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A Study on Efficacy and Safety of Etanercept in Patients with Rheumatoid Arthritis (AbstractView.aspx?PID=2016-9-11-25)

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A Study on Efficacy and Safety of Etanercept in Patients with Rheumatoid Arthritis

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ABSTRACT:

Aim and objective: To assess the efficacy of Etanercept and also to evaluate the safety profile of Etanercept in patients with Rheumatoid arthritis. The main objectives of the study are to evaluate the drug safety and efficacy among the Rheumatoid arthritis patients. And to monitor the ADRs observed in Rheumatoid arthritis patients with Etanercept. **Materials and Methods:** Study was carried out in a 300 bedded tertiary care hospital. The department selected for the study was orthopaedics. This method involves prospective observational analysis of Efficacy and safety of Etanercept in patients with Rheumatoid arthritis. The study was carried out by the collection and documentation of general information of the patient including personal history, past medical history, past medication history, lab investigations and treatment pain will be analysed by using visual analog scale(vas). ADR's were assessed by using Naranjo adverse drug reaction probability scale. The whole procedure was carried out in Rheumatoid arthritis patients who received Etanercept without any alteration in therapy. **Result and Discussion:** This study on sample size of 35 was carried out to assess the short term safety and efficacy of Etanercept. Moreland et al compared placebo, ETN 10 mg twice weekly (ETN20), and ETN 25 mg twice weekly (ETN50) in patients with long-standing RA and an inadequate response to DMARDs. Although both treatment arms were significantly better than placebo, as measured by American College of Rheumatology.

The study conducted by Elizabeth Mary Curtis et al., shows that Etanercept is a safe and well-tolerated treatment for RA, And another study conducted by Boulos Haraoui et al, study shows that Etanercept is both safe and effective to use in RA. Etanercept has been shown not only to reduce disease activity but also to limit progression of joint damage in early and late disease which are similar to our study. **Conclusion:** This study concludes incidence of rate of patients in the age group of 50 – 59 years were mostly affected by Rheumatiod arthritis compared to other age groups. The male patients were found to be affected more with rheumatoid arthritis than female patients. The study made use of 25mg Eternacept for the above obtained results. This could also be carried out using 50mg Eternacept and evaluated on the same. There was a decrease in pain VAS scale confirming the efficacy and safety of Etanercept. In the future, this study could be further extended to a combination therapy over longer duration of time for better results.

KEYWORDS: Eternacept, Rheumatoid arthritis, VAS Score, Naranjo Scale, Efficacy and safety, Prospective observational study.

INTRODUCTION:

Rheumatoid arthritis (RA) is a chronic inflammatory disease characterized by joint swelling joint tenderness, and destruction of synovial joints, leading to severe disability and premature mortality[1–5]. Given the presence of autoantibodies, such as rheumatoid factor (RF) and anti–citrullinated protein antibody (ACPA) (tested as anti–cyclic citrullinated peptide [anti-CCP]), which can precede the clinical manifestation of RA by many years[6–9], RA is considered an autoimmune disease[10, 11].

Tumor necrosis factor-α (TNF-α) is an important physiological inflammatory mediators in the host-mediated inflammatory response, resulting in tissue damage plays an important role. RA patients with synovial immune histochemistry analysis showed the existence of TNF-α in synovial lining cells, especially at the junction of cartilage and pannus[12]. RA patients after treatment, serum levels of TNF-α significantly decreased according to the same period improved arthritis index. Re-combinant human tumor necrosis factor-α receptor II IgG FC fusion protein (rhTNFR: Fc) is a fusion protein produced using recombinant DNA technology which can specific block the interactions between TNF-α and its receptor on the cell surface[13,14]. The intriguing possibility emerged that blocking the activity of TNF might improve RA symptoms and perhaps even slow disease progression. In the past few years, biological response modifiers capable of neutralizing TNF have been developed and tested in patients with RA.

