A COMPARISON OF CLINICAL Efficacy OF LEFLUNOMIDE VS OTHER THERAPEUTIC OPTIONS IN THE TREATMENT OF RHEUMATOID ARTHRITIS

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OBJECTIVES: The objective of this study was to compare efficacy and safety of leflunomide with biological antirheumatic drugs (adalimumab, etanercept, infliximab, rituximab, anakinra) in active rheumatoid arthritis. METHODS: Comparison was based on systematic review, carried out according to guidelines published by the Cochrane Collaboration and Agency for Technology Assessment in Poland. The most important medical databases (EMBASE, MEDLINE, CENTRAL) were searched. Two reviewers independently selected trials, assessed trial quality and extracted data. No head to head trials were identified so indirect comparison using Bučer’s method was performed. RESULTS: The results of 33 randomized controlled trials were included in indirect comparison. Leflunomide was shown to have better ACR20 response than anakinra (RR = 1.44 [1.14; 1.81]) but no significant differences in ACR response were found in comparisons with other drugs. Comparisons of HAQ disability scores indicate than leflunomide reduces disability better than adalimumab (WMD = -0.15 [-0.29; -0.01]), infliximab (WMD = -0.33 [-0.50; -0.20]), anakinra (WMD = -0.47 [-0.69; -0.23]), rituximab (WMD = -0.38 [-0.59; -0.17]), but not etanercept (WMD = -0.18 [-0.37; 0.01]). Radiographic improvement was better in comparison with anakinra (WMD = -2.99 [-5.82; -0.16]) and rituximab (WMD = -4.05 [-6.67; -1.43]) whereas worse in comparison with adalimumab (WMD = 2.67 [0.87; 4.47]), etanercept (WMD = 1.75 [0.01; 3.49]) and infliximab (WMD = 2.06 [0.42; 3.70]). Leflunomide significantly increases the risk of treatment discontinuation due to the adverse events in comparison with etanercept (RR = 3.50 [1.55; 7.88]). No significant differences in safety outcomes were noted between leflunomide and other drugs. CONCLUSIONS: Indirect comparisons indicate similar efficacy of leflunomid, adalimumab, etanercept, infliximab or rituximab. Leflunomide seems to be more effective than anakinra. Safety profile of leflunomide is worse in comparison with etanercept, whereas in comparison with other analyzed drugs no differences were found.

PMS3 COSTEFFECTIVENESS ANALYSIS OF LEFLUNOMIDE AS A TREATMENT FOR RHEUMATOID ARTHRITIS IN MEXICO

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OBJECTIVES: To estimate the cost-effectiveness relationship of leflunomide compared to infliximab, etanercept and adalimumab for the treatment of patients with rheumatoid arthritis (RA) with suboptimal response despite methotrexate (MTX) monotherapy. METHODS: Time horizon was 24 weeks. Efficacy data was obtained from systematic review of published literature. The model compares four groups: leflunomide, infliximab, etanercept and adalimumab, all in combination with MTX, under the perspective of Public Health Sector in Mexico. We included direct costs of medications during 24 weeks and costs associated with therapeutic failure due to adverse events or lack of efficacy. In those cases, we calculated initial treatment costs during 8 weeks, and after treatment changed, it was estimated an average cost of biological therapy for the 16 remaining weeks. The effectiveness measure was the response rate according to the American College of Rheumatology criteria (ACR). The analysis was conducted using Tree Age Pro Suit 2006. RESULTS: The proportion of patients reaching an ACR20 response was 50% for leflunomide, 53% for infliximab, 61.6% for adalimumab and 67.9% for etanercept. The expected costs of 24 weeks of treatment were 891.2, €4274.5, €5054.5 and €4072.3 for leflunomide, infliximab, adalimumab and etanercept, respectively. The cost per patient with ACR20 improvement was €1781.8 for leflunomide, €8205.8 for adalimumab, €8069.9 for infliximab and €5996.7 for etanercept. The average cost per patient reaching an ACR50 or ACR70 response was also much lower for leflunomide (€3,248.7, €8,999.2) than for the biological agents: etanercept (€9492.6, €23,424.6), adalimumab (€12,290.4, €23,646.5), infliximab (€14,726.1, €40,349.5). CONCLUSIONS: Leflunomide added to MTX is a cost-effective strategy compared to infliximab, adalimumab and etanercept, each one added to MTX in patients with suboptimal response to MTX monotherapy. Therefore, we recommend the use of leflunomide for patients with refractory RA with suboptimal response to MTX, before using a biological agent.

