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The therapeutic effectiveness of fluoroscopically guided intra-articular sacroiliac joint injections in patients with sacroiliac joint dysfunction, an observational study

Tyler J. Kristoff [a], Jacob T. Sinopoli [b], Tyler Farley [c], Nicholas Rabah [b], Nicolas R. Thompson [d], Kush Goyal [e,*]

[a] J. Willis Hurst Internal Medicine Residency Program, Emory University School of Medicine, Atlanta, USA
[b] Case Western Reserve University School of Medicine, Health Education Campus, 9501 Euclid Ave, Cleveland, OH, 44106, United States
[c] Department of Physical Medicine & Rehabilitation, Neurological Institute, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH, 44195, United States
[d] Department of Quantitative Health Sciences, Center for Outcomes Research and Evaluation, Neurological Institute, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH, 44195, United States
[e] Center for Spine Health, Neurological Institute, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH, 4195, United States

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ABSTRACT

Objective: The goal of this project is to evaluate the therapeutic effectiveness of fluoroscopically guided intra-articular sacroiliac (SI) joint injections in patients with diagnosed SI joint dysfunction. Patient reported outcomes related to pain and quality of life measures were evaluated.

Design: This is a retrospective observational study of patients receiving intra-articular SI joint injections under a single provider at the Cleveland Clinic from September 2013 to April 2019. Three hundred fifty-one patients received injections and were administered patient reported outcomes (PROs) including the Numeric Rating Scale, Patient Health Questionnaire, Pain Disability Questionnaire, EuroQol-5 Dimensions Questionnaire, and PROMIS-GH Physical and Mental Health at baseline and approximately 1-, 3-, 6-, 12-, and 24-month time points during follow-up appointments. The primary outcome measure was the percentage of patients receiving their first injection who achieved minimal clinically important difference (MCID) in these PROs at each follow-up time point. Secondary outcomes were the percentage of patients achieving MCID in each PRO for each injection analyzed (including patients who received repeat injections) and average change in these PROs at each time point for first and all injections.

Results: A total of 351 patients were included in the analysis, with varying time points of follow-up. The average patient age was 52.3 (±14.9) years with 74.9% female and 59.0% white. For first time injections, the MCID was achieved for Numeric Rating Scale in 60.6%, 42.1%, 47.5%, and 32.5% of patients at 1-, 3-, 6-, and 12-month follow-up, respectively. There was significant improvement in PROMIS-GH Physical Health at 3-month, 6-month, and 1-year follow-up. There was no significant improvement in PROMIS-GH Mental Health at any follow-up time points.

Conclusions: Fluoroscopically guided intra-articular SI joint injection for SI joint dysfunction is effective in providing therapeutic pain relief exceeding MCID values in greater than 60% of patients at 1 month and greater than 40% at 3- and 6- months after injection. However, while this intervention may provide significant pain relief and improvement in function, it may not address the psychosocial aspect of chronic pain to the same extent.

1. Introduction

Low back pain was the most common cause of years lost to disability and the fifth leading cause of disability-adjusted life years in the US for 2016 [1]. Long standing back pain is commonly treated with non-steroidal anti-inflammatory drugs, physical therapy, manual therapy, and chiropractic treatment. The results of these treatments can be frequently unsuccessful and have low patient satisfaction [2]. Chronic

* Corresponding author. 1730 West 25 Street, 1E, Cleveland, OH, 44113, United States.
E-mail address: goyalk@ccf.org (K. Goyal).

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back pain that is unresponsive to initial, conservative treatment can perpetuate depression, anxiety, and/or poor sleep quality, impacting patients' quality of life [3–5]. Common causes of low back pain include sacroiliac joint (SI) dysfunction, myofascial pain, facet-mediated pain, internal disc disruption, spine instability, and spinal stenosis [6]. Of these, SI joint dysfunction is thought to be responsible for 18-22.5% of low back pain [7–9]. The incidence for SI joint dysfunction increases with age, being more common after age 30, and most prevalent in ages 60–80 [9]. The SI joints represent the articulation between the lateral surface of the sacrum and the ilium. Sacroiliac joint dysfunction refers to a shift or inflammation of the joint or surrounding ligaments that causes pain [10]. Common causes of SI joint dysfunction include trauma, abnormal gait pattern, pelvic asymmetry, pregnancy, arthritis, and rheumatologic conditions such as spondyloarthropathy [11].

The diagnosis of SI joint dysfunction has several targeted treatment options, including trigger point injections, prolotherapy, SI joint Radiofrequency ablations (RFA), orthobiologics, and SI joint fusion with varying level of evidence [11]. Intra-articular SI joint injections containing anesthetic and steroid have also been used to provide pain relief. Landmark-guided or "blind" SI joint injections are not reliably intra-articular, where most of the medication is likely deposited in ligaments near the posterior aspect of the SI joint. Due to the bony overlay of the ilium over the sacrum, intra-articular access into the joint is difficult without fluoroscopic guidance along the entire joint. Despite being performed with ultrasound guidance, standard of care for obtaining intra-articular flow of injectate remains fluoroscopically guided approach to ensure proper needle placement and depth into the SI joint [12].

