Pain Physician 2021; 24:185-192 • ISSN 1533-3159

Prospective Research Study

Should a Coexisting or Suspected Diagnosis of Fibromyalgia Affect the Decision to Perform Diagnostic Blocks for Patients with Chronic Noncancer Pain — Results from an Observational Research Study

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Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 01-31-2019
Revised manuscript received: 01-03-2020
Accepted for publication: 09-15-2020

Free full manuscript: www.painphysicianjournal.com

Background: Diagnostic injections (blocks) are a valuable tool in the management of chronic noncancer pain. By precise blockade of specific neural structures and observation of pain responses, pain mechanisms can be accurately defined. With such information, therapeutic procedures targeting neural structures are possible. Fibromyalgia is a disorder of pain processing with characteristic symptoms. The 2010 American College of Rheumatologists fibromyalgia diagnostic criteria evaluates these symptoms in a scoring system, allowing more objectivity in the diagnosis.

We hypothesize that patients with fibromyalgia phenotype fulfilling the 2010 American College of Rheumatologists criteria may respond to diagnostic blocks differently when compared to patients without fibromyalgia phenotype.

Objectives: This study was designed to establish whether diagnosis or suspected diagnosis of fibromyalgia should influence the decision to perform diagnostic blocks for chronic non-cancer pain.

Study Design: A prospective observational research study was performed at our institution. IRAS project ID: 231514.

Setting: Tertiary pain clinic in the UK.

Methods: Patients were selected to receive diagnostic block by usual clinical assessment after which they were asked to consent to take part in the study. All participating patients completed the 2010 American College of Rheumatologists fibromyalgia diagnostic questionnaire prior to the diagnostic block. Patients were divided into 2 groups A and B based on the outcome of block — primary outcome. Group A experienced a 70% or greater improvement in pain severity following the block for the anticipated duration of action of the local anesthetic, Group B experienced a less than 70% reduction in pain.

Statistical analysis between groups A and B was conducted by comparing categorical data, described as percentages, with the χ^2 test. Ordinal variables such as Widespread pain index and Symptom severity score are presented as median and analyzed with Mann-Whitney test.

Results: Seventy-seven patients were included in the study. Two patients were lost to follow-up. Of the 75 remaining patients, 44 received lumbar medial branch blocks, 19 genicular nerve blocks, 3 blocks to nerves supplying the sacroiliac joint, one suprascapular nerve block, and 6 cervical and 2 thoracic medial branch blocks. Group A contained 38 patients and group B contained 37 patients.

There was no statistically significant difference in the prevalence of fibromyalgia screening questionnaire positive patients between groups A (13 out of 38 patients) and B (13 out of 37 patients), $P = 0.93$. There was no statistically significant difference in the prevalence of fibromyalgia screening questionnaire positive patients in subgroups undergoing the same type of diagnostic block (spinal pain and knee pain).

Limitations: Selection of patients prior to inclusion in the study may introduce bias. Patients were selected by individual treating clinicians using usual clinical practice; however, the exact selection criteria were not standardized.

Conclusion: We conclude that after physician selection, the presence of fibromyalgia phenotype does

not influence the outcome from diagnostic block. It is likely therefore that fibromyalgia phenotype should not influence the decision to perform diagnostic blocks if indicated based on assessment by an experienced pain physician.

Key words: Fibromyalgia, chronic pain, diagnostic blocks, fibromyalgia diagnostic criteria, interventional pain management, chronic noncancer pain, medial branch block, genicular block, central sensitization

Pain Physician 2021: 24:185-192

Chronic noncancer pain encompasses a wide range of clinical conditions. The largest group by far is spinal and radicular pain, which represents an urgent global public health concern. The estimated global point prevalence of activity-limiting lower back pain was 7.3%, representing 540 million people, with an impact on disability adjusted life years that has increased by over 50% since 1990 (1). A range of other musculoskeletal conditions also represents a significant proportion, including osteoarthritis, rheumatoid arthritis, and myofascial pain conditions. Neuropathic pain conditions are less common but confer a higher risk of socioeconomic impact (2). Functional pain disorders include fibromyalgia, functional abdominal pain, non-cardiac chest pain, functional dyspepsia, and chronic pelvic pain. These disorders are common, with a population prevalence of 2.1% for fibromyalgia (3), and 0.5 – 2% for functional abdominal pain syndrome (4).

