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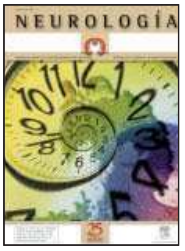

ORIGINAL ARTICLE

Assessment of the efficiency of the clinical management of neuropathic pain in specialist clinics compared to general clinics in neurology health care Units in Spain

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KEYWORDS
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Abstract
Objectives: To analyse the cost-consequences of chronic neuropathic pain (NP) outpatient care comparing management in general clinics (GC) versus specialised pain clinics (SPC) in neurology settings in Spain.
Methods: A 6-month retrospective, cross-sectional, comparative observational study including NeP subjects was designed. Sociodemographics and clinical characteristics of subjects along with pain-related healthcare and non-healthcare resource utilisation were recorded. Lost-work-days equivalent missed as a consequence of pain were also collected to compute indirect costs. Costs to society were calculated in euros for the year 2008. Severity and interference of pain were used for the main effectiveness evaluation.
Results: A total of 234 patients (53%in SPC), 56.8%women, aged 59.3±14.7 years, were included. Patients were allocated according to usual administrative procedures in each participant centre, consecutively and independently of the diagnosis and clinical status of patients. Yearly indirect costs were €1,299±2,804 in SPC compared to €1,483±3,452 in GC (p=0.660), while annual direct costs were, €2,911±3,335 and €3,563±4,797, respectively (p=0.239), with total costs of €4,210±4,654 and €5,060±6,250, respectively (p=0.249). Mean pain severity at the time of evaluation was 3.8±2.3 in subjects in SPC vs. 5.2±2 in GC (p<0.001), while the mean interference of pain on daily activities was 3.3±2 and 4.7±2.5, respectively (p<0.001).

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Conclusions: In neurology settings in Spain, the outpatient clinical management of chronic NP in SPC is a dominant alternative compared with GC healthcare, since it has shown better patient healthcare outcomes with less severity and interference of pain on daily activities, while maintaining a similar level of costs. These results could help health decision makers when planning the use of healthcare resources

PALABRAS CLAVE
Neurología;
Dolor neuropático;
Eficiencia;
Costes;
Consulta especializada;
Consulta general;
Decisión sanitaria

Evaluación de la eficiencia del manejo clínico del dolor neuropático en consultas especializadas frente a consultas generales en unidades asistenciales de neurología en España

Resumen
Objetivo: Evaluar la eficiencia del seguimiento clínico del dolor crónico neuropático (DN) en consultas especializadas (CE) frente a consultas generales (CG) en unidades asistenciales de neurología (UAN) en España.
Métodos: Estudio transversal y retrospectivo, de 6 meses, observacional y comparativo, que incluyó a pacientes con DN. Se recogió: situación laboral, nivel educativo, historia clínica, comorbilidad concomitante, capacidad funcional y utilización de recursos sanitarios y no sanitarios. Los costes indirectos incluyeron los equivalentes de días de trabajo perdidos como consecuencia del DN. El coste se computó desde la perspectiva de la sociedad en el año 2008. Como medida de efectividad primaria se registraron la intensidad y la interferencia del dolor en las actividades de la vida diaria.
Resultados: Se incluyó a 234 pacientes (el 53% en CE); el 56,8% eran mujeres, y la media de edad era 59,3 ± 14,7 años. La asignación de pacientes se realizó según criterios asistenciales de forma consecutiva e independiente del diagnóstico y el estado clínico del paciente. El coste indirecto anual de los pacientes en CE fue de 1.299 ± 2.804 euros frente a 1.483 ± 3.452 euros en CG ($p = 0,660$), mientras que los costes directos fueron, respectivamente, 2.911 ± 3.335 euros y 3.563 ± 4.797 euros ($p = 0,239$), con unos costes totales de 4.210 ± 4.654 euros y 5.060 ± 6.250 euros ($p = 0,249$). La puntuación media en la intensidad del dolor fue de 3,8 ± 2,3 en CE y 5,2 ± 2 en CG ($p < 0,001$), mientras que la interferencia del dolor con las actividades diarias fue, respectivamente, de 3,3 ± 2 y 4,7 ± 2,5 ($p < 0,001$).
Conclusiones: El seguimiento clínico del DN en CE es una alternativa dominante cuando se compara con las CG en UAN en España, al asociarse a mejores resultados clínicos con menor intensidad del dolor e interferencia con las actividades diarias mientras se mantiene un coste similar. Estos resultados pueden ayudar en la toma de decisiones sanitarias a la hora de planificar la utilización de los recursos disponibles.

Introduction

The diseases and syndromes that condition chronic pain affect millions of people around the world and produce an enormous impact on patients and on society as a whole[1]. About 50% of the population present chronic pain, and for half of them it is highly disabling, poorly treated and carries a high demand for more and better services[2]. In our country, several studies place chronic pain as the leading cause of activity limitation in industrialised countries, with the important socio-economic cost this represents[3,4].

