Comparison of a Novel Direct Measure of Rapid Pain Intensity Change to Traditional Serial 100 mm VAS Measurement of Pain Intensity

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Objectives: Key diagnostic decisions often turn on measurement of change in pain intensity after diagnostic anesthetic blocks. This study aimed to introduce a new direct measure pain intensity change and compare it with percent change as calculated from the traditional preprocedure and postprocedure pain visual analog scales.

Methods: Shoulder pain patients enrolled in a diagnostic accuracy study comparing clinical variables with image-guided local anesthetic injections were assessed with both the traditional preprocedure and postprocedure visual analog scales and the new direct method. Percent change in pain intensity was calculated with both instruments and were compared using statistical methods. The percentage pain reduction used to classify patients as responders was 80%.

Results: Patients received anesthetic injections to targeted shoulder structures (N = 146, 331 procedures). For data above the 80% pain reduction criterion, Lin Concordance statistic ranged from 0.22 to 0.55. Bland and Altman analyses revealed positive bias and the amount of reported pain reduction was higher with the traditional method. For data above the 80% pain reduction criterion, the bias was higher and ranged from 4.8% to 12.6%.

Conclusions: The 2 methods are not interchangeable. The new method measures the pain intensity change dimension directly, whereas the traditional method estimates change indirectly by calculation. Face validity is better served by adopting the new method for decisions regarding whether a patient is a "responder" or "nonresponder" to diagnostic blocks. The traditional method should be retained for estimation of pain intensity preprocedure and the duration of pain relief postprocedure.

Key Words: pain intensity, pain VAS, diagnostic injection, diagnostic imaging, local anesthesia

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Pain is an unpleasant experience, normally but not always associated with tissue damage or disease. Melzack and Torgenson[1] described 3 aspects of the experience: sensory and affective qualities, and descriptions of the overall subjective experience. The focus of this study is pain intensity, which is an attribute of all 3 aspects. The precision of pain intensity measurement required in a clinical situation varies considerably. When significant clinical decisions rely upon pain intensity measurement, the need for accuracy and precision becomes critical. Some clinical diagnoses are confirmed or rejected on the basis of changes in pain intensity, which in turn may determine whether the patient may or may not receive a specific treatment, for example, surgery or radiofrequency neurotomy.

In musculoskeletal diagnosis, local anesthetic (LA) diagnostic injections are used to aid the identification of the tissue or structural source of pain. These procedures have reached a high level of sophistication in the diagnosis of spinal pain and are most commonly applied to joint spaces,[2,3] intervertebral discs,[4–6] or the near vicinity of nerves supplying the structure in question.[7–9] Diagnosis of the pain source may be confirmed or rejected if the pain is temporarily ablated, or not, after LA injection. In practice, however, the patient report of pain intensity change after LA injection is highly variable. This variability forces the diagnostician to make judgments as to what constitutes a positive response to LA. A report of 100% abolition is a clear positive response, but what about a 90% or 50% pain reduction? There is great variability in the percent reduction chosen by researchers as a cutoff criterion. Previous publications have used a 50% reduction of pain,[10,11] 70%,[12,13] 75%,[14] and 80%.[15–17] One study has reported proportions of patients satisfying a range of percent reductions.[18]

The established methodology used in spinal pain diagnosis uses serial visual analog scales (VASs), typically 100 mm in length where one end indicates 0 or "no pain" and the other end indicates a numeric value (100 or 10), or "worst pain imaginable." There are, however, concerns regarding the psychometric properties of the 100 mm VAS when accurate estimates of rapid pain change are required. It is recommended that LA blocks should not be used in patients whose typical pain is < 40 on a 100 mm scale, or in patients whose pain, at the time when the block is to be undertaken, is < 20 on a 100 mm scale, because the natural diurnal variation of this pain may be of this magnitude, and a decrease in pain of only 20 points may not be legitimately attributable to the intervention.[19] Conformity with this advice, while appropriate, will clearly exclude from diagnostic investigation, many patients with minor but persistent pain, or patients whose pain just happens to be mild on the day of examination.