A systematic review by Hansen et al. examined the therapeutic effectiveness of fluoroscopically guided SI joint injections [13]. This review yielded only four previous studies and concluded that the evidence for the effectiveness of intra-articular SI joint injections remains limited [13]. Another systematic review in 2015 by Kennedy et al., studied the diagnostic and therapeutic value of fluoroscopically guided SI joint injection. They concluded that there was diagnostic value when correlated with at least three positive provocative physical exam maneuvers but that the evidence for the therapeutic response to fluoroscopically guided intra-articular SI joint injections was moderate [14].

Given the paucity of data reported in previous systematic reviews, the goal of this research project was to evaluate the therapeutic effectiveness of fluoroscopically guided intra-articular SI joint injections in a large sample size. In addition to determining the effectiveness of injections on pain relief, we also evaluated the impact of these injections on self-reported quality of life measures. Finally, we examined factors that may affect response to fluoroscopically guided intra-articular SI joint injection or repeat injections.

2. Materials and methods

After obtaining institutional review board approval, patients who underwent initial fluoroscopically guided intra-articular SI joint injections by a single provider between September 2013 and May 2019 were identified using a CPT procedural code [27096] for data extraction and retrospective analysis. Patients were offered SI joint injection by the interventionalist performing the injection or referred by other medical providers within the spine center (spine medicine physicians, advance practiced practitioners, and spine surgeons). Patients were suspected to have SI joint dysfunction based on history and examination. Although the number of positive provocative maneuvers was often collected for each case, it is common practice in this institution for patients to have at least 3 positive provocative maneuvers to be referred for SI joint injection. Suspected diagnosis was reinforced by the treating provider confirming at least 3 provocative maneuvers on the day of injection. Clinical factors included, but were not limited to: low back, buttock/hip, or posterior thigh pain that did not extend beyond the ankle, local tenderness over the posterior superior iliac spine, pain worse with prolonged sitting or pain with sit to stand, absence of nerve root tension or neurologic deficit. Sacroiliac joint dysfunction was clinically diagnosed by history and physical exam maneuvers including Gaenslen's test, FABER (or Patrick's) test, Yeoman's test, Fortin's finger test, thigh thrust, ASIS distraction test, sacral compression test, and/or sacral thrust. Records were reviewed for at least 2 years following the first injection and all subsequent SI joint injections. The procedures were performed by a fellowship trained Physical Medicine & Rehabilitation staff physician in the Center for Spine Health (completed Spine Medicine fellowship at the Cleveland Clinic). All patients in this cohort received at least one fluoroscopically guided unilateral or bilateral intra-articular SI joint injection and were given a pain diary, which includes a diagram of their pre-procedure pain location. Three hundred fifty-one patients were identified and included in the analysis. This included all patients who received at least one SI joint injection during the study period. No patients were excluded on initial analysis.

Basic demographic data was collected from eligible patients from the electronic medical record. Data included sex, age, race, BMI, side of injection (right, left, bilateral), baseline scores for patient reported outcomes, steroid contents of injection (Methylprednisolone vs Triamcinolone vs Betamethasone), smoking status, prior physical therapy, prior chiropractic treatment, prior hip surgery, prior lumbar spine surgery, prior lumbar or lumbrosacral spinal fusion, prior ESI (epidural steroid injection), prior facet injection, prior RFA, lumbar spondylolisthesis, scoliosis, fibromyalgia, and coccydynia. Accurate data collection of previous chiropractic treatment, physical therapy, and fibromyalgia were difficult to reliably collect and therefore not included for subgroup analysis. However, following each SI Joint injection all patients were encouraged to continue physical therapy.

2.1. Theory

We hypothesized that patients who received fluoroscopically guided sacroiliac joint intra-articular injections for pain clinically believed to be due to sacroiliac joint dysfunction (based on history and at least 3 positive provocative maneuvers at clinic visit and day of procedure) would experience a clinically important reduction in level of pain and improvement in psychosocial aspects which are affected by chronic pain.

2.2. Procedure description

After obtaining both verbal and written informed consent, each patient was placed in the prone position on a fluoroscopic table in a procedure room. Patients had the option to request moderate sedation for the procedure. 286 of 351 (81.5%) patients receiving their first injection requested moderate sedation which was almost exclusively 1-2 mg of midazolam. The posterior lumbosacral skin was prepped and draped in sterile fashion using iodine or chlorhexidine. The SI joint injections were performed using standard Spine Interventional Society guidelines [15]. Local anesthesia was achieved with a superficial skin wheal using 25 or 27-gauge 1.5-inch needle with 0.5cc preservative-free lidocaine near the inferior portion of the SI joint. Through the skin wheal a 22-gauge, 3-1/2 or (22-gauge 5-inch needle for patients with larger soft tissue to achieve depth) curved Quincke spinal needle was inserted and advanced under direct fluoroscopic visualization until the needle tip entered the SI joint. The joint space was optimized using cranio-caudal tilting as well as ipsi- or contralateral oblique tilting of the image intensifier. Proper needle placement was confirmed with 0.2 cc of Omnipaque-180 M nonionic contrast confirming intra-articular flow of contrast without any intravascular uptake of contrast seen under direct fluoroscopic visualization in multiple planes: anterior-posterior view, ipsilateral oblique (en-face), contralateral oblique views, and lateral view. (see Fig. 1). Following confirmation of proper needle placement, 40 mg of Triamcinolone, 40 mg (or 80 mg) Methylprednisolone, or 6 mg of Betamethasone and 1.0 cc of 0.75% preservative-free bupivacaine was infused into each SI joint.

