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Patient-reported efficacy 6 months after a 4-week rehabilitation intervention in individuals with chronic ankle instability

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Objective: To track the patient-reported efficacy of a 4-week intervention [wobble board (WB) or resistance tubing (RT)] in decreasing symptoms of Chronic Ankle Instability (CAI) at 6 months post-intervention (6PI) as compared to immediately post-intervention (IPI). **Design:** Randomized controlled trial. **Participants:** Fourteen out of 21 participants (66.7%) responded to an electronic 6 month follow-up questionnaire (age: 19.6±0.9years, height: 1.63±0.18m, weight: 70.5±16.3kg, 2 males, 12 female, 5 WB, 9 RT). All participants met CAI criteria at enrollment, including a history of ankle sprain and recurrent episodes of giving way. **Interventions:** Participants completed either RT or WB protocols, both 12 sessions over 4 weeks of progressive exercise. WB sessions consisted of five 40 second sets of clockwise and counter-clockwise rotations. RT sessions consisted of 30 contractions against resistance tubing in each of 4 ankle directions. **Main Outcome Measurements:** Patient reported symptoms of giving-way pre-intervention and at 6PI, Global rating of change (GRC) frequencies at IPI and 6PI, and re-sprains at 6PI were reported descriptively. Changes in Global rating of function (GRF) and giving-way were compared using Wilcoxon tests, while GRC was compared with Fisher's exact test. **Results:** All participants reported giving-way pre-intervention, only 57.1% reported giving-way at 6PI. Re-sprains occurred in 21.4% of participants. Giving-way frequency ($P=0.017$), but not GRF or GRC ($P>0.05$), was significantly different at IPI versus 6PI. **Conclusions:** Simple 4-week interventions maintained some but not all improvements at 6PI. Importantly, at least 42.9% of participants would no longer meet the current study's CAI inclusion criteria due to a reduction in giving-way.

Introduction

Ankle sprains are one of the most common injuries associated with physical activity, with a prevalence of 42-70%.[1, 2] Developing following initial sprain in 32±9% of patients, chronic ankle instability (CAI) is characterized by sensations of giving-way of the ankle, repeated sprains and instability.[3-6] The residual symptoms of CAI can limit physical activity and activities of living for years post-injury,[3, 7, 8] and have been reported to decrease health related quality of life.[9, 10]

Thus, treatment that improves the long-term outcomes of this pathology is very important to clinicians. Currently, there is limited data available on long-term (defined as ≥6 months) maintenance of improvements seen after rehabilitation interventions for CAI. For example, of 14 controlled interventions targeted at CAI reviewed by O'Driscoll and Delahunt in 2011[11], only 1 reported follow-up of 6 months or greater;[12] instead most studies recorded laboratory measures (e.g. strength, force plate variables, muscle latency) immediately following the intervention. Eils and Rosenbaum[12] reported a 60% reduction in frequency of ankle inversion episodes (giving-way) 1 year after a 6 week multi-station proprioceptive exercise program. Recent studies are more likely to include important patient-oriented outcomes measures in addition to clinician-oriented and laboratory measures, but still largely lack long-term follow-up.[13-22]

While there is limited long-term data on interventions specifically targeted towards decreasing symptoms of CAI in currently symptomatic patients, a larger evidence base exists regarding interventions aimed at preventing acute lateral ankle sprains and/or the incidence of CAI post-acute ankle sprain. Specifically, prophylactic balance and coordination training (including wobble board training) in a general athletic population can decrease injury incidence, especially in those with a previous history of ankle injury.[23] Additionally, balance and coordination training following an acute lateral ankle sprain reduces the risk of re-injury in the

next 8-12 months by 54-76%,[24, 25] and prevented felt instability of the ankle in all training group participants (compared to an incidence of 25% in the control group).[25] Despite its common clinical use, the efficacy of ankle joint strengthening using resistance tubing at reducing CAI or repeated sprains has not been previously reported in the literature (although it has been shown to increase strength[26]).[27]

In summary, while there is good evidence for the effectiveness of rehabilitation interventions to prevent initial and recurrent sprains of the ankle, there is insufficient evidence regarding the long-term effectiveness of interventions specifically targeting stability in individuals who have already developed CAI. The immediate effect of an intervention is important and helpful in understanding the mechanisms by which an intervention either is or is not effective.[13-22] However, if benefits obtained through rehabilitation do not last, the utility of the intervention is limited. Although potentially costly and logistically difficult to obtain, long-term follow-up data provides essential information to clinicians about the efficacy of treatment. Thus, it was the purpose of the current research to track the patient-reported efficacy of a 4-week intervention aimed to decrease symptoms of CAI at 6 months after the completion of the intervention.

