To review the PRO end-points appearing in the product labels of pain treatments with a particular focus on products approved both in the United States (US) and in Europe, METHODS: Pain treatments approved in the US since 1998 and in Europe through the centralized procedure established in 1995, and including PRO evaluations in the approved labeling were identified from the PROLabels database. PROlabels is a unique on-line tool providing information on the products for which the FDA and EMEA have granted PRO labeling claims. For each product approved by both agencies, we will compare the PRO endpoints appearing in the approved labeling and also analyze the PRO studies submitted by the sponsor. RESULTS: Overall, 26 products indicated for the treatment of pain were identified, accounting for 24 different indications and ten different domains. Various domains were used to measure pain (VAS, Likert scales). Of these 26 drugs, only two showed evidence of treatment efficacy using additional PRO endpoints (function and patient satisfaction). The PRO appearing in the approved labeling are rather consistent between both regulatory agencies. Information on additional PRO endpoints that were assessed in the clinical studies submitted by the sponsors but were not accepted in the approved labeling was available for nine out of the 26 dosiers. The concepts assessed were health-related quality of life, psychological functioning, physical functioning (including interference with sleep) and patient global impression. A focus was made on the different reasons of rejection of the most recent claims, in the light of the current PRO guidelines published by both regulatory agencies. CONCLUSIONS: Overall, only a few pain treatments include other PRO endpoints in addition to pain in their labeling. An interesting finding is the similarity between the American and the European PRO claims for pain therapies.

USE OF POLYPHARMACY IN PATIENTS WITH FIBROMYALGIA

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OBJECTIVES: Fibromyalgia (FM) is a chronic disorder characterized by multiple symptoms (e.g., pain, fatigue, cognitive dysfunction, sleep disturbance). The efficacy of most medications currently used to treat FM is limited, however, and problems of tolerability are often encountered, possibly causing many patients to discontinue therapy. This study examines patterns of use of prescription (Rx) medications with an eye toward assessing possible unmet clinical need. METHODS: Using a large US health insurance database spanning the period 2003–2007, we identified all patients with ≥1 medical encounters for FM (defined as ICD-9-CM diagnosis code 729.1) in each of these three calendar years (“FM patients”). Rx medications possibly related to the treatment of FM (“FM-related”) were defined to include antiepileptics, benzodiazepines, nonsteroidal anti-inflammatory drugs, muscle relaxants, sedative/hypnotics, opioids, serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, L-dopa, and carbidopa. We examined receipt of FM-related Rx medications from an alternative perspectives (i.e., point prevalence [receipt among all FM patients at any point in the calendar year]; and [2] point prevalence [evidence of use on July 1 of each calendar year]. Substantial differences between period prevalence and point prevalence rates may be suggestive of high rates of medication discontinuation. RESULTS: A total of 51,885 patients met all study entry criteria. In each of the three years, approximately two-thirds of study subjects had evidence of receipt of FM-related Rx medications (65.2% in 2005, 66.5% in 2006, 66.7% in 2007). Corresponding point prevalence estimates, however, were substantially lower (July 1, 2005: 38.1%; July 1, 2006: 60.9%; July 1, 2007: 43.3%). CONCLUSIONS: While roughly two-thirds of FM patients received FM-related Rx medications in any given year, point prevalence estimates were substantially lower, potentially suggestive of high rates of medication discontinuation. Further research is needed to better understand the extent to which these treatment patterns are indications of unmet medical need with currently available Rx medications in patients with FM.

USE OF PRESCRIPTION PHARMACOTHERAPY IN PATIENTS WITH FIBROMYALGIA: EVIDENCE OF UNMET NEEDS

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SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

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