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Research Article

The Reduced Incidence of Lumbar Surgery for Low Back Pain Following Enhanced Mechanical Diagnosis and Therapy Intervention

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Abstract

Background: The high costs associated with lumbar surgery warrants consideration of diagnostic triage toward more conservative and less costly management. **Purpose:** The purpose of this prospective trial was to describe the process of a highly standardized and Quality Assured Musculoskeletal assessment and care approach (QAMDT) and its impact on the rate of lumbar surgery in a specific population. **Methods:** A one-year longitudinal, retrospective claims analysis was performed using ICD-10 codes for all non-emergent musculoskeletal conditions examined and treated for a Fortune 500 company during the year 2019. The QAMDT was described and surgical rates for patients managed in the community (CC) were compared to those managed by QAMDT. Differences between the community and the QAMDT intervention group were calculated using a two-sample t-test. A logistic regression analysis controlled for differences in demographic variables between groups and produced adjusted surgery rates. **Results:** QAMDT assessment and treatment for lumbar conditions reduced the incidence of surgery by 52% unadjusted and 44.9% when adjusted for health risk and demographic variables. **Conclusions:** Low back pain patients considering surgery may benefit from a quality assessment and care approach to determine if their condition may be amenable to conservative care.

Introduction

Low Back Pain (LBP) is a leading cause of disability worldwide, [1,2] and is the most common reason for medical consultation in the United States [3]. Its impact on North American society ranges from personal impairment associated with decreased work productivity to utilization of short and long-term disability programs [2,4,5]. The determination of specific causes for the majority of presentations remains elusive to most clinicians, no one single treatment approach has proven superior [6,7] and the effectiveness of most non-surgical paradigms is unproven [6,8]. As a result, clinical decision making may be arbitrary, ineffective and result in increased health care costs.

Current research has focused on the identification and validation of subgrouping low back pain patients to better match health care decisions to clinical presentations [9]. Mechanical Diagnosis and Therapy (MDT) is one such approach to managing LBP and is explained in Appendix 1. The inter-tester reliability of the MDT approach has been well documented in the literature [10-12] however, the support for its validity is varied [13,14]. For a lower back pain care approach to bring value to all stakeholders, the clinical outcome must meet accepted levels and occur at a cost that is commensurate with these levels (Healthcare Value=health of outcomes/cost of outcomes) [15]. The most favorable outcome, delivered at the lowest cost, results in the greatest value. For an approach to musculoskeletal disorders to universally produce these clinical and economic outcomes, the reliability and validity must be consistent across various settings and populations.

The purpose of this study was to describe a quality assured Mechanical Diagnosis and Therapy (QAMDT) approach and its impact on the rate of surgery for lower back pain in a specific population. A self-funded Fortune 500 company deployed a highly standardized and quality assured musculoskeletal assessment and care approach through its onsite health centers. This study compares the lumbar surgical rates of employees and beneficiaries utilizing some components of this paradigm to those managed entirely in the community. The hypothesis is that those examined and treated within the onsite health centers require and utilize fewer surgical procedures to manage their lower back conditions, thus reducing costs to the individual and to society.

Materials and Methods

IRB Approval

As this study is retrospective using pre-existing de-identified claims data it was determined that a formal IRB approval was not required. However, a formal review of the methodology and results by an internal Security Director determined that there were no human risks associated with the study.

Study Design

This study is an observational, longitudinal, retrospective analysis of medical claims data. The primary concern is surgical rates of subjects that remained in the community for their lumbar care compared to surgical rates of subjects that received conservative care under a strict Quality Assurance Mechanical Diagnosis and Therapy (QAMDT) model for their lumbar diagnoses. We analyzed the claims data for each subject's care for one year after the initial diagnosis or until they had a lumbar surgery. Patients were considered part of the QAMDT group if they had received intervention from a QAMDT certified clinician (physical therapist or chiropractor) during care for their lumbar diagnosis prior to any lumbar surgery. Care was also sorted by risk (low to high). This is done by ranking procedures in severity from lowest to highest: office visit, x-ray, chiropractic care, physical therapy, injection, emergency room visit, advanced imaging (CT scans and MRIs), and surgery. We considered a case high risk if the patient experienced any treatment ranging from physical therapy to surgery during their episode. We included only high-risk patients in the study for both groups. Demographic information included age, sex, prospective risk, and retrospective risk.