Methods

Participants

Twenty-one physically active individuals with CAI were recruited from a university undergraduate population. These individuals are a subset of a larger two-site randomized controlled trial[27]; all participants from 1 clinical site were recruited for this 6 month follow-up. Inclusion criteria included a history of ≥1 inversion ankle sprain which required protected weight bearing, immobilization, and/or limited activity for ≥ 24 hours.[28] The initial sprain must have

occurred greater than 1 year prior to study enrollment.[29] Additionally, subjects had to self-report recurrent episodes of giving-way, and have a Cumberland Ankle Instability Tool (CAIT) on the involved side of ≤ 25.[30] In the case of bilateral instability, the subjectively reported worse ankle was considered the involved ankle.

Participants were excluded if they had a history of fracture or surgery to the involved knee, lower leg or ankle, or if they participated in <1.5 hours of moderate-vigorous physical activity per week. Participants were also excluded if they had any acute symptoms of lower extremity musculoskeletal injury on the day of testing. The University Institutional Review Board approved the study.

Testing Procedures

Participants reported to the testing facility for enrollment procedures and baseline evaluation. Following informed consent, participants completed an injury history questionnaire, the CAIT and a global rating of function (GRF). The injury history questionnaire collected information about the initial ankle sprain, symptoms of giving way and re-sprains, and rehabilitation history (see Table 1). A customized computer program (Access, Microsoft Corporation, Redmond, WA) recorded and scored the CAIT and GRF. The GRF is a single-item question: "On a scale from 0-100, what would you rate your ankle use as if 0 = no use of your ankle (cannot put weight on it at all) and 100 = full use of your ankle (not limited at all)?" The CAIT evaluates perceived ankle instability, has excellent test-retest reliability (intraclass correlation coefficient $[ICC]_{2,1} = 0.96$), and is scored on a 30-point scale, with lower scores indicating decreased stability.[30, 31]

Next, the investigator measured and recorded participant height, weight, and ankle laxity. Ankle laxity testing procedures have been previously described,[32, 33] but in brief, consisted of a standardized anterior drawer test and talar tilt test. Both tests were graded on a scale of 1 to 5

per the methods of Ryan[33] then condensed into clinically-relevant categories of positive (>3) and negative (≤3). Intra-rater reliability of these methods has been reported as ICC>0.80 and standard error of the measure <0.25 points.[34] Participants completed baseline testing that included completion of several additional patient-oriented questionnaires and clinical tests, which are reported elsewhere.[27] Following all baseline testing, the participant was block randomized to either the resistive tubing (RT) or wobble board (WB) training group. The WB protocol[16,27] has been previously reported, in brief it consisted of five repetitions of standing balance on a wobble board while rotating clockwise and counterclockwise for 40 seconds each repetition. The RT protocol has also been previously reported,[26, 27] and in brief consisted of resistance tubing exercises in each of four ankle movements (dorsiflexion, plantarflexion, eversion and inversion) for 3 sets of 10 repetitions. Both protocols were progressed systematically as previously described. The participant received instruction for his or her training group and completed the first exercise session on the enrollment day. Each participant then continued to complete 3 supervised sessions each week for 4 weeks (total of 12 sessions).[35-37]

Upon completion of the 4 week protocol, all baseline measures were post-tested and participants completed a global rating of change (GRC) survey. The GRC asked participants to rank on a 13-point scale any change in the condition of their ankle. Participants selecting any of the nine responses ranging from "a very great deal worse" to "somewhat better" were dichotomously categorized as not improved, whereas the four responses ranging from "moderately better" to "a very great deal better" were categorized as improved. Participants did not formally continue ankle exercises after the 12th session. It is possible (but unlikely) participants continued these exercises on their own as they were not given the rehabilitation equipment nor was it easily accessible to them. Then at 6 months post-completion, a single

email was sent to all participants requesting that they complete a simple 7-question online survey. This survey recorded ankle sprain incidence, the presence and frequency of episodes of giving-way, GRC and GRF at 6 months post-intervention.

