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Better late than never? Impact of delayed elective interventional pain procedures due to the COVID-19 pandemic



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ABSTRACT

Despite the well documented importance and success of interventional pain procedures in the management of painful spine conditions, detractors have questioned their role as part of the care paradigm since their inception. One of the many unexpected consequences of the COVID-19 pandemic in the United States was the forced shut down of elective procedures in early 2020. This caused many patients suffering with pain, who had already been deemed appropriate for an interventional procedure to have to wait an extended period of time. This unprecedented period in modern healthcare provided the opportunity for a long term examination of how this cohort of patients suffering with pain faired while being forced to wait for pain relieving intervention, and to demonstrate the vital importance of these procedures for not only pain relief but for improvement in quality of life. This study will show that an overwhelming number of patients reported that their pain had not improved spontaneously over time, and were anxious to proceed with intervention once given the opportunity.

1. Introduction

The recent Coronavirus Disease 2019 (COVID-19) pandemic profoundly disrupted interventional pain management for chronic pain, which affects 20.4% of the general population and accounts for \$560 to \$635 billion per year of total US healthcare costs [1,2]. Many interventional pain treatments were cancelled or postponed in the early period in accordance with government mandated guidelines [3]. Although these measures were deemed necessary to curtail the spread of COVID-19 and reallocate healthcare resources, it inevitably led to a delay in treatment for patients with ongoing pain. Undertreatment of chronic pain may lead to negative consequences such as increased pain, disability, and psychological morbidities as well as increased opioid use [4]. A joint statement released in March 2020 by the American Society of Regional Anesthesia and Pain Medicine and the European Society of Regional Anesthesia and Pain Therapy acknowledged the need to stop all elective pain procedures early in the pandemic, but also pointed out that not all pain procedures are elective, classifying some "semi-urgent" and urged

continuation of these procedures in a safe manner [5].

Utilization of interventional procedures has dramatically increased in the past quarter century, in part as a result of new and improved interventional pain medicine techniques and options. Typically, minimally invasive, these options can mitigate use of analgesics including opioids and can be used for either diagnostic or therapeutic purposes [6]. When properly indicated, interventional pain treatments can effectively reduce or relieve chronic pain. A variety of interventional procedures are available to address pain of spinal origin, which can present as axial or radicular patterns [7]. Axial pain, which may arise from facet disease, can be treated with a facet injection or radiofrequency ablation (RFA) following positive diagnostic medial branch blocks (MBB). Radicular pain occurs from spinal nerve compression or irritation and can be treated with an epidural steroid injection (ESI). Discogenic pain may cause neuropathic or nociceptive pain and can be further evaluated through a lumbar discography. For vertebral fractures causing intractable pain without neurological deficits, a vertebral augmentation can be performed. When sacroiliac joint (SIJ) pain is suspected, an

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intra-articular SIJ injection can be both diagnostic and therapeutic. In refractory cases of chronic pain such as post laminectomy syndrome, spinal cord stimulation may be beneficial [7,8].

Despite their popularity, detractors submit that there is a paucity of evidence in the literature which prove that in properly indicated patients, pain will not improve without appropriate intervention, despite the fact that there is a plethora of strong evidence which support the efficacy of these procedures [9-13]. One explanation for this may be that in contrast to medical therapy, applying randomized, placebo- or sham-controlled study designs into interventional procedure trials for chronic pain carries some unique challenges. First, the heterogenous etiology of chronic pain makes it difficult to address strictly one mechanical problem in a single interventional pain procedure [10]. Second, enrolling patients with intractable pain into a clinical study in which there is generally 50% chance of receiving a placebo or sham, or no treatment at all, may be considered unethical [14]. With that in mind, designing unbalanced allocation trials which would favor a subject's chance of receiving an interventional procedure would likely undermine the statistical power [15]. These circumstances have resulted in challenges in designing studies which demonstrate class 1 level data which supports the efficacy and importance of interventional pain procedures.

