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Lack of Correlation Between Opioid Dose Adjustment and Pain Score Change in a Group of Chronic Pain Patients

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Abstract: Despite the increasing use of opioid analgesics for chronic pain management, it is unclear whether opioid dose escalation leads to better pain relief during chronic opioid therapy. In this study, we retrospectively analyzed clinical data collected from the Massachusetts General Hospital Center for Pain Medicine over a 7-year period. We examined 1) the impact of opioid dose adjustment (increase or decrease) on clinical pain score; 2) gender and age differences in response to opioid therapy; and 3) the influence of clinical pain conditions on the opioid analgesic efficacy. A total of 109 subjects met the criteria for data collection. We found that neither opioid dose increase, nor decrease, correlated with point changes in clinical pain score in a subset of chronic pain patients over a prolonged course of opioid therapy (an average of 704 days). This lack of correlation was consistent regardless of the type of chronic pain including neuropathic, nociceptive, or mixed pain conditions. Neither gender nor age differences showed a significant influence on the clinical response to opioid therapy in these subjects. These results suggest that dose adjustment during opioid therapy may not necessarily alter long-term clinical pain score in a group of chronic pain patients and that individualized opioid therapy based on the clinical effectiveness should be considered to optimize the treatment outcome.

***Perspective:** The study reports a relationship, or lack thereof, between opioid dose change and clinical pain score in a group of chronic pain patients. The study also calls for further investigation into the effectiveness of opioid therapy in the management of chronic nonmalignant pain conditions.*

***Key words:** Opioid therapy, chronic pain, opioid dose adjustment, numeric pain score.*

Although opioid analgesics are frequently used for the treatment of acute, chronic, and cancer-related pain conditions, it remains unclear whether opioid therapy is effective in chronic pain management.[1,2] The effectiveness of opioid analgesia may be influenced by the occurrence of opioid tolerance, opioid-induced hyperalgesia, and a history of substance abuse, as well as other factors such as genetics and comorbid mental illness.[7,11,25] At the center of this debate are the issues as to whether 1) opioid therapy is effective for pain relief; and 2) opioid dose escalation during a prolonged course of opioid therapy would improve pain relief. These issues appear to have a significant impact on physicians' decisions to initiate and maintain opioid therapy for chronic nonmalignant pain.[1,2]

The aim of this study was to examine the relationship between opioid dose and the effectiveness of pain relief reflected by changes in pain score. To achieve this goal, we retrospectively analyzed clinical data collected from the Massachusetts General Hospital (MGH) Center for Pain Medicine over a 7-year period. Specifically, we examined 1) the relationship between opioid dose increase or decrease and changes in clinical pain score; 2) gender and age differences in response to opioid therapy; and 3) the influence of clinical pain conditions on the opioid analgesic efficacy. The findings of this study are discussed in the context of the methodological limitations of this study and the available clinical literature on this topic.

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Methods

Data Sources

With the approval from the Partners Healthcare Institutional Review Board we accessed patient charts at the MGH Center for Pain Medicine dated from January 2001 to December 2007. Using the Research Patient Database Registry (RPDR), we searched for patients who were on opioid medications identified at more than 2 visits to the MGH Center for Pain Medicine during this period. RPDR is a database maintained by the Partners Healthcare System including the Massachusetts General Hospital, Brigham and Women's Hospital, and other affiliated hospitals. Patients who are interested in participating in clinical research are registered in this database. Investigators can request a list of potential study subjects based on the study protocol approved by the institutional review board. The RPDR search yielded 871 charts that met this initial cutoff criterion. To avoid exclusion of the most recent patients who may not have been entered into the RPDR, we also reviewed current physician schedules at the MGH Center for Pain Medicine. Fifty-six additional patient charts were identified using this method. In total, 927 (871 + 56) charts were identified using these 2 methods, and review of these charts was completed in an alphabetical order by last name.

Selection Criteria

The final set of charts used for the data collection were determined using the following criteria: 1) patients who have nonmalignant chronic pain conditions; 2) patients who are on opioid medication(s) during 3 or more office visits; and 3) clinical charts containing information on opioid medication, opioid dose, clinical pain condition, medical history, other medications, and clinical pain score (numeric pain score). Since this is a retrospective study, there was no single protocol that was followed by treating physicians. All pain scores are numeric pain scores (0–10; 0 being no pain and 10 being the worst pain) recorded at the time of office visit and are not recollections or average pain score among various office visits. A total of 109 charts were identified for the final analysis based on these criteria. It should be pointed out that the goal of this study was not to focus on month-to-month changes in opioid dose; instead, our focus was to examine the outcome of long-term opioid therapy by comparing the difference in opioid dose and pain score between the recorded initial and last visits at the MGH Center for Pain Medicine during a 7-year period. This approach minimized the fluctuation of month-to-month dose adjustment and allowed us to examine whether long-term opioid therapy would improve clinical pain score regardless of the fluctuation of opioid dose change. Specifically, the data are presented by providing 1) a summary table for the overall dose change in each subgroup of subjects (opioid dose increase, decrease, or no change between these 2 time points) with the corresponding change in pain score (ie, group analysis); and 2) a plot of each individual subject in each subgroup with regard to his/her opioid dose adjustment and pain score change.

Data Collection and Statistics

The following data were collected from the charts: patient demographics, diagnosis and any change of pain condition, medical condition, opioid medication(s), opioid dose, other medications, pain score, and side effects documented at each office visit. Raw data was entered into a Microsoft ACCESS database (Microsoft Corp, Redmond, WA). To compare the opioid analgesic effect across all patients, all opioid regimens were converted into oral morphine equivalent dose (MED; in milligrams) according to our published report.[7] We then divided all subjects into 3 subgroups based on the difference in opioid dose between the initial and last visits, ie, opioid dose increase, decrease, or no change, corresponding to at least 20% increase, 20% decrease, or less than 20% change from the initial visit, respectively. Chi-square test or Student t-test was used, when appropriate, to determine the statistical significance at $\alpha = .05$. In addition, Spearman correlation coefficient analysis was used to determine correlations, or lack thereof, between 2 sets of clinical data (eg, opioid dose and numeric pain score).

The primary endpoint of our analyses was to determine the relationship between changes in opioid dose and clinical pain score by comparing these 2 values between each subject's initial visit and last visit at the MGH Center for Pain Medicine (up to the point of data collection). Secondary endpoints of our analyses included the relationship between age, gender, opioid dose, and clinical pain condition and changes in clinical pain score. Although functional status was documented in most charts, the statement was often vague and not well defined. This information did not allow us to make a quantitative analysis and, therefore, is not included in this report.

Results

Overview

Data from 109 subjects were used in our analyses. These subjects had a minimum of 3 office visits and a maximum of 58 office visits, with a mean of 10 office visits, to the MGH Center for Pain Medicine. The average interval between 2 office visits was 66 days (1 to 1,070 days) among these subjects. The total follow-up time was, on average, 704 days (29 to 1,866 days) (Table 1). Subjects' ages ranged from 14 to 83 years at the time of their first visit, with the mean age of 49.5 years (Table 1).

A total of 52 male and 57 female subjects were included. There was no documented progression of chronic pain conditions for which opioid therapy was intended, nor were there significant changes in medical conditions (eg, new onset of comorbid medical condition such as depression) and pain treatment regimen (eg, new adjunctive medications, interventional procedures) between the recorded initial and last office visit during