ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

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Retrospective Cohort Study of Gabapentinoid Drug Use in Hospitalized Physical Medicine and Rehabilitation Clinic Patients

Fiziksel Tıp ve Rehabilitasyon Kliniğinde Yatan Hastalarda Gabapentinoid İlaç Kullanım Yaygınlığının Retrospektif Kohort Çalışması

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ABSTRACT Objectives: The aim of this study is to investigate the gabapentinoid utilization rates in musculoskeletal system inpatients and to review the conditions, doses and durations of utilization. **Material and Methods:** All inpatients over 18 receiving treatment in Physical Medicine and Rehabilitation Clinic of Bursa City Hospital between July 2019 and July 2020 were included in this retrospective study regardless of gender differences. The demographic characteristics of patients, smoking habits, diagnoses, the name of the gabapentinoid drug utilized, the dose used, the duration of utilization, and other drugs utilized concomitantly with gabapentinoid and any additional diseases were recorded. **Results:** Gabapentinoid use was detected in 173 (27.9%) of 620 patients. It was determined that 88 of 173 patients used gabapentin and 85 were using pregabalin. It was determined that gabapentinoids used mainly for neuropathic pain indication were used at lower doses than recommended. **Conclusion:** Gabapentinoid use is quite common in our group of inpatients with physical medicine and rehabilitation. More studies are needed to investigate the reasons for using gabapentinoids at lower doses than generally recommended. Although they cause concerns about addiction, their frequent use for pain control shows that gabapentinoids are very beneficial when used in the correct indications and doses.

Keywords: Gabapentinoid; gabapentin; pregabalin; pain; neuropathic pain

ÖZET Amaç: Bu çalışmanın amacı, yatarak tedavi gören kas iskelet sistemi bozukluğu olan hastalarda, gabapentinoid kullanım oranlarını araştırmak ve bu ilaçların hangi durumlarda, hangi dozlarda ve süreyle kullanıldığını gözden geçirmektir. **Gereç ve Yöntemler:** Temmuz 2019 ile Temmuz 2020 tarihleri arasında Bursa Şehir Hastanesi Fizik Tedavi ve Rehabilitasyon Kliniğinde yatan 18 yaş üstü tüm hastalar, cinsiyet farkına bakılmaksızın çalışmaya dâhil edildi. Hastaların demografik özellikleri, sigara alışkanlıkları, tanıları, kullanılan gabapentinoid ilacın adı, kullanım süre ve dozu, gabapentinoid ile birlikte kullanılan diğer ilaçlar ve hastalıklar kaydedildi. **Bulgular:** Toplam 620 hastanın, 173'ünde (%27,9), gabapentinoid kullanımı tespit edildi, 173 hastanın 88'inin gabapentin, 85'inin pregabalin kullandığı belirlendi. Ağırlıklı olarak nöropatik ağrı endikasyonu ile kullanılan gabapentinoidlerin tavsiye edilenden daha düşük dozda kullanıldığı belirlendi. **Sonuç:** Yatarak tedavi gören fizik tedavi ve rehabilitasyon hastaları grubumuzda, gabapentinoid kullanımı oldukça yaygındır. Gabapentinoidlerin genel olarak tavsiye edilenden düşük dozlarda kullanılmasının nedenlerini araştıran ileri çalışmalara ihtiyaç duyulmaktadır. Her ne kadar bağımlılıkla ilgili endişelere yol açsa da ağrı kontrolünde sıkça tercih edilmeleri gabapentinoidlerin doğru endikasyon ve dozlarda kullanıldığında oldukça yararlı olduğunu düşündürmektedir.

Anahtar Kelimeler: Gabapentinoid; gabapentin; pregabalin; ağrı; nöropatik ağrı

Pain is one of the major reasons why people seek for health services. Chronic pain is an important health issue faced by the clinicians in practice. Approximately 20% of the people throughout the world suffer from chronic pain.[1] When the enormous variety of chronic pain syndromes is taken into consideration, it is a challenge to measure the exact prevalence of it and therefore it is thought to be much

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more common.[1] Chronic pain which affects millions of people every year is the most frequent reason of disability and the most important reason that disrupts life quality. In general, the most common reason of chronic pain throughout the world is the musculoskeletal system pain, being low back pain in the first instance.[2] Along with substantial increase in health expenses, it causes the disruption of functionality of the patient and lack of work force. It constitutes an important burden both in personal and in social aspects. The pharmacological approach in the chronic pain treatment management requires the utilization of many agents including acetaminophen, non-steroid anti-inflammatory drugs (NSAID), opioids and anti-convulsants.[3] Acetaminophen is usually ineffective on moderate and severe pain.[3] NSAIDs are problematic or contraindicated in most patients having complicated medical status. Opioids have a potential to cause addiction.[3] The success of all these treatments is limited and the clinicians prescribe gabapentinoids more often in order to fill this gap in pain management.

