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Observational study

Long-term treatment in chronic noncancer pain: Results of an observational study comparing opioid and nonopioid therapy

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HIGHLIGHTS

- Outcome data of long-term opioid therapy versus nonopioid treatment are provided.
- No clear advantage of opioid vs. non-opioid analgesics could be revealed.
- Treatment with pain medication proved insufficient.
- Worse benefit to risk relationship with higher doses and potency of opioids.

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ABSTRACT

Background and aims: Recent studies reveal high prevalence rates of patients receiving long-term opioids. However, well designed studies assessing effectiveness with longer than 3 months follow-up are sparse. The present study investigated the outcomes of long-term opioid therapy compared to nonopioid treatment in CNCP patients with respect to measures of pain, functional disability, psychological wellbeing, and quality of life (QoL).
Methods: Three hundred and thirty three consecutive patients at our pain clinic were included and divided into patients with continuous opioid treatment for at least 3 months (51%) and patients receiving nonopioid analgesics (49%). Further, outcome of different doses of opioid (<120 mg vs. >120 mg morphine equivalents) and differences between high and low potency opioids were examined.
Results: The opioid and nonopioid groups did not differ with regard to pain intensity or satisfaction with analgesic. Patients with continuous opioids treatment reported higher neuropathic like pain, longer duration of pain disorder, lower functional level, wellbeing, and physical QoL in comparison to patients receiving nonopioid analgesics. Higher opioid doses were associated with male gender, intake of high potency opioids and depression but there were no differences with regard to pain relief or improvement of functional level between high and low doses. Similarly, patients on high potency opioids reported more psychological impairment than patients on low potency opioids but no advantage with regard to pain relief. Overall, remaining level of pain, functional disability and poor QoL were quite high irrespective of the analgesic used or opioid dosing.
Conclusion: In the long-term no clear advantage of opioid vs. non-opioid analgesics could be revealed. In terms of remaining pain intensity, functional disability and quality of life, treatment with pain medication proved insufficient. Additionally, with higher doses of opioids the benefit to risk relationship becomes worse and patients on high potency opioids reported more psychological impairment than patients on low potency opioids but no advantage with regard to pain relief.
Implications: Our results raise questions about the long-term effectiveness of analgesic treatment regimens irrespective of analgesics type employed and call for more multidisciplinary treatment strategies.

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1. Introduction

Since the assumption of opioids as a promising therapy for patients with chronic noncancer pain (CNCP) during the 1990s, the use of opioid analgesics in this setting is now well established in modern medicine [1,2]. Empirically robust data demonstrate significant pain reduction with opioids in the short term compared to placebo [3,4]. Accordingly, data from North-America and Europe show continued increases in prescription rates and higher numbers of daily doses per recipient over the last few decades [1,2]. Additionally, increasing prevalence rates of long-term use have been reported with 85–96% of the patients continuing intake for 5–10 years after their first prescription [5,6]. However, whether opioids are superior to nonopioids even in the short-term [7] and whether long-term treatment with opioids is effective is still under debate.

Evidence of effectiveness of opioid therapy for treatment periods >3 months is limited as most studies focus on initial therapy effects during the first 6 to 12 weeks of treatment as recently pointed out by Welsch et al. [7] in a systematic review with a metaanalysis. Furthermore, most studies refer to pain reduction as the main outcome measure, whereas improvement of quality of life (QoL), daily functioning and wellbeing as potentially equally important treatment gains appear to be widely neglected in both the short- and long-term evaluation. Recent systematic literature reviews focusing on outcomes of opioid therapy over at least 6 months show insufficient evidence based on randomised control studies (RCTs) [8]. There are only single studies like the RCT by Breivik et al. [9], but their conclusions of better outcome with opioids are limited to osteoarthritis patients and buprenorphine. Just as important, there is also a lack of long-term opioid studies that evaluated effects on pain, function, or QoL in comparison to other treatment strategies such as nonopioid therapy [10]. Additionally, concerns about adverse effects need to be taken into account. Controlled studies point to a higher risk of overdose [11], myocardial infarction [12], and fractures with opioid analgesics [13,14]. Use of opioids has also been linked to an increased risk of depression [15] and hyperalgesia [16,17] prompting an ongoing debate about cause and consequence. Finally, drawing conclusions about the effectiveness of opioid therapy in CNCP is further complicated by dose dependent effects. Higher doses of opioids (above 120 mg morphine equivalent) have been found to be associated with a less favourable balance of benefit to risk compared to lower doses [12]. However, even at doses within a more typical therapeutic range, differential effects have been reported. A lower risk of fractures [18] and better QoL [19] were observed under low-dose opioid therapy (doses up to 50 mg) in comparison to higher opioid doses of up to 120 mg.

