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Review

Humanistic and economic burden of painful diabetic peripheral neuropathy in Europe: A review of the literature



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ABSTRACT

Aims: Painful diabetic peripheral neuropathy (PDPN) is a common complication of diabetes mellitus. A systematic literature review was conducted to provide an overview of published literature in the last 10-years on the epidemiology, humanistic burden and economic burden of PDPN in Europe.

Methods: A search was performed according to pre-defined strategy and review criteria in Embase, Pubmed, and conference proceedings databases from 2003 till December 2012. In total, 30 publications written in English covering the relevant patient population and topics of interest.

Results: European prevalence ranges from 6% to 34% in diabetes mellitus patients. PDPN has a significant humanistic and economic impact. Patients are limited in their general functioning and their ability to sleep and often experience anxiety and depression. Not surprisingly, PDPN is associated with reduced Health-Related-Quality-of-Life (HRQoL). PDPN patients incur high health care costs due to hospitalizations and outpatient visits. In addition, the painful symptoms cause impaired work productivity. Studies suggest both humanistic and economic burden increase with higher pain severity.

Conclusions: The burden from PDPN appears to be higher with increasing pain severity. More severe pain leads to a higher impairment in daily functioning, sleep and HRQoL. Higher pain intensity also leads to increasing healthcare costs and work productivity losses.

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1. Introduction

Diabetic polyneuropathy (DPN) is one of the most common complications of diabetes and the most common form of neuropathy in the developed world [1]. Clinical manifestations of DPN include painful diabetic neuropathy (PDPN), troublesome autonomic features such as orthostatic hypotension [2], cardiac autonomic neuropathy (a clinical condition which can result in sudden death) [3], other conditions caused by non-cardiac autonomic neuropathy (such as gastro-paresis and erectile dysfunction) [3], and insensitivity to trauma (which can result in ulceration, infections, and lower extremity amputations) [2].

PDPN develops as a result of damage to or dysfunction of the system that signals pain [4]. Patients suffering with PDPN describe symptoms as burning, aching, shooting, and stabbing; usually with nocturnal exacerbations [1,5]. PDPN is often present in arms, hands, legs, and feet. It can affect the ability of patients to perform daily activities, their sleep, their work, how they feel, and therefore reduce the enjoyment of life for these patients [6]. Health related quality of Life (HRQoL), sleep and mood are frequently impaired in patients with PDPN [6,7]. Generally, pain reduction (as a result of treatment) is related to improvement in QoL [8,9].

The only intervention that has been shown to reduce the risk of development of neuropathy in diabetes patients is intensive glucose control [1,10]. Apart from suboptimal glycaemic control, patients with longer diabetes duration, of older age, hypertensive, with cardiovascular disease or who smoke are more likely to develop diabetic neuropathy [1].

In Europe, duloxetine is recommended as the first-line treatment option for PDPN, by the European Federation of Neurological Societies (EFNS) [9] and the National Institute for Health and Clinical Excellence (NICE) [4]. Pregabalin, gabapentin, amitriptyline, other tricyclic antidepressants (TCAs), tramadol, topical lidocaine, strong opioids and a combination of these drugs are advised as second-line and third-line treatments; the choice of drug(s) is made on an individual patient basis. Large studies are required to better define patient responder profiles for specific drug treatments [9].

Although a wide range of treatment options are available, an unmet need among PDPN patients still exists since neuropathic pain is often difficult to treat due to the resistance to many medications or due to their associated adverse effects. Many people require treatment with more than one drug, but the correct choice of drugs and the optimal sequence for their use

is so far unknown [4]. The use of multiple drugs (polypharmacy) may also increase the risk of additional adverse events and incorrect use of medication [11].

Due to their pain, PDPN patients are expected to incur higher health care costs compared to the general population and diabetes patients without PDPN as they take pain reducing medication and are likely to visit health care professionals more frequently. In addition, the absence from work or reduced functionality at work can result in additional costs for society.

The objective of this literature review was to collect and discuss European data regarding the epidemiology, humanistic and economic burden associated with PDPN in order to provide a complete overview from a European perspective of the evidence published in the last 10 years. The research questions to be answered by the review are ‘What is the prevalence and incidence of PDPN?’, ‘What are the identified risk factors and patient subgroups in PDPN?’, ‘How are PDPN patients affected in their general functioning, sleep, anxiety, depression and overall HRQoL?’ and ‘What is the resource use associated with PDPN, including direct and indirect costs?’

2. Literature review process

2.1. Search strategy

A systematic literature search was performed to obtain available European literature on epidemiology, and the humanistic and economic burden associated with PDPN. In addition, the search included publications on PDPN management to provide background information regarding current treatment patterns. Before commencing the search, a protocol was developed following the PRISMA statement [12].

Embase and PubMed were searched for relevant publications from January 2003 to December 13th 2012. Websites of European Health Technology Assessment (HTA) organizations and conference proceedings from the International Association for the Study of Pain (IASP) were searched from January 2010 to December 13th 2012. These last two sources were searched for the last 3 years only, as it is expected that abstracts of high quality are highly likely to be published in peer reviewed journals during this period. Disease terms for PDPN were combined with search terms for the topics of interest, such as epidemiology, prevalence, incidence, humanistic burden, quality of life, comorbidities, anxiety, depression, healthcare cost, budget impact, resource use,

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