The psychometric limitations of the traditional preprocedure and postprocedure VAS were the stimuli to explore other methods of measuring the rapid change in pain intensity by patients undergoing diagnostic LA blocks. In this respect, there is a need for research that focuses the patient's attention on change in pain intensity rather than absolute levels of pain, which is the focus of the traditional method. In doing so, it was thought that this more likely reflected the question posed by clinicians to patients after a procedure or treatment. In addition, a focus on change in pain uses a single anchor for preprocedure pain regardless of intensity. Thus, it has the following advantages: it directly measures the dimension of interest (pain intensity change); it avoids or minimizes problems associated with low preprocedure pain intensity; the error rate associated with marking the instrument is halved because it is done just once postprocedure compared with twice with the traditional method. A previous study[20] examining different nongraphical techniques has focused upon reductions in pain much less than those generally sought after LA injections and has also been focused upon intravenous opioids for acute pain, hence the need for further research in this area. Therefore, it was of interest to test whether the new method that focused upon change in pain, provided similar values to the traditional technique of requesting absolute values of pain preintervention and postintervention.

MATERIALS AND METHODS

Participants

Consecutive shoulder pain patients drawn from primary care clinics of physiotherapists and general medical practices in metropolitan Christchurch, New Zealand were recruited for a study evaluating the diagnostic accuracy of the clinical examination in relation to the reference standard of image-guided diagnostic LA injections.[21] Data for this secondary analysis are abstracted from this project and are not reported elsewhere. The participants received a comprehensive clinical evaluation in which up to 6 specific clinical tests were found to increase or produce pain typical of their presenting symptom.

Inclusion Criteria

Age older than 18 years; pain dominantly in the shoulder joint region; able to comprehend and read the English language.

Exclusion Criteria

Significant and related pain in the neck or symptoms and signs suggestive of pain arising from the cervical or thoracic spine; known medical or other conditions able to refer pain to the shoulder region; previous steroid injection or diagnostic LA injection to the shoulder during the current episode of pain; previous surgery to the affected shoulder; or inability of the patient to complete the clinical examination.

Procedure

The study was approved by Ministry of Health—Upper South Regional Ethics Committee. Patients were scheduled for an initial assessment, which involved reading and signing an approved informed consent form and acquisition of demographic and baseline measures of medical history, pain, disability, general health, and fear-avoidance beliefs. The clinical examination included tests for ranges of active and passive motion, resisted tests for pain provocation and measurement of pain using a hand-held dynamometer,[22] and a suite of special orthopedic tests for specific pathologies.[23]

After this initial assessment, all patients were scheduled for standardized radiograph and ultrasound imaging studies immediately followed by ultrasound-guided injection of LA into the subacromial bursa (SAB). One week after the SAB injection, all patients received a fluoroscopically guided injection of LA into the acromioclavicular joint (ACJ). A proportion of cases were further investigated with a magnetic resonance arthrogram that included an injection of gadolinium and LA into the glenohumeral joint (GHJ). Immediately before all guided LA injections, each patient was examined with tests shown to provoke pain typical of the presenting symptom, and the intensity of the provoked pain was measured using 100 mm VASs for each positive test. One test was selected randomly for use as the index test. Fifteen minutes after the LA injection, the selected painful test was repeated and pain intensity was again documented. After this procedure, the new direct method of rapid pain intensity change (DM-RPIC), was scored and the percent change recorded. Flow of patients through the study is depicted in the flow diagram (Fig. 1).

Pain Measurement

The traditional serial VAS rapid pain intensity change method (Trad-RPIC) (Appendix 1): Before injection of LA, the patient was asked to indicate current pain intensity on the VAS by placing a mark or cross on the line for tests previously identified as provocative of notable pain. The patient was then instructed that after the LA injection, the same painful tests would be repeated and rescored. Percent change was calculated for the index test using the formula [(postprocedure VAS − preprocedure VAS)/preprocedure VAS) × 100. Positive integers indicate increased pain, and negative integers indicate decreased pain.

