Journal of Pain & Relief
ISSN: 2167-0846

Case Report Open Access

A Systematic Review and Bayesian Meta-Analysis of Medical Devices Used in Chronic Pain Management

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Abstract

Chronic non-cancer pain is a highly debilitating condition affecting approximately 20% of the global population. Chronic pain may lead to significant physical disability, emotional distress, social isolation and financial burden. Whilst. Pharmacological therapies remain the cornerstone of pain management in non-cancerous chronic pain, factors including the current opioid epidemic have led to non-pharmacological techniques becoming a more attractive proposition. We explored the prevalence of medical device use and their treatment efficacy in non-cancer pain management. A systematic methodology was developed, peer reviewed and published in Prospero. Key words of medical device, pain management devices, chronic pain, lower back pain, back pain, leg pain and chronic pelvic pain using Science direct, PubMed, Web of Science, Prospero, Medline, Embase, PorQuest and ClinicalTrials.gov. All clinical trials, epidemiology and mixed methods studies that reported the use of medical devices for non-cancer chronic pain management published between the 1st of January 1990 and the 30th of April 2022 were included. 13 studies were included in systematic review, of these 6 were used in the meta-analysis with 173 participants. Our meta-analysis for pain reduction in each study showed that transcutaneous electrical nerve stimulation combined with instrument-assisted soft tissue mobilization treatment and pulsed electromagnetic therapy produced significant treatment on chronic lower back pain patients. Pooled evidence revealed the use of medical device related interventions resulted in 0.7 degree of pain reduction under a 0-10 scale. Significant improvement in disability scores, with a 7.44 degree reduction in disability level compared to a placebo using a 50 score range was also seen. The application of medical devices in patients with chronic pain has gained popularity due to increasingly cost effective techniques, minimally invasiveness and greater awareness of risks associated with pharmacological management. Our analysis has shown that the optimal use of medical devices in a sustainable manner requires further extensive research, needing larger cohort studies with greater gender parity, in a more diverse range of geographical locations.

Keywords: European economies; Global burden; Global migratory patterns; Mental health; Combination treatments; Clinical support

Introduction

Chronic pain is a complex condition that is burdensome at an individual and societal level. It impacts approximately 20% of the global population with significant mobility restrictions, emotional distress, social isolation and financial difficulty [1]. The impact on society is significant with health care expenses and lost productivity costing European economies over 200 billion dollars and the US economy 635 billion dollars each year. Reaffirmed by The Global Burden of Disease study 2016 which highlighted high prevalence of pain and pain-related comorbidities as a significant source of disability and disease burden globally. Chronic pain populations are heterogeneous and this presents many challenges to patients, clinicians, clinical researchers and policy makers to design healthcare services that can meet the complex demands. Chronic pain prevalence and incidence varies by gender, biological sex and other social determinants. Epidemiological studies show older women, people from lower socioeconomic backgrounds and those with physical and psychological comorbidities are more likely to be at risk of long-term chronic pain [2]. Aging population means the risk of long-term chronic pain management is ever increasing due to increased exposure to comorbidities. These statistics are further impacted by changes to the global migratory patterns between developed, emerging and developing countries. Lack of government policy, inadequate resources precluding the formation of chronic pain clinics and limited access to effective treatments lead to inadequate management of chronic pain in low-income countries. Overcoming this disparity required focus on education of health care professionals, building research capacity, addressing cultural beliefs and stigmas related to pain and increasing availability of pharmacological therapies and medical devices. In high-income countries, migratory patterns change, making the eminent tracking of changes in prevalence and incidence of those with chronic pain challenging. The UK experienced high levels of total long-term immigration estimated at 1.1 million in 2022 [3]. Of the 10 million people in the UK born overseas, approximately 37% are European, 24% Asian, 9% Black and 2% Middle Eastern. Data from Public Health England reveals that black ethnic groups have a significantly higher prevalence of chronic pain compared to white ethnic groups, with Asian ethnic groups having comparable levels of chronic pain. Whilst data showing prevalence of pain in different ethnicities is applicable, data showing prevalence of pain in the different countries which people have migrated from isn't available. In comparison with host populations, immigrants may display greater multi-morbidity, strongly associated with chronic pain [4]. Forced displacement, loss of social support networks and uncertainty in future employment result in heightened emotional distress and worsening mental health contributing to poorer responses to treatment. Pharmacological therapies have remained the cornerstone of pain management which influenced non-cancerous chronic pain. In particular, the current opioid epidemic indicates global consumption

