

Evaluation and Intervention of Quality of life in individuals with Diabetic Peripheral Neuropathy: A Quantitative Cross-sectional Content Analysis

KUMAR SENTHIL P., MPT*; ADHIKARI PRABHA, MD**; JEGANATHAN, PS, PHD***; D'SOUZA MARIELLA, MPHIL****; D'SOUZA SYDNEY C., MD**; MISRI Z.K., DM (NEUROLOGY)*****

*Founder-President, Academy of Orthopaedic Manual Physical Therapists (AOMPT)TM, Freelancer Physiotherapist and private practitioner, Mangalore, India;
**Professor, Department of Medicine;
***Professor, Department of Physiology;
****Selection Grade Lecturer, Department of Psychiatry; *****Associate Professor, Department of Neurology; Kasturba Medical College (Manipal University), Mangalore, India.

Abstract

Background: Foot and ankle dysfunction secondary to peripheral nerve damage is the most common microvascular complication in individuals with diabetes mellitus.

Purpose: This study aimed to perform a systematic review and quantitative content analysis of articles emphasizing Quality of life (QoL) in people with Diabetic peripheral neuropathic pain (DPNP) and Painful diabetic peripheral neuropathy (PDPN).

Materials and Methods: The extracted data about every study included: journal, year of publication, number of authors, country of manuscript origin, goal of article (evaluation or intervention or both), subtypes of evaluation (tool development or measurement of QoL or multiple tools or mixed) and intervention (medical, surgical, or allied health), population characteristics (homogeneous or heterogeneous), type

of article (original or review) which was further subclassified under study designs and respective Center for Evidence-Based Medicine (CEBM) levels of evidence.

Results: Descriptive analysis showed more number of QoL articles: from Diabetes Care; with more than three authors; published in the year 2008; originated from USA; on evaluation; on heterogeneous population; more original articles; and more articles with levels 4 or 5 evidence.

Conclusion: The study findings provided a content analysis and synthesized findings from articles published on QoL in population with PDPN or DPNP, and the predominance of evaluation studies was evident, with inter-measure analyses, and more number of articles on medical management among the intervention studies. Levels of evidence for most of the articles were low, and there is need for future high quality studies and reporting standards in articles for effective evidence-informed foot and ankle rehabilitation in people with PDPN.

Keywords: Evidence-based diabetes care; Diabetic peripheral neuropathic pain; Foot and ankle dysfunction; Painful diabetic peripheral neuropathy.

Corresponding author: Senthil P. Kumar, Founder-President, Academy of Orthopaedic Manual Physical Therapists (AOMPT)TM, Freelancer Physiotherapist and private practitioner, Mangalore, India

E-mail: senthilparamasivamkumar@gmail.com

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Introduction

Foot and ankle dysfunction secondary to peripheral nerve damage is the most common microvascular complication in individuals with diabetes mellitus[1] and is associated with altered somatosensory functions such as severe chronic disabling pain, bilateral 'glove and stocking' distribution of pins and needles, sensory and motor deficits in the legs and feet, and impaired gait, balance and psychosocial functions.[2]

The painful state is recognized as Diabetic peripheral neuropathic pain (DPNP)[3] and the clinical condition is termed as Painful diabetic peripheral neuropathy (PDPN)[4] which presents commonly as distal symmetric polyneuropathy affecting both legs and feet.

Impaired functional activities from foot and ankle dysfunctions in PDNP individuals include nocturnal pain associated with sleep disturbances, difficulty in foot positions and movements, difficulty in walking and general mobility.[5]

Due its multifactorial aetiopathologic association and multidimensional clinical presentation, the individuals with PDPN have serious psychosocial consequences of the disorder that influence their limitations in activity and causes restrictions in participation.[6] This invariably affects their overall well-being which is measured as 'Quality of life' (QoL).[7] According to an evidence-informed paradigm of care for patients with diabetes and its complications, a comprehensive multi disciplinary biopsychosocial model of evaluation and intervention emphasizing on QoL was recommended by practice guidelines, consensus documents and position statements.[8] Thus there is a need to evaluate the existing evidence for research articles on QoL in PDPN so that future policies regarding scientific conduct, research reporting, journal publication and database indexation processes could be derived.