DM-RPIC (Appendix 2): The DM-RPIC is a 200 mm vertically oriented VAS with the midpoints and endpoints clearly indicated. Before the LA procedure, the patient was instructed that the midpoint on the vertical line represents the amount of pain experienced for the painful index test. The patient was also told that this was so regardless of whether the pain was mild, moderate, or severe. The patient was then instructed that after the LA injection, the same test would be repeated and the change in pain was to be scored on the vertical VAS scale. Above the midpoint in the scale represented an increase in pain with the extreme endpoint designated as "pain very much worse." Below the midpoint in the scale represented a decrease in pain with the extreme endpoint being designated as "complete abolition of pain." It was made clear to the patient that distance from the midpoint on the scale represents the magnitude of change, and that placing a mark at the midpoint would indicate no change at all (0%) and the extreme ends represent the maximum change (± 100%). After the injection procedure, the patient was reminded of what the midpoints and endpoints represented. Acquiring the percent change requires no calculation, only the measurement of the distance of the patient's mark from the midpoint in millimeters for example, 40 mm represents 40% of the 100 mm line either side of the midpoint. Positive integers indicate increased pain, and negative integers indicate decreased pain.

Data Analysis and Statistical Testing

Data were initially recorded on physical forms and transposed into an electronic database. The comparison of the Trad-RPIC and DM-RPIC methods was focused on the variable: percentage of change in pain, and separate analyses

