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ORIGINAL ARTICLE

Assessing chronic pain in general practice: Are guidelines relevant? A cluster randomized controlled trial

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Abstract
Objectives: To evaluate the impact of using pain assessment scales on the management of musculoskeletal chronic pain. *Methods:* Cluster-randomized controlled multicentre trial in French general practice settings. Practices were randomized by region before patient recruitment. The inclusion concerned patients suffering from musculoskeletal chronic pain. General practitioners assigned to the scale group used two validated assessment instruments; those assigned to the control group cared for their patients according to their usual practice. The primary end-point was the level of relief obtained and the secondary changes in prescription of painkilling modalities. *Results:* A total of 155 general practitioners included 772 successive patients suffering from musculoskeletal chronic pain. The control group reported a mean level of relief of 50.7% compared with one of 41.1% in the scale group ($p < 0.0001$). In the intervention group, physicians decreased significantly their prescription of level two painkillers.

Conclusions. In general practice, the use of pain assessment scales is not associated with greater pain relief. The lesser level of pain relief obtained in the scale group does provide evidence that using pain assessment scales does not enhance the relief of chronic pain in patients in primary care. Guidelines which recommend the systematic use of scales for the assessment and monitoring of chronic pain are not tailored to either the context or the patients encountered in the primary care setting.

Key words: *Assessment scales, chronic pain, general practice, guidelines*

Introduction

National (1) and international guidelines (2,3) emphasize the usefulness and necessity (4) of using pain assessment scales when managing outpatients suffering from chronic pain. Scales may improve prescriptions for patients with chronic pain and should thus enable more effective analgesic prescription and more pain relief especially for those patients who are under-treated. However, no study has ever been conducted to assess the impact of this strategy on the level of pain relief obtained, nor on the prescription of painkillers, neither in primary nor secondary or tertiary care.

French guidelines recommend using six assessment instruments, only two of which have been validated, namely the Visual Analogue Scale (VAS) for pain intensity and the Hospital Anxiety and Depression (HAD) scale which is not a not a pain assessment scale, but is indicated, in the French guidelines, for the global assessment of the painful patient. However, a French study has shown that only 13.5% of general practitioners used these scales, and that only 6% of patients suffering from chronic pain were concerned (5).

This study, which measures the impact of using pain assessment scales, stems from the discrepancies observed between guidelines and medical practices,

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and the absence of data showing the benefit of using such instruments in daily practice.

The research question was as follows: does the use of validated assessment scales (VAS and HAD) increase the relief of outpatients suffering from chronic non-malignant pain affecting the musculoskeletal system, which is the most frequently encountered pain in general practice (5) and in the community (6)?

The aim of this study was to compare the level of relief obtained in patients treated by physicians using scales (scale group) with that of patients treated without the use of instruments (control group). The initial hypothesis was that patients in the scale group would show more pain relief.

Method

This randomized controlled multicentre trial involved 20 regional colleges of general practitioners. All investigators were members of the French College of Teachers in General Practice at 20 different medical universities. Randomization was stratified by university, and all the physicians recruited by each university centre received the same allocation.

Investigating physicians

Ten investigating physicians were recruited by each university-based college. These investigators included the first patient complaining of chronic pain affecting the musculoskeletal system, up to a total of seven patients per investigator. The data collected included the patient's general characteristics, the diagnosis, duration and pain location, together with the painkilling treatment prescribed 1 month before the first consultation (T-1), but also at the first consultation (T0) and at the follow-up consultation (T1).

The physicians from the ten colleges randomly allocated to the scale group used two validated scales (the VAS and the HAD) at two consultations at a month's interval. The VAS is the most commonly used system measuring the intensity or magnitude of sensations and subjective feelings of pain. The scale consists of a 100-mm straight and horizontal line with verbal descriptors at each end. NO PAIN is placed at the left and WORST PAIN at the right. The patient puts a mark on the line at the point that best describes the intensity of his or her pain. The HAD scale measures the anxiety and depressive status in patients. All physicians assigned to the scale group were trained to use these instruments but received no training on painkiller strategy prescription.

The physicians randomly allocated to the control group met during 2 hours, only to discuss the observation forms for appropriation. They treated their patients as usual, unaware of the procedures used by their colleagues in the scale group. In order to avoid any contamination bias, physicians from both groups never met during the course of the study.

Inclusion criteria

All included patients were over 18 years of age, had been suffering for at least 3 months from sustained daily chronic pain, of musculoskeletal origin, affecting the locomotor system, and were regularly taking painkillers (1,6). Chronic pain affecting the locomotor system was chosen as it accounts for 43%–54% of all cases of chronic pain seen in general practice (5) and in the community (6).

Exclusion criteria were: ongoing cancerous pain, HIV infection, migraine, illiteracy and first time consultation.

End-points

The main end-point was the level of pain relief measured through the use of a numerical relief scale recommended in France (1).