Interventional pain management involves targeting structures believed to be involved in pain generation or processing, in order to modify the somatosensory pathway and reduce symptoms. Therapeutic delivery of pharmacological agents to such structures involves needle-based application of steroids, local anesthetics, as well as neuroablation by either chemical or thermal means — radiofrequency ablation (RF).

The therapeutic effect from RF ablation of targeted nerves requires precise identification of somatosensory structures involved in the generation and transmission of pain. Due to the complexity of pain presentations, it is generally not possible to accurately predict who will respond to neuroablative procedures without a diagnostic block (5). These diagnostic blocks involve injecting small volumes of local anesthetic around nerves supplying potential pain-generating structures. The patient monitors symptoms over the expected duration of the local anesthetic and reports to the clinician. Based on the change of pain symptoms from baseline, the clinician makes a judgment regarding whether the structure blocked with the diagnostic injection is likely to be the cause of the patient's symptoms.

Fibromyalgia is a common chronic widespread pain disorder characterized by pain, somatic symptoms as well as tiredness, waking unrefreshed, and cognitive symptoms. The 2010 American College of Rheumatologists (ACR) diagnostic criteria provides a scoring system evaluating the extent of the above symptoms to give some objectivity to the diagnosis (6). A case is defined as positive if widespread pain index (WPI) ≥ 7 and symptom severity (SS) scale score ≥ 5 or WPI is between 3 – 6 and SS ≥ 9.

The pathophysiology of fibromyalgia syndrome is not well understood but is believed to involve altered nociceptive processes within the central nervous system. This results in an augmentation of pain perception and an increased sensitivity to stimulation, amplifying pain (7). This is referred to as "central sensitization," "central sensitivity syndrome," or "central amplification."

Despite the exact mechanisms involved in fibromyalgia being unclear, the altered pain processing experienced by these patients is well demonstrated, with pain being amplified and nonnociceptive sensory input being perceived as pain. When considering diagnostic or therapeutic procedures on fibromyalgia patients, this altered pain processing is likely to be relevant as most interventional procedures are predicated on the pain generator hypothesis.

Several studies have examined outcomes from surgical procedures in patients with a diagnosis of fibromyalgia. In an observational study of 464 patients published in 2015, higher scores on the fibromyalgia diagnostic criteria were found to be associated with less improvement in pain following hip or knee arthroplasty (8). The authors proposed that the presence of a sensitized central nervous system such as in fibromyalgia was a risk factor for ongoing pain after surgery.

Fibromyalgia is common in the chronic pain clinic population, and it may be present but not formally diagnosed in many more. Central sensitization is thought to be a key mechanistic feature of many chronic pain states including lower back pain, and pelvic and abdominal pain.

We wanted to test the hypothesis that confirmed or suspected fibromyalgia phenotype should influence

the decision to perform diagnostic blocks, making these procedures less suitable for this cohort of patients.

Methods

A single center prospective observational research study was designed for which ethical approval was granted, IRAS project ID: 231514. The observation period extended from November 2017 until January 2019. The research included diagnostic and therapeutic procedures, but for the purpose of testing this hypothesis, only the diagnostic arm of the study is described. Inclusion criteria were all English speaking chronic pain patients listed for a first set of diagnostic blocks for non-cancer chronic pain in a tertiary pain clinic in the UK. Exclusion criteria were no consent or withdrawal of consent, incomplete data available (incomplete ACR criteria or diagnostic scoring) or diagnostic block not performed or not adequately performed. Study size was determined pragmatically based on numbers of patients recruited during the observation period; there was no power calculation.