Gabapentinoid drugs (gabapentin and pregabalin) were initially developed as anti-epileptics, however, at the present time they are increasingly being prescribed for pain treatment.[3-6] Gabapentin has been approved by U.S. Food and Drug Administration (FDA) for the first time in 1993 for the treatment of epileptic attacks, and then in 2002 for the treatment of post-herpetic neuralgia.[3,5] In addition, they have been approved by European Medicines Agency (EMA) for neuropathic pain treatment.[7] Pregabalin, however, has been approved in 2004 for epileptic attacks, post-herpetic neuralgia and diabetic neuropathy, in 2007 for fibromyalgia (FMS) and in 2012 for the pains associated with spinal cord injuries.[3] Pregabalin has been approved by EMA, in addition, for generalized anxiety disorder and neuropathic pain indication.[7] Besides, even though the relevant FDA approval is not available, gabapentinoids have been listed as primary drugs for the treatment of neuropathic pain in the decision support source of American Center for Diseases Prevention and Control and of a Popular Online Clinic.[8,9] Canadian Pain Association also suggests gabapentinoids for the primary treatment of chronic neuropathic pain. In Turkey, apart from epileptic attacks, pregabalin is being utilized for neuropathic pain and FMS, while gabapentin is being utilized for neuropathic pain indications, whereas they are both covered by the social security institution.

In the studies carried out, the cases in which mostly gabapentinoids are effective or ineffective, the physicians prescribing them the most, the cases of abuse, the addiction status and the side effects have been assessed.[3,4,6] In a recent study, all outpatient visits in the U.S. between 2003 and 2016 have been scanned and it has been observed that the most common diagnosis among the first three diagnoses utilizing gabapentinoids were associated with musculoskeletal system (18.6%). Next come the diagnoses associated with nervous system (12.9%), mental disorders (8.2%) and diabetes mellitus (DM) (4.5%). The aim of this study is to investigate the gabapentinoid utilization rates in musculoskeletal system inpatients and to review the conditions, doses and durations of utilization.

MATERIAL AND METHODS

All inpatients over 18 receiving treatment in Physical Medicine and Rehabilitation (PMR) Clinic of Bursa City Hospital between July 2019 and July 2020 were included in this retrospective study regardless of gender differences. The patient files were scanned by two attending physicians and those using gabapentinoid medication were determined. The patients using gabapentinoid for at least 1 month were included in the study. Patients with multiple admissions during the relevant period were taken into consideration if they were using gabapentinoid during at least one admission or according to their first appropriate admission record. A form created particularly for the study was used to record the information of these patients determined. The demographic characteristics of patients (age, gender, marital status, occupation), smoking habits, diagnoses (the first three diagnoses), the name of the gabapentinoid drug utilized, the dose used, the duration of utilization, and other drugs utilized concomitantly with gabapentinoid (paracetamol, NSAID, opioid, etc.) and any additional diseases (DM, hypertension, chronic obstructive pulmonary disease, etc.) were recorded on these forms. Patients with cancer-associated pain, headache, perioperative

pain and a history of drug abuse were not included in the study. Gabapentinoid doses and durations were calculated by taking into account the discharged patient prescriptions. Each of the parameters examined in the patient group studied were evaluated separately and comparatively for the two gabapentinoids. The average doses used were determined by initially examining the two gabapentinoids separately and by considering all the diagnoses, and then again for both gabapentinoids separately but by comparing them with each other this time.

The study protocol was approved by the Ethics Committee of Bursa City Hospital (date: 29.07.2020/ no: 2020-4/1). The study was conducted in accordance with the principles of the Declaration of Helsinki.

STATISTICAL ANALYSIS

Statistical evaluation was made with IBM SPSS 20.0 (IBM Corp., Armonk, NY, USA) package software. Numerical variables were given as average±standard deviation, while categorical variables were given as frequency (%). Differences between groups were evaluated by using the Mann-Whitney U test. For the testing of two way hypotheses, $p<0.05$ was considered sufficient for statistical significance.