According to the International Association for the Study of Pain (IASP), neuropathic pain (NP) is defined as that resulting from a lesion or from central or peripheral nervous system dysfunction[5]. NP always has a distribution or a topography that corresponds to an anatomical territory defined by a central or peripheral nerve pathway, which justifies its management by the neurologist. It is a disease with a diagnosis and an aetiology, as well as a treatment, which are often complex, among which are most often found trigeminal neuralgia, postherpetic neuralgia and painful diabetic polyneuropathy[6,7]. In general, the severity of pain is moderate to severe and responds poorly to standard pain medication such as NSAIDs and opiates[8]. Antiepileptic drugs represent a therapeutic approach to be considered in these patients because of their action on the mechanisms of neuronal transmission, and are the most commonly used (70.9%) by neurologists for NP treatment, along with tricyclic antidepressants (14.9%)[9]. Very often, NP profoundly affects patient mood and triggers depressive

processes or pathological anxiety disorders that, coupled with decreased sleep quality, negatively affect the patient's quality of life and normal functioning[10,11].

Neuropathic pain is the eighth most frequent diagnosis in neurology consultations and the highest care demand in hospital consultations[12]. The prevalence in neurology consultations is of 3.88% 6.09%in hospital consultations and 2.92% in extra-hospital consultations[9]. In many cases, neurology consultations are overcrowded and neurologists consulted about a patient are not particularly linked to NP. Patients with NP require a comprehensive aetiological study, evaluation and quantification with pain severity scales reflecting its impact on daily activities and quality of life, as well as a complex treatment[7]. This implies the need for more time than is usually established for a first outpatient visit in the field of neurology. The majority of patients seen must be referred to specialist consultations, given the need for more complex assistance[13]. The Spanish Society of Neurology (SEN) itself recommends carrying out studies on usage of health services to establish a cycle of analysis and improvement[14].

A general neurology clinic (GC) is that which attends both diagnostic and therapeutic elements of neurological care. Its aim is not to filter out diseases to outpatient hospital care. It is considered that a specialized consultation in neurology cannot be at carried out in less than 20-30 min for an initial visit and in less than 15-20 min for successive consultations[14-16]. The recommended time for a first visit is 45 min and the required time is 25 min. These times were obtained by SEN[16] through a consensus among neurologists and through descriptive studies carried out in Spain[17]. The times scheduled for neurological consultations in similar studies in other countries are much higher, ranging between 40 and 90 min for first visits[18,19]. A specialized neurology consultation (SPC) is that which is organised with the purpose of healthcare for a particular process, under the responsibility of a physician who is experienced in the disease, using protocols or clinical pathways based on the available scientific evidence. If healthcare for a process is carried out by different experts, in a multidisciplinary and integrated manner, according to protocols or clinical pathways based on scientific evidence, as a reference for a given population, then we refer to a specialized neurology unit[13]. This unit should maintain some active basic/ clinical or clinical research, with research projects funded by external agencies, and should be accredited for teaching and incorporated into specific training programs.

This study was proposed to assess the efficiency and improvement of the quality of NP care in specialized pain clinics (SPC) in neurology care units versus in GC. It evaluated the healthcare and non-healthcare costs as well as the effectiveness of healthcare carried out. As indicators of effectiveness and quality of NP care, in addition to assessing the healthcare and non-healthcare costs, we measured the impact of healthcare on the intensity and the interference of NP in daily life. Secondarily, we analysed the concomitant symptoms of anxiety, depression, sleep disturbances and quality of life related to health. Finally, we determined patient satisfaction with different aspects of the healthcare received.

Material and methods

Design and type of study

This was a cross sectional, multicentre, observational and comparative study between two models of healthcare in SPC. In no case was the decision of the researcher about the most appropriate care for the patient interfered with. A total of 9 tertiary centres, in 6 regions (Andalusia, Catalonia, Galicia, Madrid, Basque Country and Valencia), with GC and SPC participated in the study between September 2007 and October 2008. Patients recruited had to be of both genders, aged over 18, diagnosed with NP according to common medical practice, with a medical history (NP-related) that included a follow up of 6 months, and with the sufficient cultural and educational level to complete health questionnaires formulated in Spanish. All patients were informed and were given details about the study, its nature and objectives, and about the information required to participate in the study. All patients were asked for their witnessed oral informed consent for the use and subsequent analysis of their data. The protocol and case report data were submitted for review and approval to the Clinical Research Ethics Committee of the Hospital Clínico San Carlos in Madrid.

The assignment of patients to each type of consultation was carried out according to healthcare criteria at each participating centre, consecutively and independently of patient diagnosis and clinical status. None of the doctors who assessed and collected patient data were involved in the allocation of patients to one or another consultation type. Study sample size was calculated from the study by Rodriguez et al.[20], which found an unadjusted monthly healthcare cost per patient with NP of 422±1,266 euros. This difference was considered to be relevant between the two healthcare models to calculate the sample size required for the study. Given the cross-sectional and retrospective design, no losses were considered for the statistical analysis. The two tailed t-test with a significance level of 5% and power of 80% (beta error=0.2) to detect statistically significant differences and 1:1 balanced groups required 143 patients per care model.

Health interventions and treatments

Given its observational nature, the study recorded the type and duration of interventions, both pharmacological and non-pharmacological. The treatment was freely chosen by each participant according to common medical practice. There were no specific therapies or special treatment regimes associated with participation in this study.