Patients were listed for diagnostic blocks after being assessed in the usual way by the physician responsible for their care. The decision to perform diagnostic blocks was according to usual practice, consisting of comprehensive and individualized biopsychosocial assessment, history, examination, and investigation results. Routine screening was also available as part of our routine pain assessment including Brief Pain Inventory (short form), Pain Self Efficacy Questionnaire, GAD-7, PHQ-9, and Euroquol EQ-5D. This screening data is part of usual pain assessment. It was not used specifically for this study or included in any analysis but may have formed part of the selection process for the treating clinician. Once the decision to perform the diagnostic blocks was made, patients were approached by the research team to be included in the study and provide written consent. Consented patients were asked to self-complete the 2010 ACR diagnostic criteria prior to their procedure. The physicians referring for diagnostic blocks were blinded and not aware of further outcomes of the research findings to remove this source of bias.

Results from self-completed ACR fibromyalgia diagnostic criteria were collated and analyzed. Scores for each patient in the domains SS and WPI were calculated. For each patient it was determined whether they crossed the diagnostic threshold of WPI $\geq$ 7 and SS $\geq$ 5 or WPI 3 – 6 AND SS $\geq$ 9 (6). If patients crossed this threshold then they were defined as fibromyalgia ACR positive. If fibromyalgia diagnostic criteria were not completed then the patient was excluded from the study.

Results from diagnostic blocks were collected by paper proforma, completed by the patient at home, contemporaneously and returned to the investigators via pre-paid post. Responses were self-completed pain diaries evaluating targeted pain over a 24 hour period, assessed using 11-point (0 – 10) numeric rating scale (NRS). Outcome of the diagnostic blocks (primary outcome) allowed the division of patients into 2 groups: A and B. Group A was the "positive" group, if the patient experienced 70% or greater improvement in pain severity of the targeted pain during the expected onset and duration of local anesthetic used. Group B was the "negative" group defined as less than 70% pain reduction. If no diagnostic information was returned by the patient, they were classified as lost to follow-up and excluded from analysis. Percentage pain reduction was calculated using the 11-point pain scores pre- and post-diagnostic block. For example, if the patient's pre-procedure pain score was 8/10, then a score of < 2.4/10 must be reached during the expected duration of the local anesthetic to satisfy as a positive result. A threshold of 70% pain reduction was used in this study as a balance between the more usual threshold of 50% pain reduction (maximizing sensitivity), and 80% (more specific) reported by some authors. We felt that the 70% reduction threshold represented a balance between the 2.

Statistical analysis between groups A and B was conducted as follows: continuous variables with normal distribution are presented as mean ± SD and the comparison of means for such data (age of patients) was performed by t-test (normal distribution confirmed with Kolmogorov-Smirnov test). Categorical data are described as percentages and compared with the χ^2 test. Ordinal variables: WPI and SS score are presented as median and analyzed with the Mann-Whitney test.

Results

Assessments of patients presenting with non-cancer pain was performed by 3 interventional pain physicians performing approximately 200 injection-based treatments each per year, of which approximately 20% are diagnostic injections. In the 14 months during of data collection, an estimated 140 patients were eligible for inclusion. Of the estimated 140 patients eligible for inclusion, 77 patients were recruited for the study between November 2017 and January 2019 and had

diagnostic blocks performed. Two patients were lost to follow-up due to incomplete information returned by the patient following diagnostic block. Of the 75 patients, 44 received diagnostic lumbar medial branch blocks, 19 genicular nerves of knee blocks, 3 diagnostic blocks to nerves suppling the sacroiliac joint, one suprascapular nerve block, and 6 cervical and 2 thoracic medial branch blocks (Fig. 1).

Patients were divided, based on defined primary outcome – 70% pain improvement after diagnostic block, into 2 groups. Thirty-eight patients (group A) had a positive response and 37 patients (group B) had a negative diagnostic block (Fig. 1). Age distribution and gender in both groups were similar; 24 women were included in group A vs. 23 in group B, $P = 0.93$. Mean age of group A was 53.9 +/- 14.2 vs. 54.2+/- 14.9 in group B, $P = 0.943$. The types of diagnostic blocks done in both groups do not differ significantly (Table 1).