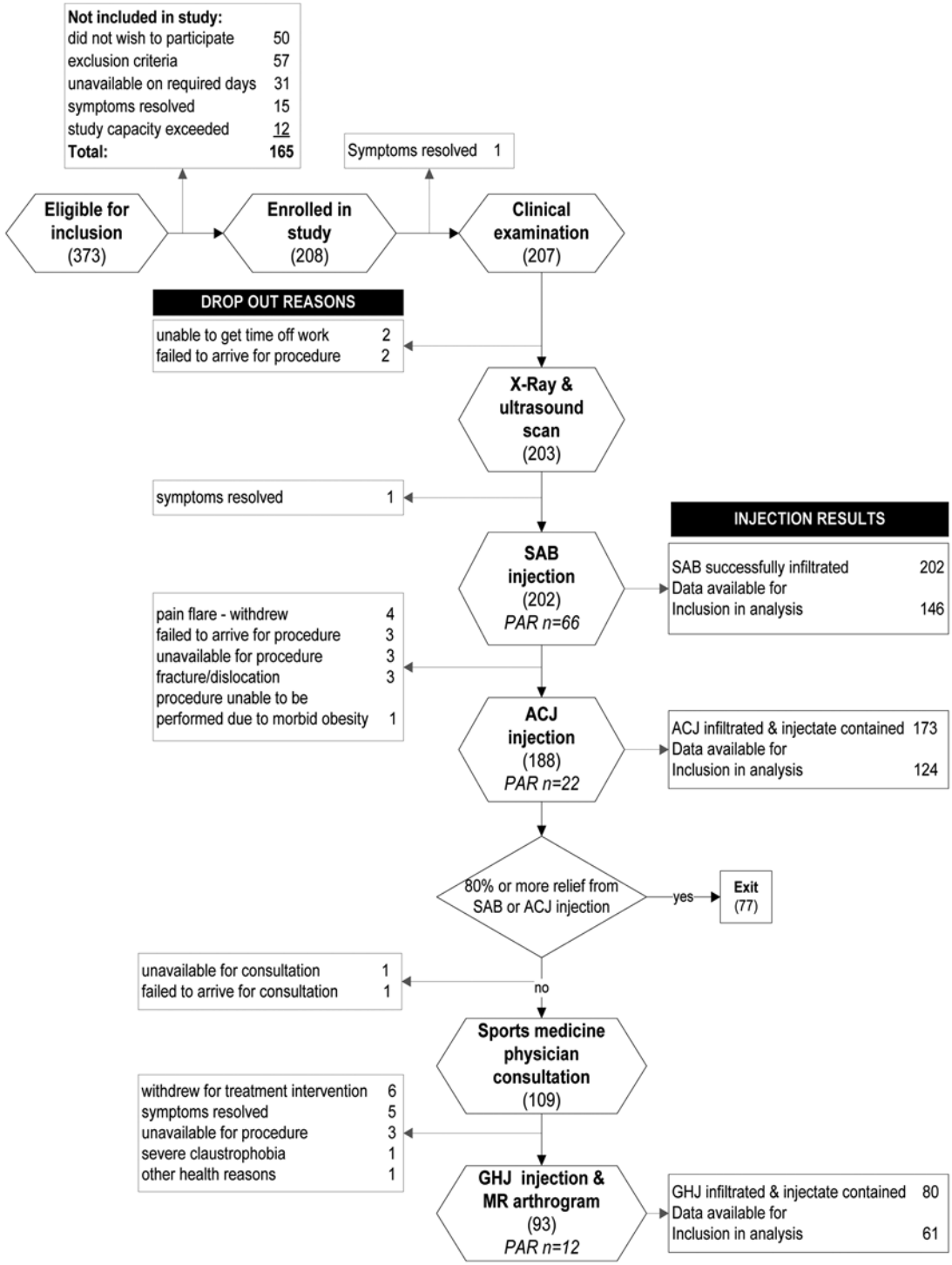


FIGURE 1. Flow diagram of patient flow through the study. ACJ indicates acromioclavicular joint; GHJ, glenohumeral joint; SAB, subacromial bursa.

were undertaken for 3 anatomical sites: SAB, ACJ, and the GHJ. Exploratory data analysis assessed normality of the distribution of the data. Thereafter, Lin concordance statistic[24] was used to assess the degree of association between Trad-RPIC and DM-RPIC methods. This statistic provides an assessment of the intercept being 0 and how far the slope of agreement between the 2 measures deviates from 1. The statistic can vary between 0 and 1, with 1 being perfect agreement. Data were plotted using Bland and Altman graphs[25] enabling an appreciation of the distribution of error between the Trad-RPIC and DM-RPIC methods (Figs. 2–4). Bland and Altman's Bias and 95% Limits of Agreement were calculated. The former refers to the mean of the difference scores, and the latter as the bias plus or minus 1.96 times

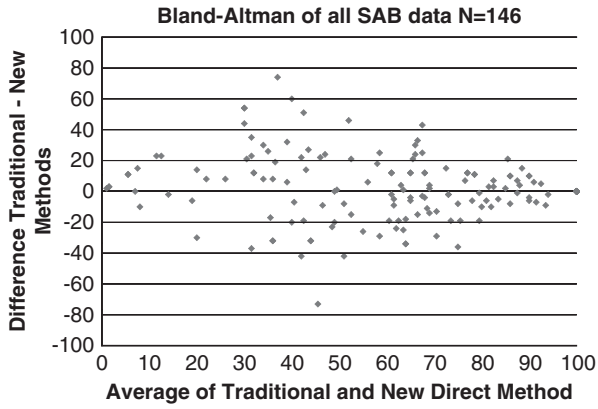


FIGURE 2. Bland and Altman plots between the traditional serial visual analog scale rapid pain intensity change method and direct method of rapid pain intensity change for subacromial bursa (SAB) injection subset.

its standard deviation. Typical Errors[26] were calculated by dividing the standard deviation of all participants' difference scores by the square root of 2. The difference scores were the Trad-RPIC—DM-RPIC methods for each participant. A subanalysis using the above mentioned statistical tests was also undertaken for pain decreases of 80% or more. The choice of 80% was arbitrary, but has been used previously[15,17,18,27,28] examining the effect of LA injections. In this subanalysis, a cross-tabulation table was also generated to establish the level of misclassification across the 2 pain measurements using the 80% or greater reduction in pain criterion (Table 2).

RESULTS

Three hundred seventy-three patients were referred for possible inclusion in the study. After removal of cases where Trad-RPIC and DM-RPIC data were incomplete, 146 participants received an LA injection into the SAB, 124 received an LA into the ACJ, and 61 received an LA into the GHJ. The demographic characteristics of these groups are presented in Table 1.