Effectiveness variables: health results

Health outcomes to assess the effectiveness of medical care in NP treatment according to consultation type were evaluated in a single visit, once it was found that the patient met the inclusion-exclusion criteria established and the socio-demographic data were collected. Effective health

outcomes were determined through self-administered health questionnaires, in versions adapted to and validated in Spanish.

The intensity and interference of NP were measured with the *Brief Pain Inventory* (BPI), an easy to understand, self-administered questionnaire. It was developed by Daule in 1983 and the Spanish version was validated by Badia et al.[21] in 2002. The BPI is a multidimensional instrument for pain assessment that provides information on its intensity and interference in the daily activities of patients. The version used in this study was the abbreviated one, with 11 items. This abbreviated version has two dimensions: pain severity (mean of the first 4 items) and interference with activities (last 7 items). Each item is scored from 0 (no pain / it did not affect me) to 10 (worst pain imaginable / it completely affected me.) These 11 items provided two summary scores, one for each dimension (with an interval from 0 to 10).

Any sleep disturbances were measured with the Medical Outcomes Study (MOS) sleep scale. This scale consists of a 12-item instrument exploring the impact or interference caused by the disease or a treatment or, in general, any external stimulus on the attributes of sleep architecture that correspond to 7 subscales: adequacy (2 items), optimal sleep (1 item), quantity (1 item), sudden awakenings (1 item), snoring (1 item), altered sleep (4 items) and somnolence (3 items)[22]. It also produces a general index for sleep interference (consisting of 9 items, with a range from 0, no interference or impact, to 100, maximum possible interference) and a subscale for sleep problems (consisting of 6 items). Each attribute is scored independently, also from lowest to highest impact (the higher the score, the more negative the impact), except for the attributes of adequacy and optimal sleep (a lower score represents worse quality of the attribute) and the amount of sleep (number of hours slept per day).

The Hospital Anxiety and Depression Scale (HADS) was designed as an instrument for detecting depressive and anxiety disorders in the context of non-psychiatric hospital services meeting the following conditions: not being contaminated by physiopathological symptoms presented by the patient and clearly differentiating between depression-type disorders and anxiety-type disorders[23]. Traditionally, HADS is used in a self-administered manner with a reference frame of the previous week, and this is how it was used in this study. The patient has to answer each item using a Likert-type scale of 4 points, which sometimes refers to the intensity of symptoms and sometimes to their frequency of presentation. The scale ranges from 0 to 3. The HADS consists of 14 items, which are grouped into two subscales, each with 7 symptoms. The anxiety subscale: this focuses on psychological manifestations (tension, nervousness, apprehension, worry, anxiety, "butterflies" in the stomach, anguish). These are the odd items and their range is from 0 (best) to 21 (worst). The depression subscale: this focuses on anhedonia (enjoyment, laughter, joy, clumsiness, interest in personal appearance, illusion). These are the even items and their range is also from 0 (best) to 21 (worst).

Health-related quality of life was measured with the EQ5D health questionnaire. This is a standardized, generic instrument that assesses health-related quality of life[24,25]. It consists of two parts: the first is the health status profile, consisting of 5 items to assess 5 dimensions: mobility, personal care, daily activities, pain/discomfort and anxiety/depression. Three states are defined for each dimension, from which the patients have to choose the one that best reflects their situation. These 3 states describe absence of problems in that dimension (1 point), moderate problems (2 points) and serious problems (3 points). The second part corresponds to the visual analogue scale represented by a 20-cm vertical line, graded from 0 (worst imaginable health state) to 100 (best imaginable health state). The patient has to indicate in this scale the point that best represents his/her overall health on the day of the interview.

Likewise, through a questionnaire, we assessed patient satisfaction with medical care received in the following sections: medical monitoring and overall satisfaction extracted from the generic questionnaire on satisfaction with medication treatment SATMED-Q[26]. This is a self-administered questionnaire consisting of 17 items with scores ranging from 0 (none) to 4 (very much). It records an overall satisfaction score with treatment in a metric from 0 to 100 (not satisfied to completely satisfied), although the 17 items can also be grouped into six domains: "adverse effects" (items 1, 2, 3), "efficacy of medication" (items 4, 5, 6), "convenience of medication" (items 7, 8, 9), "impact of the medication on daily life" (items 10, 11, 12), "medical monitoring of the illness" (items 13 and 14), which includes information from the physician about the disease and about its treatment, and "general opinion" (items 15, 16, 17), which includes the intention to continue the treatment, general satisfaction and whether the patient feels comfortable or not with that treatment. All scores are standardised from 0 (not at all satisfied) to 100 (completely satisfied)[26]. In this study only the items corresponding to the last two dimensions mentioned (medical monitoring and general opinion) were administered. In addition, the patients were asked whether they were satisfied (binary response) with the following aspects of healthcare: waiting times, time dedicated by the doctor to the patient, explorations requested, recommended treatment and pain relief.