Of the 38 patients in group A, 13 (34%) fulfilled the ACR diagnostic criteria, while 25 (66%) did not. Of the 37 patients in group B, 13 (35%) fulfilled the ACR diagnostic criteria, while 24 (65%) did not (Fig. 2). There was no statistically significant difference between the 2 groups ($P = 0.93$).

Further sub-analysis of medians of WPI and Symptom severity score (SS in each subgroup revealed no statistically significant difference between groups A and B, $P = 0.65$ and $P = 0.3$, respectively.

The further sub-analysis of 55 patients undergoing only spinal diagnostic blocks failed to spot any statistically significant differences as well. The prevalence of ACR fibromyalgia positive patients did not differ in both sub-groups. There were 9 patients out of 25 who had a positive diagnostic block and positive ACR fibromyalgia diagnosis vs. 10 out of 30 who had a negative diagnostic block and positive ACR fibromyalgia diagnosis, $P = 0.9$.

Discussion

Fibromyalgia is understood as a disorder of pain processing. Patients are known to have heightened sensitivity to stimuli, and experience pain during low threshold stimulation. In our study we have not found there to be an association between the outcome from diagnostic blocks for chronic noncancer pain and the presence of a fibromyalgia positive screening. Our hypothesis is therefore rejected.

The association between fibromyalgia syndrome

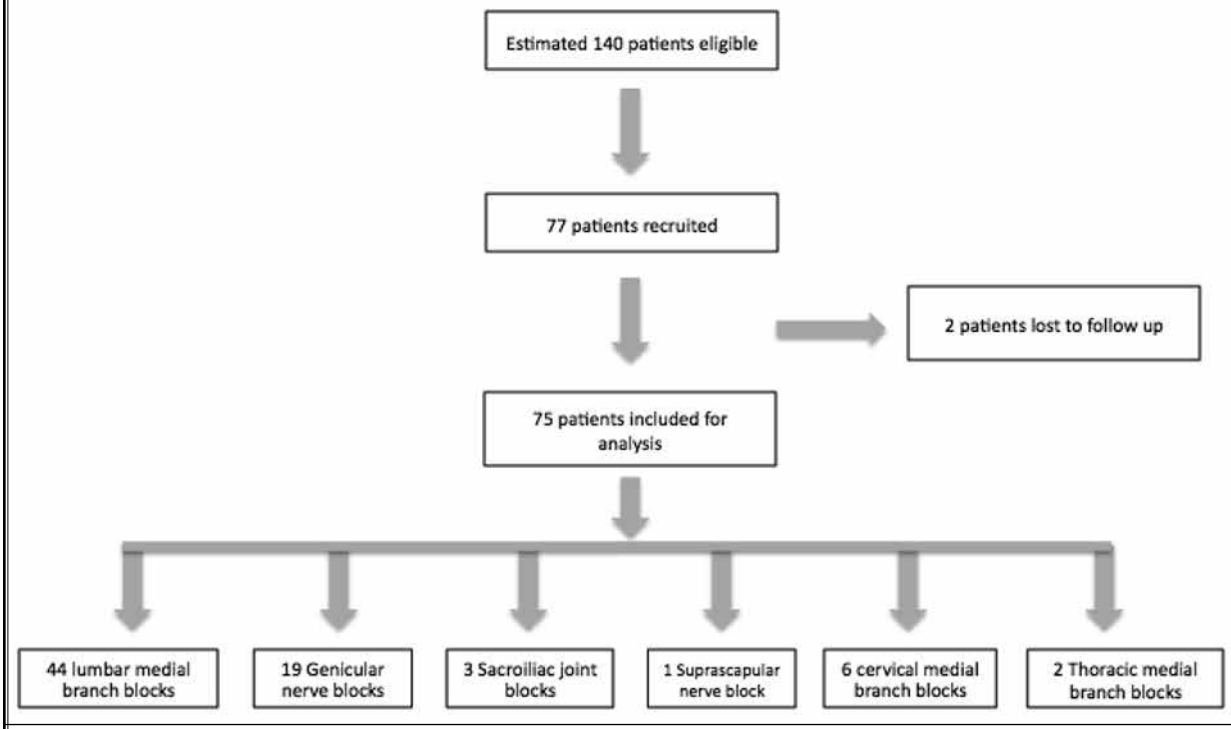

Fig.1 *Flow diagram presenting recruitment to the study with a minimal loss to follow up.*

and outcomes following surgical procedures for painful conditions has been examined in various studies. Studies examining these effects are relevant because they examine the relationship between abnormal pain processing and the response to treatments designed to reduce pain by surgical means, usually by excision or replacement of the pain generating structure.

Fibromyalgia is common in patients referred to the pain clinic with chronic spinal pain. In a 2013 study of spine pain patients presenting to a tertiary pain clinic, the incidence of fibromyalgia criteria positive screening was 42%, slightly higher than the 34% found in our study. Significantly higher levels of depression and anxiety and lower physical function were found in the 2010 ACR fibromyalgia criteria positive group (9).