This study aimed to perform a systematic review and quantitative content analysis of articles emphasizing QoL in people with DPNP and PDPN.

Materials and Methods:

Study design

Systematic review

Search methods

The search methodology was a replication of a previously used method by Kumar.[9]

Search strategy

The search terms, 'quality of life', 'diabetes/diabetic' and 'neuropathy/neuropathic' were used through advanced search feature of PubMed[10] as follows: "quality of life" [Title] AND (diabetic [Title/Abstract] OR diabetes [Title/Abstract]) AND (neuropathy [Title/Abstract] OR neuropathic [Title/Abstract]). The initial list of retrieved citations were scrutinized for their relevance to DPNP or PDPN to obtain final list of articles for inclusion in data extraction and synthesis.

Data extraction

The extracted data about study included: journal, year of publication, number of authors, country of manuscript origin, goal of article (evaluation or intervention or both), subtypes of evaluation (tool development or measurement of QoL or multiple tools or mixed) and intervention (medical, surgical, or allied health), population characteristics (homogeneous or heterogeneous), type of article (original or review) which was further

subclassified under study designs and respective Center for Evidence-Based Medicine CEBM levels of evidence.[11].

Data synthesis

The categories and sub-categories were compared between QoL evaluation and intervention studies to derive the relative prevalence of reporting for various article characteristics in QoL studies.

Data analysis

Overall analysis was done descriptively and reported in frequencies calculated through Microsoft excel worksheet.

Results-main findings

Our initial search yielded 50 articles and after further scrutiny, we obtained a final list of 43 articles for inclusion into data extraction and synthesis. The seven excluded articles were not on diabetic neuropathy or neuropathic pain in diabetes.

A total number of 34 journals published the 43 articles[11-53] on QoL in DPN, and the journals were AMI[22], AMS[37], BJA[14], BRN [42], CE[15], CJP[47], CT[53], DAM[27], DC [11,45,46,52], DIA[17,40], DMRR[36], DRCP [18,32,49], FAI[43], FAS[29], HQLO[21,31], IJLEW[20], IJPM[23], JAANP[26], JACC[35], JACM[12], JDST[25], JFAS[33], JPSM[24],