The Executive order 202.10 issued on March 23, 2020 led to a temporary cessation of all elective medical procedures in the state of New York [16]. Located in the epicenter of the pandemic in New York City and all elective procedures were immediately stopped as of that date. This forced patients who had previously been scheduled for elective procedures to seek out alternative treatment options for the duration of the state of emergency. Given this unprecedented context, and in order to demonstrate the importance of timely, properly indicated interventional pain management techniques, we used this as a unique opportunity to evaluate the long term course of patients who were forced to wait for these previously prescribed procedures, and to demonstrate how important interventional pain care is to their overall improvement. To the best of our knowledge, this "wait and see" approach to interventional pain procedures has not been previously studied. This study assesses the impact of the forced delay of interventional procedures during the COVID-19 pandemic including the clinical outcomes of pain patients in the setting of an academic pain management center.

2. Methods

Prior to March 23, 2020, 687 patients had been already evaluated and scheduled for elective interventional pain procedures in one practice at a single academic institution. These procedures had to be indefinitely postponed due to the aforementioned executive order. Approximately 12 weeks later, our institution reopened in June 2020 for elective procedures. These 687 patients who met the clinical indications for interventional pain procedures but were forced to have their procedures cancelled were included in this study.

After approval from the Institutional Review Board was obtained, patients were contacted by phone and given the opportunity to reschedule. Among patients who declined to reschedule, a brief voluntary survey was conducted by phone to denote the specific reason for their choice, generating 12 unique reasons for declining as follows: deceased, does not want COVID-19 test (required prior to procedure), fear of coming to the hospital due to COVID-19, financial issues, improved spontaneously since previous visit, new medical problem, no longer willing to have an invasive spine procedure, received intervention elsewhere, received other intervention (surgery, physical therapy, occupational therapy, or medications), reconsidering and wants office visit prior to rescheduling, relocated, and "other". The "other" category was comprised of a variety of reasons, each of which were infrequently given such as time restrictions and various procedural concerns, and were therefore grouped together. A total of 47 subjects were excluded from the final analysis. Of those, 1 was deceased, and we were unable to contact the remainder. This left a sample size of total 640 patients.

In addition to reasons for declining, patients were categorized into groups based on the specific procedures for which they were scheduled. Such intervention groups included advanced procedures (stimulator trial, kyphoplasty), epidural steroid injections (ESI; transforaminal and interlaminar ESI, caudal with or without adhesiolysis), facet joint interventions (intra-articular injection, medial branch block (MBB), radiofrequency ablation (RFA)), nerve block (ganglion of impar (GOI) block, sympathetic block), peripheral joint procedures (hip injections), sacroiliac joint injections (SIJ), and other procedures (discography, other). The breakdown of procedures is shown in Fig. 1. In a separate analysis, patients were sorted by the anatomical region for which they had scheduled interventions, which included cervical, thoracic, lumbar, SIJ/hip/pelvic and peripheral/other, which is shown in Fig. 2.

The primary outcome of analysis was the spontaneous improvement or resolution of symptoms no longer requiring elective procedures. The percentage of patients with spontaneous improvement of pain was estimated in the whole sample with a 95% confidence interval using exact binomial test. The percentage was then compared by procedure type and anatomical grouping using Fisher's exact tests. If a significant overall difference was found, post-hoc pairwise comparisons were conducted with Hochberg adjustment. The analyses were repeated for the secondary outcome of intervention declination. All tests were two-sided and statistical significance was set as p < 0.05. All analyses were conducted using R 3.5.1.

3. Results

We reached out to a total of 687 patients, 47 of whom were lost to follow up as described above. Of the 640 patients whom we were able contact and offer a procedure, 90 declined intervention, resulting in 550 total patients rescheduling their procedures (see Fig. 3). Of those, 537 rescheduled at our institution and 13 rescheduled elsewhere. Of the 90 patients who declined intervention, 17 patients reported spontaneous improvement in their back pain (14.1% [CI =(11.5%, 17.0%), p < 0.001]) as the reason for not wanting intervention.