We performed an English language literature search via Ovid technologies searching 'Journals@ Ovid Full Text, Your Journals@Ovid, AMED 1985-Jan 2019, Embase 1974- Jan 2019, HMID 1979 – November 2018. We used the search terms 'fibromyalgia' combined with either 'surgery' 'orthopedic' 'arthroplasty' 'spinal surgery' 'abdominal surgery' 'cholecystectomy' 'gynecology,' We also performed a 'PUBMED' search for the terms 'fibromyalgia' and 'surgery' or 'surgical outcomes.' We selected papers relevant to the subject of outcomes following surgical procedures in patients with fibromyalgia.

In the orthopedic literature, an observational study of 464 patients published in 2015 showed that higher scores on the fibromyalgia diagnostic criteria were associated with less improvement in pain following hip or knee arthroplasty. They found a 17.8% increase in failure to meet the threshold for 50% improvement in pain 6 months after surgery for each one-point increase in FM score. The authors used a combined fibromyalgia score taking the total score from both WPI and SS and analyzing as a total out of 31 points. The authors proposed that the presence of a sensitized central nervous system such as in fibromyalgia was a risk factor for ongoing pain after surgery. This study however excluded patients who fulfilled the diagnostic threshold on the ACR criteria and therefore did not include fibromyalgia positive patients (6% of the study population) (8).

In an observational study of matched patients undergoing total knee arthroplasty (TKA), patients with fibromyalgia were less satisfied and had lower self-reported health compared with matched controls; however, improvements in pain after surgery were comparable (10). Patients with fibromyalgia are also

Table 1. *Types of diagnostic blocks and frequency of positive responses.*

Type of block	Group A (positive blocks)	Group B (negative block)	*P*
Lumbar spine diagnostic blocks	21	26	0.179
Genicular blocks of knee	12	7	0.207
Other blocks	5	4	0.754