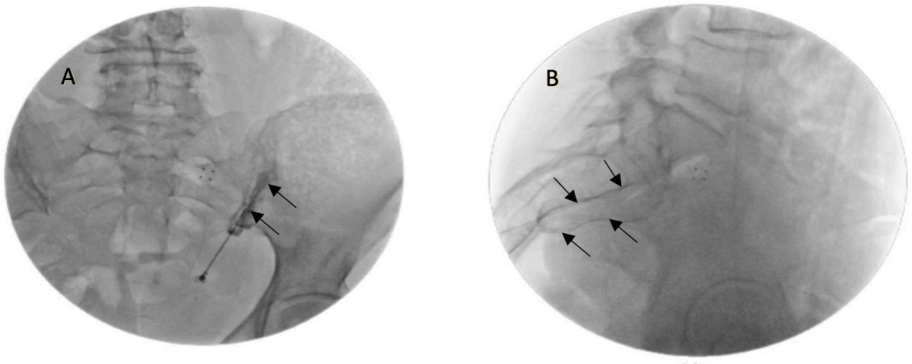

Fig. 1. AP (A) and lateral (B) views of the sacroiliac joint with injection of contrast (arrows) seen traveling cephalad along the joint line and spreading throughout the sacroiliac joint in an inferior to superior fashion.

The total volume injected into the intra-articular SI joint (including contrast), was no more than 2.5cc in all cases. One cc of preservative-free 1% lidocaine was also injected into the posterior ligamentous complex as the Quincke needle was slowly removed out of the joint. Adequate hemostasis was obtained at the needle puncture site. The patient's back was cleaned, and a sterile dressing was applied. All patients were examined prior and post injection with lower extremity strength, FABER and PSIS tenderness.

Not all procedures achieved distinct intra-articular flow of contrast in multiple planes as seen in Fig. 1. There is a certain proprioceptive "feel" of entering the SI joint like a needle piercing through a "pencil eraser" that is different than the proprioceptive "feel" of contacting soft tissue, fat, ligaments, or the bony articular surface of the sacrum or ilium. If there is little pressure or resistance upon entry into the SI joint, there is a high likelihood that the contrast is superficial to the intra-articular joint or too inferior and can be in the piriformis muscle. It often takes a significant effort to push contrast or medication into the SI joint. Another feature of entering the SI joint, similar to the facet joint is the stylet "popping out" of the spinal needle. While retracting out of the intra-articular SI joint and injecting medication into the ligamentous complex and superficial tissue, there is a clear drop off in pressure/resistance.

2.3. Outcome measures

Our primary outcome measures consisted of the following patient reported outcomes (PROs): numeric rating scale (NRS) for pain, patient reported depression, patient perceived disability, and patient health related quality of life. The latter four domains were measured with patient health questionnaire (PHQ-9), Pain Disability Questionnaire (PDQ), EuroQol 5 Dimensions Questionnaire (EQ-5D), and Patient-Reported Outcomes Measurement Information System-Global Health (PROMIS-GH) Physical Health and Mental Health, respectively. Numeric rating scale was collected pre-procedurally and during follow-up office visits along with percent relief and duration of pain relief by medical providers. The remaining PROs were administered via standardized electronic surveys pre- and post-procedurally. Although data were analyzed at approximately 1-, 3-, 6-, 12-, and 24- month time frames, follow-up time points were not precise due to patient and clinic scheduling constraints. In 2015, the EQ-5D was replaced with the PROMIS Global Health (PROMIS-GH) scale at our institution; PROMIS-GH scores can be converted to EQ-5D index scores using an established method [16]. The PDQ was similarly discontinued at our institution in November of 2018; no replacement survey was used after its discontinuation. Secondary outcome variables, patient progression to repeat injection, were collected and analyzed.

2.4. Statistical analysis

The proportion of patients exceeding minimal clinically important difference (MCID) for each outcome was computed. Total point change of >2.5 for NRS and ≥ 5 for PHQ-9 is considered clinically significant [17,18]. For EQ-5D index, we computed the baseline standard deviation score to be 0.205. A conservative estimate of 0.11 was found by taking ½ of the baseline standard deviation [19]. The same approach was used to determine a MCID of 16 for PDQ and MCID of 5 for both PROMIS-GH Physical and Mental Health. This is a well-established method for interpretation of changes in health-related quality of life measures.