Target Population (Inclusion Criteria)

Subjects were employees or beneficiaries of the Fortune 500 Company. They were included in the study if they were over 18 years old and had an in-scope diagnosis for their lumbar region in the year 2019. A diagnosis was considered in-scope if it related to a lumbar musculoskeletal condition and was not related to a fracture, infection, or dislocation. We removed all subjects whose first claim in the first quarter of 2019 was a lumbar surgery. Lumbar diagnoses were identified using the ICD10 codes in their claims records. All subjects could be referred to a QAMDT certified clinician either through the company's health center, from the community, or through self-referral. In addition, subjects referred or scheduled for an MRI were required to complete three appointments with a QAMDT certified clinician to be approved for the MRI, or they would be charged a significant copayment.

Diagnostic Triage

Diagnostic triage is considered an essential guideline in managing LBP and involves a history and clinical examination, the goal of which is to exclude non-musculoskeletal conditions and to assign patients to categories of specific spinal pathology, radiculopathy, or non-specific LBP [16]. More specific categorization of musculoskeletal related conditions can stem from a Mechanical Diagnosis and Therapy (MDT) assessment. The McKenzie Method of Mechanical Diagnosis and Therapy is a reliable and valid system used to classify and treat musculoskeletal pain based on the clinical response to patient- and clinician-generated procedures. [10] This method involves assessment of symptomatic and mechanical baselines during testing to classify patients into one of four syndromes: derangement; dysfunction; posture; or other [11].

Quality Assured MDT Care (QAMDT)

QAMDT consisted of two levels of training along with an ongoing data-enabled quality assurance program that monitored each patient's progress allowing for real-time indicated adjustments to the conservative assessment and care processes. First, all primary care clinicians (physicians, nurse practitioners and physician assistants) practicing in five separate onsite health centers for the Fortune 500 company underwent an 8-hour training program. The program consisted of 4 hours of online training

and 4 hours of live (face-to-face) training designed to improve their understanding and skill set in the detection of symptomatic, mechanical, and functional responses to joint specific loading strategies.

Second, nine onsite conservative care clinicians (physical therapists and chiropractors) practicing in the five health centers were licensed in the state which they practiced, held a competency certification from the McKenzie Institute U.S.A. or International in MDT, had passed a standardized test in musculoskeletal clinical management with a 75% or better grade, and were enrolled in a real-time quality assured patient management program (QAMDT).

QAMDT was developed to enhance clinician capabilities in the assessment and care of the wide variety of patho-mechanical musculoskeletal conditions for which they are responsible to assess and treat. Further, under a quality assurance model, all patient outcomes were monitored. During care, patient reported outcomes determined whether current practices were yielding effective results or if practice patterns needed to be altered with the intent of an improved clinical outcome.

Patients arrived at the QAMDT practice through one of four processes: self-referral, referral from the community, referral from the onsite primary care team or through a pre-certification process around MRI for musculoskeletal conditions.

Community Care (CC)

Decisions around care choices provided by the community were determined by the subject or the subject's primary care physician. As a result, the care provided in the community was varied dependent on which clinician the subjects chose to manage their condition. Though some clinicians in the community had undergone standard MDT training, none had access to QAMDT and therefore no subject in the CC group received QAMDT.

Data Sources

We were provided with 3 different claims datasets: inpatient services, outpatient services, and professional services. The data also included retrospective and prospective risk scores, generated using a proprietary risk-adjustment algorithm and added by the third-party administrator to the claims data.

Determining Group-Differences

Due to the minimal amount of demographic information provided in claims data, the ability to explore differences between the groups was limited. Included in the claims data were subject's age, gender, retrospective risk score, and prospective risk score.