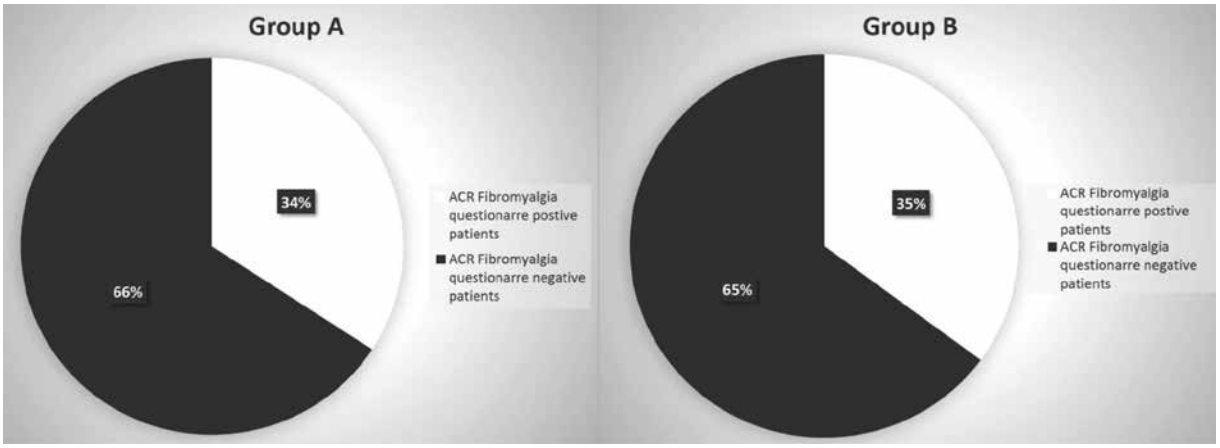

Fig. 2. *The prevalence of ACR questionnaire positive fibromyalgia patients among patients undergoing diagnostic tests. Thirteen patients in group A out of 38 (34%) fulfilled the ACR diagnostic criteria, while 25 (66%) did not. Thirteen out of 37 patients from group B (35%) fulfilled the ACR diagnostic criteria, while 24 (65%) did not. There was no statistically significant difference between the 2 groups (P = 0.93).*

more likely to suffer ongoing pain after TKA, with 44% having ongoing pain (11) compared to approximately 20% in unselected TKA patients (12).

In analysis of patients undergoing shoulder arthroscopy, higher FM scores did not predict increased morphine consumption but was associated with poorer quality of recovery scores at day 2 and 14. This study also analyzed based on a 31-point continuous fibromyalgia scale rather than the use of ACR diagnostic criteria as a diagnostic tool (13).

In patients undergoing spinal surgery, FMS is both highly prevalent (22.5% of patients), and associated with less reduction in pain post-surgery compared to FMS negative patients (14). This study grouped patients based on whether they fulfilled the ACR 2010 diagnostic criteria. In a 2018 study of complication rates and costs following spinal surgery, patients with previously diagnosed fibromyalgia were found to be at significantly higher risk of post-operative anemia, readmission, pneumonia, and incurred 5.31% more hospital charges (15). Outcomes for pain were not studied and the reasons for the above risks were not established.

Outcomes following non-orthopedic/spinal surgery have been less well studied. A study of patients with symptomatic gallstones undergoing laparoscopic cholecystectomy showed that symptoms of fibromyalgia transiently worsened after surgery but returned to baseline at 3 months before improving compared to pre-operative levels. The authors concluded that pain from gallstones was a peripheral driver of FMS symptoms but did not find evidence of worse long-term pain in patients with fibromyalgia (16).

In patients undergoing hysterectomy, higher FM scores (2010 ACR criteria) were associated with increased post-operative opioid requirements, an indicator of post-operative pain (17). More severe post-operative pain is a known risk factor for chronic post-surgical pain. This study used a 31-point fibromyalgia scale and did not analyze long-term outcomes.

For maxillofacial surgery, a fibromyalgia diagnosis was not found to correlate with outcomes following surgical correction of the internal derangement of the temporomandibular joint when assessed up to 5 months after surgery. This was a small (n = 28) retrospective analysis and relied on patients already being diagnosed with fibromyalgia rather than active screening (18).

For interventional pain medicine and fibromyalgia, the literature is sparse. A 2015 study of 187 patients undergoing diagnostic medial branch block revealed no significant difference in the numbers of positive or negative diagnostic blocks between fibromyalgia negative and positive patients, however it showed a difference in the longitudinal analgesic response across time (19). The authors observed that fibromyalgia negative patients were more likely to experience analgesia for the expected duration of the local anesthetic, whereas a more aberrant pattern was noticed in the fibromyalgia positive group. The fibromyalgia positive group experienced less initial pain reduction and the duration of analgesia was more prolonged. The authors hypothesized that temporary blocking of nociceptive input may cause some central nervous system unwinding leading to greater duration of analgesia. In another study with patients undergoing a therapeutic injection of a steroid for chronic lateral epicondylitis, patients with fibromyalgia were less likely to benefit when assessed at 2 weeks and 3 months after injection (20).

