Original Article

Preliminary study on patients located at the Kashani/Isfahan Hospital with multiple sclerosis between the years 2011 and 2013

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Abstract

Background: Multiple sclerosis (MS) is a multifactorial disease that could result from demyelination of the myelin sheath. The aim of this study is to investigate the demographic features and rank the immunomodulating drugs in patients with MS.

Materials and Methods: This study was conducted in the MS clinic of the Isfahan Kashani Hospital, from 22 May, 2011 to 18 March, 2013. The data analyses ($n = 1067$) were divided into two periods: (1) 2011/05/22 to 2012/03/18 denoted as P1 and (2) 2012/04/02 to 2013/03/18 denoted as P2.

Results: Most of drugs prescribed within the population studied were: Avonex, Betaferone, and Rebif. There was an increase in the number of female ($n = 811$) and male subjects ($n = 256$). During P1/P2 there was an increase from 460 to 607 in the total number of patients, respectively. The number of patients who attended the MS clinic once was 250 (P1) versus 430 (P2), and those more than four times was 71 (P1) versus 59 (P2) correspondingly.

Conclusion: The number of females increased from 2011 to 2013. Because of dissimilar ingredients additive of different pharmaceutical companies, it could be suggested that pharmacotherapy strategies, especially in Iranian population of MS with first-line treatment using Avonex, Betaferone and Rebif, more spotlighted on inter- and intra-individual variability based on clinical pharmacokinetics parameters.

Key Words: Demographic, methylprednisolone, multiple sclerosis, pharmacokinetics, pharmacotherapy

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INTRODUCTION

Multiple sclerosis (MS) is the most widespread continuous inflammatory disease of the central nervous system (CNS) occurring recurrently and resulting in early disability, many other severe problems, and even death. A recent article published by Tullman, in 2013, described that MS persuades about 400,000 people in the United States. Optic neuritis, central paralysis, sensory disturbances, and complexities in management and stability, cognitive dysfunction, fatigue, and sleep disorders are the main characteristic medical symptoms. Relapsing–remitting is the preliminary course of the disease presentation. Subsequently, related to patients' variability and the quality of disease management, it converts into a secondary progressive form. As in a majority of

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autoimmune diseases, there is a clear higher feminine predominance.[1-3] In Isfahan, there was a prevalence of 73.3/100,000 between April 2003 and July 2010 and an incidence rate of 9.1/100,000 in 2009.[4-7] However, introduction of the disease-modifying therapy (DMT) has altered the management of MS, but none of the procedures is entirely efficient in limiting the disease activity in all patients. There are many reports that corroborate that patients could experience relapses while on treatment. Therefore, an important issue is to categorize the clinical and pharmacological management of breakdown or breakup in an individual patient. Earlier, periodical accounting dealing with corticosteroids management considerably improved a patient's symptoms. The remedial profit of the adrenocorticotropic hormone (ACTH) in MS is typically attributed to its corticotropic events. The ACTH proceeds via corticosteroid-independent melanocortin tracks to provoke downmodulating events on the immune system cells and the cytokines they produce. In the dynamic stage of MS, steroid pulse therapy has been recognized as a cure for individuals.[8-12] According to previous publications on managing acute disease attacks, pulse therapy using Methylprednisolone (MP) comprised the majority set of expected drugs. It has a wide range of effects, including changes to the metabolism and immune responses.[13-16] The purpose of this research has been to investigate the demographic and pharmacotherapy features of patients with MS between the years 2011 to 2013.

MATERIALS AND METHODS

A cross-section study of 1067 patients (females; n = 811 and males; n = 256) in 1984 episodes was carried out from 22 May, 2011, until 18 March, 2013. All patients attended the MS clinic located at the Kashani Hospital/Isfahan/Iran, affiliated to the Isfahan Neurosciences Research Center (INRC). Analysis of the data was based on two periods; (1) Time of study of period one (P1) was from 2011/05/22 to 2012/03/18 and (2) time of study of period two (P2) was from 2012/04/02 to 2013/03/18.

Out of the total population studied, 460 patients comprising 358 females and 102 males attended the MS clinic within P1 and 607 patients comprising 453 females and 154 males attended MS clinic within P2. Demographical data, the code number of patients in the hospital records, the exact interval of MS clinic attendance, drug used as first-line treatment, pulse therapy (date-frequency-time) were noted in the d-Base. The statistical analyses of the d-Base were performed using Microsoft Excel and SPSS for windows.

