Link Medical Journal
of Health and Community Research

Volume 1, Issue 2 (July-December 2023)

Original Article

Effectiveness of Cognitive Behavioral Therapy, Physical Therapy, and TNF Inhibitors in Managing Chronic Lower Back Pain in Ankylosing Spondylitis Patients

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ABSTRACT

Background: *Background: Ankylosing Spondylitis is a chronic inflammatory condition of primarily the spine and causes immense pain and functional limitation. The current treatment with Tumor Necrosis Factor inhibitors is effective in controlling inflammation but does not provide a solution to the multi-dimensional aspects of the disease, which includes both chronic pain and psychological suffering.*

Objective: *This study attempted to evaluate the effectiveness of the combined treatment regime of TNF inhibitors, PT, and CBT in the management of chronic lower back pain, quality of life in patients with AS.*

Methods: *A clinical controlled randomized trial conducted on 45 AS patients and divided them randomly into three groups of 15 each: TNF inhibitors alone, combined PT and CBT, and all treatments combined. Collected data through Numeric Rating Scale (NRS), Bath Ankylosing Spondylitis Functional Index (BASFI), and the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire, also the estimation of biomarkers of inflammation CRP and ESR. The research was in compliance with the Declaration of Helsinki. The study obtained the consent of the institutional review board. Data were tabulated for analysis on SPSS Software Version 25. The same was computed by one way ANOVA, and chi-square were applied wherever necessary.*

Results: *Post-intervention, the group receiving all combined treatments showed a significant improvement in NRS (F-statistic: 12.362, p=0.000060), BASFI (F-statistic: 21.590, p=0.000036), and ASQoL (F-statistic: 44.499, p=0.000422). A statistically significant reduction of CRP (F-statistic: 26.*

Conclusion: *The combination of TNF inhibitors, PT, and CBT has significantly improved the treatment outcomes in patients diagnosed with AS. It was noted that a multidisciplinary approach was more effective in handling the complex symptoms of AS, like chronic lower back pain. The comprehensive care model ensures the physical symptoms are alongside the increase in quality of life.*

Keywords: *Ankylosing spondylitis, TNF inhibitors, Physical Therapy, Cognitive-Behavioral Therapy, chronic lower back pain, quality of life, inflammation biomarkers*

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INTRODUCTION

Psoriatic Ankylosing spondylitis is characterized as a chronic inflammatory disease mainly affecting the axial skeleton and presenting with intense and persistent lower backache. It deteriorates the overall quality of life by not only degrading physical functioning but also affecting the psychological health of patients to a great extent (1-3). The conventional treatment option of ankylosing spondylitis has been the use of inhibitors of tumor necrosis factor. Although these medications are highly effective in both reducing inflammation and slowing the course of the disease, they frequently do not target the multisystem experience of pain and functional limitation that many patients suffer (3, 4).

Emerging evidence shows that inclusion of non-pharmacologic therapies like Physical Therapy (PT) and Cognitive Behavioral Therapy (CBT) to traditional medical treatments will allow a comprehensive way of managing chronic conditions like AS. Physical therapy aims to improve physical functions and reduce pain by customizing exercises that promote mobility and strength increase (5, 6). On the other hand, cognitive-behavioral therapy aims to alter one's perception of pain and provide techniques to manage pain with new behaviors, as well as to work against psychological stressors that may worsen the physical symptoms (5-7).

As suggested by the complex interaction of psychological and physical components in chronic pain, an integrated treatment approach may add to the effectiveness of treatment. Indeed, for conditions such as AS, the fact that pain can become persistent and cause significant psychological distress provides an additional rationale for some kind of integrated approach to treatment. The combination of cognitive-behavioral therapy, physical therapy, and TNF inhibitors is effective in the management of chronic lower back pain in ankylosing spondylitis through the rationale of treating somatic and psychological disease components concomitantly. Structured physical and psychological therapies, in addition to pharmacological suppression of the pain and inflammation, are designed to improve coping strategies, functional capacity, and quality of life in the affected subjects (8, 9).

With this approach, it is hoped that understanding of a comprehensive treatment paradigm can be developed through the study of these modalities together, which may be more effective than the sum of their parts. (10-13).

MATERIAL AND METHODS

It was a clinical controlled study, and the target population was adults who had been diagnosed with Ankylosing Spondylitis under which they had long-term lower back pain. The study had an inclusion criterion of having been diagnosed with AS under the modified New York criteria and suffering from chronic lower back pain for at least six months. Subjects aged between 18 and 60 years were included in the study to make generalizations into the adult population with AS, thereby ruling out the pediatric and older populations, which

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may have different disease dynamics and responses to treatment. Exclusion criteria were as follows: recent spine surgery, participation in other clinical trials, severe comorbid conditions such as uncontrolled cardiovascular diseases and diabetes, former adverse reactions to TNF inhibitors, or contraindications for physical therapy or cognitive behavioral therapy (14, 15).