The level of association and error across the Trad-RPIC and DM-RPIC is presented in Table 2. It shows that for all levels of pain reduction, Lin concordance statistic

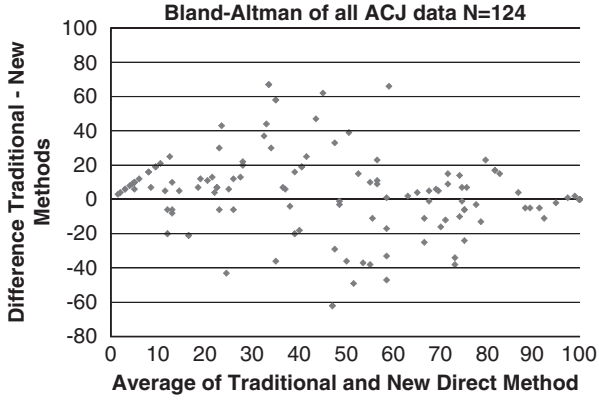


FIGURE 3. Bland and Altman plots between the traditional serial visual analog scale rapid pain intensity change method and direct method of rapid pain intensity change for acromioclavicular joint (ACJ) injection subset.

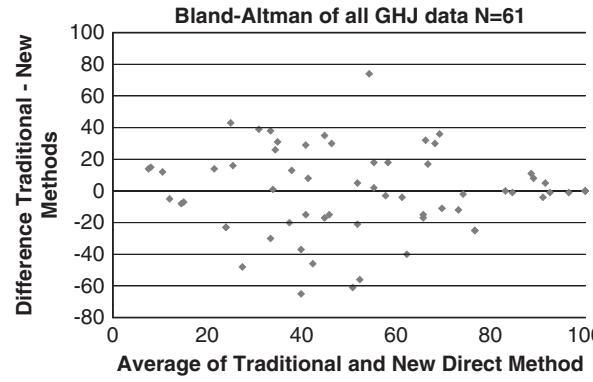


FIGURE 4. Bland and Altman plots between the traditional serial visual analog scale rapid pain intensity change method and direct method of rapid pain intensity change for glenohumeral joint (GHJ) injection subset.

varied from 0.57 to 0.74 across the clinical conditions. For data above the 80% pain reduction criterion, Lin Concordance statistic was generally lower and ranged from 0.22 to 0.55 across conditions.

In respect to the Bland and Altman analyses, the bias was positive for all data indicating that the amount of reported pain reduction was higher when the Trad-RPIC was used. For all pain reduction data, the bias was relatively low and ranged from 0.2% to 3.7% across the anatomic sites. For data above the 80% pain reduction criterion, the bias was higher and ranged from 4.8% to 12.6% across the anatomic sites. Bland and Altman plots showed a pattern of error (Figs. 2–4) in which the greatest error was observed in the mid range of pain reduction for all clinical conditions. Across anatomic sites, for all pain reduction data, the typical error ranged from 14.6% to 19.1% and for data above the 80% criterion, the typical errors were between 7.5% and 15.3%. Using the 80% criterion, the cross-tabulation of data showed that 8%, 13%, and 15% of participants would be classified differently after ACJ, GHJ, and SAB injections respectively, using the new method.

DISCUSSION

In clinical practice, patients are often asked to provide a pain level for a bothersome activity or may be asked how pain level changes with treatment. This study compared 2 different methods of assessing change in pain over a short time span and investigated whether they might be used interchangeably in clinical examinations. The key finding was that there is notable variation in the data obtained from the 2 methods of pain measurement. The highest levels of agreement were observed for the SAB and the ACJ data and these could only be rated as moderate at best. Furthermore, the typical error was relatively high across the 3 anatomic sites. Thus, the 2 methods cannot be used interchangeably with confidence. This conclusion is different from Cepeda et al[29] who examined patients with acute posttraumatic and postsurgical pain who received intravenous opioids. On the basis of limits of agreement that were up to 17%, Cepeda et al argued that the 2 methods could be used interchangeably as the level of "determinable pain reduction" by patients was 20%. However, if one uses the same criteria in this, the levels of agreement were notably higher than 20%.

