

**A critical appraisal of “RegentK and Physiotherapy Support Knee
Function after Anterior Cruciate Ligament Rupture without
Surgery after 1 Year: A Randomized Controlled Trial”**

By

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**In partial fulfillment of the
requirements for the course:**

PT 7240 Evidence-Based Practice in Physical Therapy

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October, 2020

Abstract

The critical appraisal of this article was completed within the context of the clinical question: In young adult patients suffering from a torn anterior cruciate ligament (ACL), can a physical therapy program alone produce an outcome equal to, or greater than, a treatment plan requiring surgery. This appraisal is to determine whether a conservative treatment for an ACL injury can provide the best outcome for patients. Providing patients with the best possible outcome should be paramount for the physical therapist. This study investigates the effectiveness of two types of conservative treatment. The study is a randomized controlled trial, twenty participants, of no significant difference, were divided into two treatment groups, both receiving conservative treatment for a ruptured ACL, RegentK and myofascial mobilization technique (MMT). Both groups underwent treatment for one year with outcome measures being taken before, during, and after the treatment. The outcome measures used were MRI, International Knee Documentation Committee (IKDC) 2000 score, and standard clinical test. The authors clearly reported these scores and after analysis, both groups were found to have no significant difference. Both groups were found to have returned to full function based on the outcome measures. The authors used quality evidence for the discussion and support of their findings and further connected the results of this study to current literature. The article presented for critical appraisal supports the consideration of conservative treatment for ACL recovery to maximize the outcome for each patient.

Key words

Conservative intervention, anterior cruciate ligament, ACL reconstruction, RegentK, myofascial mobilization technique

Introduction

Recovering from an anterior cruciate ligament (ACL) tear can be both mentally and physically difficult as well as expensive. It should be the goal of the therapists to be able to provide the most effective treatment to facilitate the efficient return to prior level of function for the patient. The current “gold standard” of ACL tear recovery is surgical intervention. Even though surgery is the most widely used treatment of ACL ruptures, it is important to use quality research to continue searching for a better alternative to ensure the best outcome for patients. The reason for this critical appraisal is to answer the clinical question: In young adult patients suffering from a torn ACL, can a physical therapy program alone produce an outcome equal to, or greater than, a treatment plan requiring surgery.

Methods

The literature review was conducted using PubMed.gov with the search words, conservative AND ACL. To focus the search results, only clinical studies, clinical trials, meta-analysis, and systemic reviews in English were included. This was to ensure the results only included primary research that could be understood without a translator. The search criteria were also limited to young adult (18-35 years) humans to match inclusion criteria. The inclusion criteria for this critical appraisal were studies investigating ACL recovery in young adult patients using conservative protocols. The use of these inclusion and search criteria resulted in twenty-three hits for review.

The article presented for this critical appraisal is “RegentK and Physiotherapy Support Knee Function after Anterior Cruciate Ligament Rupture without Surgery after 1 Year: A Randomized Controlled Trial” by Michael Ofner, Andreas Kastner, Gerhard Schwarzl, Hermann

Schwameder, Nathalie Alexander, Gerda Strutzenberger, and Herald Walach. This study was conducted in Austria and published in the November 2017 issue of Complementary Medicine Research. The study was designed to address whether the conservative treatment RegentK could provide a better outcome than myofascial mobilization technique (MMT) for anterior cruciate ligament (ACL) repair. This study was selected for appraisal due to its design and the methods used for intervention and data collection. The study also directly addresses the clinical question and will be useful in providing an answer. It specifies conservative interventions to be used as an alternative to surgery and shows they can be as effective as surgery for a ruptured ACL.

Results

Summary of the study

The study analyzed the recovery of twenty subjects and was organized using the randomized controlled trial format to compare the outcome of one session of two conservative treatments, RegentK and MMT, on the subjects' recovery. MRI was taken pre and post-study in addition to the International Knee Documentation Committee (IKDC) 2000 score and other clinical testing being recorded at several intervals throughout the study. Both groups were randomly divided and had similar baselines at the outset of the study. The analysis of the results showed treatment duration was a leading factor on a positive outcome and both groups produced similar results. Participants of both groups returned to full function and activity level after one year. Based on the results of the study, one session of either RegentK or MMT, lasting approximately one year, can lead to a positive outcome and recovery from a torn ACL.

Appraisal of the study introduction

The authors effectively used the introduction to introduce the topic and give the necessary background information on the study and its goals. The authors utilized the introduction to address keywords in the title and to support the aims of the study with the findings from a literature review. The references used in this section are of good quality. The independent variable in this study is which type of conservative treatment the patient receives, RegentK, or MMT. The dependent variables are the overall outcome of the patient's ACL recovery and their outcome measures. Overall, this introduction is clear and well written.

While the introduction was well written, improvements could be made to better inform the reader. The high attrition rate of the study could be mentioned to address the impact of attrition on the results of the study. Another improvement would be a better explanation of the test group demographics.