RESULTS

From 2011 to 2013, a total of 1067 patients attended the MS clinic. The patients were studied on 1984 occasions (1206 within period P1 and 778 within period P2). From PI/P2, there was a total ratio of 460/607 in the number of patients. The total female/male ratio was 811/256. The characteristics of the patients in each group are presented in Table 1. The incidence of pulse therapy was with a mean of 3.2 times (range: 1-13 times). The mean time interval between pulse therapy was 44.4 days (range: 1-532 days). As shown in Figure 1, the distribution ratio according to gender was ranged as P1 (358)/P2 (453) females and P1 (102)/P2 (154) males.

Figure 2 shows that the highest rate of patients belongs to the age group between 20 and 39 years (65.6%) followed by the age group of 40-59 years (24.4%) and 60-87 years (10%).

Out of 460 patients, 250 with a mean age of 35 years (range 10-87 years) attended the MS day clinic for MP pulse therapy, within P1, on one occasion. The ratio of females/males was 201/50 in that order. The mean frequency for attendance of MS day clinic for MP pulse therapy was two times with a minimum of one and maximum of twelve. As seen in Figure 3, the incidence of attendance were as follows: Eighty-nine patients (n = 2 times), 50 patients (n = 3 times), 33 patients (n = 4 times), 18 patients (n = 5 times), nine patients (n = 6 times), three patients (n = 7 times), three patients (n = 8 times), three patients (n = 9 times),

Table 1: Baseline characteristics of patients with multiple sclerosis from P1 to P2

Variable	P1	P2
Occasions	1206	778
Male	102	154
Female	358	453

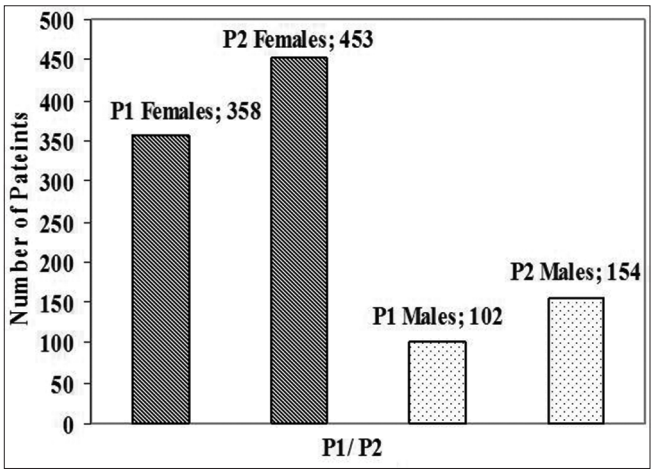

Figure 1: Distribution of patients according to gender (n = 1067)

one patient (n = 10 times), and 1 patient (n = 12 times). A total of 71 patients (i.e., 55 females and 16 males) with a mean age of 35.6 years (range: 21-62 years) attended the MS clinic for MP pulse therapy more than four times.

Out of 607 patients with a mean age of 34 years (range 10-87 years) who attended the MS clinic within time P2, 430 patients (i.e., 321 females and 109 males) attended the MS clinic only once. The incidence for MS clinic attendance was with a mean of two times (range: 1-13 times). As seen in Figure 4, the incidence of attendance were as follows: Seventy-eight patients (n = 2 times), 40 patients (n = 3 times), 22 patients (n = 4 times), 14 patients (n = 5 times), 12 patients (n = 6 times), five patients (n = 7 times), one patient (n = 8 times), two patients (n = 9 times), one patient (n = 11 times), and two patients (n = 13 times). A total of 59 patients (i.e., 45 females and 14 males) with a mean age of 33.9 years (range: 15-56 years) attended the MS clinic for MP pulse therapy more than four times.