Statistical Analysis

Differences between the CC and QAMDT intervention group were calculated using a two-sample t-test. Table 1 contains a summary of the demographic data for the CC and the QAMDT groups for the initial analysis. The average age for both groups was forty-six. The QAMDT group was 41% female and the CC group was 50% female. Retrospective risk scores, which were each subject's risk of health-related costs in the previous year, and prospective risk scores, which were the subject's risk of health-related costs in the current year, were low for both groups. However, they were slightly higher in the community group. A lower score reflects less risk. The difference between the two group's demographic variables, except age, were statistically significant, but their clinical relevance was small as seen in the minimal differences in means (Table 1). The primary independent variable was the treatment group, and the primary dependent variable was the presence of a surgery procedure in the year of care. We performed a logistic regression to control for differences in demographic variables between groups and produced adjusted surgery rates. The logistic regression used surgery rates as the dependent variable and treatment group, age, gender, p.risk, and r.risk as independent variables (Table 2).

	Treatment groups / N Counts						
	CC N = 1,077		QAMDT N = 809			Overall N = 1,886	
Variable	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**P[1]=**	**Mean**	**Std Dev**
Age(yrs.)	46.4	13.2	46.1	11.6	.601	46.2	12.5
Retrospective Risk	3.0	3.28	2.08	2.11	<.001	2.6	2.87
Prospective Risk	2.6	2.45	1.9	1.52	<.001	2.3	2.13
Gender	.5	.5	.59	.5	<.001	.54	.5
P value reflects the differences in CC and MDT means for each demographic variable							

Table 1: Demographic Information Initial Analysis.

Unadjusted	LogOdds	Odds	Probability
Community	-2.058	0.1277	11.30%
QAMDT	-2.856	0.0575	5.40%
Adjusted	**LogOdds**	**Odds**	**Probability**
Community	-2.228	0.1077	9.70%
QAMDT	-2.883	0.056	5.30%

Table 2: Unadjusted and adjusted log odds, odds, and probability.

Results

The first instance of a lumbar diagnosis in 2019 initiated the case, and the course of care for that case was followed for one year, or until the subject had a lumbar surgery. There were one-thousand, eight-hundred and eighty-six subjects who met the inclusion criteria. Eight-hundred and nine subjects were part of the QAMDT group, and one-thousand and seventy-seven subjects comprised the CC group. One hundred twenty two (11.3%) subjects in the community group had lumbar surgery in the year of analysis. Forty-four (5.4%) patients in the QAMDT group had lumbar surgery in the year of the analysis. After controlling for demographic differences and comorbidity risk between the two groups, the adjusted surgery rate was 9.7% for the community and 5.3% for the QAMDT group. The results of the chi-squared test comparing the differences in surgical rates between the two groups demonstrated significant difference ($p<.01$).

Discussion

Main Findings

This study compared surgical utilization for lumbar disorders in a standard medical community environment to those examined and treated in a medical home under a QAMDT model. The risk adjusted results demonstrated that 9.7% of the community-based care patients underwent surgery, whereas 5.3% of the QAMDT patients underwent surgery for their lower back issues. The burden that lower back pain has put on societies around the world, in terms of disability and cost, demonstrates the need for an improved health care delivery system for the condition [1,2,4]. The reduction in the need for surgery in the QAMDT group offers support for further training for primary care clinicians and the implementation of a quality assured MDT approach at the beginning of care. In a study by Agarwal et al, 2000, [17] patients seen by the physician trained in MDT had a decreased likelihood of medication use including both opioids and non-opioid pain pills, diagnostic imaging, electromyography/nerve conduction velocity testing, specialty referrals, injections (joint and spinal injections), surgeries, emergency room visits, and inpatient admissions. Also, patients who were seen by the physician trained in MDT cost significantly less to the system ($3481 per member per year versus $4852, $p<0.001$), despite being older and having more medical problems and pain complaints [17]. Generalization, however, is not possible as only one physician participated in the MDT group. Donelson, et al. demonstrated a statistically significant decrease in costs($p>00.1$) associated with the treatment of lower back pain when primary care clinicians received specific training and worked closely with MDT trained clinicians working under a quality assurance model similar to the one described in this paper [18]. The results of this study add to these findings.

Quality assurance

QAMDT treatment starts with an MDT assessment, which has demonstrated inter-tester reliability when studying clinicians with recognized training [11,12]. The reasoning behind training clinicians to further standards and then enrolling them in a real-time quality assurance program is the variability in clinical outcomes that have been demonstrated by MDT trained clinicians in the literature [19,20]. Quality assurance programs are not common in the treatment of musculoskeletal conditions; however the results of this study demonstrate their potential value.