Descriptive statistics of baseline (pre-injection) patient and clinical characteristics were computed and analyzed. Change in PRO scores from baseline (pre-injection) to post-injection and each of 1-month, 3-month, 6-month, and 1-year follow-up time points were estimated using mixed-effects linear regression models. During data collection, PRO scores were assigned to time points closest to the amount of time from injection to each follow-up appointment. Patients typically scheduled follow-up appointments at 3-month intervals, so the dates were approximately within 2 weeks of their assigned interval. Pain relief and PRO scores were collected after the first injection, but before the 2nd injection (for those that had repeat SI joint injections or a different lumbrosacral spine procedure or lumbar spine surgery); therefore, depending on the time of the 2nd injection, data for these patients included in the 'first injection' group may only have been obtained at the earlier endpoints, but were not excluded from the analysis of response for this injection. For example, if repeat injection occurred 5 months after the first injection, data were only included for the 1-month and 3-month time points. This, in addition to some patients not returning to follow-up appointments, accounts for the decreasing number of patients included at the later follow-up periods. Subsequent injections were analyzed independently using PRO scores obtained prior to the repeat injection and at each follow-up time point following that injection. These results and the results from the "first injection" group represents the "all injections" group. Time was treated as a categorical fixed-effect predictor with the above post-injection time points as categories. A random effect for patients was included to account for repeated measures. We tested for significance of mean change in score from pre-injection to last follow-up score using paired t-tests. Given that a large number of patients being lost to follow-up, the denominator used to determine percentages at various time points was determined by the number of patients who completed the follow-up questionnaires for each PRO, as comparing those with MCID to the total number of injections would result in disproportionately low averages. Those who did not complete follow-up for each given time point were excluded from analysis at that time.

To examine factors associated with change in NRS scores, univariate linear regression models were created where change in score from baseline to last follow-up before any repeat injections was the dependent

variable. After examining all univariate models, we fit a multivariable model for each outcome where predictors found to be significant at 0.05 were included in the multivariable model.

To examine factors associated with whether a patient had repeat, logistic regression models were created. We first examined univariate models and then fit multivariable models using predictors that were found to be significant at the univariate level. Odds ratios and 95% confidence intervals were computed. All computations were done in R, version 3.6.1 [20]. All tests were two-sided and p-values less than 0.05 were considered statistically significant. Holm's method was used to correct for multiple testing.

3. Results

Three hundred fifty-one patients receiving a total of 538 injections were included in analysis. The average patient age was 52.3(±14.9) with 74.9% female and 59.0% white. Among all SI joint injections, the average time from injection to last recorded follow appointment was 259 days. No patient in this cohort had previous SI joint injection within 2 years as documented in our EMR. Additional demographic characteristics can be seen in Table 1. Table 2 shows results of the mixed-effects linear regression models examining average change from baseline to various follow-up time points for each patient reported outcome. Data showing the number or patients who achieved MCID in their PROs is shown in Table 3. Of the patients who achieved at least 50% improvement in their pain after their first injection, the percentage of pain relief experienced by each patient can be seen in Table 4.

When examining only a patient's first injection, the MCID for NRS was achieved in 60.6%, 42.1%, 47.5% and 32.5% or patients at 1-, 3-, 6-, and 12-month follow-up, respectively. When examining all patient injections collectively, the trend in NRS was similar, showing a MCID in 61.5%, 42.1%, 42.2%, and 28.8% at 1-, 3-, 6-, 12-month follow-up, respectively. At the univariate level, using 40 mg of Triamcinolone was associated with less improvement in NRS; those receiving Triamcinolone improved .81 less on average. However, it is noted that Depomedrol and Triamcinolone have approximately equivalent anti-inflammatory potency and 80 mg Depomedrol was used for some of the injections, which may account for this difference. A subset of patients had concomitant ESI and SI joint injection (N = 32); these patients did not see any significant difference in NRS reported pain response. These 32 patients were included in analysis with those receiving only SIJ injections as their pain relief was documented separately according to leg or radicular pain and their pain attributed to SIJ dysfunction. It is noted that the improvement of leg symptoms in these patients may have contributed to improvement in other PROs which were assessed, and this must be taken into context when analyzing results. It should be noted that these patients were suspected to have both SI joint dysfunction and additional lumbar pathology contributing to their pain and were included in analysis with potential confounding effect.

For the PHQ9 outcome variable, 17.9%, 24.8%, 25.4%, and 20.7% of patients achieved the MCID on their first injection at 3-, 6-, 12-, and 24-month follow-up, respectively. These rates were less when examining all injections, showing 13.4%, 14.7%, and 15.1%, at 3-, 6-, 12-month follow-up, respectively.

For the EQ-5D outcome variable, we saw MCID achievement rates of 32.5%, 30.7%, 29.7%, and 32.6% among patients receiving first time injections at 1-, 3-, 6-, and 12-month follow-up, respectively. The rates were similar for all injections, showing MCID achievement rates of 32.4%, 29.9%, 26.9% and 30.7% at 1-, 3-, 6-, and 12-month follow-up, respectively.

For PDQ total scores, rates of achieving MCID were 31.7%, 27.1%, 39.5% and 16.7% for patients' first injection at 1-, 3-, 6-, and 12-month follow-up, respectively. This trend continued when analyzing all injections, showing rates of 31.3%, 26.4%, 29.7%, and 14.4% at 1-, 3-, 6-, and 12-month follow-up, respectively.