Figure 1: Comparison for number of QoL in PDPN articles among the journals

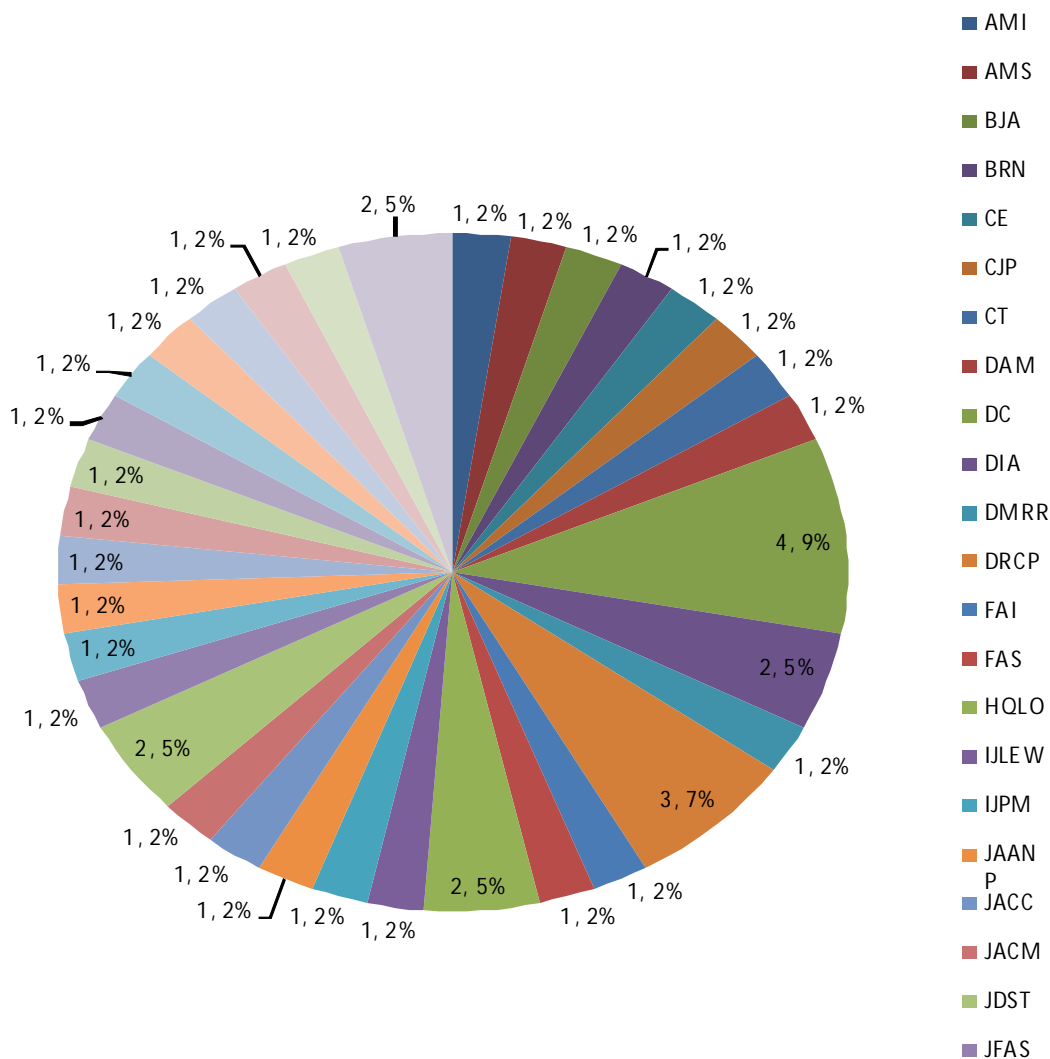
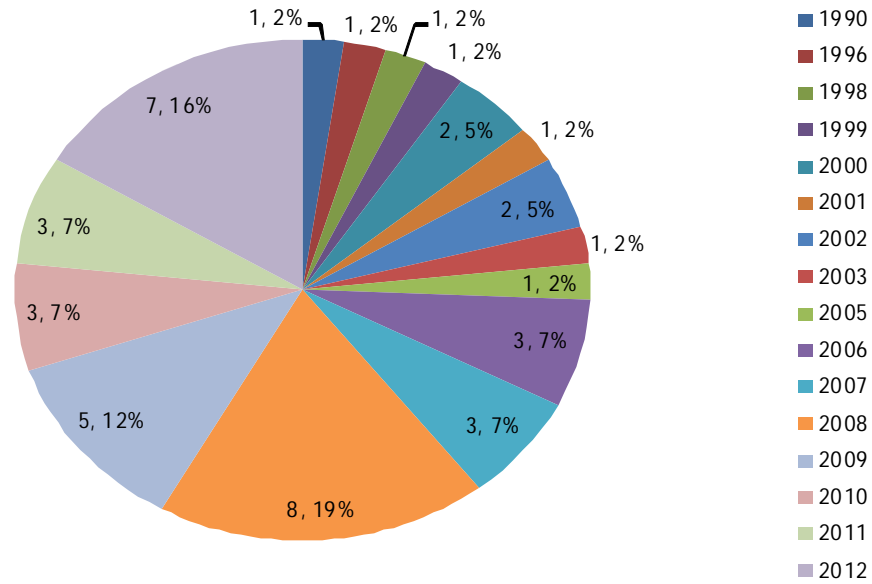


Figure 2: Comparison for number of QoL in PDPN articles among the years of publication



MCP[41], N[39], NHS[13], NNR[44], P[28], PCN[30], PDI[50], PM[38], QJM[51], RLAE [16], and VH[34,48] (Figure 1).