Like many autoimmune diseases, the etiology of RA is multifactorial. Genetic susceptibility is evident in familial clustering and monozygotic twin studies, with 50 percent of RA risk attributable to genetic factors [15]. Genetic associations for RA include human leukocyte antigen-DR4[16] and -DRB1, and a variety of alleles called the shared epitope [17, 18].

Genome-wide association studies have identified additional genetic signatures that increase the risk of RA and other autoimmune diseases, including *STAT4* gene and CD40 locus. Smoking is the major environmental trigger for RA, especially in those with a genetic predisposition [19]. Although infections may unmask an autoimmune response, no particular pathogen

has been proven to cause RA[20]. RA is characterized by inflammatory pathways that lead to proliferation of synovial cells in joints. Subsequent pannus formation may lead to underlying cartilage destruction and bony erosions. Overproduction of proinflammatory cytokines, including tumor necrosis factor (TNF) and interleukin-6, drives the destructive process [21].

Morning stiffness, persisting more than one hour but often lasting several hours, may be a feature of any inflammatory arthritis but is an especially characteristic of rheumatoid arthritis. Its duration is a useful gauge of the inflammatory activity of the disease. Similar stiffness can occur after long periods of sitting or inactivity. In contrast, patients with degenerative arthritis complaint of stiffness lasting but a few minutes [22]. Risk factors are older age, a family history of the disease, and female sex are associated with increased risk of RA, although the sex differential is less prominent in older patients. Both current and prior cigarette smoking increases the risk of RA (relative risk [RR] = 1.4, up to 2.2 for more than 40-pack-year smokers)[23]. Pregnancy often causes RA remission, likely because of immunologic tolerance [24]. Parity may have long-lasting impact; RA is less likely to be diagnosed in parous women than in nulliparous women (RR = 0.61)[25- 27]

MATERIALS AND METHODS:

Study was carried out in a 300 bedded tertiary care hospital. The department selected for the study was orthopaedics. This method involves prospective observational analysis of Efficacy and safety of Etanercept in patients with Rheumatoid arthritis. The study was carried out by the collection and documentation of general information of the patient including personal history, past medical history, past medication history, lab investigations and treatment pain will be analysed by using visual analog scale (vas). ADR's were assessed by using Naranjo adverse drug reaction probability scale. The whole procedure was carried out in Rheumatoid arthritis patients who received Etanercept without any alteration in therapy. The current study included 35 rheumatoid arthritis patients, and the study duration took around 9 months. The inclusion criteria were those patients above 18 years of age of both gender, and those who were diagnosed with rheumatoid arthritis. The exclusion criteria were inclusive of patients with less than 18 years of age, pregnant and lactating women's, and also those who did not satisfy ACR 1987 criteria.

RESULTS:

Table 1: Age Wise Distribution

Age in years	Number of patients (n=35)	Percentage of patients
18 – 39	4	11.43
40 – 49	10	28.57
50 – 59	11	31.43
60 – 69	9	25.72
70 – 79	1	2.85
Total number of patients	35	100%

Table 2: Gender Wise Distribution

Gender	Number of Patients (N=35)	Percentage of Patients
Male	23	65.72%
Female	12	34.88%
Total Number of Patients	35	100%

Table 3: Social Habit Wise Distribution

Social Habit	Number of Patients	Percentage of Patients
Smoker	9	25.72%
Alcoholic	6	17.14%
Both	8	22.85%
None	12	34.28%

Table 4: Mean and Standard Deviation Changes of Vas Pain Score

	Baseline	Review 1 (4 Weeks)	Review 2 (8 Week)
Mean	6.714	5.057	3.142
Standard Deviation	±1.82	±1.52	±2.24

Table 5: Adverse Effects Observed In Etanercept Patients

Type Of ADR	Number Of Patients	Percentage
Definite ADR	1	8.33%
Probable	7	58.33%
Possible	2	16.66%
Doubtful	2	16.66%