For PROMIS-GH Physical Health, rates of achieving MCID for patients' first injection were 31.2%, 25.0%, and 31.2%, and at 3-, 6-, and 12-month follow-up, respectively. There was significant improvement in PROMIS-GH Physical Health at 3-month, 6-month, and 1-year follow-up compared to pre-injection PROMIS-GH Physical Health. All changes reported had a statistical significance of less than p = .003 (see Fig. 2). PROMIS scores were not collected at 1 month based on availability of follow-up appointment with the spine provider.

For PROMIS-GH Mental Health, rates of achieving MCID for patients' first injection were 26.6%, 22.6%, and 27.9%, at 3-, 6-, and 12-month follow-up, respectively. This population had a pre-injection PROMIS-GH Mental Health of 42.2 ± 9.5 with an average increase of 1.60 ± 7.9 by their follow-up appointment. There was no significant improvement in PROMIS-GH Mental Health at any follow-up time points.

Of the 351 patients included in the study, 122 (34.8%) had repeat injections, 22 (6.3%) had spine surgery within one year of their first injection, and 10 patients went on to have SI joint lateral branch RFA (2.8%). In this cohort, the average number of intra-articular SI Joint injection per patient was 1.53 (SD 0.91). Repeat injections were performed for a variety of reasons including return of pain following steroid response at various times and inadequate relief after first injection, among other reasons unique to each patient. At the univariate level, BMI and spondylolisthesis were each associated with higher likelihood of having repeat injections. At the multivariate level BMI and spondylolisthesis showed odds ratios of 1.05 (95% C.I. 1.01, 1.09, P = .005) and 2.05 (95% C.I. 1.22, 3.46, P = .007) respectively. Age, prior hip surgery, prior spinal fusion, prior ESI, and spondylolisthesis were each associated with higher likelihood of having spine surgery within one year of their first injection at the univariate level.

Table 1
Baseline characteristics for patients who underwent sacroiliac joint injection.

N	351
Age, mean (SD)	52.3 (14.9)
Female	263 (74.9%)
Race	
White	207 (59.0%)
Black	39 (11.1%)
Other	105 (29.9%)
Body Mass Index, mean (SD)	30.3 (6.5)
Smoking Status	
Current	75 (21.4%)
Former	126 (35.9%)
Never	150 (42.7%)
SI Injection Side	
Right	111 (31.6%)
Left	114 (32.5%)
Bilateral	126 (35.9%)
Kenalog 40 mg	129 (36.8%)
Depomedrol 40 mg	9 (2.6%)
Depomedrol 80 mg	216 (61.5%)
Celestone	1 (0.3%)
Prior PT	260 (74.1%)
Prior Spine Surgery	75 (21.4%)
Prior Hip Surgery	16 (4.6%)
Prior Lumbar Spinal Fusion	27 (7.7%)
Prior Lumbar ESI	123 (35.0%)
Prior Lumbar Facet Injection	47 (13.4%)
Prior RFA Type	
Lumbar	13 (3.7%)
Sacral	4 (1.1%)
Spondylolisthesis	128 (36.5%)
Same Day ESI	32 (9.1%)
Pain, mean (SD)	7.6 (1.7)
PHQ-9 score, mean (SD)	9.0 (6.5)
EQ-5D Index, mean (SD)	0.49 (0.21)
PDQ Total Score, mean (SD)	83.3 (30.7)
PROMIS-GH Physical T-score, mean (SD)	36.4 (7.1)
PROMIS-GH Mental T-score, mean (SD)	42.2 (9.5)

SD – standard deviation.

Table 2
Results of mixed-effects models for change from baseline of Patient Reported Outcomes.