In one study, 45 subjects were randomly allocated to one of three treatment groups. This sample size was considered adequate for anticipated effect sizes and variance in this population, established statistical power, and allowed for full analysis to be conducted in the practical constraints of clinical research. These standardized tools applied for data collection were questionnaires and clinical assessments regarding level of pain, functional ability, and quality of life measured at baseline and postintervention (16-17). These are: Numeric Rating Scale for Pain, Bath Ankylosing Spondylitis Functional Index, and Ankylosing Spondylitis Quality of Life. Furthermore, serum levels of CRP and ESR were assayed in blood samples collected at the respective time points (18).

This study was conducted under all the rules governing human subjects and after receiving prior approval by the Institutional Review Board. All participants signed the written informed consent form after receiving an adequate explanation about the aim, procedures, and possible risks and benefits of the study. Data analysis was performed by SPSS software version 25. Descriptive statistics were used to summarize the demographic and clinical characteristics. For comparison between the groups, the one-way ANOVA test was applied for continuous variables, while chi-square tests were applied for categorical variables. The level of significance was maintained at $p<0.05$. The post-intervention effects were further analyzed with one-way ANOVA testing the effectiveness of each intervention modality on changes in the NRS, BASFI, ASQoL, CRP, and ESR scores, to identify the statistical significance of the improvements in the study outcomes (18-21).

RESULTS

In a study published, considering treatment strategies for chronic low back pain in patients with ankylosing spondylitis, it revealed that three diversified treatment groups had been included. This study investigated patients on TNF inhibitors, patients on combined PT and CBT, and patients on a combination of all three types of treatment. The groups had each 15 patients.

Demographic analysis showed that the mean age of patients treated with TNF inhibitors was 45.1 years, with a standard deviation of 9.94 years. The mean age of patients in the combined PT and CBT group was 41.1 years and the standard deviation was 7.78 years. In totality, the receiving-all-treatments group demonstrated an age of 42.3 years, with a standard deviation of 10.18 years. Gender was also distributed differently between the groups, with 46.7% of the patients being male in the TNF inhibitors group, 60% in the PT and CBT group, and 73.3% in the combined treatment group. Ethnicity was also greatly distributed differently, with 46.7%

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being Caucasian in the TNF inhibitors group, 80.0% in the PT and CBT group, and 73.3% in the combined treatments group.

Educational backgrounds revealed that 53.3% of those within the TNF inhibitors group had attended college, in comparison to 40.0% within the PT and CBT group and 66.7% within the combined treatment group. The employment rates were virtually the same, with 60.0% in both the TNF inhibitors and PT and CBT group, increasing slightly to 66.7% in the group receiving all the treatments. Duration of diagnosis presented a range, the TNF inhibitors group diagnosed on average 4.60 years, the PT and CBT group diagnosed 6.03 years, and the combined treatment diagnosed 4.84 years.

In terms of treatment specifics, the distribution of medication type demonstrated that 40.0% of the TNF inhibitors and combined treatment groups were on Adalimumab, and 0.0% in the PT and CBT group. Etanercept was used by 33.3% of the TNF inhibitors group and 20.0% in the combined treatment group. The use of infliximab was 20.0% in the TNF inhibitors group and had an increase to 40.0% in the combined treatment group.

Table 1 Demographic and Clinical Characteristics of Study Participants

Characteristic	**TNF Inhibitors (n=15)**	**Combined PT and CBT (n=15)**	**Combined All Treatments (n=15)**
Age (years)	45.1 ± 9.94	41.1 ± 7.78	42.3 ± 10.18
Gender, male (%)	46.7	60.0	73.3
Ethnicity, Caucasian (%)	46.7	80.0	73.3
Education, College+ (%)	53.3	40.0	66.7
Employment, Employed (%)	60.0	60.0	66.7
Duration of Diagnosis (years)	4.60 ± 1.44	6.03 ± 2.45	4.84 ± 2.16

Table 2 Comparative Statistics Table

Variable	**Response**	**TNF Inhibitors**	**Combined PT and CBT**	**Combined All Treatments**	**p-value**
Medication Type	Adalimumab	40.0%	0.0%	40.0%	>0.05
	Etanercept	33.3%	0.0%	20.0%	
	Infliximab	20.0%	0.0%	40.0%	
Medication Dosage	100 mg	100 mg	-	100 mg	>0.05
	200 mg	-	-	200 mg	-
	50 mg	-	-	50 mg	-
Medication Frequency	Bi-weekly	-	-	Bi-weekly	>0.05
	Monthly	Monthly	-	Monthly	-
Therapy Attendance	Mean Sessions	-	10.07 ± 1.39	10.13 ± 1.36	>0.05
Treatment Adherence	High	80.0%	66.7%	80.0%	>0.05
	Low	6.7%	20.0%	6.7%	
	Medium	13.3%	13.3%	13.3%	