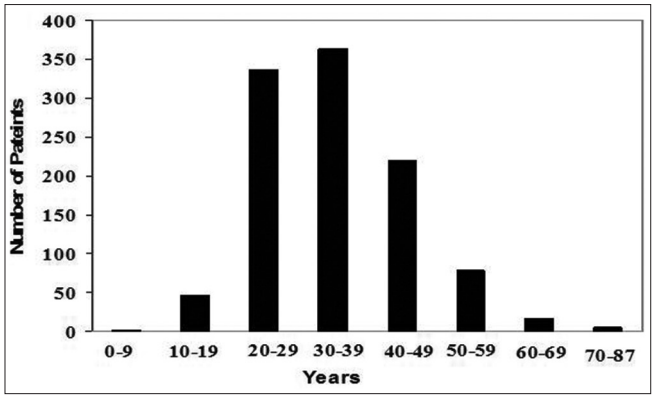

Figure 2: Distribution of patients' age (n=1067)

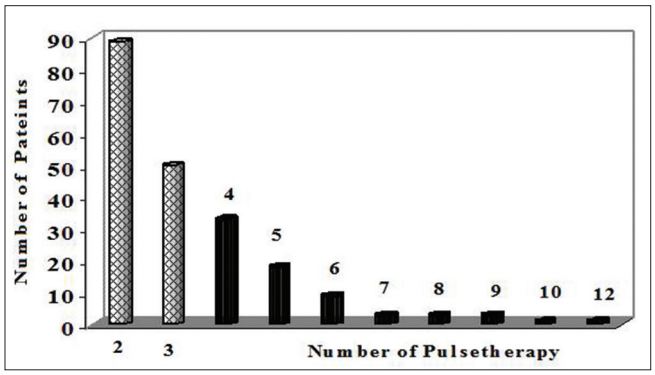

Figure 3: Distribution of patients intended for pulse therapy, more than once within P1 (n=210)

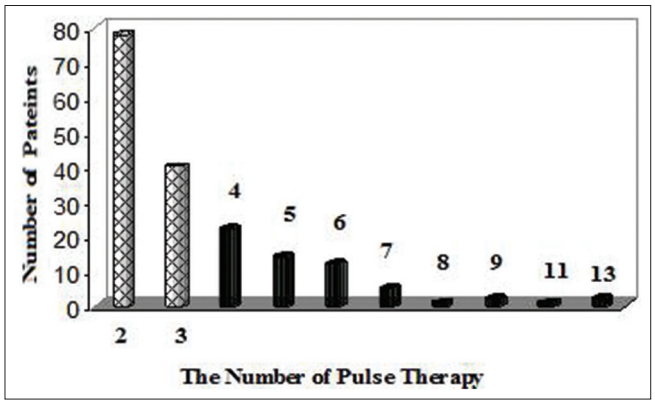

Figure 4: Distribution of patients intended for pulse therapy, more than once within P2 (n=177)

The preliminary ranking of drugs used as first-line treatment showed that: Avonex > Betaferone > Rebif were the most prescribed drugs. In 50% of the patients, the Expanded Disability Status Scale (EDSS) at the last visit was lower than 3.5. In 64.1%, the relapse rate was < 1 per year. In 61.1% of patients, the duration of MS was between two and ten years.

DISCUSSION

Demographic and pharmacotherapy studies of patients with MS from the years 2011 to 2013 revealed that the highest prevalence with MS was in patients in the age group of 20 to 39 years (65.6%). A previous publication reported that Isfahan could be considered as an area with a medium-to-high risk of MS. In this study, the total number of patients with MS, who attended the day clinic for pulse therapy was 460; P1/607; P2. The ratio of females/males was 77.8%; P1/74.6%; P2. This was in agreement with the previous publications that confirmed an increase in female/male ratio over time in many countries around the world.[1-7] Analysis of the data obtained from this study (n = 1067) showed that 15.4 and 9.7% of the patients attended the MS clinic more than four times within the periods P1 and P2, respectively. A potential explanation for such patients who attended the MS clinic repeatedly might be related to a period of no treatment (self-discontinuation of prescribed drugs) or a period in which the new treatment was not fully effective, and during which time relapses could have occurred. To prevent adverse effects related to intravenous steroid therapy, such as, weight gain, glaucoma, osteoporosis, psychosis, sleeplessness, increased appetite, indigestion, nervousness or restlessness, headache, decreased or blurred vision, frequent urination, increased sweating, unusual increase in hair growth on body or face and 'down' moods,[13-16] we propose to study this feature of altering MS presentation that could be mentioned as one potential negative outcome of treatment.

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