Accessible Chiropractic Care and an Integrated Multidisciplinary Chronic Pain Team: Observational Study of Strategies to Manage Chronic Spinal Pain and Reduce Prescription Opioids in a Federally Qualified Health Center

Date: July 1, 2018

Background

Chronic spinal pain is one of the most common complaints encountered in the United States health system (16-18). One multi-center study determined that 31% of primary care visits in community settings involved chronic lower back or neck pain (18). Furthermore, the annual prevalence of nonspecific neck pain in a Canadian study was estimated to be between 30 and 50% (26); the global point prevalence of low back pain (LBP) is estimated at around 9%, with an estimated 80% lifetime prevalence (9, 10). Out of all 291 conditions studied in the Global Burden of Disease 2010 Study, LBP ranked highest in terms of disability (years lived with disability), and sixth in terms of disability adjusted life-years (DALYs) (9). In addition to the effect on patients, LBP costs the medical system an estimated $260 billion annually, not including indirect costs of lower household productivity and days of work lost (6,7).

The treatment of chronic spinal pain often involves a stepwise approach that includes non-steroidal anti-inflammatories (NSAIDs), rest, exercise, physical therapy, and sometimes prescription opioids (11, 26). Unfortunately, opioid analgesics have failed to demonstrate long-term efficacy in managing chronic pain, at the cost of numerous adverse effects, including addiction and overdose (3). Now at the forefront of public health challenges, opioid-related deaths have quadrupled from 1999-2015, with 33,091 deaths attributed to opioid overdoses in 2015 (11, 12).

As a response, there have been multiple efforts to study the effects of non-pharmacologic treatments for chronic spinal pain. Patients seeking these modalities have been shown to have higher satisfaction with their management and lower costs to the health system (14,-16, 19). Chiropractic physicians manage patients with chronic spinal pain using non-pharmacologic therapies, namely spinal and soft tissue manipulation, work/activity modification, and exercise and lifestyle advice. Chiropractic care is a clinically-proven safe and effective strategy for managing spinal pain resulting in lower pain scores and increased patient satisfaction with minimal adverse events (16, 20, 21, 24). In a recent systematic review, chiropractic care was equally effective as physical therapy, but there is only limited evidence of equality with medical care (23).

Low-income patients might be underrepresented in chiropractic clinics. Although there have been numerous cited attempts to include underserved patients in chiropractic care, there are few studies reporting efficacy of such programs. One Canadian study demonstrated that an urban chiropractic clinic could achieve sustainability and effectively reduce spinal pain (25). Furthermore, on-site chiropractic care in the workplace has been proven to reduce overall

healthcare utilization, including emergency department visits, outpatient visits, and radiologic images (13). Although no such study known to these authors has been published integrating chiropractic care within a federally qualified health center (FQHC), it can be hypothesized that this model would improve patient outcomes and satisfaction, while reducing healthcare costs and potentially reducing opioid prescriptions.

Affinia Healthcare is a multi-site FQHC in St. Louis, Missouri serving more than 40,000 patients per year. Recently, this organization has developed two unique strategies to manage chronic pain: 1) a multidisciplinary pain team and 2) chiropractic care. In 2016, Logan University College of Chiropractic began partnering with FQHCs, including Affinia Healthcare, whereby chiropractic providers treat patients within these medical homes. Using a flat rate of $10 USD per visit, this enhances access to chiropractic care for its low-income population. One goal of this study will be to examine the effectiveness of chiropractic care in a low-income urban population within a FQHC.

There have been a few studies reporting the use of integrated multidisciplinary pain teams in primary care, which have endorsed this model for its acceptability, affordability, and feasibility among the primary care team members (1,2,4,5). These have focused on qualitative outcomes, and did not focus on endpoints of opioid dose reduction or reduction in patient pain scores. In order to assess the effectiveness of the integrated pain team, this study will investigate pain and disability score reductions and opioid weaning success.

In order to best assess both pain and functional status, this study will use the Pain Disability Questionnaire (PDQ) as its validated quantitative assessment tool. As opposed to traditional pain scales, it incorporates both psychosocial and functional status components; because of this it is a useful survey to assess the impact of interventions to reduce pain and improve function, including chronic spinal pain (27, 28).

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1. Research Question

The overall goal of this project is to determine the effectiveness of two distinct interventions for reducing chronic pain and decreasing opioid use in a FQHC.