Data Analysis

Patient-reported symptoms of giving-way pre-intervention and at 6 month post-intervention, and GRC frequencies immediately post-intervention and at 6 months post-intervention are presented descriptively (Table 2). A Wilcoxon signed rank test was used to test differences between (1) GRF immediately post-intervention and at 6 months post-intervention**,** and (2) giving-way frequency pre-intervention and at 6 months post-intervention. GRC was compared immediately post-intervention to 6 months post-intervention using Fisher's exact test. Data is presented separately by treatment group and combined across treatment groups; however, due to small sample size statistical analysis was only performed on combined data. To assess for bias in follow-up survey responders versus those lost to follow-up, characteristics of both groups were also compared: continuous variables (such as height, age, etc.) were compared using paired t-tests, all categorical variables (such as gender, laxity, etc.) were compared using Fisher's exact test except for initial injury severity which was compared using a chi-squared test. All alpha were set a priori at $\alpha=0.05$.

Results

Fourteen out of 21 participants (66.7%) responded to an electronic 6 month follow-up questionnaire. Respondent demographics and injury characteristics are shown in Table 1. Four recurrent ankle sprains were reported in 3 separate participants; all other patient reported outcomes are shown in Table 2. GRF did not change significantly between measurement

immediately post-intervention and 6 months later (Z= -1.185, P=0.236). However, episodes of giving-way per month were significantly decreased at 6 months post-intervention compared to pre-intervention (Z= 02.121, P=0.034). The frequency of participants whose GRC indicated they were improved was not different between immediately post-intervention and 6 months later (Fisher's exact test P=0.559). Individuals who were lost to 6 month follow-up were not significantly different than survey participants in any variable except whether or not they had previously completed some type of ankle rehabilitation (Table 3). Specifically, individuals lost to follow-up reported a prior history of ankle rehabilitation at a greater frequency than follow-up survey participants.

Discussion

Twenty-one ankle rehabilitation participants were invited to complete a 6 month follow-up survey, and 14 (66.7%) responded. In these participants, the simple 4-week WB and RT interventions used in the current study maintained improvements in GRF and GRC at 6 months post-intervention, decreased total number of participants reporting episodes of giving-way to 43%, as well as decreased the monthly frequency of these episodes of giving-way. However, re-current ankle sprains were still experienced by 3 (21.4%) participants.

Effect on symptoms of giving-way

To our knowledge, this is the first time that long-term follow-up has been completed on a simple single-exercise protocol like our WB and RT. The limited existing literature on long-term results for individuals with CAI only provides evidence regarding a comprehensive multi-exercise program.[12] Eils and Rosenbaum[12] reported a 60% reduction in episodes of giving-way 1 year post-intervention, which is similar to the magnitude of reduction found in the current study

(61%). Additionally, previous research using the same WB and RT protocol documented improvements in patient- and clinician-oriented outcomes immediately post-intervention.[27] Interestingly the magnitude of those differences was similar to that reported in previous multi-exercise interventions.[27] This indicates that immediately post-intervention, the RT and WB protocols are at least as effective as more complex interventions, while potentially saving time and resources. The current research adds additional evidence that a single-exercise protocol can also be effective at reducing symptoms of CAI for least 6 months post-intervention.

Our CAI inclusion criteria largely aligned with the International Ankle Consortium (IAC) position statement (which was published after data collection began).[29] This statement recommends inclusion criteria for CAI include at a minimum (a) a history of 1 significant ankle sprain, and (b) a history of the injured ankle giving-way and/or recurrent sprain and/or feelings of instability.[29] More specifically, participants should report at least 2 episodes of giving-way in the past 6 months and self-reported instability would preferably be confirmed with questionnaires such as the CAIT.[29] While the first criterion (history of ankle sprain) is non-modifiable, the second criterion can change over time. Perhaps the most significant finding of the current study was that 42.9% of participants would no longer meet CAI inclusion criteria due to lack of giving-way at 6 month follow-up. Unfortunately, we were not able to re-administer the CAIT at 6 month follow-up, thus, it is unknown whether even more participants would have been excluded for exceeding the CAIT cutoff score of $\leq$25. Even without this data, it is important that almost half of participants had improved sufficiently to no longer be classified as CAI according to IAC criteria.[29]

Effect on Global Rating of Change

Although not significantly different, the number of participants who self-reported that the condition of their ankle was improved was lower at 6 months than directly after the intervention