The aim of this study was to examine any superiority of long-term opioid treatment compared to nonopioid treatment strategies. Considering chronic pain as a multi-dimensional phenomena, treatment outcome was measured in terms of pain intensity scores, psychological wellbeing, quality of life, and functioning, as well as patient satisfaction with their treatment as a variable potentially influencing medication adherence [20]. A secondary aim was to identify differential effects of opioid dosing and opioid potency on long-term outcome.

2. Material and methods

2.1. Study design

The present observational study has a cross sectional design. Data collection took place at one assessment occasion and comprised collection of interview and questionnaire data from the patients. As supplement, information with regard to diagnosis was extracted from the medical record. Assignment of the patients into the study groups is based on retrospective information about the history of analgesia intake (i.e. ex-post-facto).

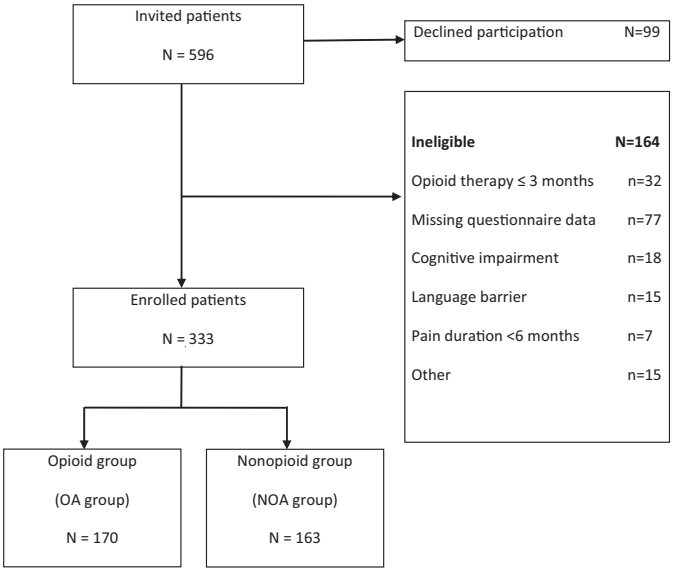

Fig. 1. Flow diagram for enrollment of potentially eligible participants.

2.2. Participants

Due to a power analysis a total sample of 210 would be required to detect medium effect sizes with regard to group differences. Considering the necessity of excluding patients and single missing data a higher number of patients were assessed in order to finally reach an adequate sample size for analyses.

A total of 596 consecutive patients with chronic pain (>6 months) were enrolled from the pain management services at the Clinic for Pain Medicine of the Sankt Josef Krankenhaus, Wuppertal (Fig. 1). Inclusion criteria were: age above 18 years, fluency in German, and pain duration of at least 6 months. Participants with pain due to cancer, comorbid dementia, psychotic or bipolar disorder, and patients with a history of alcohol and/or opioid dependence were excluded.

A total of 99 patients (16.6%) refused to take part in the study. All other patients gave their informed consent. More than a quarter of the sample ($N = 164$; 27.5%) was excluded from further analysis due to reasons displayed in Fig. 1. The final study population included 333 patients which were assigned into two groups: The opioid analgesic group (OA group) comprises patients with continuous opioid intake during at least the previous 3 months. The nonopioid analgesic group (NOA group) include patients treated with different kinds of analgesics or coanalgesics but had not received opioids in the previous three months. Patients with opioid analgesics for less than three months were completely excluded from further analysis, as the study focused on long-term outcomes of opioids in comparison to treatment with nonopioids. Involvement in other kinds of treatment (e.g. physical therapy, TENS) did not lead to exclusion in any group.

With the given sample size of 333 patients, our study was adequately powered to detect medium and large effect sizes, but not smaller effects.

2.3. Procedure

Data collection took place during a scheduled medical consultation at the Clinic for Pain Medicine which serves as part of primary