We sought to compare the 550 unique patients that required intervention with the 17 patients that reported spontaneous improvement, yielding a total sample size of 567. Importantly, results show that 3% of patients improved spontaneously [CI=(1.8%, 4.8%), p<0.001]. When sorting by anatomical groups, the rate of spontaneous improvement did not differ significantly (Table 1). However, when sorting by procedure type, the rate of spontaneous improvement does differ significantly (Table 2). Pairwise comparisons show that the rate of spontaneous improvement differs between facet joint intervention and SIJ and hip injections (1% vs. 12.8%, corrected p=0.0127) (Table 3). This indicates that patients scheduled for SIJ and hip injections were more likely to improve spontaneously compared to patients scheduled for facet joint interventions.

Next, we sought to compare the 550 unique patients that required intervention with the 90 patients that declined intervention, yielding a sample size of 640. As mentioned previously, results show that 14.1% of patients declined intervention [CI =(11.5%, 17.0%), p < 0.001]. Once again, when sorting by anatomical groups, the rate of declining intervention does not differ significantly (Table 4). However, when sorting by procedure type, the rate of declining intervention does differ significantly (Table 5). Pairwise comparisons show that the rate of declining intervention is significantly lower for facet joint interventions compared to ESI (6.3% vs. 16.6%, corrected/adjusted p = 0.0083) and to SIJ (6.3% vs. 25.5%, corrected/adjusted p = 0.0032) interventions (Table 6). This indicates that patients scheduled for SIJ and hip injections were more likely to decline intervention than those scheduled for facet joint interventions. Similarly, patients scheduled for ESI interventions were more likely to decline an intervention when offered, than those scheduled for facet joint interventions.



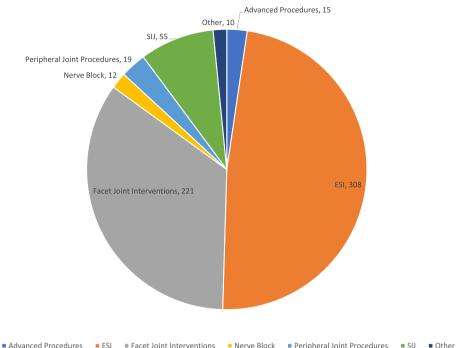


Fig. 1. Patient groups by procedure type.

Patient Groups by Anatomical Region

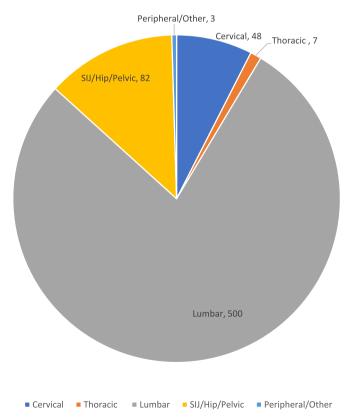


Fig. 2. Patient groups by anatomical region.

4. Discussion

Interventional procedures have long been criticized for lacking in proven efficacy, with underlying opinions that they are not necessary in the treatment of pain. The purpose of this study was to prove that patients in need of treatment will typically not improve over time without indicated interventional pain treatment. The suspension on elective procedures during the early period of the COVID-19 pandemic in 2020 allowed direct large-scale observation and analysis of outcomes of withheld interventional pain treatment, providing an ideal scenario for studying this question.

Our results demonstrate that only 3% of patients improved spontaneously when indicated interventional procedures had been withheld for three months. In the vast majority of cases, patients preferred to be rescheduled for interventional procedures when given the opportunity; these results strongly suggest that their pain symptoms failed to improve in the absence of the indicated interventions. Available literature suggests that patients have a significant decline in health-related quality of life and psychological well-being during 6 months of wait time from referral to treatment for chronic pain [13]. Our results are consistent with previous findings in literature. It is our belief that this is the first study to specifically evaluate symptomatic improvement when interventional treatment for pain is delayed.

