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Original article

Are there risk factors for musculoskeletal procedural pain? A national prospective multicentre study of procedural instantaneous pain and its recall after knee and spine injections

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ABSTRACT

Background: Little is known about the risk factors for procedural pain during spinal and joint injections.
Methods: In this prospective national multicentre study, procedural pain was investigated by rheumatologists who visited four consecutive patients undergoing synovial aspiration and infiltrations of the knee (K), and four consecutive patients undergoing spinal (S) injections. Pain assessments were carried out just before, during, and 48 hours after the procedure.
Results: The 249 rheumatologists enrolled 1350 patients (720 K and 630 S; 64 ± 14 years, 64.6% female). Instantaneous procedure-induced pain was reported in 76.1% of cases, was generally mild (mean 2.6 ± 2.5 on 10) and not different between the two sites. The frequency of procedure-induced pain increased significantly with pain related to the underlying disease and level of anxiety before the procedure. Procedure-induced pain was recalled after 48 hours later by 66.2% of the patients, with an intensity of 2.4 ± 2.6. The recall of procedure-induced pain increased with pain due to the underlying condition, with the intensity of instantaneous procedure-induced pain, with the level of anxiety, but was less frequent if the patient underwent the procedure for the first time. Patients' and physicians' estimates of procedural pain were poorly concordant (kappa coefficient 0.45), physicians tended to overestimate the frequency of pain but to underestimate its intensity.
Conclusion: Procedural pain is common, but mild, in patients undergoing musculoskeletal injections. Instantaneous procedural pain and its recall 48 hours later depend principally on the level of underlying pain and anxiety, regardless of the injection site and the analgesic procedure performed.

1. Introduction

Many procedures commonly performed in acute and critical care settings are known to be painful to patients [1–3], however, about two thirds of patients undergoing medical procedures receive no analgesic medication [1].

Very few studies have investigated the pain induced by intra-articular and soft tissue injections [4–8]. The intensity of procedural pain in musculoskeletal conditions and their risk factors have never been described. Most of the published studies on procedural pain were carried out in children, with the local application of anaesthetic cream before puncture [3] and arterial cannulation [9].

The identification of risk factors for procedural pain is an important step towards improving the quality of care offered to patients suffering from musculoskeletal pain, and may help to improve the definition of specific management practices for procedural pain. A large programme on procedural pain in rheumatology was developed in France, with several steps. The first step was an epidemiological cross-sectional study during 1 month, in 249 rheumatologists and their 8446 patients, carried out by the Pain Section of the French Rheumatology Society [10]. We present herein the second step, a prospective multicentre, cross-sectional study, in patients undergoing two of the most frequently used procedures in rheumatology, with specific differences: injections of the knee (a procedure that can be seen by the patient, in a nociceptive pain condition, both for diagnostic and therapeutic goals), and infiltrations of the spine (not visible to the patient, in a mixed pain condition, mainly for therapeutic goal). This prospective study aimed to compare procedural pain intensity assessments for these two procedures, to identify potential risk factors for procedural pain and its recall 48 hours later, and to compare the assessments of procedural pain made by patients and rheumatologists.

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2. Methods

2.1. Study design

The aim of this observational, prospective, multicentre, cross-sectional study was to identify potential risk factors for pain (whether assessed immediately or recalled 48 hours later) induced by two common procedures carried out routinely by rheumatologists. Patients undergoing synovial fluid aspiration and infiltrations of the knee (KI) or spinal infiltrations (SI) were included in the study, which was carried out by French rheumatologists between October 2006 and January 2007.

The study was conducted in accordance with the Helsinki Declaration, Good Epidemiological Practice and French regulations. All patients were provided with both oral and written information before inclusion. Information concerned the study design, the questionnaires and type of assessments but did not explain any procedures. Explanation on the procedures was performed by the physicians, as in his routine daily practice.

2.2. Patients

Each participating rheumatologist was asked to include the first four consecutive patients (> 18 years of age) with a nonmalignant condition undergoing KI and the first four consecutive patients undergoing SI, after agreeing to participate in the study. The accrual period was fixed at two months of consultations.

2.3. Selection of rheumatologists

Rheumatologists were selected from the TVF database (source CEGEDIM group), a representative database of French healthcare professionals. Information about the study and a request to participate were sent to all general rheumatologists across France. The rheumatologists contacted in the first mailing were selected at random, with stratification for administrative region.

