased lumbar mobility.

We believe that a clinically significant reduction in pain and disability is associated with MT and exercise therapy programs, including home exercises. To ensure positive and long-lasting treatment effects, we motivated people with LBP to change their lifestyle and adopt therapeutic home exercises into their daily routines. The main goal of home exercises was to prolong the positive effects of LBP treatment on functional status and prevent LBP recurrence in the long term. A recent meta-analysis focusing on LBP prevention through exercise found that self-administered exercise resulted in a 33% reduction in back pain risk [10]. Home exercise programs alone have been effective in reducing chronic LBP and improving functional status; however, the effects are minor [40–42]. We found only a few studies comparing the effects of MT, exercise therapy, and home exercises on chronic LBP [43–45]. Daulat and Goodlad’s [43] study results showed that after a home-based total body strengthening program (12 weeks, 3 times a week) combined with manual therapy (3 procedures), as well as standard physiotherapy exercises at home combined with MT, functional disability was reduced by about 26% and pain by 32–40 units. These results were considered clinically relevant in treating nonspecific chronic LBP. Schulz et al. [44] compared the effectiveness of adding 12 weeks of MT or exercise therapy to a home exercise program for adults with LBP. Pain intensity decreased by 30–40% after treatment in all three groups; the greatest difference was in the MT and home exercise group than in the home exercise group. Bronfort et al. [46] showed that MT compared to a home exercise program or supervised exercise did not indicate any differences between interventions for pain or disability in either the short or long term. In a study conducted by Tagliaferri et al. [45], one group of subjects received MT and 12 physical therapy sessions over 6 months. They performed motor control exercises for transverse abdominal TrA, multifidus, and pelvic floor muscles, as well as postural correction exercises. The same home exercise program was administered to participants every day between sessions. Another group of subjects participated in aerobic and muscle resistance training twice a week for 6 months and exercised at home by walking or jogging. The main study findings were that after six months, pain and disability decreased, lumbar muscle endurance improved, and kinesiophobia decreased in both groups with chronic LBP. However, disability and kinesiophobia decreased and lumbar muscle endurance increased more in the aerobic exercise and muscle resistance group than in the MT and motor control exercise group [45]. In our study, we found that participants’ kinesiophobia decreased more after MT than after exercise therapy.

Although studies have widely used MT to treat LBP, the results have been mixed. According to Hidalgo et al. [18], various MT procedures combined with exercise can improve patients’ LBP management. Standaert et al. identified that structured exercise and MT provide equivalent benefits for pain and functional improvement in those with chronic LBP, with clinical benefits evident within 8 weeks of treatment [47]. In individuals with recent-onset LBP, MT reduced pain and improved function for up to 6 weeks [48]. Another study showed that MT combined with trunk-strengthening exercises and education had a
statistically significant reduction in disability for people with recent-onset LBP. However, the improvement was minor and did not reach the minimum clinically significant difference compared to usual care [49]. Eight-session MT was more effective in reducing chronic LBP and improving patients’ range of motion and trunk muscle strength than conventional kinesiotherapy [50]. Sixteen MT procedures reduced LBP and functional disability and increased spinal range of motion more than exercise therapy. Consequently, 67% of MT patients returned to work immediately after a 2-month treatment period compared with 27% of exercise therapy patients [35]. Another study showed that spinal stabilization exercises and MT had the same effect on quality of life, but MT is more effective at reducing LBP and disability [51].

Our study results showed that manual therapy combined with home exercises is an effective method for treating LBP; however, when comparing manual therapy and exercise therapy, the clinical benefits in individuals with chronic non-specific LBP are equivalent.

This study was limited by its short duration and no control group. Furthermore, of the duration, quality, and performance of home exercises was not monitored. Therefore, the lasting effects of treatment on pain and disability may be a relevant topic for future studies.

5. Conclusions

Home exercise programs and manual therapy, or home exercise programs and supervised therapeutic exercises by a physical therapist, showed relevant clinical changes in low back pain, disability, and functional status.

Reduction in low back pain and disability as well as increased lumbar spine mobility were clinically important in both groups. Increased abdominal muscle endurance was clinically important in the exercise therapy group.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/app14051725/s1, Figure S1: Exercise program; Figure S2: Manual therapy procedures.

Author Contributions: Conceptualization, S.S. and V.P.; methodology, V.P. and S.S.; software, V.P.; validation, V.P.; formal analysis, V.P.; investigation, V.P.; resources, V.P.; data curation, V.P.; writing—original draft preparation, V.P. and S.S.; writing—review and editing, S.S. and V.P.; visualization, V.P. and S.S.; supervision, S.S.; project administration, V.P. 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.

Data Availability Statement: Datasets are available on request to the corresponding author. The data are not publicly available due to privacy.

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

References