When comparing the spontaneous recovery rates by anatomic locations of pain, there was no significant difference. However, when comparing the spontaneous recovery rates by procedure type, a statistically meaningful difference was noted. Improvement or resolution of pain generally varies by etiology and the underlying pathology. Given that the selection of an interventional technique is pathology-dependent, these results are not unexpected. Anatomic location itself, on the other hand, does not elucidate the underlying pathology that is responsible for producing the pain symptoms.

Our study found two interesting patterns regarding spontaneous recovery by procedure type. First, the rate of spontaneous recovery was significantly higher in patients who were scheduled to undergo SIJ or hip injections than facet joint injections. Possible explanation for this could

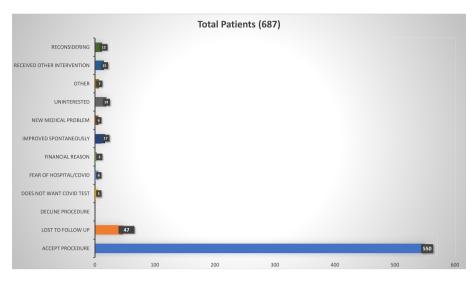


Fig. 3. Total patients.

Table 1Rate of Spontaneous Improvement by Anatomic Group

	Full Sample (N = 567)	Cervical (N = 42)	Lumbar (N = 447)	Peripheral/Other (N $=$ 3)	SIJ/HIP/Pelvic (N = 69)	Thoracic (N = 6)	P Value
Improved, N(%) 0. Did Not Improve 1. Improved	550(97) 17(3)	41(97.6) 1(2.4)	437(97.8) 10(2.2)	3(100) 0(0)	63(91.3) 6(8.7)	6(100) 0(0)	
Spontaneously							

Table 2Rate of Spontaneous Improvement by Procedure Type

	Full Sample(N = 567)	$\begin{array}{c} \text{Advanced} \\ \text{Procedures(N} = 13) \end{array}$	ESI (N = 265)	Facet (N = 209)	Nerve Block(N = 11)	Other (N = 7)	$\begin{array}{c} \text{Peripheral} \\ \text{Joint}(N=15) \end{array}$	SIJ(N = 47)	P Value
Improved, N(%) 0.Did not improve 1.Improved Spontaneously	550(97) 17(3)	12(92.3) 1(7.7)	257(97) 8(3)	207(99) 2(1)	11(100) 0(0)	7(100) 0(0)	15(100) 0(0)	41(87.2) 6(12.8)	0.012

Table 3Pairwise Comparison of Rates of Improvement

Comparison	Adjusted P Value
Advanced Procedures vs. ESI	1
Advanced Procedures vs. Facet	1
Advanced Procedures vs. Nerve Block	1
Advanced Procedures vs. Other	1
Advanced Procedures vs. Peripheral Joint	1
Advanced Procedures vs. SIJ	1
ESI vs. Facet	1
ESI vs. Nerve Block	1
ESI vs. Other	1
ESI vs. Peripheral Joint	1
ESI vs. SIJ	0.1992
Facet vs. Nerve Block	1
Facet vs. Other	1
Facet vs. Peripheral Joint	1
Facet vs. SIJ	0.0127
Nerve Block vs. Other	1
Nerve Block vs. Peripheral Joint	1
Nerve Block vs. SIJ	1
Other vs. Peripheral Joint	1
Other vs. SIJ	1
Peripheral Joint vs. SIJ	1

be that SIJ and hip pain is more prone to being misdiagnosed than facet joint pain as there is no definitive way to diagnose SIJ pain by historical, physical, or radiologic features [17] and hip pain is not always secondary to intra-articular hip pathology or degenerative arthritis. In other words, the spontaneous improvement experienced by patients who were scheduled to undergo SIJ or hip injections may have had pain secondary to a different cause. Second, the rate of declining intervention was significantly higher in patients who were scheduled to undergo ESIs than facet joint injections. This may be due to the fact that radiculopathy can be secondary to reversible causes such as disc pathology, which is reported to improve over time, while facet arthropathy is associated with irreversible, age-related degenerative changes of the intervertebral discs or facet joints [6].