Use of health resources and work productivity

From a doctor-administer interview, patients reported on the health resources that had been used in the previous six months: pharmacologic and non-pharmacologic treatment, number and type of medical visits, hospitalisations and complementary tests (number and type) carried out due to pain. This information was collected through direct interview with the patients and from the medical history records. At the same time, they were asked about the impact of pain on their work productivity over the past 12 months. Information was collected about the number of days that patients stopped

working or performing daily activities because of pain, the number of days when they worked or performed their daily activities with pain (which were computed with a work productivity reduced by 50%). From these data, we calculated the number of lost workday equivalents (LWDE) in the past 12 months due to pain by applying the formula: LWDE=W1 + W2 (1-P); where W1 was the number of days with inability to work or undertake normal activities because of pain in the past 12 months, W2 was the number of days of work with pain in the past 12 months and 1-P was the percentage of disability at work; P is the percentage of effectiveness at work, which was considered as 0.5 in this study[27].

Cost estimation

We calculated the total annual cost per patient, including direct health costs (pharmacologic and non-pharmacologic treatment, doctor visits, hospitalisations and tests) and non-medical and indirect LWDE costs. The cost of pharmacologic treatments was obtained from the Catalogue of the Official College of Pharmacists for 2008[28] and corresponded to the retail price (RRP - VAT) of the cheapest generic drugs or less expensive, proprietary drugs or their reference prices if there was no generic. The costs of non-pharmacological treatments, doctor visits, hospitalisations and complementary tests were obtained from the 2006 Oblikue database of healthcare costs (updated according to the consumer price indices [December 2007] to 2008 costs) (table 1)[29]. Finally, to determine the cost of each LWDE, we applied the human capital method, through which we obtained the mean total wage sum per worker and per month (first quarter of 2008) divided by 30 days, which was obtained from the National Institute of Statistics to allocate the cost of 1 LWDE.

Statistical methodology

The accuracy and thoroughness of the analysis were ensured at all times. The population used for statistical analysis included all patients who fulfilled all the selection criteria. We carried out descriptive statistics for all variables including measures of central tendency and dispersion for quantitative variables, and absolute and relative frequency for qualitative variables, with confidence intervals of 95% in both cases. We studied the type of distribution of quantitative variables and evaluated their adjustment to the Gaussian distribution through the Kolmogorov-Smirnov test. When the data failed to meet assumptions of normality, we used nonparametric statistical methods. For the comparison of independent data (between analysis groups: specialized and general NP neurology consultation), we used Student's t-test for quantitative variables and the χ^2 test for qualitative variables. For continuous variables that did not follow a normal distribution, the nonparametric Mann-Whitney U test was used. Statistical tests were bilateral and were performed with a significance level of 5%. The statistical package SAS® version 8.2 was used for all statistical analysis.

Table 1 Unit costs of healthcare resources (non-drug treatments, medical visits and complementary tests) and labour productivity losses

Resource	Unit cost (Euros)
Non-drug treatment (per session)	
Physiotherapy	10.23
TENS	23.57
Infiltrations (joints, etc.)	150.29
Electrotherapy	7.56
Blockage (epidural, etc.)	90.20
Iontophoresis	10.18
Spinal stimulator	7,072.14
Pumps	8,434.45
Acupuncture	35
Corrective gymnastics	12.78
Lymphatic massage	20.51
Mesotherapy	17.10
Osteopathy	50
Reflexotherapy	35
Medical visits	
To primary care	20.34
To pain unit	52.61
To the specialist	57.93
To the emergency service	114.94
Hospitalisation (1 day)	308.63
Complementary tests	
Computerized tomography	149.20
Magnetic resonance	352.94
Electromyogram	129.93
Eco-Doppler	134.72
Thermography	136.87
Conventional radiography	17.73
General analysis (blood and blood biochemistry)	24.11
Bone scintigraphy	136.85
Work productivity	
Cost of day not worked	52.65

TENS: transcutaneous electrical nerve stimulation.

Results

We included a total of 234 patients, 124 (53%) in SPC (differences not significant), with 56.8% of women, and a mean±SD age of 59.3±14.7 years. This number of patients was somewhat lower than that determined in the initial sample size calculation, so the power of the study was limited to 71%. Table 2 describes the demographic data of patients included in the study and some clinical aspects such as evolution, symptom duration and waiting times. The patients attended at SPC had a significantly lower mean waiting time from symptom onset (19.8 vs. 32.3 months) (p=0.010) (table 2), whereas no significant differences were observed in the evolution times since diagnosis, number

Table 2 Descriptive patient data

Variable	Specialized clinic	General clinic	p
Patients	124	110	
Women	70 (57.9%)	60 (55.6%)	0.726
Age (years)	59.8±13.9	58.7±15.5	0.574
BMI	26.6±3.8	27.2±4.2	0.280
Obesity (BMI≥30)	21 (17.2%)	17 (18.3%)	0.982
Level of education			0.272
Illiterate	13 (10.6%)	23 (21.1%)	
Primary	47 (38.2%)	39 (35.8%)	
Secondary	34 (27.6%)	27 (24.8%)	
College studies	16 (13%)	11 (10.1%)	
University studies	13 (10.6%)	9 (8.3%)	
Employment status			0.43
Retired / permanently disabled	31 (25.4%)	39 (35.8%)	
Housewife	34 (27.9%)	26 (23.9%)	
Employed	30 (24.6%)	23 (21.1%)	
Self-employed	17 (13.9%)	9 (8.3%)	
Unemployed	4 (3.3%)	8 (7.3%)	
Unpaid work	2 (1.6%)	2 (1.8%)	
Long-term disability	3 (2.5%)	1 (0.9%)	
Others (off work)	1 (0.8%)	1 (0.9%)	
Evolution (months) [a]	11.0±23.3	11.1±20.2	0.964
Waiting time (months) [b]	19.8±26.3	32.3±43.3	0.010