TABLE 1. Demographic Profile of Included Patients

	Subacromial Bursa Injection					Acromioclavicular Joint Injection					Glenohumeral Joint Injection				
	N	Min.	Max.	Mean	Std. Deviation	N	Min.	Max.	Mean	Std. Deviation	N	Min.	Max.	Mean	Std. Deviation
Age (y)	146	18	81	43	14	124	18	79	42.64	14.02	61	18	81	42.48	13.54
Duration of symptoms from onset (d)	146	6	1230.00	86.56	124.66	124	6.00	1230.00	102.99	161.44	61	8.00	849.00	91.33	123.35
SF-8-mental health score	145	31.6	56.80	50.21	7.38	124	31.60	56.80	50.67	7.06	61	31.60	56.80	50.40	7.44
SF-8-mental component score	145	28.0	65.80	52.61	8.32	124	26.70	65.50	52.56	8.35	61	30.20	62.80	52.83	7.52
SPADI-Pain score (%)	145	0	100.00	51.37	21.42	124	0.00	100.00	49.79	20.92	61	0.00	100.00	49.97	21.51
SPADI-disability score (%)	145	0	96.00	31.11	22.71	124	0.00	96.00	28.60	21.45	61	0.00	96.00	28.82	21.53
FABQ-work score (%)	141	0	78.00	26.38	23.24	120	0.00	78.00	23.85	22.53	60	0.00	74.00	26.05	24.11
FABQ-physical activity score (%)	143	8	100.00	64.54	21.78	122	0.00	100.00	62.57	21.91	61	0.00	100.00	66.75	20.93
FABQ-general score (%)	143	0	79.00	26.87	16.95	122	0.00	75.00	26.71	15.63	61	0.00	78.00	28.31	18.29
	N	%				N	%				N	%			
Male	74	50.7				66	53.2				40	65.6			
Right side affected	76	52.1				62	50.0				27	44.3			

FABQ indicates Fear Avoidance Beliefs Questionnaire; Max., maximum; Min., minimum; N, number; SF-8, Short Form 8 questionnaire on general health status; SPADI, Shoulder Pain and Disability Index Questionnaire; Std Deviation, Standard Deviation.

Our data suggest that the patients' understanding and interpretation of the Trad-RPIC and DM-RPIC are different within the context of a standardized and thorough explanation and protocol. A key point of difference between the Trad-RPIC and the DM-RPIC is the terms used to describe maximal endpoints reflecting the different dimensions the 2 methods refer to. That is, 100 described as "worst imaginable pain" in the traditional method, whereas in the new method, the dimension of change is used—"very much worse." Imagination may differ notably across patients depending upon their previous experiences of pain, their "psyche" on the day of testing, contributing to variations in their assessment of such pain. The Trad-RPIC also requires more cognition as the patient has to gauge the amount of pain generated during the clinical testing procedure in relation to their worst imaginable pain. If the type of pain that is worst imaginable is different in character from that generated during the clinical procedure, this might hinder their ability to score it accurately. Another consideration when using the Trad-RPIC is the scenario when a patient reports low pain intensity on the day of the diagnostic procedure, the inherent measurement error in placing a mark on a straight line is magnified, and the advisability of proceeding with diagnostic injection is questioned.[6] However, low preprocedure scores are not uncommon as pain often varies considerably through each day and from day to day. With low initial pain intensity scores, percentage changes in pain postprocedure are magnified even though the absolute change may be quite small. For example, if the preprocedure score is 15/100 and the postprocedure score is 10/100, the percentage change is −33.3%, yet the absolute change is just 5 points, which is probably within the range of error inherent in the process of placing a mark on a straight line.

In contrast, when using the DM-RPIC, the patient needs only to establish a memory of the pain intensity for the pain experienced during the clinical test and that memory can serve as a starting point without a need for it to be quantified and scored. Unlike the Trad-RPIC, the DM-RPIC requires only that the patient recall the intensity of pain before the procedure, and estimate how much better or worse the pain is after the procedure and therefore has

TABLE 2. Error Statistics Associated With the 2 Different Pain Change Assessment Techniques

Condition	Sample N	Concordance*	Bias	95% L of A†	Typical Error
SAB (all data)‡	146	0.74 (0.68)	1.8	−39 to 42	14.6
SAB (> 79%)§	47	0.55 (0.44)	4.8	−16 to 26	7.5
ACJ (all data)	124	0.74 (0.68)	3.7	−41 to 48	16.1
ACJ (> 79%)	22	0.29 (0.11)	5.2	−26 to 36	11.2
GHJ (all data)	61	0.57 (0.42)	0.2	−53 to 53	19.1
GHJ (> 79%)	15	0.22 (0.05)	12.6	−30 to 55	15.3

*Data are Lin concordance statistic and 95% lower confidence level.
†95% limits of agreement.
‡Pain reductions between 0% and 100%.
§Pain reductions > 79% using traditional serial VASs.
ACJ indicates acromioclavicular joint; GHJ, glenohumeral joint; SAB, subacromial bursa; VAS, visual analog scale.

inherent recall bias. Although the problem is acknowledged, the time after the injection to the time of the test is relatively short (5 to 15 min), and in our experience, patients have not expressed difficulty with this issue.