Table 6: Type of ADR Observed In Etanercept Patients

Type Of ADR	Number of Patients (N=35)	Percentage of Patients
Injection site infection	7	19.26
Rhinitis	2	6.66
Thrombocytopenia	1	2.85
Giddiness	2	6.66
None	23	64.71

DISCUSSION:

This study on sample size of 35 was carried out to assess the short term safety and efficacy of etanercept. Moreland et al compared placebo, ETN 10 mg twice weekly (ETN20), and ETN 25 mg twice weekly (ETN50) in patients with long-standing RA and an inadequate response to DMARDs. Although both treatment arms were significantly better than placebo, as measured by American College of Rheumatology.(28)

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There were few reports of injection site reaction, rhinitis, giddiness, thrombocytopenia, oral ulcer in this study as compared to the study conducted by Ramanathmisraetal., showing 3 patients with injection site reaction, 2 patients with giddiness , 4 patients with rhinitis and 1 patient with thrombocytopenia and oral ulcer.(30)

REFERENCES:

1. Scott DL, Symmons DP, Coulton BL, Popert AJ. Long-term outcome of treating rheumatoid arthritis: results after 20 years. Lancet 1987;1:1108–11.
2. Mitchell DM, Spitz PW, Young DY, Bloch DA, McShane DJ, Fries JF. Survival, prognosis, and causes of death in rheumatoid arthritis. Arthritis Rheum 1986;29:706–14.
3. Pincus T, Callahan LF, Sale WG, Brooks AL, Payne LE, Vaughn WK. Severe functional declines, work disability, and increased mortality in seventy-five rheumatoid arthritis patients studied over nine years. Arthritis Rheum 1984;27:864–72.
4. Isomaki H. Long-term outcome of rheumatoid arthritis. Scand J Rheumatol Suppl 1992;95:3–8.
5. Wolfe F. The natural history of rheumatoid arthritis. J Rheumatol Suppl 1996;44:13–22
6. Aho K, Heliovaara M, Maatela J, Tuomi T, Palusuo T. Rheuma- toid factors antedating clinical rheumatoid arthritis. J Rheumatol 1991;18:1282–4.
7. Aho K, von Essen R, Kurki P, Palusuo T, Heliovaara M. Antik- eratin antibody and antiperinuclear factor as markers for subclin- ical rheumatoid disease process. J Rheumatol 1993;20:1278–81.
8. Nielen MM, van Schaardenburg D, Reesink HW, van de Stadt RJ, van der Horst-Bruinsma IE, de Koning MM, et al. Specific autoantibodies precede the symptoms of rheumatoid arthritis: a study of serial measurements in blood donors. Arthritis Rheum 2004;50:380–6.
9. Rantapaa-Dahlqvist S, de Jong BA, Berglin E, Hallmans G, Wadell G, Stenlund H, et al. Antibodies against cyclic citrullinated peptide and IgA rheumatoid factor predict the development of rheumatoid arthritis. Arthritis Rheum 2003;48:2741–9.
10. Firestein GS. Evolving concepts of rheumatoid arthritis. Nature 2003;423;356–61.
11. Smolen JS, Aletaha D, Koeller M, Weisman M, Emery P. New therapies for the treatment of rheumatoid arthritis. Lancet 2007; 370:1861–74.
12. Maini RN, Brennan FM, Williams R, Chu CQ, Cope Ap,et al. (1993) TNF-alpha in rheumatoid arthritis and prospects of anti-TNF thrapy[J]. Chin Exp Rheumatol 8: S173-S175.
13. Moreland LW, Schiff MH, Baumgartner SW, Tindall EA, Fleischmann,et al. (1999) Etanercept therapy in rheumatoid arthritis: a randomized ,controlled trial. Ann Inte Med 130: 478-486.
14. Nanda S, Bathon JM. (2004) Etanercept: a clinical review of current and emerging indications. Expertop Pham acother 5: 1175-1186.
15. Mac Gregor AJ, Snieder H, Rigby AS, et al. Characterizing the quantitative genetic contribution to rheumatoid arthritis using data from twins. *Arthritis Rheum*. 2000; 43(1): 30-37.
16. Orozco G, Barton A. Update on the genetic risk factors for rheumatoid arthritis. *Expert Rev Clin Immunol*. 2010; 6(1): 61-75.
17. Balsa A, Cabezón A, Orozco G, et al. Influence of HLA DRB1 alleles in the susceptibility of rheumatoid arthritis and the regulation of antibodies against citrullinated proteins and rheumatoid factor. *Arthritis Res Ther*. 2010; 12(2): R62.
18. McClure A, Lunt M, Eyre S, et al. Investigating the viability of genetic screening/testing for RA susceptibility using combinations of five confirmed risk loci. *Rheumatology (Oxford)*. 2009; 48(11): 1369-1374.
19. Bang SY, Lee KH, Cho SK, et al. Smoking increases rheumatoid arthritis susceptibility in individuals carrying the HLA-DRB1 shared epitope, regardless of rheumatoid factor or anti-cyclic citrullinated peptide antibody status. *Arthritis Rheum*. 2010; 62(2): 369-377.
20. Wilder RL, Crofford LJ. Do infectious agents cause rheumatoid arthritis? *Clin OrthopRelat Res*. 1991; (265): 36-41.
21. Scott DL, Wolfe F, Huizinga TW. Rheumatoid arthritis. *Lancet*. 2010; 376(9746): 1094-1108.