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Received: 20-Jun-2023, Manuscript No.JPAR-23-105600; **Editor assigned:** 23-Jun-2023, Pre-QC No. JPAR-23-105600(PQ); **Reviewed:** 07-Jul-2023, QC No. JPAR-23-105600; **Revised:** 12-Jul-2023, Manuscript No. JPAR-23-105600(R); **Published:** 19-Jul-2023, DOI: 10.4172/2167-0846.1000527

Citation: Oliver J (2023) A Systematic Review and Bayesian Meta-Analysis of Medical Devices Used in Chronic Pain Management. J Pain Relief 12: 527.

of pharmacological regimens doubling from 3.01 billion defined daily doses each year to 7.35 billion defined daily doses between 2001 and 2013. Increases in opioid addiction and vulnerabilities to overdosing have led to increased global mortality rising to approximately 350,000 deaths per annum. Therefore, non-pharmacological techniques have become more attractive to all stakeholders. Non-pharmacological treatments for chronic pain can be categorised into two primary categories of medical devices and complex or combination treatments. Medical devices for chronic pain management in particular are based upon gate-control theory proposed by Melzack and Wall, especially for those applying Neuro-modulation principles. Stimulation of both peripheral and central nervous somatosensory fibres may attribute to inhibiting chronic pain. One of the first medical devices used for chronic pain management are those used for spinal cord stimulation.

Methodology

A systematic methodology was developed, peer reviewed and published in Prospero. The systematic methodology included an eligibility criterion and the use of statistical method to evaluated pooled mean differences along with 95% confidence intervals. The search strategy used key words of medical device, pain management devices, chronic pain, lower back pain, back pain, leg pain and chronic pelvic pain using Science direct, PubMed, Web of Science, Prospero, Medline, Embase, PorQuest and ClinicalTrials.gov. All clinical trials, epidemiology and mixed methods studies that reported the use of medical devices for non-cancer chronic pain management published between the 1st of January 1990 and the 30th of April 2022 were included [5]. Commentaries, editorials and opinions were excluded along-side of all publications published in any other language than English. All studies included a population of patients with non-cancer chronic pain that were considered to use medical devices. The data extraction methodology was developed based on a study specific extraction template that included detailed information such as geographical location, age, sex, pain type, interventions and key statistical indicators such as interventions, measures of tool and numeric results. An extraction template specific to the objectives of the study was developed to gather a wider dataset with vital data for statistical analysis. The number of studies was the number of independent RCTs included in analysis; however sub-studies were extracted from the same clinical trials with different duration periods [6]. The results of different stages in one designed study can be regarded as new sub-studies as new rows in data analysis. Data was extracted by two investigators and any disputes for eligibility was discussed and agreed with the Chief Investigator of the study. All studies included within the analyses were independently reviewed. Outcomes were reported as median, standard deviation, mean and confidence intervals. Mean and standard deviation were extracted as the main outcomes including pre-treatment pain scores at baseline, post-treatment pain scores and pain score changes of each group. A variety of interventional tools were used to assess the severity and progress of chronic pain [7]. These include visual analogue scale, numeric rating scale, Brief Pain Inventory interference scale, McGill Pain Questionnaire, Face Pain Rating Scale, Oswestry Disability Index, Supine Bridge Test, Passive Straight Leg Raise, Pittsburgh Sleep Quality Index, Beck depression index, Short Form of the Brief Pain Inventory, SF-BPI pain interference with sleep. There are also other multiple tools we did not obtain numerical results in our analysis, such as EQ-5D index, SF-36, Pain Acceptance Questionnaire.