RESULTS

Between July 2019 and July 2020, 620 patients received inpatient treatment at the PMR clinic of Bursa City Hospital. Gabapentinoid use was detected in 195 (31%) patients and 22 patients were excluded from the study since they had used the drug for less than 1 month. It was found that 88 of the remaining 173 (27.9%) patients used gabapentin while 85 used pregabalin. Although there was no significant difference between gabapentin and pregabalin users in terms of age, gender, occupation, marital status and smoking, concomitant use of antidepressant drugs was found to be higher in the pregabalin group (44.7%) (Table 1). DM association was more common in the

TABLE 1: Characteristics of patients using gabapentinoid.

	Pregabalin (n=85)	Gabapentin (n=88)	p*	Total (n=173)
Gender (n) (%)				
Female	65 (76.5)	56 (63.6)	0.66	121 (69.9)
Male	20 (23.5)	32 (36.4)		52 (30.1)
Age (year) (means±SD)	61.8±13.8	63.2±13	0.351	62.5±13.4
Marital status (n) (%)				
Married	77 (90.6)	85 (96.6)	0.106	162 (93.6)
Single	8 (9.4)	3 (3.4)		11 (6.4)
Working status (n) (%)				
Working	13 (15.3)	9 (10.2)	0.317	22 (12.7)
Not working	72 (84.7)	79 (89.8)		151 (87.3)
Smoker (n) (%)	11 (12.9)	13 (14.8)	0.728	24 (13.9)
Systemic diseases (n) (%)				
Diabetes mellitus	25 (29.5)	8 (9.4)	0.026	70 (40.5)
Hypertension	33 (38.9)	41 (46.6)		74 (42.9)
Chronic kidney disease	8 (9.4)	7 (7.9)		15 (8.6)
Chronic pulmonary disease	3 (3.6)	3 (3.4)		6 (3.6)
Other medications (n) (%)				
Paracetamol	18 (21.2)	17 (19.3)	0.761	35 (20.2)
NSAID	40 (47.1)	47 (53.4)	0.404	87 (50.3)
Opioid	4 (4.7)	1 (1.1)	0.161	5 (2.9)
Antidepressant	38 (44.7)	18 (20.5)	0.001	56 (32.4)
Average duration of drug use (month) (means±SD)	10±6.6	7.8±4.1	0.348	8.9±5.6

NSAID: Non-steroid anti-inflammatory drugs; SD: Standard deviation.

gabapentin group (51.1%) (Table 1). No difference was observed between the two groups in terms of the average duration of drug use (Table 1). The indications of gabapentinoid use, the number of patients using gabapentinoid in these indications, the average doses utilized and the recommended daily doses are shown in Table 2. In approximately 90% of the patients, the indication was found to be associated with neuropathic pain. In the pregabalin group, patients with FMS, neck-arm pain and gonarthrosis were more common than those in the gabapentin group, while patients with diabetic neuropathy and paraplegia were more common in the gabapentin group. When the diagnoses of patients on pregabalin were evaluated, low back and leg pain, FMS, gonarthrosis/hemiplegia took the first three places, while diabetic neuropathic pain, low back and leg pain, paraplegia/hemiplegia took the first three places in patients using gabapentin. The average doses utilized were mostly in the amounts recommended in the gabapentinoid group, whereas they were found to be below average in FMS, neuropathic pain, and restless leg disease. The doses utilized in the pregabalin group for diabetic neuropathic pain, hemiplegia, FMS, and neuropathic pain were lower than recommended. The number of patients on medications concomitantly with gabapentinoids according to the diagnoses was shown in Table 3, while the distribution of first 3 diagnoses investigated in patients was shown in Table 4.

DISCUSSION

In this study, which was carried out to investigate the utilization rate of gabapentinoid in inpatients in the PMR clinic and to determine the conditions, doses and duration of utilization; the utilization of gabapentinoid was determined in approximately one-third of all inpatients. In a previous study carried out in a general hospital in Canada, all utilization indications in inpatients were investigated, 4,103 patients were screened, and 550 (13.4%) patients were found to be on gabapentinoid.[4] The high utilization rate in our study is thought to be associated with the fact that we are a clinic that primarily deals with pain treatment. To the best of our knowledge, our study is the first study to screen the inpatients only in the PMR clinic in order to investigate the utilization of gabapentinoid and it provides important data on the determination of indication and drug utilization patterns. In our study, the indication of gabapentinoid

TABLE 2: Gabapentinoid indications for use and mean doses.