Appraisal of the study methods

This study is an experimental design, specifically, a double-blind randomized controlled trial with longitudinal duration. The between-subject design of the study compared two treatment groups, patients treated with RegentK and those treated with MMT. The between-subjects design allows the comparison to determine the better treatment option for patients. During enrollment of the study, those responsible for enrolling the patients were blinded to the assignment groups. Additionally, both groups were found to have no significant difference demographically and the only difference in management was the intervention. No significant difference between the two groups allows for the lowest possibility of uncontrollable factors skewing the result. The outcome measures used were the IKDC 2000 subjective functional score, standard clinical tests,

and MRI. The measures were accurately described facilitating a clear interpretation of data. Additionally, the outcome assessors were blinded to the treatment groups, minimizing the chance of bias. The collected data were compared using a repeated-measures analysis of variance, which was appropriate.

The study only tracked twenty patients, which was later worsened by the attrition of eight patients who dropped out for ACL reconstruction surgery (3) and personal reasons (5) causing the authors to adjust the data for inconsistencies where applicable. The authors state this did not statistically affect the outcome; however, a larger participant pool would have given a better representation of the population and allowed for a larger margin of error in the attrition of subjects. The other two weaknesses are concerning the RegentK treatment. The clinician performing the RegentK intervention, a public figure in ACL recovery, was the treatment's creator and it is still relatively proprietary. Although the patients were blinded to their treatment group, the clinician's fame was a potential introduction of bias, as the patients recognized his treatment. Additionally, due to the proprietary nature of the RegentK treatment, a better description of the intervention would aid in the future repeatability of the study.

Appraisal of the study results

The results section is organized and succinctly states the results of the outcome measures and the study in the same order they were introduced. Also, these results do effectively address the hypothesis put forth in the introduction. The tables and graphs are presented clearly and are labeled and explained. The values used for determining statistical significance are the p-value threshold at 0.05 and a confidence interval of 95%. These are appropriate and were used to find no significant difference between the test groups. The only statistically significant value found

was the effect of treatment length on the outcome. While the results do not support the hypothesis of the paper, they are still clinically relevant.

The authors do not mention the number needed to treat or minimal clinical significance. This potentially calls into question how to apply the interventions in a clinical setting. Additionally, the authors do not list the results for all outcome measures directly. However, the authors do mention earlier in the article the omitted results would be reported separately.

Appraisal of the study discussion

The authors of this study begin the discussion by providing a foundation for expounding on their results by starting with a recap of the results. The authors use the rest of the discussion section to further explore the results by relating them to existing, relevant literature and stating how the results could be improved or used by others. As with all references reviewed for earlier sections, no concerns were found with the literature referenced in this section. The authors utilized this section to recognize some of the limitations of the study. The main limitation mentioned was the need to interpolate and adjust the results of the eight participants who dropped out. The authors also stated time constraints for data collection forced the acceptance of patients with longer disease history than was preferred. Given these limitations, the authors made rational conclusions based on their results and the results of other literature while making it a point to explain their thoughts. The authors do not make any specific mention of future testing protocols; however, they did state the need to anticipate the attrition of subjects to prepare before data collection begins. It was also mentioned the use of a control group would help validate findings; unfortunately, ethical concerns prevent this from being a possibility. Throughout the discussion, the authors also relate their findings to potential clinical uses and scenarios.

The authors could have presented a better case for future research by being more specific with ideas for future research. While leaving future ideas broad will allow researchers to formulate their own questions and take the research in the direction they want, it does not show where the authors of this study would like to go with the research. This potentially calls into question the investigators' desire to continue this research.

Discussion

While a significant portion of people who rupture their ACL are athletes, this is a relatively common injury, especially in young adults. When it comes to treating patients for this injury it is important to find the most effective and least-invasive intervention possible to ensure the recovery and quality of life for patients. The clinical question for this appraisal was related to the use of conservative treatment for these ruptures as opposed to surgical intervention. This shift in preferred intervention could save a patient all the associated costs of surgical intervention along with many other benefits. This article was chosen due to its use of conservative treatments to restore full function in patients with this injury and the article also used proper design for the subject matter and used reliable outcome measures.

Conservative treatment for an ACL injury is indicated in this article to be able to provide an outcome equal to that of surgical outcomes for the same injury. The major benefit of conservative intervention is avoiding surgery-induced complications and narcotics. Additionally, if the patient does not respond well to conservative treatment, surgery is still an option for the patient. This leaves little risk in conservatively treating ACL ruptures. If all appropriate protocols are followed, the benefits to conservative treatment far outweigh any risks. To further support the

use of conservative treatment, a study could be done including a broader age group and a third, surgical, intervention group to compare the conservative therapies to.

Physical therapists help rehabilitate patients with ACL ruptures frequently. While further research should be done to continue refining conservative treatment protocol, it is the opinion of this author that this article validly shows evidence of a return to full function in patients with this injury, and conservative treatment should be considered between the patient and their provider before committing to surgical intervention. After learning therapeutic exercise and other relevant skills to treat ACL ruptures conservatively later in my curriculum, I plan to offer this intervention for those patients seeking it.

This article provides firm support to the hypothesis: In young adult patients suffering from a torn ACL, can a physical therapy program alone produce an outcome equal to, or greater than, a treatment plan requiring surgery. The authors supported their hypothesis and inferences with literature to create a background for the performance of a well-designed study to collect relevant and supportive data. The authors also minimized the introduction of bias where possible in their methods and used quality interventions and outcome measures. The results were organized and presented in a way that allowed a clear understanding for the authors to make reasonable conclusions. This author feels the article presented provides sufficient, quality evidence to pursue the use of conservative ACL interventions.