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Original Research

The Effect of Intra-articular Hyaluronic Acid Injections and Payer Coverage on Total Knee Arthroplasty Procedures: Evidence From Large US Claims Database

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ABSTRACT

Background: There is debate regarding the efficacy of intra-articular (IA) hyaluronic acid (HA) injections for the management of knee osteoarthritis (OA). This study aimed to determine if IA HA utilization and payer coverage of viscosupplementation affected the prevalence of total knee arthroplasty (TKA) procedures and the age of TKA patients.

Methods: We performed a retrospective analysis from 2014 to 2020 using a large national commercial claims data set. We analyzed the number of TKA procedures and the age of the patients in states that covered IA HA vs those with limited coverage. Mixed random effects and slopes models were used to identify the impact of the IA HA injections.

Results: Of 7,335,301 patients with knee OA, 440,606 (6.0%) received a TKA procedure at an average age of 59 years. The rate of TKA procedures increased by 0.56% per year (95% confidence interval [CI] 0.46-0.66; $P < .001$). Payer coverage of IA HA injections had no effect on TKA prevalence ($P = .926$). The age of surgical patients increased yearly by 0.15 years (95% CI 0.12-0.18; $P < .001$), regardless of IA HA injections ($P = .990$). After controlling for demographics and comorbidities, patients that received an IA HA injection had a higher probability of receiving a subsequent TKA (odds ratio = 2.83; 95% CI 2.80-2.87; $P < .001$); this finding was conditional of patients' age at the first diagnosis of knee OA.

Conclusions: Additional clinical trials should be employed to identify the role of HA injections in the treatment armamentarium for knee OA.

Introduction

Intra-articular (IA) hyaluronic acid (HA) injections, also referred to as viscosupplementation, are used for symptomatic relief of pain in knee osteoarthritis (OA). A growing body of evidence, however, questions the efficacy of these injections. Conflicting literature suggests that IA HA, at best, offers a modest effect in the treatment of symptomatic knee OA [1–3]. Negative reviews highlight the heterogeneity of the published literature, absence of a definitive difference from placebo, and publication bias [4–8]. Many major governing bodies and organizations do not recommend unconditional use of IA HA, including the American Academy of Orthopaedic Surgeons (AAOS) [9]; the United Kingdom's National Institute for Health and Care Excellence [10]; American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee [11]; and the Osteoarthritis Research Society International [12]. Nevertheless, a lack of treatment consensus in the orthopaedic community persists with an apparent disconnect between what is recommended by the AAOS and other governing bodies' clinical practice guidelines (CPGs) and what occurs in daily practice [13].

Although the AAOS explicitly states that its CPG recommendations are not intended for payor coverage-based determinations, some insurers have used the CPG as a part of their support for not allowing IA HA injections. These coverage-based determinations

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vary by state and payor. As such, several articles have voiced concern regarding the AAOS CPG on IA HA utilization [14], highlighting the dominating presence of private payers in certain states and the effects of denied coverage on arthritis care. Others report the AAOS CPG fails to acknowledge medical benefits not addressed in guidelines, such as delayed time to knee replacement [15,16]. To help address these findings, we examined both state- and patient-specific data (1) to determine if IA HA utilization affected the prevalence of total knee arthroplasty (TKA) procedures, (2) to examine the effect of IA HA on the average age of TKA patients, and (3) to evaluate the role of IA HA insurance coverage on TKA procedures. We hypothesize IA HA injections and payer coverage of viscosupplementation will not alter TKA utilization and patients' age.

Material and methods

This study received institutional review board approval, including waiver of the requirement of participant informed consent.

Setting

Data from a large national commercial claims administrative data set containing Health Insurance Portability and Accountability Act compliant deidentified data for more than 45 million people were queried from January 01, 2014, to December 31, 2020. The data set contains deidentified eligibility information, pharmacy claims, and medical claims data for all members. Patients with diagnosed knee OA or knee pain were included in the study, as identified using the presence of International Classification of Diseases (ICD) diagnosis codes and/or TKA Current Procedural Terminology (CPT) codes; CPT TKA code: 27447; ICD 9 codes for knee OA and knee pain: 715.16, 715.26, 715.36, 715.96, 719.46; ICD 10 codes for knee OA and knee pain: M17.0, M17.1, M17.10, M17.11, M17.12, M17.4, M17.5, M17.9, M17.2, M17.30, M17.31, M17.32, M25.561, M25.562, M25.569.