Indications	Total n=173 (%)	Gabapentin n=88	Median dose (mg)	Recommended dose (mg)	Pregabaline n=85	Median dose (mg)	Recommended dose(mg)
Low back and leg pain (chronic radiculopathy)	36 (20)	19	1052	900-3600	17	220	150-600
Diabetic neuropathic pain	27 (15.6)	22	1030	1200-3600	5	120	150-300*
Hemiplegia	23 (13.2)	13	1130	900-3600	10	172	300-600
Paraplegia	19 (10.98)	13	1453	900-3600	6	250	150-600*
Fibromyalgia	17 (9.82)	2	600	900-2400	15	221	300-450*
Gonarthrosis	15 (8.67)	5	1600	900-3600	10	225	300-600
Frozen shoulder	10 (5.7)	4	1125	900-3600	6	225	300-600
Neck-arm pain (chronic radiculopathy)	10 (5.7)	2	1200	900-3600	8	190	150-600
Neuropathic pain	5 (2.89)	3	800	900-3600	2	225	300-600
Tetraplegia	4 (2.31)	1	1600	900-3600	3	316	150-600*
Restless leg	2 (1.15)	1	600	900-3600	1	300	150-600*
Multiple sclerosis	1 (0.57)	0		900-3600	1	300	300-600
Algoneurodystrophy	1 (0.57)	1	1800	900-3600	0		300-600
Parkinson's disease	1 (0.57)	1	300	900-3600	0		300-600
Post-polio syndrome	1 (0.57)	1	1200	900-3600	0		300-600
Phantom pain	1 (0.57)	0		900-3600	1	150	300-600

*FDA recommended doses.

TABLE 3: Distribution of patients using additional drugs together with gabapentinoids according to diagnosis.

Indications	Gaba*+ paracetamol	Preg**+ paracetamol	Gaba*+ NSAID	Preg**+ NSAID	Gaba*+ antidepressant	Preg**+ antidepressant	Gaba*+ opioid	Preg**+ opioid
Low back and leg pain (chronic radiculopathy)	6	3	12	10	3	4	0	1
Diabetic neuropathic pain	5	2	12	3	4	3	0	0
Hemiplegia	2	1	5	3	0	5	1	1
Paraplegia+ Tetraplegia	1	2	8	2	6	4	0	1
Fibromyalgia	0	4	2	6	1	9	0	0
Gonarthrosis	3	1	1	7	1	5	0	0
Frozen shoulder	1	1	3	5	0	1	0	1
Neck-arm pain (chronic radiculopathy)	0	5	0	1	1	5	0	0
Neuropathic pain	0	0	2	0	1	1	0	0
Restless leg	0	0	1	0	0	0	0	0
Multiple sclerosis	0	0	0	0	0	1	0	0
Algoneurodystrophy	0	0	1	0	0	0	0	0
Parkinson's disease	0	0	0	0	0	0	0	0
Post-polio syndrome	0	0	0	0	0	0	0	0
Phantom pain	0	1	0	0	0	1	0	0

*Gaba: Gabapentin; **Preg: Pregabalin; NSAID: Non-steroid anti-inflammatory drugs.

utilization was found to be predominantly related to neuropathic pain and is consistent with the literature.[4] Neuropathic pain is the most important component of chronic pain, and it is thought to affect one out of every ten people.[10,11] Gabapentinoids are increasingly being utilized in its treatment.[12-25] In this study, the number of patients being on pregabalin and gabapentin was found to be very close. This may be associated with the fact that the PMR specialists do not make distinction while choosing gabapentinoids for pain treatment. In the pregabalin group, 44% of the patients were using antidepressants concomitantly, and it is observed that almost half of them (47.3%) had FMS as one of the first two diagnoses. This has been attributed to the fact that antidepressants are the commonly recommended medications in the treatment of FMS. In our patient group, the rate of opioid utilization concomitantly with gabapentinoids (2.9%) was found to be significantly lower according to the studies in the literature (28.9% -32.9%).[4,6] The reason for this is associated with the fact that the opioids were not initially preferred for the treatment of chronic pain in our group but were concomitantly recommended for treatment-resistant patients. Furthermore, general patients were screened during two other studies in the literature, whereas the patients with drug abuse, and the patients with opioid and benzodiazepine addiction were included in the study.[3,4] From the viewpoint of systemic diseases, particularly DM was found with a higher rate in gabapentin users. This may be associated with the use of gabapentin as the first choice, by considering that it causes less serious adverse events.