PMS5 PREVALENCE OF FIBROMYALGIA IN GERMANY

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OBJECTIVES: To assess the estimated prevalence of fibromyalgia syndrome (FM) among the adult population in the general population, in Germany, using the London Fibromyalgia Epidemiology Study—Screening Questionnaire (LFESSQ) and American College of Rheumatology (ACR) classification criteria. METHODS: Every patients going to visit the rheumatologist in Munchen hospital during a 30-days period, were interviewed using the validated LFESSQ (4 items) with two additional questions on fatigue (LFESSQ 6 items), and examined to confirm the diagnostic of FM using ACR classification criteria. The screening questionnaire was also administered to a representative community sample more than 15 years old, selected by the quota method. The prevalence of FM was estimated in the general population, applying the predictive positive value observed in rheumatology consultation, to the positive screens, RESULTS: A total of 52.6% patients interviewed in the rheumatology department were screened positive for chronic widespread pain (LFESSQ 4), 42.7% for widespread pain and fatigue (LFESSQ 6), 16.4%[15.8–16.9] were confirmed FM cases. Based on positive screens for chronic widespread pain and LFESSQ 4, the prevalence of FM in general population, is 5.8 % (95% IC: [4.3–7.2]; 7.5% in females and in 3.8% males respectively). If fatigue is added, the prevalence is 3.2 % (95% IC: [2.1–4.3] ; 3.9% in females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM sufferers are females and 2.5% in males respectively). Prevalence rises with age until the age group 75–84 years old. FM suffers...
perceived differently according to the individuals questioned. The minimum prevalence estimated of 3.2% in Germany corresponds to 2.26 million of FM sufferers.

**PMS6**

**PREVALENCE OF FIBROMYALGIA IN FRANCE**

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**OBJECTIVES:** Fibromyalgia syndrome (FM) is an under diagnosed disorder of unknown etiology. The prevalence rate is thought to be about 2% in the general population, 5.8% of women ages 40–60 and as high as 8% in women ages 55–64. Recent European estimates are needed. This aim of the study was to estimate the prevalence of FM in the general adult population, in France and describe the socio-demographic characteristics of patients.

**METHODS:** The French validated version of the London Fibromyalgia Epidemiology Study Screening Questionnaire (4 items relating to widespread pain and 2 items on fatigue) was administered to a representative community sample of 1014 subjects aged over 15 years, selected by the quota method. The questionnaire was submitted to a sample of rheumatology outpatients (n = 178), who were then examined by a trained rheumatologist to confirm or exclude the diagnosis of FM according to the 1990 American College of Rheumatology criteria. The prevalence of FM in the general population was estimated by applying the predictive positive value to eligible community subjects (i.e., positive screens).

**RESULTS:** In the community sample, 9.8% and 5.0% screened positive for widespread pain without and with fatigue, respectively. Among rheumatology outpatients, 47.1% and 34.8% were screened positive respectively, whereas 10.6% were confirmed FM cases. Based on widespread criteria, the prevalence of FM was estimated at 2.2% (95% CI: 1.3%–3.1%) in the French general population. The corresponding figure was 1.4% (95% CI: 0.7%–2.1%) if pain is added. FM sufferers are females with an average age of 52.9 years old (SD: 14.2). Prevalence rises with age until the age group 75–84 years old. FM is considered. If fatigue is added, the prevalence of 3.7% \[2.6–4.8\].

**CONCLUSIONS:** Our findings are in agreement with those of earlier national survey reports. A point prevalence of 1.8% would translate in approximately 880 thousands of patients with FM in UK.