BMI: body mass index.
[a] Time from the onset of symptoms to diagnosis.
[b] Time from diagnosis to start of the study.
The data expresses n (%) or mean±standard deviation. The percentages shown have been calculated from the subjects who presented the datum. Sample sizes may vary for the different variables and are smaller than the sample size of assessable population.

and type of comorbidities (table 3) or in the other demographic variables analysed.

The percentages shown were calculated from the subjects who presented the data. Sample sizes could vary for the different variables and be smaller than the sample size of the entire assessable population.

Use of health resources and costs

The utilisation of health resources (medical visits, hospitalisations, drugs, etc.) were almost similar in both care models (table 4), except that patients treated at SPC were prescribed a significantly greater number of resonances as

Table 3 Comorbidities related to the origin of neuropathic pain in patients seen in specialized and general neurology clinics

Comorbidity	Specialized clinic (n=124)	General clinic (n=110)	p
Patients with some comorbidity	90 (72.6)	75 (68.2)	0.553
Number of comorbidities	2.3±1.2	2.2±1.1	0.743
Diabetic polyneuropathy	33 (26.6)	29 (26.4)	0.916
Other polyneuropathy	3 (2.4)	6 (5.5)	0.312
Trigeminal neurology	6 (4.8)	8 (7.3)	0.612
Herpes zoster	5 (4)	2 (1.8)	0.452
Other mononeuropathy	5 (4)	8 (7.3)	0.427
Radiculopathy	30 (24.2)	23 (20.9)	0.658
Pain after stroke	5 (4)	2 (1.8)	0.452
Hypothyroidism	5 (4)	2 (1.8)	0.452
Others*	32 (25.8)	30 (27.3)	0.916

The data expresses n (%) or mean±standard deviation.
*Includes neoplasm, complex regional pain syndrome, facial pain, plexopathy, peripheral entrapment syndrome.
The percentages shown have been calculated from the subjects who presented the datum. Sample sizes may vary for the different variables and are smaller than the sample size of assessable population.

Table 4 Usage of health and non-health resources by type of consultation

Resources	Specialized clinic (n=124)	General clinic (n=110)	p
Health (last 6 months)			
Drugs (number)	1.8±0.9	1.5±1	0.054
Physiotherapy (session)	2±4.9	1.8±6.7	0.731
TENS (session)	0.8±2.4	0.5±2.3	0.389
Infiltrations (session)	0.3±1	0.2±0.8	0.367
Electrotherapy (session)	0.2±1	0±0.3	0.088
Medical visits (number)			
Primary care	2±1.4	1.9±1.6	0.687
Pain unit	0.6±1.3	0.4±1	0.146
Emergency room	0.4±0.7	0.6±1.5	0.151
Neurology	2±0.6	2.2±1.3	—
Other specialist	0.9±1.2	1.2±1.8	0.212
Hospitalisation (days)	0.2±1.1	1±4.8	0.065
Complementary tests (carried out)			
CT	48 (38.7%)	48 (44%)	0.526
Resonance	59 (47.6%)	31 (28.4%)	0.001
Electromyogram	83 (66.9%)	64 (58.7%)	0.429
Echo-Doppler	2 (1.6%)	6 (5.5%)	0.147
Thermography	3 (2.4%)	4 (3.7%)	0.554
Radiography	28 (22.6%)	24 (22%)	0.918
General analysis	58 (46.8%)	43 (39.4%)	0.320
Bone scintigraphy	7 (5.7%)	3 (2.8%)	0.299
Non-health (last 6 months)			
Health transport (number of times)	0.3±0.8	0.5±1.3	0.069
Formal caretakers (hours/ week)	0.8±3.2	0.9±2.3	0.807
Workdays (last 12 moths)			
Sick leave (days)	10.9±49.4	14.6±61.3	0.624
Reduced performance (days)	27.5±37.6	27.2±48.5	0.964
LWDE (days)	24.7±53.3	28.2±65.6	0.660

LWDE: lost workday equivalents= days not worked + (days worked with reduced performance × 0.5); CT: computed tomography; TENS: transcutaneous electrical nerve stimulation.
Values expressed as mean±standard deviation or n (%).

additional procedures (p<0.001) (table 4), and received a nearly significantly higher mean of drugs for NP (1.8 vs. 1.5; p=0.054) (although for a shorter time, data not shown). Some drug treatment for NP was received by 96% of SPC patients and 93% of GC patients (p=0.280), with a similar distribution of therapeutic classes in both care level types. The only two exceptions were ibuprofen, which was significantly more frequent in the SPC group than in the GC (9 vs. 1%; p=0.006), and topiramate, which was more frequent in GC (6 vs. 1%; p=0.037). Patients seen in GC were, on average, hospitalised for 1 day due to their NP, in contrast to 0.2 days for those in the SPC group, although the differences did not reach statistical significance (p=0.065) (table 4). The use of direct non-health resources was similar, with the exception of an increased use of medical transport by GC patients, which was nearly statistically significant (p=0.069) (table 4).