The articles were published over the past 22 years-1990[53], 1996[52], 1998[51], 1999[50], 2000[44,49], 2001[48], 2002[46], 2003[45], 2005[43], 2006[40,41,42], 2007[37,38,39], 2008[25,29,31-37], 2009[22,26-28,30], 2010 [21,23,24], 2011[16,19,20], and 2012[11-18] (Figure 2).

The number of authors per article were

zero[52], one[28,36,47], two[12,50,53], three [18,49,21,39,44,38,51,48], four[22,19,25,33,41], five[17,32,43,23,35,13,30], six[31,20,16,34], seven[11,29], eight[42,27,40], nine[45,46], ten[24,26,37], eleven[15], and twelve[14] (Figure 3).

The articles were published from 15 countries including Belgium[27], Brazil[16], Canada[29], China[13], Germany[32], Iran[22], Japan[30], Netherlands[14,36],

Figure 3: Comparison for number of QoL in PDPN articles among the number of authors per article

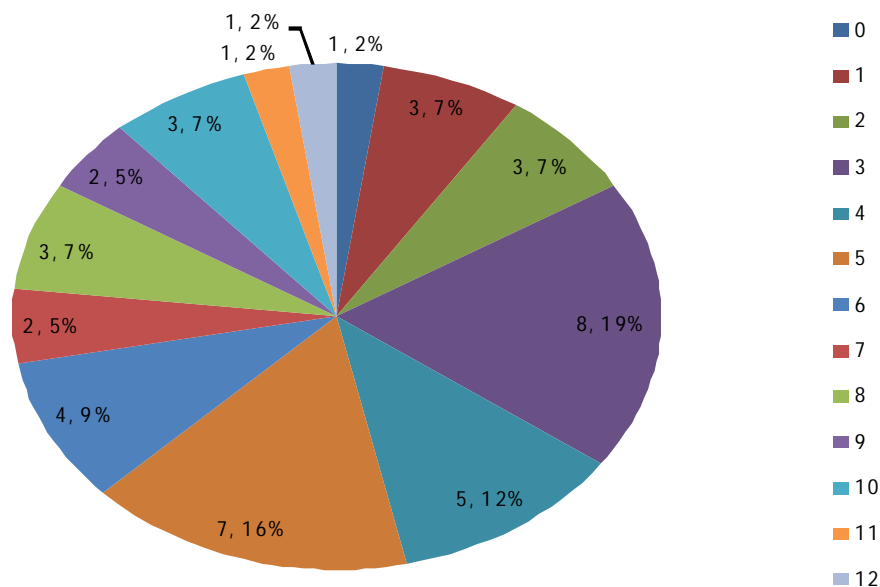
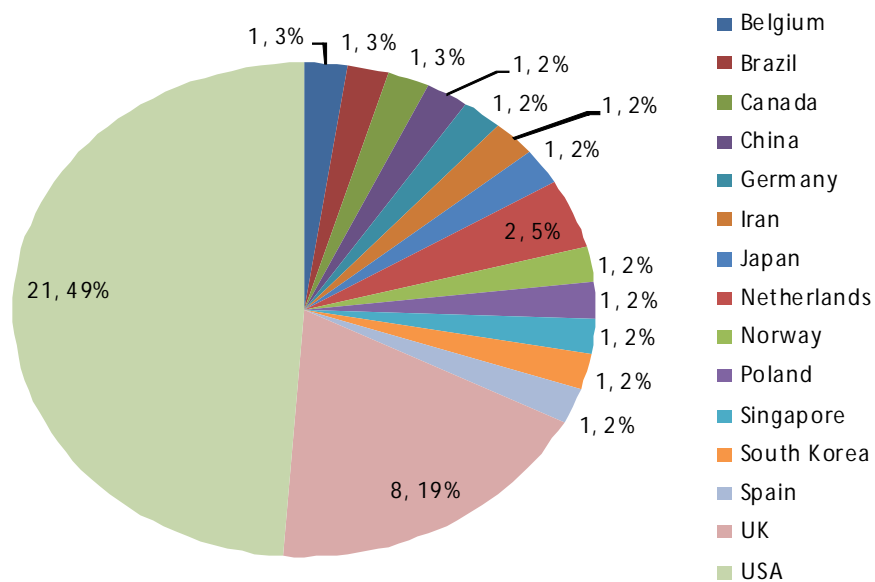