**PMS7**

**PREVALENCE OF FIBROMYALGIA: A LARGE-SCALE EUROPEAN SURVEY: EARLY RESULTS IN UNITED-KINGDOM**

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**OBJECTIVES:** To assess the estimated prevalence of fibromyalgia syndrome (FM) among the adult population in United-Kingdom in the general population, using the London Fibromyalgia Epidemiology Study—Screening Questionnaire (LFESSQ) and American College of Rheumatology (ACR) classification criteria.

**METHODS:** The LFES-SQ was administered to a representative community sample of 1500 subjects aged over 15 years, selected by the quota method. A positive screen was to a representative community sample of 1014 subjects aged over 15 years, selected by the quota method. The questionnaire was submitted to a sample of rheumatology outpatients (n = 178), who were then examined by a trained rheumatologist to confirm or exclude the diagnosis of FM according to the 1990 American College of Rheumatology criteria. The prevalence of FM in the general population was estimated by applying the predictive positive value to eligible community subjects (i.e., positive screens).

**RESULTS:** In the community sample, 9.8% and 5.0% screened positive for widespread pain without and with fatigue, respectively. Among rheumatology outpatients, 47.1% and 34.8% were screened positive respectively, whereas 10.6% were confirmed FM cases. Based on widespread criteria, the prevalence of FM was estimated at 2.2% (95% CI: 1.3%–3.1%) in the French general population. The corresponding figure was 1.4% (95% CI: 0.7%–2.1%) if pain is added. FM sufferers are females with an average age of 52.9 years old (SD: 14.2). Prevalence rises with age until the age group 75–84 years old. FM is considered. If fatigue is added, the prevalence of 3.7% \[2.6–4.8\].

**CONCLUSIONS:** Our findings are in agreement with those of earlier national survey reports. A point prevalence of 1.8% would translate in approximately 880 thousands of patients with FM in France.

**PMS8**

**PREVALENCE OF FIBROMYALGIA IN ITALY**

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**OBJECTIVES:** To assess the estimated prevalence of possible fibromyalgia (FM) suffers among the adult population in Italy using a screening questionnaire, the London Fibromyalgia Epidemiology Study—Screening Questionnaire (LFESSQ).

**METHODS:** Every patients going to visit a rheumatologist at a hospital in Firenze, during a 30-day period, what the reason of their visit, were interviewed using the LFESSQ with two additional questions on fatigue, and examined to confirm or exclude the diagnostic of FM using American College of Rheumatology (ACR) classification criteria. The screening questionnaire was also administered to a representative community sample more than 15 years old, selected by the quota method. The prevalence of FM was estimated in the general population, applying the predictive positive value, observed in consultation, to the positive screens. **RESULTS:** 31.3% patients interviewed were found positive for chronic widespread pain, 20.7% for widespread pain and fatigue and in 26.2% \[25.6–26.7\] the diagnosis of FM was confirmed. In the general adult population, 10.1% subject were positive for widespread pain and 5.2% for widespread pain and fatigue. The prevalence in general population, is 6.6% \[5.1–8.1\], if patients screened positive for chronic widespread pain are considered. If fatigue is added, the prevalence of 3.7% \[2.6–4.8\].

**CONCLUSIONS:** Our study confirms the results from Canada, US or Spain, with slight differences probably due to the different methodologies and populations employed. The minimum prevalence estimated of 3.6% in Italy, these means that approximately 1.8 millions of Italians, largely women, may suffer from FM.

**PMS9**

**PREVALENCE OF FIBROMYALGIA IN PORTUGAL**

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**OBJECTIVES:** To estimate the prevalence of fibromyalgia syndrome (FM) in rheumatology consultation and in the general adult population, in Portugal. **METHODS:** All patients going to visit the rheumatologist in the Hospital Egas Moniz and in Hospital Santa Maria in Lisbon during a 30-days period, were interviewed using the London Fibromyalgia Epidemiological Study (LFES) Screening Questionnaire, with two additional questions on fatigue, and examined to confirm or exclude the diagnostic of FM using American College of Rheumatology (ACR) classification criteria. The screening questionnaire validated in Portuguese