With respect to work activity, 17.2% of patients attended in SPC and 13.8% of those attended in GC had to leave work at least one day due to pain and 59.8% and 49.5%, respectively, had worked with a reduced performance (non-significant differences). The mean number of workday equivalents lost due to NP was 24.7 and 28.2 days, respectively, for SPC and GC (p=0.660), resulting in an annual indirect cost (costs due to lost productivity) of 1,299±2,805 euros in SPC and 1,483±3,453 euros in GC (p=0.660) (table 5).

There were statistically significant differences (p<0.05) between the groups analysed in terms of annual cost of medical visits, being higher in GC patients, and the annual cost of diagnostic and complementary tests, being higher in the SPC patients (table 5). However, both the annual direct costs (the sum of the direct healthcare and non-healthcare

Table 5 Cost value of neuropathic pain management in specialized and general neurology clinics

Annualized costs	Specialized clinic (n=124)	General clinic (n=110)	p
Indirect	1,299±2,805	1,483±3,453	0.660
Total health	2,282±1,848	2,854±3,993	0.175
Drugs	571±472	563±633	0.906
Non-drug treatments	305±1,407	272±1,576	0.865
Medical visits	604±396	827±608	0.001
Hospitalisations	101±689	640±2,942	0.065
Complementary tests	682±482	544±450	0.025
Non-health	629±2,426	703±1,768	0.791
Health + non-health	2,911±3,335	3,563±4,797	0.239
Totals	4,211±4,654	5,060±6,250	0.249

Values expressed in euros, as mean±standard deviation.

costs) and the total annual costs were numerically lower in SPC than in GC, but without reaching statistical significance (4,210±4,654 euros and 5,060±6,250 euros, respectively; p=0.249) (table 5).

Effectiveness and results in health

The mean score of the "pain severity" dimension of the BPI scale was 3.8±2.3 in the group treated at SPC and 5.2±2 in the group treated at GC (p<0.001). The mean interference of pain in daily life activities was 3.3±2 in SPC and 4.7±2.5 in GC (p<0.001) (table 6). In addition, interference by individual type of activity was significantly lower in all activities measured by the BPI in SPC than in GC (fig. 1). There were statistically significant differences (p<0.001) between the two groups in the domain of sleep: disturbed sleep, snoring, sudden awakenings, somnolence and sleep problems. The mean score of the overall rate of sleep interference on the MOS scale was significantly lower in the group of patients treated in SPC (30.8±14.1 vs. 40.4±16.1; p<0.001) (table 6). These health outcomes were also associated with significantly lower mean scores of the symptoms of anxiety and depression in the HADS subscales in the group followed in SPC compared to GC and also to a significantly higher percentage of patients without symptoms of anxiety or depression (p < 0.01) (table 6).

The previous health outcomes (significantly better in patients treated at SPC) corresponded with better scores on the EQ-5D questionnaire, which measures the quality of life related to health. In particular, health status according to the health barometer was 63.9±16.2 in those treated at SPC compared to 54.6±18.2 in those treated at GC (p<0.001), with significant differences in the dimensions of anxiety/depression and problems with personal care (table 6).

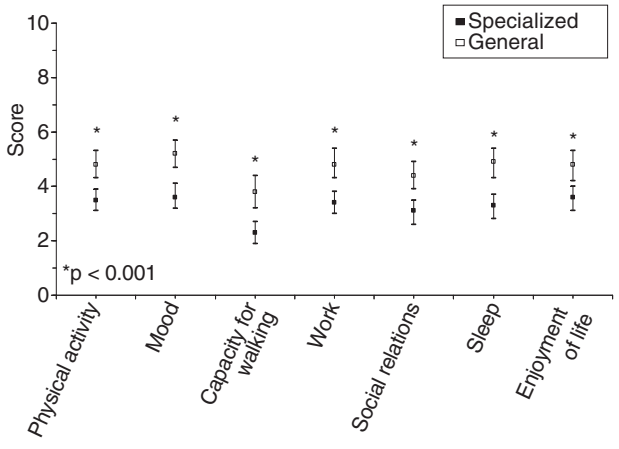

Figure 1 Interference of pain in the last week with various activities of daily living in patients with neuropathic pain treated in monographic or general neurology consultations. Interference, ≥ 5 for each item in the interference subscale in the short questionnaire on pain.