Figure 4: Comparison for number of QoL in PDPN articles among the countries



Norway[21], Poland [37], Singapore[15], South Korea[12], Spain[20], UK[11,17,18, 40,45,48,50,51] and USA [19,23-26,28,31,33-35,38,39,41-47,49,52,53] (Figure 4).

There were articles on evaluation[13,15-18,20,21,23,25-35,37,39-51], intervention[11, 12,14,19,22,24,38,52,53] and both[36,39] (Figure 5). Among the article on evaluation of QoL, there were articles on tool development/adaptation/validation[16,23,25,31,34,44,45], measurement of QoL[13,29,32,46,51], multiple

variables comparison/correlation/association [15,20,21,26,27,30,33,35,40,42,43,47-50] and mixed[17,18,28,41] (Figure 6). Among the articles on intervention, there were articles on medical/pharmacological management[11,19, 38,52], surgical (invasive/non-invasive)[14,53] and allied health interventions[12,22,24] (Figure 7).

There were articles that focused mainly on diabetic neuropathy or neuropathic pain in diabetic population[11,12,14,16,19,24,27,29,32,

Figure 5: Comparison for number of QoL in PDPN articles on evaluation, intervention or both

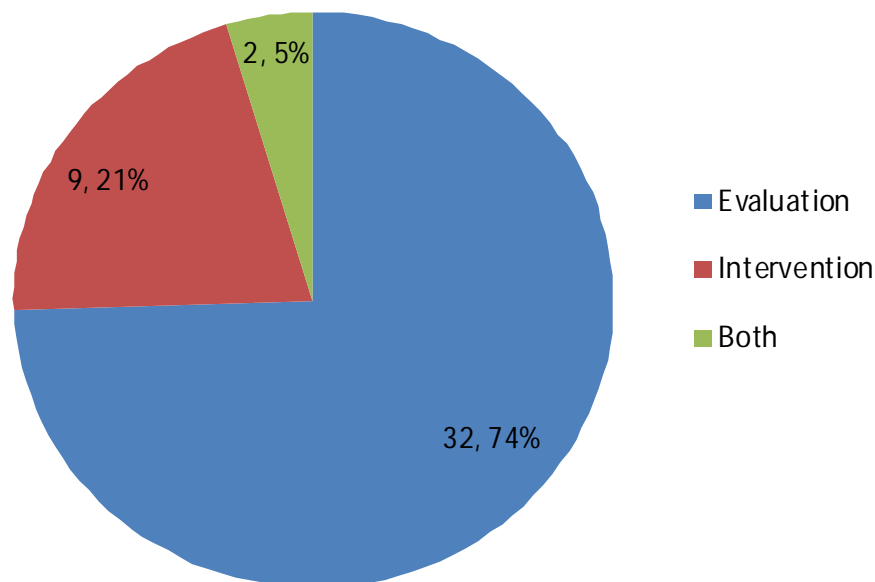
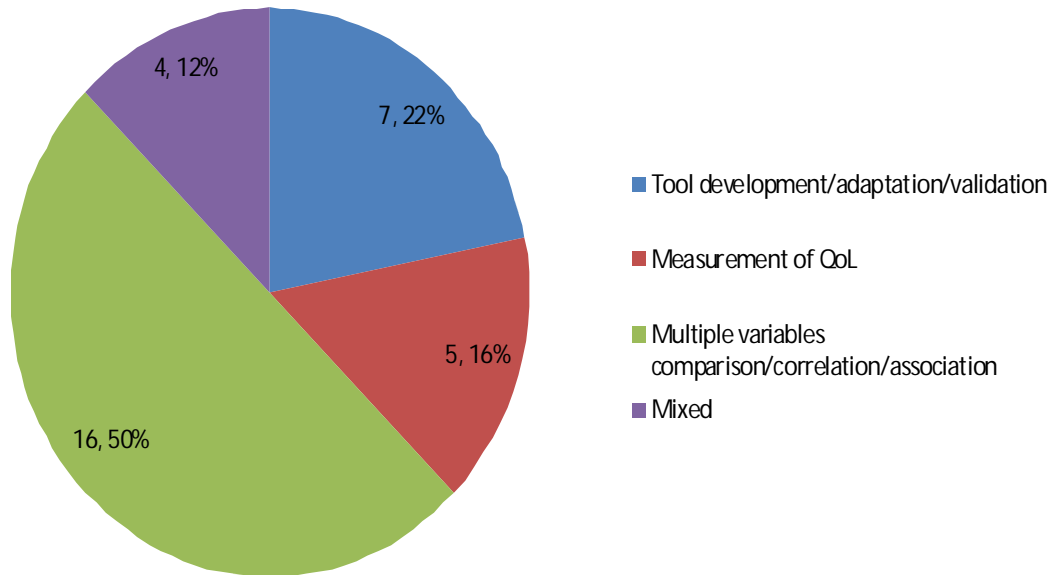