The ACR fibromyalgia criteria published in 2010 was a significant amendment to the previous 1990 diagnostic criteria (6). The change from tender point examination to WPI allowed self-assessment by patients. The addition of characteristic symptoms to the criteria was a major change and these categorical scales created the SS subset of the criteria. The case definition was defined as WPI ≥ 7 and SS ≥ 5 or WPI 3 – 6 and SS ≥ 9.

The 2016 proposed amendment to the 2010 diagnostic criteria included a generalized pain criterion to avoid misdiagnosis of regional pain disorders (21). This amendment has not, however, been widely adopted and we did not use it in our study. In our study we have used the 2010 fibromyalgia criteria as described originally and not as a 31-point continuous scale (8,12). We believe that the combination of discrete variables (WPI), and categorical variables (SS) may lead to misleading conclusions. This method may bias towards patients with higher WPI sub-score because is possible to gain more points on WPI (out of 19) rather than SS (out of 12). The use of the ACR criteria as a 31-point scale has not been validated.

The literature regarding long-term outcomes following intervention or surgery for pain in patients with fibromyalgia is sparse and somewhat conflicting. Some studies found worse long-term outcomes and some did not. There is also a low volume of publications on this topic. Despite the common belief that these treatments lead to worse outcomes in fibromyalgia patients, this is not consistently supported by the literature. It is widely accepted that patients with fibromyalgia have altered pain processing and an increased sensitivity to noxious and nonnoxious stimuli. When patients with symptoms

of fibromyalgia present with focal pain, it is important to establish clear evidence of the pain generating structure before proceeding to definitive treatment. Because patients with fibromyalgia present with multiple painful body sites this is more challenging. When imaging or clinical assessment fails to provide acceptable accuracy, diagnostic blocks may be employed to provide further information.

Limitations

The observational nature of the study design means that bias is possible as the groups observed may differ in nonmeasured ways. The selection of patients for diagnostic block, taking place prior to inclusion in the study, cannot be controlled, nor can the exact criteria for selection in each case. Patients were selected by individual treating clinicians, who may have differences in selection criteria. It may be that clinicians selecting patients for interventional diagnostic procedures are less likely to select patients with widespread pain or multiple somatic complaints. Such a mechanism may select out patients likely to have more severe fibromyalgia. This cannot be demonstrated by this study design but is a potential limitation.

The lack of inclusion of all eligible patients within the study period is also a limitation; however, this was not systematic and we do not believe it is a significant source of bias.

Generalizability

This study was performed in a tertiary pain clinic in the UK and studied patients typical for this clinical setting. Therefore, we believe our results are generalizable among the adult chronic pain population undergoing diagnostic blocks for axial back pain and knee pain in the UK or similar health care settings. We cannot generalize to diagnostic blocks not included in our data set which may be used by other physicians. With our data we cannot assess the incidence of false positive diagnostic blocks within this cohort. Further data analyzing the outcomes following therapeutic procedures for those patients with positive diagnostic block is needed to assess incidence of false positive blocks and the clinical utility of these findings.

Conclusion

Prevalence of patients who fulfill the 2010 ACR fibromyalgia criteria did not differ between positive and negative diagnostic block groups. Both groups were well matched and the types of diagnostic injection did not differ.

We conclude that, after physician selection, the presence of fibromyalgia phenotype does not appear to influence the outcome of diagnostic blocks for chronic non-cancer pain. Therefore, the presence of fibromyalgia phenotype will not aid, and should not influence, the decision to perform diagnostic blocks if clinical judgment supports it after comprehensive clinical assessment. Further research is needed to establish if, when using pre-determined, standardized selection methods, the presence of fibromyalgia phenotype influences the outcome of a diagnostic

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