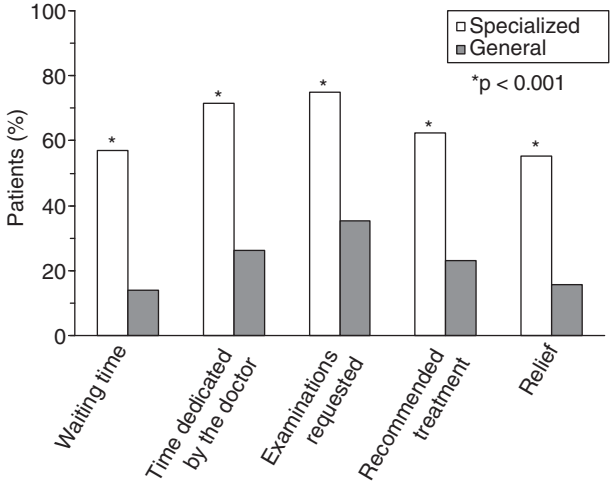

Figure 2 Percentage of patients who declare being very/extremely satisfied with various aspects of medical care received, by type of neurology clinic.

Table 6 Effectiveness ratio of neuropathic pain management in specialized and general neurology clinics

	Specialized clinic (n=124)	General clinic (n=110)	p
Pain (BPI)			
Pain severity (0-10)[a]	3.8±2.3	5.2±2	<0.001
Interference with daily activities (0-10)[b]	3.3±2	4.7±2.5	<0.001
Patients without pain / mild pain (BPI<4)	60 (49.2)	28 (25.5)	<0.001
Days without pain / mild pain (in the last week)	3.3±3.5	1.2±2.7	<0.001
Interference with sleep (MOS-sleep)			
Global interference (0-100)	30.8±14.1	40.4±16.1	<0.001
Hours of sleep per day	6.3±1.2	6±1.2	0.121
Disturbed sleep (0-100)	29.6±15.6	41.7±17.5	<0.001
Shoring (0-100)	34.2±31.9	58.3±31.5	<0.001
Abrupt awakenings (0-100)	19.7±24.5	33.7±27.7	<0.001
Adequacy of sleep (0-100)	55.8±23.3	54.2±22.8	0.615
Drowsiness (0-100)	25.8±21	38.3±24.5	<0.001
Sleep problems (0-100)	32±15.1	40.8±16.9	<0.001
Symptoms of anxiety and depression (HADS scale)			
Mean score in anxiety subscale	6.8±3.6	9.1±4.1	<0.001
No symptoms of anxiety (0-7)	68 (57.1)	42 (38.2)	<0.001
Mean score in depression subscale	6.7±4	8.7±4.4	<0.001
No symptoms of depression (0-7)	73 (60.8)	41 (37.6)	<0.001
Quality of life (EQ-5D)			
No mobility problems	80 (66.1)	66 (60.6)	0.381
No problems in personal care	103 (85.1)	77 (70.6)	0.008
No problems in daily activities	69 (57.5)	55 (50.5)	0.286
No problems with pain / discomfort	35 (28.9)	27 (24.8)	0.478
No problems with anxiety / depression	71 (58.7)	50 (45.9)	0.052
VAS (0-100)	63.9±16.2	54.6±18.2	<0.001

BPI: Brief Pain Inventory ([a]0= no pain, 10= worst pain imaginable; [b]0= no interference, 10= complete interference); VAS: health visual analogue scale of the EQ-5D questionnaire; HADS: Hospital Anxiety and Depression Scale (range, 0-21 for each subscale of anxiety and depression; 0= no symptoms, 21=very severe symptoms); MOS-sleep: Medical Outcomes Study Sleep Scale of disturbance or interference with sleep (range, 0-100, overall and for each dimension; 0=no interference or unaltered, 100= maximum interference or alteration). Values expressed as mean±standard deviation or n (%). The percentages shown have been calculated from the subjects who presented the datum. Sample sizes may vary in the different variables and are smaller than the sample size of assessable population.

As a corollary, these better health results were transferred to the degree of patient satisfaction with medical care. A significantly higher percentage of patients in SPC than in GC were satisfied with the waiting time, the time spent on their health problems, the explorations requested, the recommended treatment or pain relief. In general, over 50% of patients in SPC declared being satisfied (categories extremely / very satisfied) with these aspects of healthcare compared to 15-35%of patients treated in CG (p<0.001) (fig. 2). In general, SPC patients showed significantly higher mean scores of satisfaction with the medical monitoring and treatment received than GC patients (p<0.001) (fig. 3).

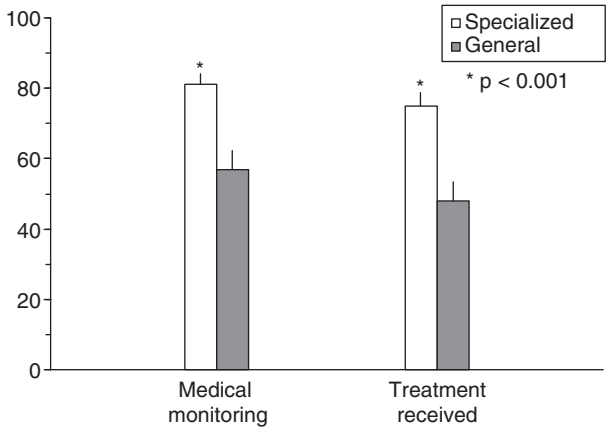

Figure 3 Patient satisfaction with medical monitoring and with treatment received, by neurology clinic at which they were seen (SATMA-Q questionnaire; mean and 95%confidence interval).