Outcome	Time Point	First Injection Only			All Injections		
		N	Average Change (95% CI)	P-value	N	Average Change (95% CI)	P-value
Pain (NRS) (MCID = 2.5)	1-month follow-up	264	-3.59 (-3.91, -3.27)	<0.001	384	-3.58 (-3.84, -3.32)	<0.001
	3-month follow-up	202	-2.50 (-2.85, -2.14)	<0.001	302	-2.49 (-2.76, -2.21)	<0.001
	6-month follow-up	101	-2.42 (-2.88, -1.96)	<0.001	161	-2.26 (-2.62, -1.91)	<0.001
	12-month follow-up	77	-1.38 (-1.90, -0.87)	<0.001	125	-1.21 (-1.61, -0.82)	<0.001
PROMIS-GH Physical Health T-score (MCID = 5)	3-month follow-up	79	2.47 (1.33, 3.60)	<0.001			
	6-month follow-up	54	2.35 (1.04, 3.67)	<0.001			
	12-month follow-up	65	2.43 (1.21, 3.65)	<0.001			
	24-month follow-up	42	2.27 (0.82, 3.73)	0.003			
PROMIS-GH Mental Health T-score (MCID = 5)	3-month follow-up	79	0.84 (-0.60, 2.28)	0.256			
	6-month follow-up	54	1.04 (-0.63, 2.71)	0.226			
	12-month follow-up	68	1.89 (0.37, 3.42)	0.016			
	24-month follow-up	41	0.05 (-1.82, 1.92)	0.956			
PHQ-9 (MCID = 5	1-month follow-up	114	-1.37 (-2.31, -0.43)	0.005	161	-0.69 (-1.41, 0.02)	0.057
	3-month follow-up	107	-0.83 (-1.78, 0.12)	0.089	159	-0.50 (-1.21, 0.21)	0.171
	6-month follow-up	48	-0.78 (-2.12, 0.55)	0.254	78	-0.16 (-1.12, 0.79)	0.737
	12-month follow-up	59	-1.31 (-2.53, -0.08)	0.038	87	-0.73 (-1.65, 0.19)	0.119
EQ-5D (MCID = 0.11)	1-month follow-up	166	0.055 (0.026, 0.083)	<0.001	226	0.053 (0.030, 0.076)	<0.001
	3-month follow-up	149	0.053 (0.023, 0.083)	<0.001	217	0.050 (0.027, 0.073)	<0.001
	6-month follow-up	111	0.021 (-0.012, 0.055)	0.212	173	0.024 (-0.002, 0.049)	0.067
	12-month follow-up	141	0.019 (-0.011, 0.050)	0.218	217	0.017 (-0.006, 0.040)	0.147
PDQ Total Score (MCID = 16)	1-month follow-up	126	-12.7 (-16.9, -8.5)	<0.001	177	-9.5 (-12.7, -6.4)	<0.001
	3-month follow-up	91	-9.8 (-14.6, -5.0)	<0.001	134	-8.1 (-11.6, -4.6)	<0.001
	6-month follow-up	39	-7.1 (-14.1, -0.2)	0.046	67	-4.2 (-8.8, 0.5)	0.081
	12-month follow-up	40	-0.6 (-7.6, 6.4)	0.876	62	-1.8 (-6.6, 3.1)	0.473

4. Discussion

Previous literature has established the diagnostic value of fluoroscopically guided intra-articular SI Joint injections [14,21]. These findings suggest that fluoroscopically guided intra-articular SI joint injections with anesthetic and steroid can be therapeutic for patients diagnosed with SI joint dysfunction. Patients on average saw statistically and clinically significant decreases in pain at all-time points in this study, as reported by NRS scores. Seeing a reduction in pain post injection is consistent with previous research. The percentage of pain relief immediately following injection was not calculated and would have likely been helpful to exclude patients who did not experience diagnostic relief. Liliang et al. prospectively studied 39 patients who received SI joint steroid injection with 66% of their patients having significant relief for more than 6 weeks [22]. Suleiman et al. studied the effect of SI joint injections at one year in a tertiary hospital in Nigeria, finding that roughly half of their 26 patients saw at least a 2.5 score drop in NRS [23]. These two studies are consistent with our findings that show greater than 60% of patients achieved the MCID threshold for at least one month and greater than 40% reaching at least 6 months. The percentage of patients maintaining MCID level relief decreased to about 30% at the 12-month mark. The patients who had relief at one year, did not have any other spine injection during that 12-month period. The present study adds to the previous research by including a larger patient population and long-term follow-up.

For those patients who only received one injection, the reason for not pursuing repeat injections varied. While not included in the data analysis, it was noted anecdotally that most of such cases were for one of three reasons: either the patient's pain improved enough after the first injection that they did not seek a repeat injection during the study period, pain relief was insufficient and they chose to pursue other treatment options, or they were lost to follow-up with unclear reasoning.

To the best of our knowledge, this is the first study to use PHQ-9, PDQ, EQ-5D, and PROMIS-GH survey results for studying the therapeutic effectiveness of SI joint injections. The Oswestry Disability index (ODI) is a common scale used in the study of SI joint injections [24]. While the ODI provides information specific to the low back, these other surveys can provide us with a broader view on how this intervention impacts patient quality of life. PHQ-9 has become a staple in screening for depression amongst patients and clinically significant changes are generally viewed as changes in PHQ-9 > 5 [18]. Prior to intervention PHQ-9 scores were 8.9, suggesting that this population had mild depression at baseline [25]. While patients in this study on average saw statistically significant improvement in PHQ-9 at 1- and 12-months following their first injection, the response was minimal. For all injections, statistically significant improvement was not seen on average for PHQ-9. Approximately 20% of patients saw clinically significant improvement following their first injection at all-time points, a proportion that decreased to about 15% when studying all injections. The trend seen in PHQ-9 was similar when analyzing the EQ-5D outcome variable, a measure of health-related quality of life. On average, patients saw statistically significant results at 1 and 3 months for both first and all injections. However, they did not achieve the MCID on average and only about 30% of patients achieved the MCID at any given time point. EQ-5D is a survey aimed at studying health related quality of life. The total PDQ scores provide us with insight into how patients perceive their total functional disability before and after the procedure [26]. For total PDQ scores we saw that the average baseline score for this patient population was 83.3. Scores between 71 and 100 are generally classified as severe disability. While on average the population did not achieve the MCID threshold, about 30% of patients did have clinically significant improvement by their one-month follow-up that persisted for 6 months. Similar to NRS pain response, the number of patients reaching MCID criteria decreased by the one-year follow-up. Compared to pre-injection PROMIS-GH Physical Health, there was statistically significant improvement in PROMIS-GH Physical Health at 3-month, 6-month, and 1-year follow-up, but not significant improvement in PROMIS-GH Mental Health at any follow-up time point. When interpreting this along with our other PROs, it appears that this intervention may provide significant pain and functional relief but may not help patients deal with the psychosocial aspect of chronic pain to the same extent.