Figure 6: Comparison for number of articles on evaluation of QoL in PDPN for its subcategories



44,45,49,51] which were regarded as homogenous and articles that focused on neuropathic pain with diabetic subgroup or diabetes individuals with neuropathic symptom subgroup or diabetic neuropathy with other disorders[13,15,17,18,20-23,25,26,28,30,31,33-43,46-48,50,52,53] which were considered as heterogeneous (Figure 8).

There were original articles[11-16,19-27,29-35,37,40,42-49,51-53] that included randomized controlled trials[11,19,24,52], non-

randomized controlled trials[12,22], case-control studies[15,20,21], quasi-experimental studies[14] and cross-sectional studies[13,16,23,25-27,29-35,37,40,42-49,51,53]; and review articles[17,18,28,36,38,39,41,50] which were narrative[28,36,38,39,41,50] and systematic [17,18] (Figure 9,10).

The articles were of level-1 evidence[11,17,18,19,24,52], level-2 evidence [12,22], level-3 evidence[15,20,21], level-4 evidence[13,14,

Figure 7: Comparison for number of articles on intervention of QoL in PDPN for its subcategories

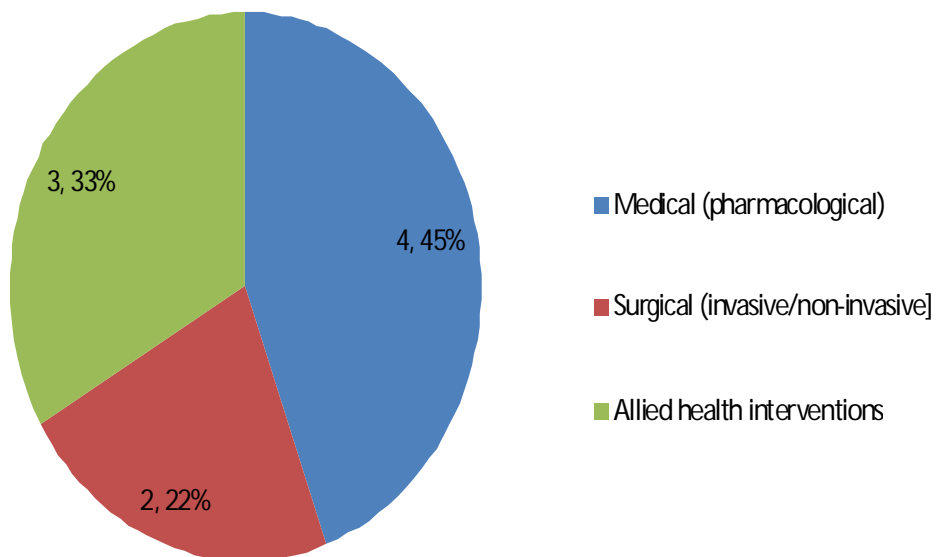


Figure 8: Comparison for number of articles on QoL in PDPN for homogeneous and heterogeneous population characteristics

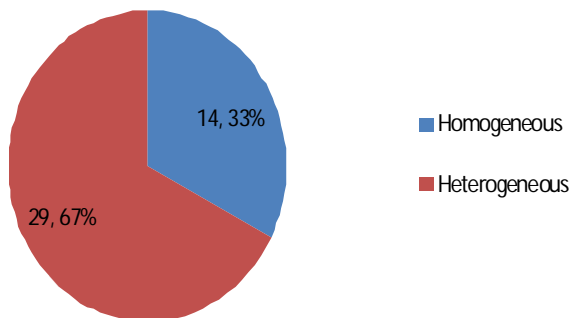
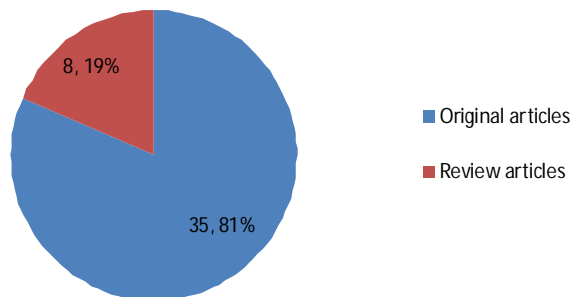


Figure 9: Comparison for number of articles on QoL in PDPN for article types



16,23,25-27,29-35,37,40,42-49,51,53] and level-5 evidence[26,36,38, 39,41,50] (Figure 11).

Discussion

This study aimed at evaluating articles emphasizing QoL among studies on PDPN patients and found an alarmingly lesser number of studies, with a positive shift towards increased number of articles as original articles,

The reasons for this lesser number of studies could be partly due to the non-validated search strategy and use of only one database such as PubMed, though such method was previously reported in literature.[54] PubMed was used since it was freely available online, and is the largest and most accepted source of scientific information around the world.[55] An effort

to initialize a scientific movement in the direction of emphasis on QoL was attempted through assigning the QoL term in title, whilst other search options would have yielded different results.

More articles were indexed in year 2008, the cause for which could be explored by longitudinal trend analysis of evidence for QoL in PubMed. Coincidentally, the WHO policy on QoL and Biopsychosocial model was established much earlier under the ‘health for all’ policy.[56] More articles on QoL had more than three authors and multiple authorship was a positive trend for research since it was shown to be involved with interprofessional collaborative works in a ‘publish or perish’ era.[57]

Amongst the journals which published the few studies found, Diabetes Care had the largest number of four articles, which indicates