Outcomes and variables

We utilized both state- and individual-level analyses to evaluate our outcomes of interest. The state-level analysis provided the prevalence of TKA for patients with a preexisting knee OA or pain diagnosis within each state. We defined the outcome as TKA rate per state through a utilization equation. The numerator was defined as the total number of unique members with a TKA CPT code. The denominator of our rate equation encompassed the total number of members with a CPT for TKA procedures and the combination of members with knee OA or knee pain based on ICD 9 and 10 codes.

The rates of TKA procedures were stratified by state to elucidate the effect of IA HA insurance coverage. The focal independent variable for state-level analysis was the binary grouping of states that offer full coverage for IA HA injections and the states with deceased coverage. The claims database used for this study had decreased payer coverage in the states of Alaska, California, Colorado, Connecticut, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Massachusetts, Maine, Missouri, New Hampshire, Nevada, New York, Rhode Island, Ohio, Virginia, Washington, and Wisconsin [14]. The focal independent variable for the patient-level analysis was whether the patient received a previous IA HA injection—we did not stratify based on the number of subsequent injections.

On a patient-level outcome, we assessed whether an individual patient had a TKA procedure, allowing for further examination of confounders. All members with an ICD diagnosis of knee OA or knee pain were included. Of note, if the patient had a diagnosis for both knees, they were included twice. Any subsequent laterality-controlled IA HA injection and/or TKA CPT code was then highlighted as potential covariates. Patients with a minimum of 2 years of follow-up from original knee OA or pain diagnosis were included in the final patient cohort.

For our potential confounders, we included the year of surgery, age at initial knee OA or pain diagnosis, gender, and Elixhauser Comorbidity Index (ECI) for all patients. ECI is a method of categorizing comorbidities of patients based on ICD diagnosis codes [17]. The age of the patient was further examined as an interaction between age of OA diagnosis, IA HA injections, and subsequent TKA procedures. Procedure year was added as a covariate because of the increase in TKA procedures throughout the study period [18,19], allowing us to account for the differences in patient selection and the temporal increase of TKA procedures throughout the study period.

Analysis

State-level data were analyzed using a random slopes and intercepts mixed effects model. Time, states with high and low coverage of IA HA injections, and the interaction between the 2 were entered as the fixed effect, while individual states were entered as random effects. The outcome was the rate of TKAs performed in each state over time as a proportion of total patients with a knee OA or pain diagnosis. In addition, age at surgery was compared at the state level using the same mixed effects modeling framework with the same fixed and random effects.

Patient-level data were analyzed both in a univariate and multivariate context. Patients diagnosed with knee OA or pain that received no subsequent recorded intervention (ie, IA HA injection or TKA) were compared against IA HA injection only, TKA only, and both interventions across gender, age, and ECI utilizing independent samples t-tests for continuous variables and chi-square tests for categorical variables. Multivariate binary logistic regression was utilized to investigate the probability of subsequent TKA for patients that did or did not previously receive an IA HA injection and the interaction of age and IA HA injection after controlling for gender and ECI. Aldrich-Nelson pseudo-R^2 was populated to determine model performance.

Results

State-level data

A total of 7,335,301 unique patients were included with ICD coding of knee OA or knee pain from January 01, 2014, to December 31, 2020. Across the study population, 440,606 (6.0%) members received a TKA procedure at an average age of 59 years. The rate of TKA procedures increased by 0.56% per year in all states (95% confidence interval [CI] 0.46-0.66; $P < .001$). There was no effect of IA HA injections on TKA prevalence in states that covered the injections compared to those that had decreased coverage ($P = .926$). (Table 1; Fig. 1) The mean patient age at the time of TKA increased yearly by 0.15 years (95% CI 0.12-0.18; $P < .001$); there was no change in age at the time of surgery for patients in states that covered IA HA injections ($P = .990$). (Table 2)

Patient-level data

A total of 4,343,679 patients were included with ICD coding of knee OA or knee pain. Differences in sample sizes for state- and patient-level cohorts are due to the need for ICD-10 codes (contains information on laterality) beginning in October of 2015 and the need to capture at least 1 year of data before OA or knee pain

Table 1
State-level analysis of TKA rate by year.

Predictors	TKA rate		
	OR	95% CI	*P* value
Year	0.56	0.46 to 0.66	**<.001**
IA HA injection	0.1	−1.92 to 2.11	.926
Year * IA HA	−0.01	−0.14 to 0.12	.889

CI, confidence interval; IA HA, intra-articular hyaluronic acid given; OR, odds ratio; TKA, total knee arthroplasty.
Marginal R^2/conditional R^2: 0.256/0.906. Year * IA HA represents the interaction between injection and the year of analysis.
Bold values indicate statistaical significance.

Table 2
State-level analysis of TKA rate by age.