It must be noted that we do not recommend abandoning the Trad-RPIC instrument. The DM-RPIC may be used to replace only 1 part of the diagnostic LA pain intensity measuring procedure. The use of the traditional 100 mm VAS scale for estimation of pain intensity preprocedure and for estimating the duration of pain relief using serial VAS instruments postprocedure as recommended by the International Spinal Intervention Society, remains valid and important. We recommend that the DM-RPIC replace only that part of the measurement procedure that estimates percent change, which is the basis for determining if the patient is categorized as a "responder" or a "nonresponder" to LA.

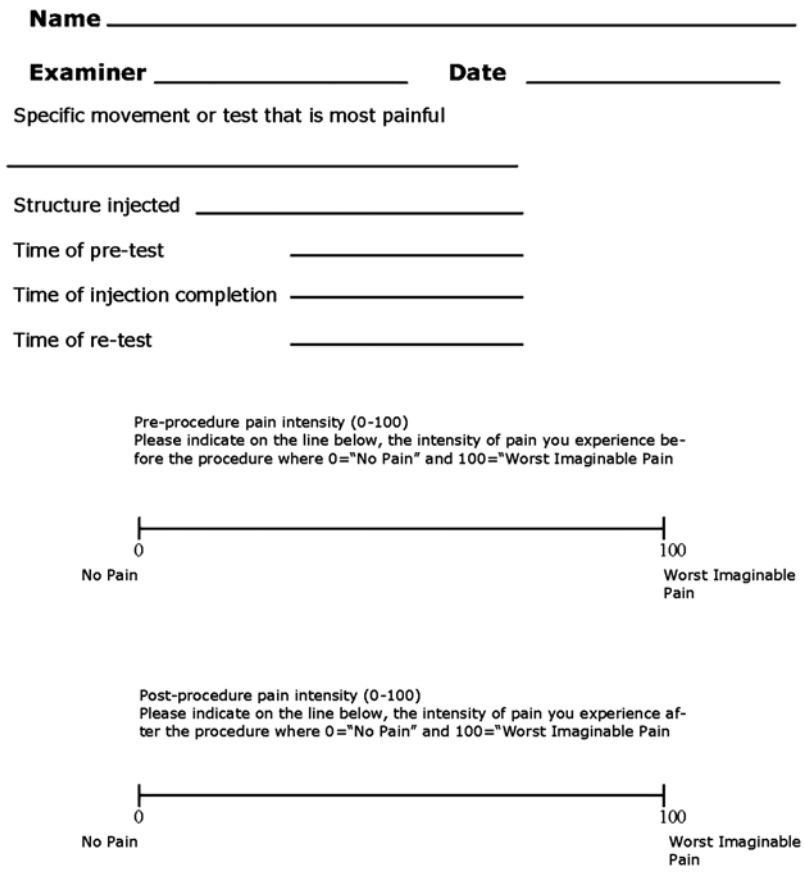
In this study, a greater amount of pain reduction was observed when using the Trad-RPIC, the amount varying according to clinical condition. This finding was in contrast to Cepeda et al[29] who noted a 3% underestimation of pain when using patient reported percentage pain reduction. In both studies, if one considers the overall data sets, the clinical relevance of our respective findings related to bias is low. In this study, we noted that greatest errors were apparent with moderate reductions (30% to 50%) in pain. Cepeda et al also noted increased errors across 2 methods at higher pain levels (> 30%).