As all outcomes of interest were continuous, the calculation based on pain scores was performed by using mean differences with a 95% confidence interval to report the effects between the group comparisons.

Discussion

The findings of this study indicate that most common medical device clinical trials explore lower back pain although the pooled sample size of 875 patients. Pain reduction was a key outcome in the pooled study sample. Physical therapy is considered as an important facet of strengthening muscles, posture and flexibility [8]. Whilst chronic pain localised to the lower back is defined as axial lower back pain, radicular pain is classified as pain that extend to the buttocks and legs. Chronic pain can be further classified into lower back pain post-laminectomy for example and those with non-surgical refractory lower back pain. The most common pain condition that was treated based on the gathered evidence was lower back pain. All studies did not report demographic data, physical examinations and medical histories [9]. For example, body mass index, weight, smoking status and height was not reported by all studies. These are important aspects to understand both direct and indirect relationships patients may have with pain management. The treatments for chronic back pain can be challenging and refractory to a variety of interventions. Spinal cord stimulation has shown much promise although the pooled evidence in this study shows immediate relief; most clinical trials did not include longitudinal data. In a clinical setting, SCS is attractive for its ability to improve quality of life, safety, cost and clinical efficacy [10]. This study findings show pain reduction was observed with TICT and PEMT for chronic lower back pain. The pain disability scores showed significant improvement indicating notable treatment effect as shown in (Figure 1). The pooled mean difference of ODI between the medical device and control group was -7.44, indicating a medical device could produce 7.44 degree reduction in disability level compared to a placebo using a 50 score range. Whilst some applications are within the medical devices regulations framework, some act as non-clinical support systems for patients with long term conditions. Mobile application based devices are gaining popularity in pain management in migraine, back pain, pelvic pain and fibromyalgia [11]. Of the systematically included studies, 4 studies used mobile applications that are clinician aids to assist with managing pain among 437 patients. This can be a useful method of long-term management of chronic pain as shown in (Figure 2). Despite perceived accessibility and potential for widespread use at minimal cost to healthcare systems it is important to consider the availability of smartphones and the internet in low resource settings [12].The subgroup analysis conducted based on gender and pain types showed a disparity between biological gender representations. The subgroup analysis in relation to gender showed studies exploring TICT excluded women and other intervention trials underrepresented women. Whilst this is a common issue noted in clinical trials conducted across most

Figure 1: Significant improvement indicating treatment effect.

Figure 2: Clinician aids to assist with managing pain among patients.

clinical areas, the lack of gender parity is a concern to evaluate clinical efficacy and effectiveness. Equally, physiological differences between genders play a role in reporting pain inference and intensity which is an indicator for patient reported and health reported outcomes that impact cost efficiency. Of the pooled studies, 4 were conducted in Korea and 1 each in Canada and Turkey [13]. The identified heterogeneity was not influenced by geographical location although there may be an indirect link due to differences in clinical practice. An awareness of variations in pain thresholds and disparities in responses to pain treatment amongst different ethnicities remains important although these details were not reported within the identified studies [14].It is evident, there is a need for robust clinical trials to better assess medical devices where the findings can be generalizable as indicated by the sensitivity analysis. The pooled sample of studies mostly used descriptive statistics and causal inferences were often not reported. This further purport the self-reported bias could have a difference between the true values versus the self-reported for the same measures [15].

Conclusion

The evidence generation to demonstrate efficacy and effectiveness of medical devices in chronic pain management requires extensive changes. Current evidence shows a variety of limitations including restriction to lower back pain when there is a variety of other pain conditions where medical devices are used for such as chronic pelvic pain. Minimally invasiveness in medical devices used in pain management can be a compelling reason for clinicians and patients to continue to use the technique in a cost effective manner. However, to optimally use medical devices in a sustainable manner, robust evidence based practice should be regarded as a key step.

Acknowledgement

None

Conflict of Interest

None

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