Predictors	TKA rate		
	OR	95% CI	*P* value
Age	0.15	0.12 to 0.18	**<.001**
IA HA injection	−0.11	−17.5 to 17.3	.990
Age * IA HA	−0.03	−0.07 to 0.01	.171

CI, confidence interval; IA HA, intra-articular hyaluronic acid given; OR, odds ratio; TKA, total knee arthroplasty.
Marginal R^2/conditional R^2: 0.001/0.503. Age * IA HA represents the interaction between injection and the age of the patient.
Bold values indicate statistaical significance.

diagnosis to populate the ECI for the patient-level analysis. After controlling for gender and ECI, knee OA or knee pain patients that received an IA HA injection had a higher probability of receiving a subsequent TKA (OR = 2.83; 95% CI 2.80-2.87; $P < .001$) (Table 3). The probability of receiving a TKA for both injection and non-injection groups was conditional on age of first diagnosis of knee OA or pain. Patients with a diagnosis prior to their 60s had a greater probability of subsequent TKA following an IA HA injection than individuals of the same age who did not receive an injection. Alternatively, if patients received their first diagnosis in their 60s or later, there was a greater probability of TKA without a prior IA HA injection (OR = 0.93; 95% CI 0.93-0.93; $P < .001$). (Fig. 2)

Discussion

Controversy exists within the medical community regarding the utility of IA HA injections for knee OA. In our study of knee OA patients with commercial coverage, IA HA did not delay nor prevent TKA procedures. After controlling for demographics and comorbidities, patients that received an IA HA injection had a higher probability of receiving a subsequent TKA than those without an injection. Payer coverage of viscosupplementation by state did not alter these results. This study has implications for the use of IA HA injections in the treatment algorithm for knee OA.

Our results show the rate of TKA procedures has continued to increase by year, regardless of IA HA utilization and varying levels of payer coverage for the injections (Table 1). While not a direct comparison, this is contrary to previous evidence that IA HA injections delay surgery, as shown in 2 previous large administrative claims database studies [15,16]. After adjusting for procedure year, we found no significant change in average patient age at the time of surgery in states that covered IA HA injections with respect to those that did not (Table 2). Additionally, there was no significant