(71.4% improved immediately post-intervention, 50% improved at 6 months). Thus, by this measure the current protocol demonstrated long term success for approximately half of participants, but failed the other half. Obviously, the ideal intervention would achieve both short-term results and maintain long-term success in 100% of patients. While achieving 100% success may not be realistic, improving on the current results is a realistic goal. Future work should test the long-term efficacy of other rehabilitation protocols or interventions, in an attempt to identify more effective techniques. One specific recommendation would be to test the efficacy of an ongoing maintenance plan following a formal intervention. The individuals in the current study were not instructed (nor provided the resources) to continue rehabilitation after the initial 4 week intervention, making it unlikely that any continued with their rehabilitation program. Based on this study design, it is unknown whether an ongoing maintenance exercise plan would have affected the 6 month follow-up data. However, common clinical reasoning is that some form of maintenance exercise is essential to maintain results. Additionally, it is interesting to note that based on reported GRC immediately and 6-months post-intervention, there may be a difference in maintenance needs for WB versus RT. Future research into the best dose and exercise type for maintenance would aid clinicians in developing evidence based exercise prescription. Additionally, future work should identify which modifiable factors were most predictive of self-reported long-term improvement as measured by the GRC, and then attempt to modify those factors to improve treatment efficacy.

Limitations and Considerations for Future Research

The chief limitation of this study is the small sample size. Unfortunately, due to an IRB limitation at one (of two) clinical sites of the original larger study, we were only able to invite the 21 participants from one clinical site to participate in the follow-up survey. Due to the small sample size we were not able to statistically compare the efficacy of our two interventions (WB

or RT). As our sample was recruited exclusively from a small residential university, our 6 month response rate was likely affected when the 6 month follow-up fell over summer break or post-graduation. Although the response rate of 67% was lower than desired, comparison of the characteristics of the individuals lost to follow-up versus those who responded to our survey provided evidence of a representative sample (Table 3). Of sixteen characteristics (including injury severity, giving-way frequency, laxity, etc.) only the frequency of a reported history of prior rehabilitation differed between survey responders and non-responders. It is unclear the meaning (if any) of this singular difference. Future work should document the long-term efficacy of these interventions in a larger sample so that statistical comparisons can be made and conclusions drawn concerning the most effective technique.

We defined long-term follow-up as 6 months post-intervention as this seems to be the minimum long-term follow-up period in related literature. Ideally, we would have tracked subjects for a longer time period, however, practical considerations limited follow-up to 6 months. Future research should track efficacy at 1 year and further time points. Additionally, if a wash-out effect over time is noted, it would be clinically advantageous to investigate the minimum frequency of exercise required to maintain rehabilitation benefits. For example, would 1 rehabilitation session a week be sufficient to maintain improvements?

Our follow-up survey asked participants to self-report the incidence of recurrent sprain and frequency of giving-way. Self-reported data is potentially subject to recall bias or error. Specifically, participants could have erred in their definition of what constituted a re-sprain. However, the questionnaire did attempt to address this issue by including the clarification "A sprain is an acute ankle injury, generally resulting in pain, swelling and decreased function". Future research could require all subsequent sprains to be documented by a healthcare provider,

however, given the fact that many people do not seek treatment for ankle sprains[38] this may underestimate the true frequency of recurrent injury.

Conclusions

A simple 4-week intervention aimed at reducing the symptoms associated with CAI maintained some but not all improvements at 6 months post-intervention. Importantly, 42.9% of participants no longer experienced giving-way, a hallmark of CAI. Results were achieved using a single-exercise protocol (WB or RT) that involved minimal time and resources, making it easily accessible to patients and clinicians.

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Table 1. Participant Demographics and Injury Characteristics

Descriptor	Wobble Board (n=5)	Resistance Tubing (n=9)	Combined (n=14)
Age, y	19.40±0.55	19.67±1.12	19.57±0.94
Height, m	1.61±0.27	1.64±10.93	1.63±0.18
Weight, kg	77.04±19.81	66.81±13.83	70.48±16.26
Time since initial sprain, y	5.80±3.96	6.11±3.98	6.00±3.82
Limited weight bearing, d	18.25±27.90	13.83±14.66	15.60±19.60
Lifetime number of re-sprains	1.80±2.05	1.67±1.50	1.71±1.64
Episodes of giving-way, month	4.20±4.49	9.01±19.30	7.29±15.53
Gender	2 (40%) male 3 (60%) female	0 (0%) male 9 (100%) female	2 (14%) male 12 (86%) female
Initial ankle sprain evaluated by a medical professional?	4 (80%) Yes 1 (20%) No	6 (67%) Yes 3 (33%) No	10 (71%) Yes 4 (29%) No
Severity of initial ankle sprain	1 (20%) Mild 2 (20%) Moderate 1 (20%) Severe 1 (20%) Unknown	1 (11%) Mild 3 (33%) Moderate 2 (22%) Severe 3 (33%) Unknown	2 (14%) Mild 5 (36%) Moderate 3 (21%) Severe 4 (29%) Unknown
Rehabilitation performed?	1 (20%) Yes 4 (80%) No	1 (11%) Yes 8 (89%) No	2 (14%) Yes 12 (86%) No
Rehabilitation supervised by therapist?	1 (100%) Yes 0 (0%) No	1 (100%) Yes 0 (0%) No	2 (100%) Yes 0 (0%) No
Anterior drawer laxity	2 (40%) positive 3 (60%) negative	6 (67%) positive 3 (33%) negative	8 (57%) positive 6 (43%) negative
Talar tilt laxity	2 (40%) positive 3 (60%) negative	4 (44%) positive 5 (56%) negative	6 (43%) positive 8 (57%) negative