In some indications, gabapentinoid doses were found to be below the recommended amount, whereas this situation was thought to be associated with dose-limiting side effects. In addition, it is known that preferring lower doses in patients with renal failure and in advanced age group patients causes the doses of gabapentinoid to be lower than recommended.[4] Similar to the literature, in 54 (31%) out of 173 patients in our study, gabapentinoid was used at a lower dose than recommended (Table 5).[4] The presence of chronic renal disease in 20% of these patients and the fact that 46% of them are over 65 years old support this view. Besides, gabapentinoid addiction concerns may have encouraged the physicians to utilize lower doses of medication.

The main limitations of the present study are sleep disturbance is not questioned, new onsets were not reserved with those admitted while using gabapentinoid, comparison is not made with patients not using gabapentinoid.

TABLE 4: Distribution of the first three diagnoses of patients using gabapentinoid.

	Pregabalin (n=85)	Gabapentin (n=88)	Total (n=173)
Indication 1 (n) (%)			
Neck-arm pain	8 (9.4)	2 (2.3)	10 (5.8)
Fibromyalgia	15 (17.6)	2 (2.3)	17 (9.8)
Restless leg	1 (1.2)	1 (1.1)	2 (1.2)
Gonarthrosis	10 (11.8)	5 (5.7)	15 (8.7)
Neuropathic pain	2 (2.4)	3 (3.4)	5 (2.9)
Diabetic neuropathy	5 (5.9)	22 (25)	27 (15.6)
Low back and leg pain	17 (20)	19 (21.6)	36 (20.8)
Frozen shoulder	6 (7.1)	4 (4.5)	10 (5.8)
Paraplegia	6 (7.1)	13 (14.8)	19 (11.0)
Hemiplegia	10 (11.8)	13 (14.8)	23 (13.3)
Tetraplegia	3 (3.5)	1 (1.1)	4 (2.3)
Multiple sklerosis	1 (1.2)		1 (0.6)
Algoneurodystrophy		1(1.1)	1 (0.6)
Parkinson's disease		1(1.1)	1 (0.6)
Post-polio syndrome		1(1.1)	1 (0.6)
Phantom pain	1 (1.2)		1 (0.6)
Indication 2 (n) (%)			
Neck-arm pain	5 (5.9)	1 (1.1)	6 (3.5)
Fibromyalgia	15 (17.6)		15 (8.7)
Gonarthrosis	6 (7.1)	8 (9.1)	14 (8.1)
Neuropathic pain	26 (30.6)	23 (26.1)	49 (28.3)
Diabetic neuropathy	8 (9.4)	18 (20.5)	26 (15.0)
Low back and leg pain	11 (12.9)	12 (13.6)	23 (13.3)
Frozen shoulder		4 (4.5)	4 (2.3)
Lymphedema		1 (1.1)	1 (0.6)
Multiple sklerosis		1 (1.1)	1 (0.6)
Parkinson's disease		3 (3.4)	3 (1.7)
Burn	1 (1.2)		1 (0.6)
Indication 3 (n) (%)			
Fibromyalgia	1 (1.2)	2 (2.3)	3 (1.7)
Gonartrhrosis		1 (1.1)	1 (0.6)
Diabetic neuropathy		1 (1.1)	1 (0.6)
Low back and leg pain		2 (2.3)	2 (1.2)

CONCLUSION

In conclusion, the use of gabapentinoid is quite common in our group of PMR inpatients, the definition of gabapentinoids during the hospitalization is an opportunity for reviewing the indications of the drug once again, evaluating its effect and preventing the side effects arising from polypharmacy. Further studies are needed to investigate the reasons for using gabapentinoids at doses lower than generally recommended. Even though they cause concerns about ad-

TABLE 5: Distribution of patients using less than recommended dose of gabapentinoid.

Indications	Gabapentin n=36	Pregabalin n=18
Diabetic neuropathic pain	14	3
Low back and leg pain	9	-
Fibromyalgia	1	7
Hemiplegia	6	5
Paraplegia/tetraplegia	2	1
Neuropathic pain	1	1
Neck-arm pain	1	1
Gonarthrosis	1	-
Parkinson's disease	1	-

diction, the frequent utilization of gabapentinoids in pain management suggests that they are considerably useful when utilized in the correct indications and doses.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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