If non-operative interventions to treat SI joint dysfunction fail to achieve significant pain reduction or improvement in function, some patients may be eligible for surgery in an attempt to relieve their low back pain. Options include SI joint fusion or further evaluation of adjacent joints, such as the hip, L4-5, or L5-S1 facet joints [27]. Surgical intervention carries increased risk of complications compared to interventional techniques, including increased risk of neurologic deficits,

Table 3
Frequency and percent of patients who improved by MCID for each scale.

		All Scores After 1st Injection		All Injections	
		N	Improve by MCID N (%)	N	Improve by MCID N (%)
Pain (NRS) (MCID = 2.5)	Post-injection	345	338 (98.0%)	528	517 (97.9%)
	1-month follow-up	264	160 (60.6%)	384	236 (61.5%)
	3-month follow-up	202	85 (42.1%)	302	127 (42.1%)
	6-month follow-up	101	48 (47.5%)	161	68 (42.2%)
	1-year follow-up	77	25 (32.5%)	125	36 (28.8%)
PHQ-9 (MCID = 5)	3-month follow-up	156	28 (17.9%)	306	41 (13.4%)
	6-month follow-up	105	26 (24.8%)	150	22 (14.7%)
	1-year follow-up	114	29 (25.4%)	166	25 (15.1%)
	2-year follow-up	82	17 (20.7%)		
PROMIS-GH Physical Health (MCID = 5)	3-month follow-up	77	24 (31.2%)		
	6-month follow-up	52	13 (25.0%)		
	1-year follow-up	64	20 (31.2%)		
	2-year follow-up	40	14 (35.0%)		
PROMIS-GH Mental Health (MCID = 5)	3-month follow-up	79	21 (26.6%)		
	6-month follow-up	53	12 (22.6%)		
	1-year follow-up	68	19 (27.9%)		
	2-year follow-up	40	6 (15.0%)		
EQ-5D (MCID = 0.11)	1-month follow-up	154	50 (32.5%)	210	68 (32.4%)
	3-month follow-up	137	42 (30.7%)	204	61 (29.9%)
	6-month follow-up	101	30 (29.7%)	160	43 (26.9%)
	1-year follow-up	132	43 (32.6%)	202	62 (30.7%)
PDQ Total Score (MCID = 16)	1-month follow-up	120	38 (31.7%)	166	52 (31.3%)
	3-month follow-up	85	23 (27.1%)	125	33 (26.4%)
	6-month follow-up	38	15 (39.5%)	64	19 (29.7%)
	1-year follow-up	36	6 (16.7%)	55	8 (14.5%)

Table 4
Percent pain relief after first SIJ injection at each follow up interval.

Follow-up Time	50% Relief	75% Relief	90% Relief	100% Relief
1 month	86/206 (41.7%)	60/206 (29.1%)	38/206 (18.4%)	22/206 (10.7%)
3 month	32/61 (52.5%)	18/61 (29.5%)	8/61 (13.1%)	3/61 (4.9%)
6 month	24/62 (38.7%)	18/62 (29.0%)	14/62 (22.6%)	6/62 (9.7%)
1 year	7/25 (28.0%)	7/25 (28.0%)	6/25 (24.0%)	5/25 (20.0%)
> 1 year	6/20 (30.0%)	6/20 (30.0%)	5/20 (25.0%)	3/20 (15.0%)

venous thromboembolic events, radicular pain to misplaced hardware, and infection [28]. In this patient population, 22 (6.3%) had spinal surgery within one year of their first injection and no patient underwent SI fusion. Although spinal surgery is a distinct entity with specific indications making extrapolation of these data to SI joint injections is difficult, SI joint dysfunction, arthrosis, and degeneration together make up 78.2% of the pathology responsible for SI joint pain or dysfunction resulting in surgical intervention [29]. While the data from this study are insufficient to form a causal relationship between SI joint injections and their role in preventing SI joint surgical procedures, our results suggest that SI joint injections may help avoid and/or delay the need for surgical intervention and present as a viable treatment option for patients who are poor surgical candidates. Further studies are warranted to assess the long-term outcomes of patients managed conservatively versus surgically.

Certain structural influences of low back pain, such as high BMI or spondylolisthesis are predictors for repeat SI Joint injections. Spondylolisthesis provides a structural reason for the patient's pain beyond what we would expect for SI joint dysfunction and may explain why some patients did not obtain significant benefit from SI joint injection as surgical intervention is more successful in this subset of patients. Furthermore, prior lumbar fusion is a known risk factor for SI joint dysfunction [30,31]. Clinical diagnosis of SI joint dysfunction based on provocative testing can be over-represented with co-existing lumbar spondylolisthesis at L4-5 or L5-S1 due to shear forces on the lumbar-sacral spine. Alternatively, this study may underrepresent the prevalence of SIJ pain in the study population by excluding patients based on lack of provocative maneuvers. Conflicting studies report the validity of these maneuvers, and they may be of little diagnostic value when compared with the reference standard of an anesthetic block [32,33]. Clinical SI joint dysfunction can be commonly misdiagnosed in patients with lumbar spondylolisthesis due to false positive SI joint provocative maneuvers in this population.