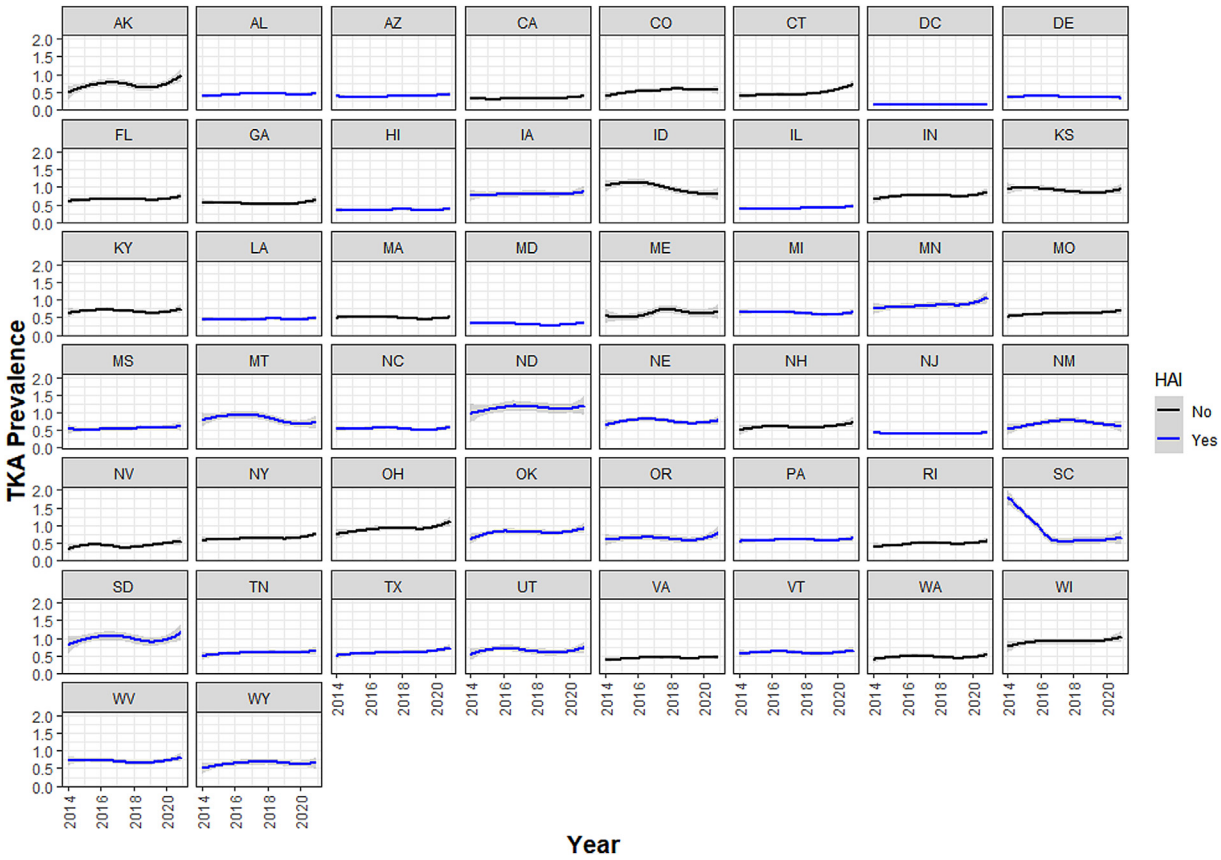

Figure 1. TKA prevalence in states that reimbursed IA HA injections compared to those that did not by year. State-level analysis showed no significant effect of IA HA injections on TKA prevalence in states that reimbursed the injections compared to those that did not ($P = .926$). Black lines represent states that did not cover the injections, while blue lines represent states that did. HAI, hyaluronic acid injection; IA HA, intra-articular hyaluronic acid; TKA, total knee arthroplasty.

Table 3
Patient-level analysis of probability of TKA procedure.

Predictors	Subsequent TKA procedure		
	OR	95% CI	*P* value
Sex: male	1.03	1.02-1.04	**<.001**
ECI: 1-4	0.94	0.93-0.95	**<.001**
ECI: ≥5	0.78	0.76-0.79	**<.001**
Age	1.13	1.13-1.13	**<.001**
HA injection: yes	2.83	2.80-2.87	**<.001**

CI, confidence interval; ECI, Elixhauser Comorbidity Index; HA, hyaluronic acid; OR, odds ratio; TKA, total knee arthroplasty.
Aldrich-Nelson pseudo-R^2 (with Veall-Zimmermann correction) = 0.14.
Bold values indicate statistaical significance.

relationship between IA HA injections and TKA prevalence in states that covered the injections with respect to those that do not (Fig. 1). This contrasts with concerns that payers' restrictive coverage policies regarding viscosupplementation may have resulted in an increase in TKA procedures due to the lack of alternative management strategies [14,20,21].

Patient-level data suggest those who receive an IA HA injection have a higher probability of receiving a subsequent TKA procedure with respect to those without an injection (Table 3). This finding could reflect the practice patterns in high-utilization regions or states with preference-sensitive care [22,23], with care providers having a lower threshold to recommend viscosupplementation and subsequent surgery. As shown in the Medicare population, the local medical opinion in high-utilization regions influences care, potentially overpowering clinical appropriateness [24]. Carlson et al. have documented the ongoing use of IA HA injections in the treatment algorithm of knee OA within the orthopedic community [13]. On the other hand, patients who receive the injections may also have greater pain and disability, potentially explaining the correlation with subsequent TKA procedure.

However, there is a conditional effect of age at initial diagnosis of knee OA or pain that suggests IA HA injections may provide a protective effect against TKA if patients are diagnosed with knee OA or pain in their mid-60s or later (Fig. 2). An alternative interpretation, although this study was not equipped to investigate severity of arthritis, is that older patients (at the age of first diagnosis) have higher severity of OA and are less likely to have a positive response to viscosupplementation than younger individuals [25,26]. Additional research should explore provider intervention strategies based on patient age and the patient factors that predict a favorable response to HA treatment.

Prior to surgical intervention, there is significant cost associated with conservative management of knee OA in patients. An estimated 30% of pre-TKA costs are due to HA injections alone [27], with up to 14.7% of knee OA patients receiving viscosupplementation within a year prior to TKA [28,29]. Zhu et al. recently demonstrated the number of HA injections have significantly increased in the past decade, with the total costs rising from $290 million to $325 million from 2012 to 2018 [30]. In conjunction with a significant rise in HA-related costs, many studies have failed to demonstrate a clinically important benefit from HA compared to placebo [4–8]. These findings highlight an area of orthopedic care that requires further evaluation for efficacy and effectiveness.