Discussion

The results of this study have shown that clinical attention for NP in SPC proved to be a dominant alternative when compared with GC, being associated to better clinical or

health outcomes (with lower pain severity and less interference with daily activities), while maintaining a similar cost, both in the health component and in labour productivity. This meant that patients attended at the SPC were significantly more satisfied with the care received than those attended at the GC. According to the study, the key results represented, on the one hand, the costs of non-health resources (transport, caregivers, poor performance at the workplace, etc.) and the cost of health resources (medicines and other treatments, medical visits, tests, hospitalizations, etc.). 12.3% of SPC patients and 17.4% of GC patients used some medical transport, while 8.2% of those attended at SPC and 14.7% of those attended at GC obtained some formal care (nursing staff, etc.), which in the case of medical transport became almost statistically significant. It should be noted that drug costs represented only 13-15% of the total costs and 20-25% of healthcare costs; the costs of labour productivity losses accounted for the most important component: about 30%

The study noted that SPC prescribed significantly more drugs to treat NP, but this was not transferred to higher mean drug costs because the mean duration of treatment contained in patient medical records was shorter in SPC than in GC (data not shown). In addition, with the exception of frequency of ibuprofen use (higher in SPC) and topiramate use (higher in GC), both types of neurological care used the different drug treatments in existence for NP in a similar proportion by type of drug. With few exceptions, and although numerical trends toward lower use or cost were observed, both healthcare models showed no significant differences in the use and cost of healthcare resources. This contrasts with the perception of increased use of resources at specialized units dedicated to a particular medical condition. However, health outcomes, measured with self-administered scales, showed statistically significant better results, and consistently across all variables analysed, when patients were cared for at SPC with respect to GC, both in the degree and in the interference of pain, and throughout the corollary of concomitant symptoms (anxiety, depression, sleep). This translated, on the one hand, into a better quality of life related to health from the perspective of the patients, which led them to declare, systematically, being more satisfied with various aspects of healthcare - and this, we must not forget, is one of the priorities in patient-centred medicine. Medical care or attention of NP in SPC proved, as derived from these results and from the evolution of costs, to be an efficient alternative to the monitoring of these patients at GC, if we assume the generally accepted definition of efficiency[30,31].

We could not find studies similar to ours in our environment or in other health systems, so we believe that, although with limitations, our study is a pioneer in the field of neurology. Rodriguez et al.[20] reported on the cost of NP in pain clinics in Spain compared with a different level of care, but they collected only health costs and assumed that the clinical management from the perspective of pain control would be better at the pain unit, because patients were referred to these units. A recent study conducted in Ireland and Poland reviewed different analgesic strategies for NP management, but without checking some economic aspects[32]. O'Connor recently reviewed the cost-effectiveness of some available interventions based on drugs for the treatment of NP in diabetic or postherpetic neuralgia, but without considering the level of assistance or medical care[33].

The results observed in our study are not only useful from the everyday clinical perspective (namely, better healthcare of patients with NP); this means improvements in quality of life for the patient who, in addition, is also more satisfied with healthcare. Our study also presents a practical usefulness from the point of view of health decision making when planning the use of health resources, at least in the area of neurology and treatment of NP. As some authors have previously requested better care in neurology[16-19], the results of this study illustrate the path to follow when organising healthcare for pain in our neurology services. The introduction of new specialized consultations in the management of NP in neurology would be an efficient decision because, without incurring higher costs and utilisation of resources, it would be possible to obtain better care for these patients, improving their quality of life and satisfaction with medical care.

However, our study is not free from some limitations. The first one refers to the fact that only nine neurology services took part, which could cause a problem of representation when generalising the results to other healthcare units from other geographical regions. While this is true, we observed no significant differences between the various units involved, which gives us confidence to some degree of national consistency in the handling of NP by the clinical neurologist. In addition, the recruited centres were located in more populated geographic areas, ensuring that they were representative. A second limitation refers to the final size of the sample recruited for the study, which was a little low compared with the size that was determined at the start of the study, thus penalising its statistical power, which was reduced to 71%. Although this means that the absence of real differences in some of the statistical tests performed might not be realistic, we believe the overall results show a trend that does not contradict these findings and the conclusions drawn, since the trend is that SPC patients may show even lower costs in health and non-health resources. This would ultimately further strengthen the general conclusion that in neurology, specialized NP care is more efficient than general care. A third possible limitation refers to the study design, which made it impossible to assess the clinical status of patients when they were first seen by a neurologist, since the assessed visit was about 11 months later in both cases. Although this is true, patients seen in both types of consultation were clearly uniform in all the demographic and clinical variables analysed (including comorbidities), differing only, as expected, in the delay or waiting time until seen by the neurologist. This was lower in SPC than in GC, which is attributable to the greater dynamism of that type of medical attention.

In conclusion, the clinical monitoring of NP in specialized neurology consultations was a commanding alternative,

associated with better clinical outcomes, lower pain severity and less interference with daily activities, while maintaining a similar cost. These facts may be of interest to health managers and policy makers when planning healthcare for neuropathic pain in neurology services in Spain.

Publication

The preliminary results of this study were presented at the congresses of AES 2009, ISPOR 2009 and SEN 2009.

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Conflict of interests

The authors declare no conflict of interests.

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