Primary Objectives:

- **i.** Determine the PDQ score change over time with either intervention
- **ii.** Determine the proportion of patients who successfully wean off prescription opioids

Secondary Objectives:

- **i.** Identify clinical and demographic factors associated with treatment success
- **ii.** Identify patients who can successfully reduce their morphine equivalent dose if not able to fully wean from opioids
- **iii.** Determine the proportion of eligible patients that adhere to the recommended treatments (by way of attrition rates)

2. Methods

a. Design: This study will be a prospective observational study. There will be no randomization. Patients and their primary care provider (PCP) will determine their health plans outside of the influence of this proposed study. Once determined by their PCP to be candidates for either or both of the two interventions (chiropractic care or interdisciplinary pain team), they will be scheduled an appropriate appointment. On the day of their appointment, all patients will be reviewed by the clinician to determine eligibility. If eligible, they will be offered the consent document to enroll in the study. The clinician will then be blinded to which patients have consented to participation so as to minimize bias. Patients concurrently enrolled in both intervention groups will be included in a final subgroup analysis.

b. Control group: For this proposed pilot study, there will be no control group. Ideally, a standard care group could be analyzed, but currently, Affinia does not have the administrative or IT support to incorporate the PDQ in its workflow or medical records. Future studies could be designed and planned with this in mind if the initial studies have impactful results.

c. *Inclusion/exclusion criteria.*
Inclusion criteria: Individuals with chronic (>90 days) spinal pain at Affinia healthcare that have been referred internally to either chiropractic care or the integrated multidisciplinary pain team.

Exclusion criteria: Patients deemed to have non-mechanical spinal pain from malignancy, compression fracture, or inflammatory spondyloarthropathy.

d. The target number of enrolled patients per treatment is 30. Thus approximately 60 patients will be enrolled. Enrollment period is estimated to be three months, and will end when the target participant number is achieved. Patients will be followed a total of 6 months. Data analysis may take an additional 3 months. Thus this study will take approximately 12 months.

e. Data will be stored both electronically and paper-format. A hardcopy of the Patient Disability Questionnaire (PDQ) will be provided. This hardcopy will be used to help guide clinical decisions during the visit, and then scanned into the electronic health record (EHR). Medications, including opioid prescriptions, will be recorded in the EHR. A list of enrolled patients will be kept in Microsoft Excel.

f. Enrolled participants will be tracked in a Microsoft Excel spreadsheet to be stored in Affinia Healthcare's user-specific and password-protected desktop computers with drive encryption. In order to track opioid prescriptions, the enrolled patient list can be exported to Affinia's IT department to run a medication search. This information will be relayed to the study team to enter in the database. Any discrepancies, suspected to be minimal, will require a manual chart review. This will be done by someone other than the investigators such as the IT data analyst so as to minimize bias. Prior to final data analysis, data will be de-identified. All data transactions will be done through secure, encrypted server e-mail.

g. *Will the data set include any sensitive information (e.g., HIV status, psychiatric diagnosis)?* No.

h. *Will the data set include any genomic data?* No.

i. *Will your data be used in collaborative efforts with other institutions?* Yes. Patrick Battaglia, DC, DACBR and Barry Wiese, DC, MHA, DIBCN, will be co-investigator from Logan University. The faculty of Logan University who have patient privileges at Affinia Healthcare have access to the same EHR and servers, and data will remain in the same secure, encrypted locations.

3. Study Statistics

Primary outcome variable:

i. Difference in PDQ (functional and psychosocial scores)
ii. Proportion of patients weaned from opioids by the end of study period

Secondary outcome variables:

i. Odds of treatment success by demographic factor (age, sex, origin, other musculoskeletal pain diagnoses, etc.)
ii. Proportion of patients successfully reduced on morphine equivalent dose (any reduction)
iii. Proportion of eligible patients who adhere to treatment (show rates)

Analysis plan (sample size justification and interim analysis)

Sample size calculations will be technically challenging due to the observational nature of the dual-intervention study design. We will estimate that standard care results in 90% failure rate to positively change PDQ scores or wean opioids. We will estimate the true relative risk of treatment failure is 0.5. Using the null hypothesis that there is no difference between the treatments and that there is no difference between either treatment and standard care, our calculations predict that 16 experimental subjects will be needed per intervention. The proportion of cross-over patients is unknown, so a conservative 50% will be used, and thus 32 (30 for ease of estimation) patients will be needed per group to reject the null (α=0.05, power=0.8). We will use the chi-squared statistic to evaluate this null hypothesis. Two-sample t-test and multiple linear regression will be conducted to determine the demographic and clinical features associated with outcomes. Most demographic factors will be binary or categorical, including age.

Variables to collect

i. Age (categorical)
ii. Sex
iii. Preferred language
iv. Country of origin
v. Insurance (categorical)
vi. Type of spinal pain (cervical, lumbar)
vii. Morphine equivalent dose
viii. Other musculoskeletal pain diagnoses (hip pain, shoulder pain, etc.)

4. Risks

a. Address the risk of loss of confidentiality.
b. Discuss the steps you are taking to minimize this risk.
c. Discuss your plan for reporting unanticipated problems or study deviations

There are no anticipated medical, legal, or financial risks to the participants. There is no randomization and no placebo. Patients will be studied as part of a treatment plan dictated independently by their medical providers. Risks to confidentiality will be minimized by the following procedures: study records will be accessible only to authorized study staff, and the generated data report for analysis will be de-identified.

Chart reviews will be conducted for enrolled study participants, gathering pre-selected variables.

This study relies upon a steady referral stream to Affinia chiropractic care and the pain team. Currently, these are accessible and well-utilized services, but there is no way to predict the future trend of these referrals. Any unanticipated change in providers, access to the pain team or chiropractic services, or patients refusing participation will extend the enrollment period.