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Table 3 One-Way ANOVA Results

Variable	F-statistic	p-value
NRS (Numeric Rating Scale)	0.715	0.495
BASFI (Bath Ankylosing Spondylitis Functional Index)	0.017	0.983
ASQoL (Ankylosing Spondylitis Quality of Life questionnaire)	1.486	0.238
CRP (C-reactive protein)	0.695	0.505
ESR (Erythrocyte Sedimentation Rate)	0.832	0.442

Table 4 One-Way ANOVA Results Post-Intervention

Variable	F-statistic	p-value
NRS (Numeric Rating Scale)	12.362	0.000060
BASFI (Bath Ankylosing Spondylitis Functional Index)	21.590	0.000036
ASQoL (Ankylosing Spondylitis Quality of Life questionnaire)	44.499	0.000422
CRP (C-reactive protein)	26.271	0.000040
ESR (Erythrocyte Sedimentation Rate)	19.010	0.0000013

Dosages and frequencies of the medication also differed in which there were Bi-weekly and Monthly regimens observed based on specific drug protocols and where the 100 mg was common in TNF inhibitors and in the combined treatment groups. On average, therapy attendance was 10.07 sessions for the PT and CBT group and a little bit higher at 10.13 sessions for the combined treatment group. Adherence rates to treatment were 80.0% for the TNF inhibitors group, 80.0% for the combined group, 66.7% for PT and CBT, and 66.7% for PT.

One-way ANOVA conducted on the results before intervention does not show any significant differences across the groups for the measured variables NRS, BASFI, ASQoL, CRP, and ESR. However, post-intervention results showed substantial improvement. The NRS showed an F-statistic value of 12.362 that is significant at a very highly significant p-value of 0.000060, whereas BASFI results are even more pronounced, indicating F-statistic of 21.590 with a p-value of 0.000036. Very significant improvement was seen in ASQoL (F-test 44.499, p 0.000422), CRP (F-test 26.271, p 0.000040), and ESR (F-test 19.010, p 0.0000013) that indicated the effectiveness in the interventions singly and more so in combination. Such results make possible the appreciation of additional benefits of the combination of medical and behavioral therapies in the treatment of chronic diseases such as ankylosing spond.

DISCUSSION

The findings from this study will provide useful insight into the multi-faceted approach used in treating chronic lower back pain in patients with Ankylosing Spondylitis (AS). The combined treatments with TNF inhibitors, added to the physical and cognitive behavioral therapy, show an improvement in the clinical outcomes of pain reduction and functional improvement, in turn, improving the quality of life of the patients, coherent with the evidence of the benefits of these multidisciplinary treatments of chronic inflammatory conditions in the

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literature. These concomitant treatments with TNF inhibitors, added to physical and cognitive behavioral therapy, improved the clinical outcomes of pain reduction and functional improvement, in turn, improving the quality of life of the patients (19-21).

Noteworthy is that post-intervention there were improvements in Numeric Rating Scale (NRS) and Bath Ankylosing Spondylitis Functional Index (BASFI) based on the current study. These results confirm the prediction since an integrated model considers the pathological symptoms of AS as well as the psychological components that are left out by traditional models of treatment (19, 20). In addition, the significant reduction of the inflammatory markers that comprises of C-reactive protein and Erythrocyte Sedimentation Rate provide more proof of TNF's inhibitors' efficiency in conjunction with PT and CBT since the results presented by Brown et al. (2017) identified that biological therapies and physical treatments were also noted to work in tandem (21).

Despite these promising findings, certain limitations are present in the study. The sample size was adequate to detect important differences but at the same time was relatively small, which may lead to the limitation in terms of the generalization of findings to all AS patients. Besides, it has been acknowledged that study design has such a limitation as a lack of long-term follow-up period for a better understanding of the sustainability of the treatment effects that might be achieved at a future date (22). Another limitation was the homogeneous nature of the study population, which majorly included Caucasian males, hence potentially reducing the applicability of the findings to females or individuals from other ethnic backgrounds (23).

In a methodological perspective, future research should be directed at larger and more varied populations and follow-ups for a longer period, to study the durability of the benefits of treatment. Further investigation is also called for on the exact impact of each of the components of the TNF inhibitors, PT, and CBT that are used together to establish the individual contribution to treatment. Other studies may also be carried out around the cost-effectiveness of such combined treatments, which would be helpful in the perspective of the health care provider and policymaker (24, 25).

CONCLUSION

In conclusion, the combination of TNF inhibitors, PT, and CBT can be considered a new promising approach in the treatment of chronic lower back pain in AS patients. The results of the present study add to the growing literature on the benefits of a comprehensive approach to the management of chronic disease, with the common feature of approaches which address the physical, as well as the psychological components of health.

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Timeline:
Received: October 13, 2023
Accepted: November 24, 2023
Scheduled for Publication: December 1, 2023
Published: December 30, 2023

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