Spinal Manipulation vs. Opioid Analgesic Therapy for Chronic Low Back Pain: Beliefs, Satisfaction with Care, and Qualify of Life among Older Medicare Beneficiaries

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METHODS

To test our hypothesis, we conducted a survey among older Medicare beneficiaries with cLBP. “X university IRB” approval was received to conduct this study. This study was registered under clinical trials.gov website (NCT03669354).

Population

Potential survey participants were identified through analysis of Medicare claims data. The study population included non-institutionalized Medicare Fee for Service (FFS) beneficiaries, either male or female, aged 65-84 years, as of 01/01/2012, and residing in a US state or the District of Columbia, and continuously enrolled in Medicare Parts A (inpatient), B (outpatient) and D (pharmacy) from 2012 through 2016.We restricted the population to subjects with an episode of cLBP beginning in 2013. cLBP has previously been defined as lasting three months or longer[14], thus, an episode of cLBP was identified by two paid claims for outpatient office visits with a primary diagnosis of LBP greater than 90 days but less than 180 days apart. Claims were further restricted to the clinician specialties of General Practice, Family Practice, Internal Medicine, Osteopathic Manipulative Medicine, Physical Medicine and Rehabilitation, Chiropractic, Physical Therapist in Private Practice, or Pain Management. Low back pain was identified by ICD-9 or ICD-10 diagnosis codes. We excluded all subjects with any diagnosis of cancer or use of hospice care. We assembled an analytic data set of claims for 28,160 Medicare beneficiaries who met study inclusion criteria. Study subjects were grouped into four cohorts as defined below. The research methods were reviewed and approved by the principal investigators’ institutional review board.

Cohort Definitions

All included patients received long term management of cLBP with SMT or OAT. SMTwas identified in clinical claims data by by Current Procedural Terminology (CPT) code 98940, 98941, or 98942. OAT was identified as opioid analgesics or analgesics containing opioids, identified by drug code and obtained by prescription through an outpatient pharmacy. For OAT, we defined long-term management as 6 or more standard 30-day supply prescription fills in a 12-month period. [15, 16] For SMT, we defined long-term management as $\geq$12 office visits for spinal manipulation for LBP in any 12-month period, including at least one visit per month. [14] We assembled two primary and two crossover cohorts as follows:

Primary Cohorts

SMT= Initiation in 2013 of long-term management with SMT, and no OAT for 12 months after initiating SMT

OAT = Initiation in 2013 of long-term management with OAT, and no SMT for 12 months after initiating OAT

Crossover Cohorts

SMTX = Any occurrence of SMT for cLBP in 2013, followed by initiation in 2013 of long-term management with OAT

OATX = Any occurrence of OAT for cLBP in 2013, followed by initiation in 2013 of long-term management with SMT

The date of accrual (index date) for patients into each cohort was the date of the first office visit associated with an episode of cLBP. For subjects with more than one episode of cLBP, only the first episode was counted for purposes of cohort accrual.

Survey Procedures

Following cohort assembly, potential survey participants were selected by random sampling of subjects in each of the four cohorts. The list of potential survey participants was securely transmitted to the Centers for Medicare and Medicaid Services (CMS), and initial contact was made by CMS in the form of a Beneficiary Notification Letter, signed by the CMS Privacy Officer. This letter notified the selected Medicare beneficiaries of the opportunity to participate in a healthcare survey, and allowed them the option to decline participation via enclosed reply forms. Upon conclusion of this process, CMS provided us with contact information for beneficiaries that had been determined to be eligible for voluntary participation in the survey. CMS provided contact information for 2,490 participants; beneficiaries who were deceased or without contact information were removed. A total of 1,986 surveys were hand-addressed and mailed to the Medicare beneficiaries on 01/10/2020. All available phone numbers were used to make reminder phone calls and two weeks after initial mailing, 1,070 reminder surveys were re-sent to cohorts with lower response rates. The data was entered into an MS Excel spreadsheet, with double data entry and data verification. Patient's signed consent was obtained prior to participate in the study.

Outcome Measures

Overall Satisfaction with SMT and PDT

The survey measured satisfaction for both SMT and PDT on a scale from 0-10, 0 being very dissatisfied and 10 being very satisfied. The patients were also given an option to select 'not applicable' if they never experienced either PDT or SMT. Literature indicates that for quantifying satisfaction among patients, Numeric Rating Scales can be used. [17-18]

Beliefs about Treatments Received

This study included an 8-item assessment of participant beliefs regarding their treatment of SMT and PDT. These survey items were taken from a validated scale (patient's treatment belief low back pain questionnaire) developed by Dima et al., with permissions from the author(s) .[19] A modified version of LBP treatment belief questionnaire scale (LBP TBQ Scale) was used for this study. An example of a belief question was: "I think spinal manipulation is pretty useless for people with back pain," or "I believe Prescription Drug therapy (PDT) is pretty useless for people with back pain." Responses ranged from Strongly Disagree, Disagree, Agree, Strongly Agree and Undecided in a 5-point Likert scale. For purposes of analysis, we combined the response options into the following three categories: "Disagree" (Strongly Disagree and Disagree), "Agree" (Strongly Agree and Agree), and "Undecided"(left as is).

Quality of Health Survey (Mental and Physical Health – SF-12)

A modified version of the SF-12 outcome measure was used. The SF-12 is a validated, health-related quality of life (HRQoL) survey. [17,20]. The SF-12 is designed to be able to measure physical and mental health. We modified the format of the original SF-12 survey to fit our population.[20] Modifications to the survey included reformatting of the item and response presentations, using a larger font size. Permission to use the survey items in our study was granted by OPTUM.

The survey instrument was pre-tested for face validity by administration to 102 Medicare patients with chronic low back pain, over the age of 65, who had received at least two chiropractic spinal manipulation treatments for their low back pain at the Southern California University of Health Sciences' University Health Center. After examining the face validity of the survey, and based on feedback, for ease of comprehension by older subjects, the survey questions were printed in larger font and carefully worded to be brief, unambiguous, and free from bias.

Data Analysis

We generated descriptive statistics including computation of means for continuous variables and percentages for categorical data. We examined between-group differences for our three measures. Specifically, we first compared outcomes for the SMT and OAT cohorts to test our primary hypotheses and subsequently compared outcomes for the SMTX and OATX cohorts as exploratory analyses.

In order to address our primary hypothesis, we collapsed the response options as follows: response options for satisfaction with care items, 8-10, we coded as 'Very satisfied' and response options <8, we coded as 'Less satisfied'. We conducted Pearson chi-square tests to examine differences between groups for the Beliefs about Treatment items as well as for the overall satisfaction with treatment items.

Additionally, for the Beliefs about Treatment items, we combined the response options using the following categories: Disagree (combined Strongly disagree with Disagree), Agree (combined Strongly agree with Agree), Undecided was left as is. Group mean differences for the SF-12 mental and physical health scores were examined using *t*-tests. We performed t-tests for group mean comparisons utilizing the entire 0-10 scale for overall satisfaction as well. Additionally, we conducted the Kruskal-Wallis non-parametric test to accommodate non-normality in the distribution of the data for the Beliefs about Treatment items . All analyses were conducted using IBM SPSS (Version 23).