The associated Fortune 500 Company implemented an MRI pre-certification program six years prior to this study in attempts to have employees and beneficiaries place the conservative care program in front of MRI and surgical consultation. As well, the MRI pre-certification for patients resulted in 71% of those that could be contacted by benefits navigators (n=615) starting their care journey, as defined in this study, in the QAMDT program. This speaks to the complexity of the MSK conditions in the QAMDT patient cohort.

Claims Data

This study was only possible because of the Fortune 500 Company's willingness to share claims data. Claims data captures all care for the condition, does not rely on reliability and validity of measurement instruments and does not have the issues associated with RCTs around dropout from care. If care occurs, it will be seen in the claims data.

Limitations

This study offers the results of a retrospective analysis of claims data. The strength of the study is that there was no loss of subjects. If patients drop out of care on the community side, the costs attributed to them cease. If the subjects left the community for a QAMDT assessment, they become part of the QAMDT cohort. If they dropped out or were referred out of care on the QAMDT side and re-entered the system on the community side for further care, QAMDT was responsible for all care costs, including surgeries, as demonstrated by the claims data.

Unfortunately, claims data does not contain clinical outcomes, which limits the strength of the risk adjustment. On the other hand, the subject sizes in this study are quite large in comparison to cost-effectiveness studies looking at clinical outcomes and cost. As well, this claims data study did not carry the cost burden typically associated with RCTs nor does it have the issues associated with drop-out and follow-up that we often see in the more desirable RCTS.

The patients involved in the pre-certification for MRI could not be sub-categorized by body part. As a result, the exact "n" count of lumbar patients referred for an MRI could not be determined. Further to this, as there were 372 patients referred for MRI who could not be contacted by the benefits navigators, it was not possible to determine if they received an MRI, were further treated in the community, or treated in the QAMDT program.

Comorbidity and demographic data were available on both groups allowing for some level of risk adjustment. Clinical outcomes data was available for the QAMDT group; however, because it was not available for the CC group, a full risk adjustment for orthopedic conditions was not possible. It may be speculated that the less complex patients would choose the QAMDT pathway; however, it can also be argued that those patients who had done poorly in the community would seek QAMDT care.

Conclusion

As there is no clear evidence of differences between the two groups, the 44% reduction in surgery after risk adjustment suggests that the diagnostic and treatment approach implemented in the onsite health centers may be responsible for the decrease in need for lumbar surgery. This demonstrates two key points: 1) a standardized and quality assured MDT approach to assessment and care of lumbar conditions may lead to a decrease in the need for lumbar surgery, and 2) the highly variable assessment and treatment paradigms utilized in the general medical community may lead to ineffective, invasive, and expensive procedures.

The MDT assessment has demonstrated a reduction in lumbar surgeries in earlier studies where subjects interested in spinal surgery were offered a pre-operative assessment [16,17]. Two of the studies demonstrated a 50% reduction in surgery in the cohorts that volunteered for assessment [16]. This study adds to the information demonstrating the importance of an MDT assessment prior to MRI and surgical consult for lower back pain sufferers.

Conflict of Interest Statement

John Mark Miller is a principal owner of Integrated Mechanical Care, Emma Thelen is a data scientist employed full-time with Integrated Mechanical Care, Steve McClellan is the Chief Security Officer and Data Analyst employed with Integrated Mechanical Care.

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The McKenzie Method® of Mechanical Diagnosis and Therapy® (MDT)

The McKenzie Method is a biopsychosocial system of musculoskeletal care emphasizing patient empowerment and self-treatment. This system of diagnosis and patient management applies to acute, subacute and chronic conditions of the spine and extremities. It offers a reliable and practical approach that focuses on "what patients need" and not on "what therapists want to do".

- Backed by years of research, evidence and clinical practice
- Known to show results in as little as two to three visits
- Assessment-driven and individualized treatment plans
- Active, not passive, therapy strategies for more successful management
- Cost efficient - treatment without expensive tests or procedures
- Non-invasive - no needles, no scalpel
- Self-directed and managed - we work with you and teach you
- Preventative - lifelong knowledge and skills

The McKenzie Method of MDT give patients control of their pain and empowers them to get back to the life they love. Solutions proven to work!

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