There are several limitations to this study. Because we utilized claims-based observational data, possible unknown confounders contributed to the results. We are unable to comment on subtle, noncoded factors that may influence the utilization of viscosupplementation and result in subsequent TKA surgeries, such as severity of disease, previous nonoperative management, patient mindset towards treatment, and operative provider practice. In addition, we

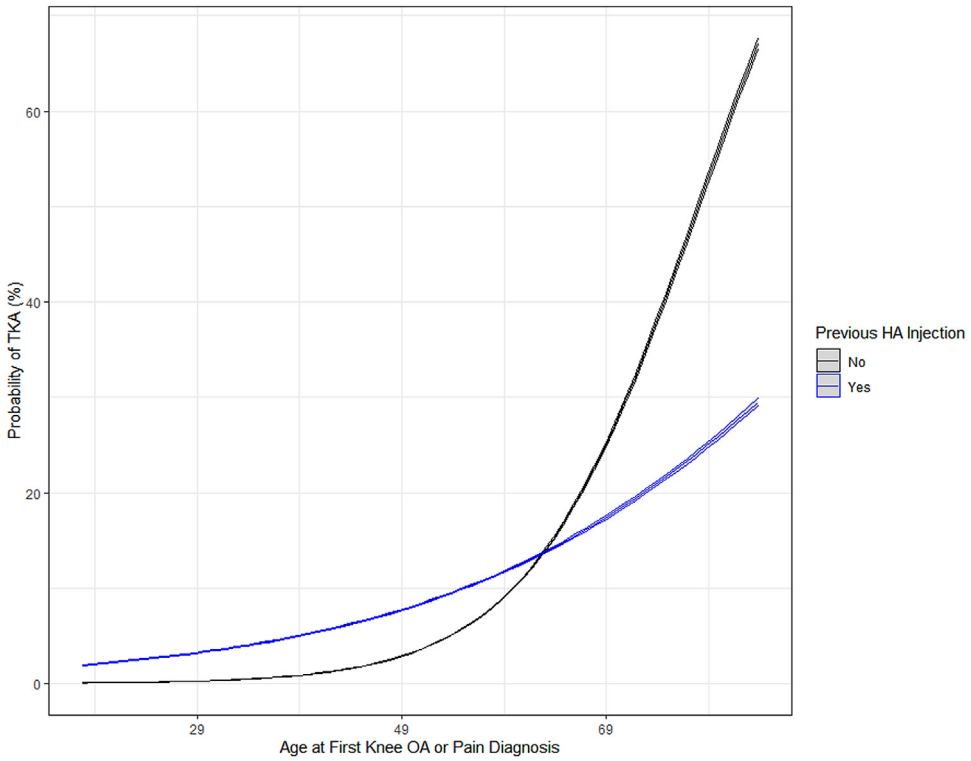

Figure 2. Probability of TKA procedure by patient age at first knee OA or pain ICD diagnosis. Patients with a diagnosis of knee OA or pain at <60 years of age had greater probability of subsequent TKA after IA HA injection than those who did not receive an injection. Patients older than 60 years at the time of diagnosis had a higher probability of TKA without prior IA HA injection (OR −0.93; 95% CI 0.93-0.93; $P < .001$). CI, confidence interval; IA HA, intra-articular hyaluronic acid; ICD, International Classification of Diseases; OA, osteoarthritis; OR, odds ratio; TKA, total knee arthroplasty.

used a commercial database that may not be illustrative of the trends seen in knee osteoarthritic patients throughout the country. Fortunately, our database represents coverage of 1 in 3 Americans nationally. We are unable to directly correlate clinical significance and outcome results to our analysis. Finally, while previous published literature has commented on the varying payer coverage by state for viscosupplementation, we do not have exact percentages available in our database. Despite these limitations, strengths of this study include the use of a large sample size and both state- and patient-level analysis. By adjusting for procedure year in the state-level data and patient-level factors for patient-level data, we were able to account for the differences in patient selection and the temporal increase of TKA procedures throughout the study period.

Conclusion

Our analysis suggests that among patients with knee OA, IA HA injections and payer coverage do not delay nor prevent TKA. Given the relatively high cost of these injections and their questionable clinical efficacy, other higher-value interventions should be encouraged for patients seeking treatment. While it is paramount that the management of OA include nonarthroplasty measures to reduce cost, lessen pain, preserve function, and improve the quality of life for patients, additional clinical trials should be employed to identify the role of HA injections in the treatment armamentarium for knee OA.

Conflicts of interest

Dr. D. S. Jevsevar has stock or stock options in Risalto Healthcare; receives research support from DePuy Synthes; and is a board member in the American Academy of Orthopaedic Surgeons devices, biologics, and technology committee and American Association of Hip and Knee Surgeons evidence based practice committee. Y. Zhao is an employee at Dartmouth-Hitchcock Medical Center and was a summer intern at the orthopedics department of Dartmouth-Hitchcock Medical Center. All other authors declare no potential conflicts of interest.

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