2.4. Data collection

Pain intensity was assessed at three time points: the physician and the patient were asked to assess pain intensity just before the procedure (pain related to the underlying condition) and immediately after the procedure (instantaneous assessment of procedural pain) and the patient was also asked to recall the level of pain experienced during the procedure 48 hours later. Questionnaires were completed by the patients and the physician during the consultation and immediately after the procedure, separately and blind to each other's responses. Patients were asked to fill in a final questionnaire, sent by post, 48 hours after the procedure.

The following data were recorded for each patient: age; sex; height; weight; body mass index (BMI); the location and type of underlying condition making the procedure necessary; pain related to the underlying condition during the preceding week. Patients were also asked about their expectations of the procedure and their experience with any previous procedures.

Anxiety and depression levels were self-assessed by the patients with the French version of the Hospital Anxiety and Depression (HADs) scale [11,12]. If one set of data was missing for both scores, the missing item was replaced by the mean value for the other items [12]. If more than one response was missing, the score was considered to be missing. Physicians also assessed patients' anxiety and depression, using a Likert scale. For statistical analyses, only patients' self-assessments were included.

2.5. Evaluation of pain intensity

Pain intensity was evaluated by the physician, using one of three scales, in the following order of preference: (i) a visual analogue scale (VAS) (mm/100); (ii) a numerical scale (0–10) or (iii) a verbal scale (none, mild, moderate or severe). For statistical analyses, physicians' assessments were provided in four categories: none, mild ($\leq$ 30 mm), moderate (> 30 mm and < 70 mm), severe ($\geq$ 70 mm), Patients were asked to evaluate pain intensity with the numerical scale only, in the self-completed questionnaires.

2.6. Statistical analysis

A descriptive analysis of the characteristics of the subjects was carried out, with means and 95% confidence intervals (95% CI) reported for quantitative variables and the percentage of patients in each category for qualitative variables. The results presented are based on the patients for whom data were available. We also compared patient characteristics between the two groups defined on the basis of the procedure carried out (knee vs. spine), using Chi^2 tests or Fisher's exact tests for qualitative variables and Wilcoxon-Mann-Whitney tests for quantitative variables.

Potential explanatory variables for procedure-induced pain were selected by univariate analysis, using Chi^2 tests or Fisher's exact tests for qualitative variables, and Wilcoxon-Mann-Whitney tests for quantitative variables. Three dichotomous variables, called models, were defined for analyses: model 1: pain (intensity > 0) vs. no pain (intensity = 0); model 2: moderate or severe pain (> 30 mm or 3/10) vs. mild or no pain ($\leq$ 30 mm or 3/10); model 3: severe pain (> 70 mm or 7/10) vs. no pain to moderate pain ($\leq$ 70 mm or 7/10).

Multivariate analysis was performed by stepwise logistic regression, using the following variables. For the *explained variables*, we carried out two analyses to identify variables associated with procedure-induced pain. The first analysis compared pain (regardless of its intensity) with no pain, whereas the second compared moderate to severe pain with mild or no pain. For the *explanatory variables*, multivariate analyses were carried out with all variables identified as significant with a significance threshold of 20% in univariate analyses, with an entry threshold fixed at 10% and a threshold for conservation of 15%. These analyses were performed on patients for whom evaluations of procedure-induced pain were available. Only variables significant at the 5% level were considered further.

We evaluated the agreement between the instantaneous procedure-induced pain assessments made by patients and their rheumatologists, by calculating the kappa coefficient.

All statistical analyses were carried out with SAS® (version 8.2; SAS Institute, North Carolina, USA).

3. Results

3.1. Characteristics of the rheumatologists

The 249 rheumatologists (57.7% male; mean age 49.2 years [range 32–74 years]) each recruited a mean of 5.4 ± 1.3 patients to the study. The rheumatologists participating in this study either worked exclusively in private practice (68.1%) or in both private and hospital practice (31.4%). We did not ask rheumatologists working exclusively in hospitals to participate in this study, since we preferred to focus our study on primary care.

3.2. Characteristics of the patients

The demographic characteristics of the patients at the time of consultation are summarised in Table 1. In total, we