Our study has limitations. First, we did not account for chronicity of pain symptoms. While most of the patients referred to our multidisciplinary pain management department have chronic pain, it is possible that some patients included in our analysis may have had acute pain. This may have resulted in overestimation of the spontaneous recovery rate, since acute pain improves with healing of potential tissue damage, whereas chronic pain is sustained after nociceptive inputs have diminished as defined by the International Association for the Study of Pain [18]. Secondly, we did not evaluate the outcomes of patients who rescheduled previously postponed interventional treatments. In a future study, we hope to compare outcomes of patients who receive

Table 4Rate of Declined Procedures by Anatomic Group

	Full Sample (N = 640)	Cervical (N = 48)	Lumbar (N = 500)	Peripheral/Other (N = 3)	SIJ/HIP/Pelvic (N = 82)	Thoracic (N = 7)	P Value
Decline_intervention, N(%)							0.141
0.Accept Intervention	550(85.9)	41(85.4)	437(87.4)	3(100)	63(76.8)	6(85.7)	
1.Decline Intervention	90(14.1)	7(14.6)	63(12.6)	0(0)	19(23.2)	1(14.3)	

Table 5Rate of Declined Procedures by Procedure Type

	Full Sample (N = 640)	$\begin{array}{c} \text{Advanced} \\ \text{Procedures (N = 15)} \end{array}$	ESI (N = 308)	Facet (N = 221)	Nerve Block ($N=12$)	Other (N = 10)	Peripheral Joint $(N=19)$	SIJ (N = 55)	P Value
Decline_intervention, N(%)			·						< 0.001
0.Accept Intervention	550(85.9)	12(80)	257(83.4)	207(93.7)	11(91.7)	7(70)	15(78.9)	41(74.5)	
1.Decline Intervention	90(14.1)	3(20)	51(16.6)	14(6.3)	1(8.3)	3(30)	4(21.1)	14(25.5)	

Table 6Pairwise Comparison of Rates of Declination

Comparison	Adjusted P Value
Advanced Procedures vs. ESI	1
Advanced Procedures vs. Facet	1
Advanced Procedures vs. Nerve Block	1
Advanced Procedures vs. Other	1
Advanced Procedures vs. Peripheral Joint	1
Advanced Procedures vs. SIJ	1
ESI vs. Facet	0.0083
ESI vs. Nerve Block	1
ESI vs. Other	1
ESI vs. Peripheral Joint	1
ESI vs. SIJ	1
Facet vs. Nerve Block	1
Facet vs. Other	0.5496
Facet vs. Peripheral Joint	0.7587
Facet vs. SIJ	0.0032
Nerve Block vs. Other	1
Nerve Block vs. Peripheral Joint	1
Nerve Block vs. SIJ	1
Other vs. Peripheral Joint	1
Other vs. SIJ	1
Peripheral Joint vs. SIJ	1

interventional procedures among those rescheduled.

5. Conclusions

The COVID-19 pandemic brought about immediate, drastic and unimaginable consequences across the healthcare landscape. One of these was the unplanned cancellation of outpatient ambulatory procedures for pain management. In an overwhelming majority of our patients, pain did not spontaneously improve when interventional pain procedures were delayed, and patients were willing and anxious to reschedule. Our findings suggest that when interventional pain procedures are withheld in patients who meet appropriate criteria, spontaneous improvement of pain does not occur in the vast majority of cases. It can therefore be concluded that the utilization of interventional techniques to help manage pain is a vitally important component to the treatment paradigm for those in pain.

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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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://do i.org/10.1016/j.inpm.2023.100266.

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