Values are presented as either mean ± standard deviation or n (percent).

Table 2. Participant reported outcomes at 6 months post-intervention

Outcome	Wobble Board (n=5)	Resistance Tubing (n=9)	Combined (n=14)
Episodes of giving way, yes or no?			
Pre-intervention	5 (100%) Yes 0 (0%) No	9 (100%) Yes 0 (0%) No	14 (100%) Yes 0 (0%) No
6 mo. Post-intervention	1 (20%) Yes 4 (80%) No	7 (78%) Yes 2 (22%) No	8 (57%) Yes 6 (43%) No
Episodes of giving way per month			
Pre-intervention	4.20±4.50	9.02±19.30	7.29±15.53[a]
6 mo. Post-intervention	6.00±13.42	1.09±1.26	2.84±7.89[a]
Global rating of change			
Immediately post-intervention	5 (100%) improved 0 (0%) not improved	5 (56%) improved 4 (44%) not improved	10 (71%) improved 4 (29%) not improved
6 mo. Post-intervention	3 (60%) improved 2 (40%) not improved	4 (44%) improved 5 (56%) not improved	7 (50%) improved 7 (50%) not improved
Global rating of function			
Immediately post-intervention[b]	95.50±2.52	89.75±6.90	91.67±6.33
6 mo. Post-intervention	90.00±16.96	90.89±11.21	90.57±12.89
Re-sprain incidence			
6 mo. Post-intervention	1 (20%)	2 (22%)	3 (21%)

Numbers are presented as mean ± standard deviation, or n (percent).
[a] Significant difference between pre-intervention and 6 months post-intervention
[b] Total N = 12 due to missing data for 2 subjects (1 wobble board, 1 resistance tubing)

Table 3. Characteristics of Survey Responders versus Non-responders

Descriptor	Responders (n=14)	Non-responders (n=7)	P-value
Age, y	19.57±0.94	19.86±1.22	0.557
Height, m	1.63±0.18	1.70±0.08	0.328
Weight, kg	70.48±16.26	71.07±10.05	0.930
Time since initial sprain, y	6.00±3.82	7.00±3.46	0.589
Limited weight bearing, d	15.60±19.60	7.14±5.15	0.286
Lifetime number of re-sprains	1.71±1.64	2.00±1.63	0.710
Episodes of giving-way, month	7.29±15.53	2.67±2.73	0.484
Global rating of function, immediately post-intervention	91.67±6.33	90.71±5.12	0.740
Global rating of change, immediately post-intervention	10 (71%) improved 4 (29%) not improved	5 (71%) improved 2 (29%) not improved	1.000
Gender	2 (14%) male 12 (86%) female	2 (29%) male 5 (71%) female	0.574
Initial ankle sprain evaluated by a medical professional?	10 (71%) Yes 4 (29%) No	6 (86%) Yes 1 (14%) No	0.624
Severity of initial ankle sprain	2 (14%) Mild 5 (36%) Moderate 3 (21%) Severe 4 (29%) Unknown	1 (14%) Mild 5 (71%) Moderate 0 (0%) Severe 1 (14%) Unknown	0.369
Rehabilitation performed?	2 (14%) Yes 12 (86%) No	5 (71%) Yes 2 (29%) No	0.017[a]
Rehabilitation supervised by therapist?	2 (100%) Yes 0 (0%) No	4 (57%) Yes 3 (43%) No	0.120
Anterior drawer laxity	8 (57%) positive 6 (43%) negative	2 (29%) positive 5 (71%) negative	0.361
Talar tilt laxity	6 (43%) positive 8 (57%) negative	6 (86%) positive 1 (14%) negative	0.159

Values are presented as either mean ± standard deviation or n (percent).
[a] Significant difference between groups using Fisher's exact test