

A Pilot Study and Retrospective Chart Review Comparing Adalimumab, Infliximab, and Etanercept in Patients with Active Rheumatoid Arthritis

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Abstract. *Introduction:* Rheumatoid Arthritis (RA) can be a very debilitating disease, as it causes pain and fatigue associated with inflammation and destruction of multiple joints. Fortunately, newer classes of drugs called tumor necrosis factor inhibitors (TNF-Is) have been proven effective in reducing joint destruction and overall disease severity. However, it is not known which of these TNF-Is is most efficacious. *Methods:* This retrospective chart review study compares three TNF-Is: Adalimumab (Humira), Infliximab (Remicade), and Etanercept (Enbrel) through a retrospective chart review completed at Arthritis and Rheumatology Clinics of Kansas in Wichita, Kansas. The study analyzed the pain score, fatigue score, and Health Assessment Questionnaire (HAQ) score for 45 women between the ages 35-65 with active RA who were taking one of the three medications mentioned above. *Results:* One-way ANOVA tests were performed to evaluate the change in pain, fatigue, and HAQ scores for each of the three drugs over one year. The change, or delta, for pain was R=1.673, E=.688, H=-2.136. The delta values for fatigue were all negative except R=.750. The p value for delta HAQ was p=.082. The mean ages for all three drugs were not significantly different. *Conclusion:* Remicade was the most efficacious drug when considering improvement in pain. The improvement of HAQ scores were not significantly different between the three drugs. A larger sample size and a longer period of time is needed if future research is done to validate research results.

1. Introduction

Rheumatoid arthritis is an autoimmune disease involving joint destruction distinguished by chronic bone erosion. Many classes of drugs are used to control inflammation in this disease, including NSAIDs, corticosteroids, and disease modifying anti-rheumatic drugs (DMARDs), both synthetic and biologic. Tumor necrosis factor inhibitors (TNF-Is) are the biologic DMARDs that are the focus of this study. Currently, there are no clinical trials comparing TNF inhibitors to one another, so although we know that this class of drugs does substantially reduce joint erosion and therefore increase quality of life, we do not know which TNF-I, if any, is superior to the others [1]. The efficacy of three TNF-Is in comparison to one another is the objective of this study.

2. Methods

Design

A retrospective chart study was done at ARCK in Wichita, Kansas under the supervision of Dr. Shadi Shahouri. The charts utilized allowed extraction and analysis of these indicators of disease severity: pain score, fatigue score, and HAQ score for the visit date before drug treatment and closest to 1 year after treatment. These values were entered into an Excel database along with patient ID number, age, and date of diagnosis. Each patient upon every visit to ARCK fills out forms from which the pain, fatigue, and HAQ scores are calculated. These scores reflect the functional status of the patient.

Study Population

Our study population includes all female patients between 35 and 65 years old who have active Rheumatoid Arthritis (positive rheumatoid factor), are/were on Humira, Remicade, or Enbrel, and began treatment before July of 2005. The study was limited to females between 35 and 65 to limit total number of subjects as well as additional comorbidities, which tend to be more prevalent in the elderly. The time period was restricted to dates before July of 2005, because at that time, the HAQ survey form was changed. Those patients who met the inclusion criteria, but had inflammatory arthritis, autoimmune disorders other than RA, other pain disorders, or were taking immunosuppressive therapy other than methotrexate, prednisone or other TNF-Is were excluded.

Measurements

Data extracted from each patient's chart were age, pain, fatigue, and HAQ score when starting the TNF-I and pain, fatigue and HAQ 1 year after beginning treatment. Also noted was whether the patient was on Methotrexate, Prednisone, NSAIDS, or Narcotics in conjunction with the TNF-I. The dose of each medication was also documented.

Data Analysis and Results

Statistical tests were performed with the help of Wichita State University Engineering professor, Dr. Janet Twomey. These tests included one-way ANOVA and Non-Parametric tests. Two-way comparisons controlling for the number of tests were performed for the ANOVAs where $p < .05$. Delta was the change in pain, fatigue or HAQ after one year. For example, (baseline pain) – (pain 1 year later) = delta pain. If delta is positive, symptoms improved, and if delta is negative, symptoms worsened. Results for pain, fatigue and HAQ are shown in Table 1 below for each individual drug.

Table 1

	Remicade N=26	Enbrel N=8	Humira N=11	P Value
Delta Pain	1.7 (2.0)*	.70 (3.0)	-2.1 (2.2)	0.00
Delta Fatigue	.75 (2.4)	-.06 (1.9)	-1.8 (3.0)	0.023
Delta HAQ	.16 (.50)	-.40 (.92)	-.18 (.73)	0.08

* = Delta (Standard Deviation)

A significant difference for pain was found within the 3 drugs. Two by two comparison indicates that Remicade patients had the most improvement for pain and was significantly different than Humira. Similar results were found for fatigue. The HAQ scores were not found to be significantly different.

3. Conclusions

This study was a Retrospective Chart Review of a very small sample of women between the ages 35-65 with active RA. When comparing 3 TNF-Is for efficacy based on change in the pain, fatigue and HAQ score over a 1 year period, results indicate that Remicade patients showed improvements for pain after 1 year of treatment. There is so much variability in this study due to many factors, therefore, a larger sample size is needed for future research.

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