Figure 10: Comparison for number of articles on QoL in PDPN for study designs

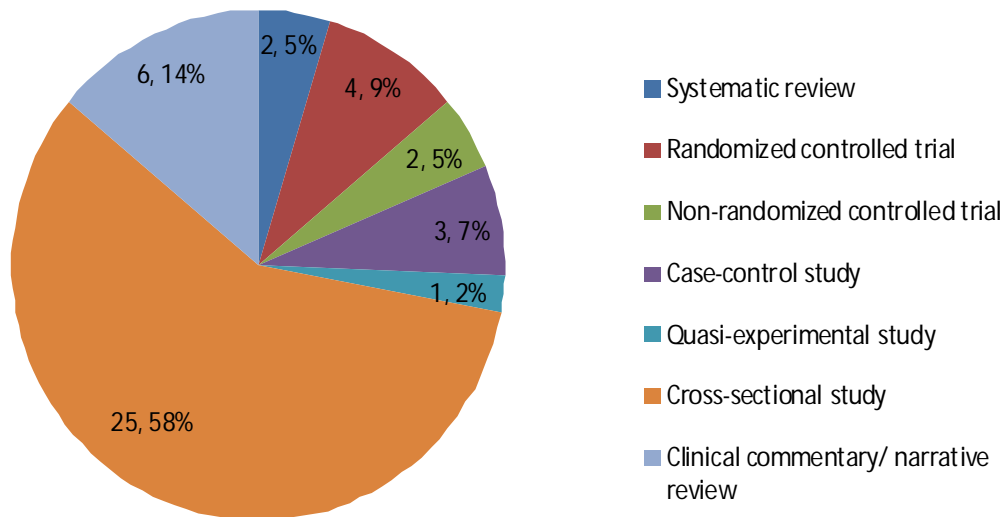
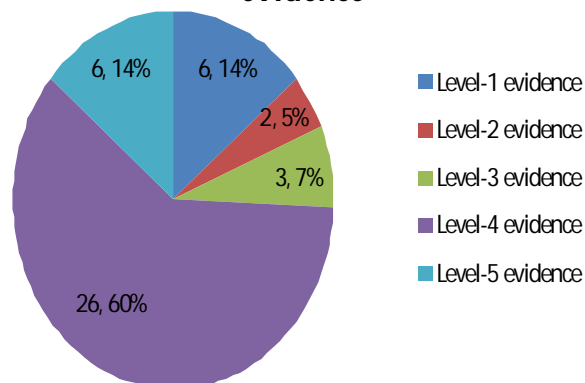


Figure 11: Comparison for number of articles on QoL in PDPN for levels of evidence



a journal-specific analysis of reporting trend for QoL. Nearly half the studies were from USA, and more than half the number of articles was on evaluation, with studies on comparison/association/correlation between QoL measure and other tools being more common. Medical management was more represented among the interventions, as supporting evidence in that area is relatively large, both for diabetes[58] and for neuropathic pain.[59]

Heterogeneous studies were more in number which explained the multidimensional impact of QoL on other aspects of clinical presentation in PDPN. Not only that neuropathic pain is one of the most common complications of diabetes, but also diabetes is the most leading cause for neuropathic pain. This fact is often well understood as many other causes for neuropathic pain other than diabetes such as post-herpetic neuralgia, chemotherapy-induced or HIV-related, as many other symptoms in diabetes patients such as retinopathy, nephropathy, angiopathy, and other foot-related complications.

This study found no articles that focused on caregivers or preventive research, which calls for an action plan on clinical research priorities in individuals with PDPN.[60,61] The QoL instruments used in the studies were relatively lesser, when compared to many generic and disease-specific measures[62] available both for diabetes[63] and for neuromuscular disorders.[65] Although a single measurement tool was not widely used or recommended, the

need for a comprehensive tool still remain unmet.

More cross-sectional studies of level-4 evidence represented the emergence of reliability[65] and validity studies[66] for questionnaires and self-reported outcome measures for evaluation of QoL in PDPN. Overall, there was a greater number of articles on levels 4,5 evidence which opens the scope for future systematic reviews and meta-analyses.[67] It should also be inferred in accordance with future development of editorial policies that randomized controlled trials need to report[68] the term QoL in title in their evaluation of effects, efficacy and effectiveness of interventions.[69]

Conclusion

The study findings provided a content analysis and synthesized findings from articles published on QoL in population with PDPN or DPNP, and the predominance of evaluation studies was evident, with inter-measure analyses, and more number of articles on medical management among the intervention studies. Levels of evidence for most of the articles were low, and there is need for future high quality studies and reporting standards in articles for effective evidence-informed foot and ankle rehabilitation in people with PDPN.

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