There are several limitations to this study. This study is limited by its retrospective design and its cohort of patients under a singular physician at a large tertiary care center. Single physician intervention was deliberately chosen in this study to reduce the variability of interventional technique that may have occurred if performed by various physicians. Additionally, follow-up time points were not standardized, and PROs were categorized by their proximity to the set time points without calculating mean time of follow-up intervals. Furthermore, NRS required that the patient was asked, and their response was recorded in the EMR while other PROs required that the patient fully complete survey data during their visit. This lack of standardized follow-up also led to attrition at distant follow-up time points. Likewise, this inconsistent follow-up raises the issue of confounding and follow-up bias both toward patients who did well returning to clinic instead of seeking care with a different department or provider, and toward patients with satisfactory relief not following up due to their symptoms being adequately controlled. We did not have a large portion of patients completing post-injection pain diary and submitting to spine provider on post-injection visit. Several patients in this study returned to clinic several years later for a different symptom, noting complete relief of back/buttock pain after fluoroscopically guided SI joint injection. Contrarily, many patients may not have followed up due to inadequate relief. The collection of PROs was complicated by the discontinuation of EQ-5D in 2015 and PDQ in 2018 and initiation of PROMIS-GH Physical and Mental Health in 2015. This study relied on the diagnosis being properly coded in the EMR. Furthermore, the clinical diagnosis of SI joint dysfunction is difficult and requires a detailed history and thorough physical exam. The diagnosis of SI joint dysfunction based on physical exam by referring providers was not consistently recorded in office notes in the EMR. This may make it difficult to extrapolate results to a different setting where selection criteria, office note templates and diagnostic examination may vary. In addition, the primary interventionalist emphasized importance of physical therapy and continued home exercise program prior to injection and after injection to all patients. Although subsequent data points were excluded if a patient had another lumbar spine injection or lumbar surgery, it is possible that some

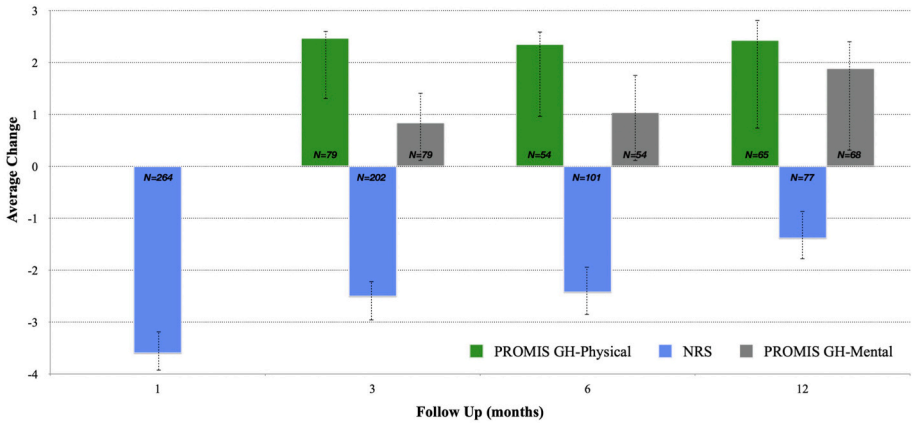

Fig. 2. Results of mixed-effects models for change from baseline for numeric pain rating scale (NRS) and Patient- Reported Outcomes Measurement Information System Global Health (PROMIS GH) Physical and Mental at 1, 3, 6, and 12 month follow-up time points.

patients received procedures by providers outside of our health system. While many of the nearby health systems are integrated with our EMR and injections would have likely been noticed, there are patients who travel vast distances and may have received an injection closer to home that they did not report during their follow-up appointment. Future prospective studies with standardized follow-up and diagnostic inclusion criteria are warranted. Finally, the follow-up period represents a period longer than what is expected for corticosteroid response. Therefore, sustained benefit may relate to other factors or management, such as physical therapy, psychological support, use of oral analgesics, or modalities, all of which are difficult to account for in a retrospective study, although all patients were managed with usual care.

5. Conclusion

This study shows that fluoroscopically guided intra-articular SI joint injection for SI joint dysfunction results in significant, therapeutic relief of pain following the injection. Most patients experience significant relief at one month with a diminishing proportion over the following year. Some patients can expect to see benefits in their perceived function, depression, and quality of life following injection, although this effect appears to be limited compared to pain relief response. Despite the promising conclusions listed above, there are limitations to this study, primarily due to the retrospective nature of the study and potential confounding variables of concurrent treatment options, varying follow-up time points, and varying degrees of compliance with physical therapy. These findings warrant further prospective, multi-institutional investigation to better understand the therapeutic effectiveness of these injections.

Disclosures

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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