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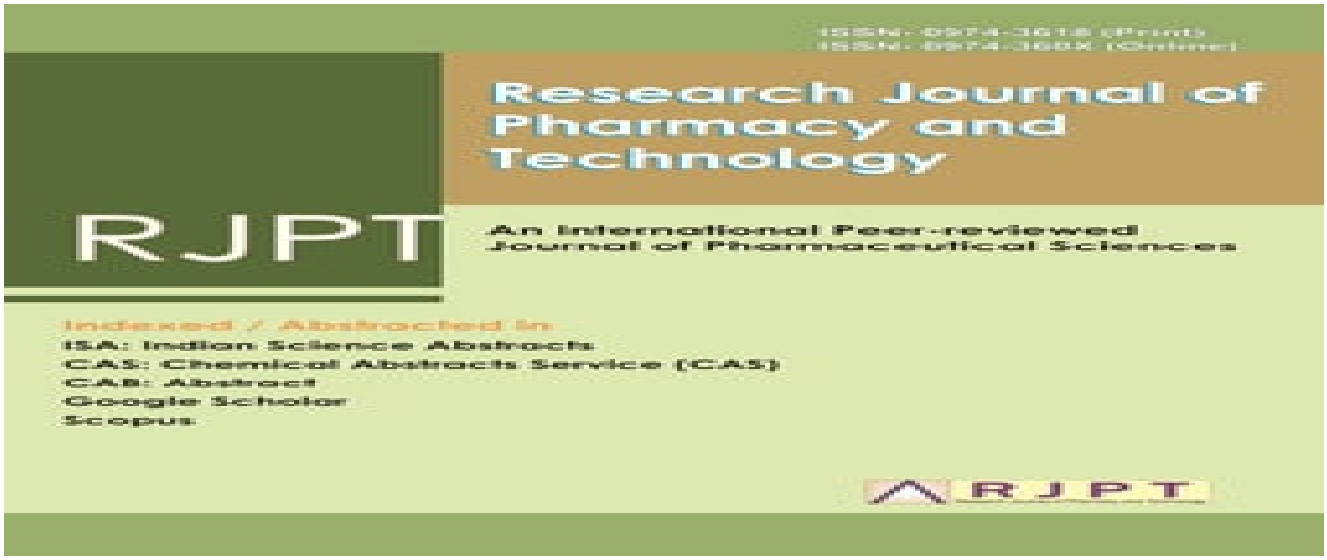

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