In interventional radiology and spinal injection procedures, placebo or comparative blocks are considered the minimum standard for classifying a patient as a "responder" or "nonresponder." One possible criticism of this study is that only single anesthetic blocks were used in the diagnostic procedures. To our knowledge, there are no published data of the false-positive rate for diagnostic anesthetic injections into the joints and structures of the appendicular skeleton. It is reasonable to presume that a false-positive rate for these injections will be similar to what has been reported in the interventional spinal diagnostic literature.[8] This analysis does not, however, evaluate the diagnostic accuracy of any index test, but simply compares 2 methods of patients' reports of pain intensity change, and so the problem of diagnostic false positives does not arise. The 2 methods compared in this study may, however, be used to evaluate the diagnostic false-positive rate.

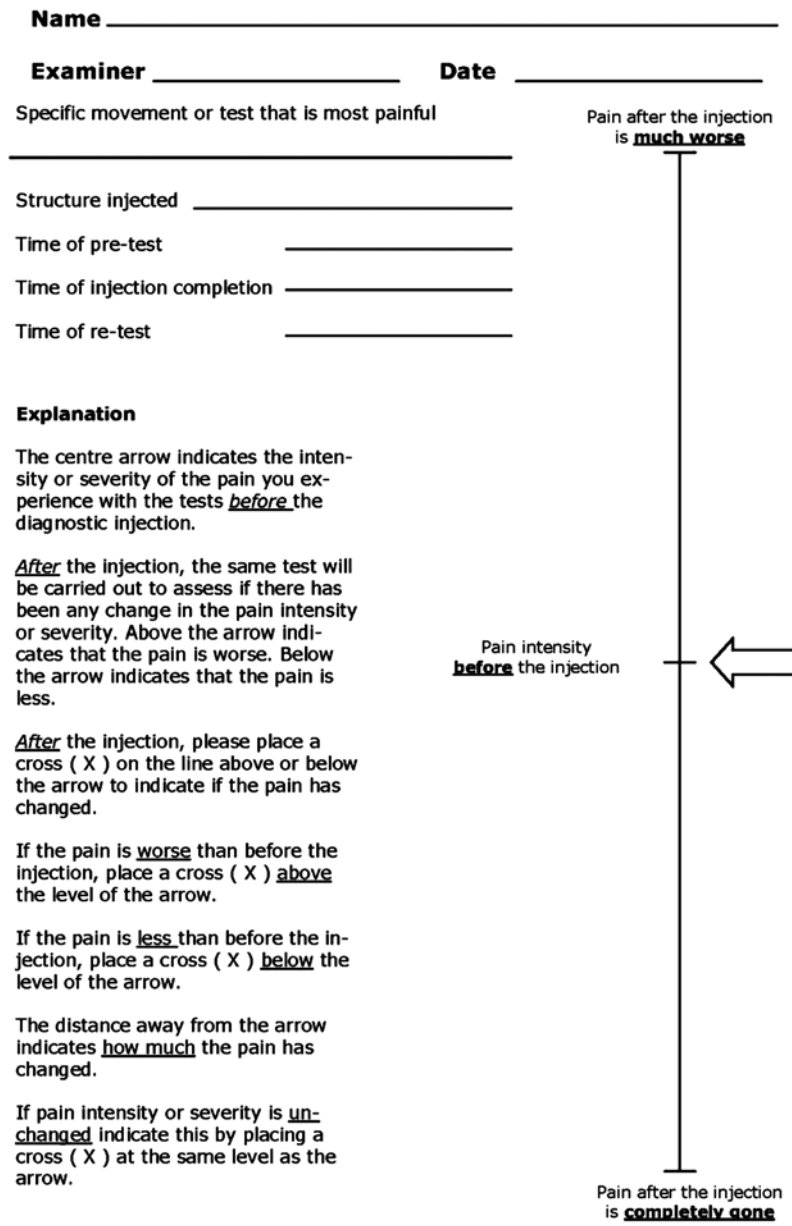
CONCLUSIONS

The 2 methods are not interchangeable, which inevitably raises the question which method is better at acquiring the information sought. Because the DM-RPIC measures the dimension of pain intensity change directly, face validity is better served by adopting the new method for concluding that the patient is a responder or nonresponder to diagnostic blocks. Further studies that assess cognitive factors and their influence upon the techniques used would be of value.

Appendix 1. The traditional serial VAS instrument for measuring rapid pain intensity change (Trad-RPIC).



Appendix 2. The Direct Method of Rapid Pain Intensity Change (DM-RPIC) instrument.



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