No relief–0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%–Maximum relief.

This scale was given to the patient at the end of the second consultation to be scored at home 7 days later and returned to the data management centre. This end-point is of relevance as the ultimate goal of any care-related instrument is to help the patient.

The secondary end-point concerned modifications in the prescribed painkilling treatments. Analgesic drugs were classified according to the WHO classification system. The coanalgesic drugs category included non-steroid anti-inflammatory drugs, antidepressants, anxiolytic, anti-epileptic and neuroleptic drugs. The 'other drug' category included non-psychotropic muscle relaxants, various products combining different analgesics and other drugs designed to relieve pain. Lastly, a 'non-medicinal treatment' category included physiotherapy, hygiene and diet counselling, consultant advice, homeopathic treatment, thermal cures, mesotherapy, acupuncture and minor orthopaedic devices (e.g. compression bandages and orthopaedic devices).

Number of subjects required and statistical analysis

The main hypothesis was that the level of pain would be reduced by 40% in the control group (5) and by 50% in the scale group, equivalent to an absolute increase in pain relief of 10% (clinically significant)

which corresponds to a relative increase of 25%. On the basis of this hypothesis, the sample size required was calculated at 356 patients per group for a power of 80% and an alpha-risk of 5%.

The secondary hypothesis was that physicians assigned to the scale group would increased their prescriptions, after the second consultation, to a greater extent than those assigned to the control group.

Statistical comparative analysis has been made by cluster. It has described and compared patients' characteristics included in the 2 groups as well as their treatment. Pain relief was compared at T1+7 days, between scale and control groups showing the closest characteristic similarities. In addition, an internal analysis within the scale group was conducted to determine variations in the VAS and HAD scores.

Data are described in terms of either means ± standard deviation of quantitative variables, or frequency histograms of qualitative variables. The 2 groups were compared using the chi-square test for qualitative variables (or a Fisher test if the numbers were small) and analysis of variance for quantitative variables. Comparative analyses within the scale group were carried out using the MacNemar test for qualitative variables, or analysis of variance of repeated series for quantitative variables.

Results

A total of 155 physicians included 787 patients, and 772 cases could be analysed. A total of 751 patients (97.2%) attended the second consultation scheduled 1 month later, and 728 (94.3% of all patients included) returned their numerical pain relief scale results 7 days after the second consultation.

The characteristics of the physicians in terms of age, duration of professional activity, gender and level of training in pain management were comparable for both groups (Table I).

Patient characteristics at inclusion

Patient characteristics are shown in Table I. There was no significant difference between the groups. The size of the groups differs as two of the university colleges assigned to the control group included very few patients. However, the patients groups served by the physicians in the treatment and in the control group were of similar nature. Pain location was comparable in the 2 groups except for back pain (Table II).

At inclusion, painkilling treatment prescribed at T-1 was comparable in both groups—the main difference being that a larger number of patients in the scale group were taking level 3 analgesics, although the number of patients concerned was very small (Table III).

Main end-point: impact on pain relief for the patient

The mean percentage of relief expressed by the patients in the control group was 50.7% compared with 41.1% in the scale group ($p < 0.0004$) (Table IV). Patients in the scale group therefore showed 9.6% (in absolute terms) and 23.4% (in relative terms) less pain relief. Similar results were obtained when patients on level 3 analgesics were not included in the analysis.

Variations in the scale group

The mean VAS score in the scale group was 45.8 ± 26.4 mm at the first consultation and 45.2 ± 26.2 mm at the second ($p = 0.41$).

Analysis of the HAD results failed to show any significant difference between the two consultations with regards to depression. However, there was a

Table I. General physician and patient characteristics at T0 (cluster analysis).

	Scale group ($n = 10$)	Control group ($n = 9$)	p
Physicians:			
Age (years)	49.8 ± 6.4	49 ± 5.7	ns
Sex ratio (F/M)	0.13	0.12	ns
Group practice%	57.4	56.4	ns
Recent CME on pain management:			
Yes % (n)	40.8 ($n = 20$)	42.6 ($n = 20$)	ns
No % (n)	59.2 ($n = 29$)	57.4 ($n = 27$)	ns
Patients:			
Age (years)	64.7 ± 3.9	64.0 ± 5.7	ns
Male percentage%	30.5 ± 9.4	28.4 ± 15.4	ns
Treatment history (years)	12.2 ± 1.5	12.7 ± 2.1	ns
Pain duration (years)	9.8 ± 2.4	9.1 ± 2.2	ns

Table II. Location of chronic pain affecting the musculoskeletal system at T0 (cluster analysis).

	Scale group $n=10$ (%)	Control group $n=9$ (%)	p
Cervical	7.8±4.0	6.5±4.8	ns
Scapular	5.2±3.8	7.5±5.2	ns
Back pain	29.8±10.7	41.9±11.4	0.03
Hip	5.4±3.2	5.2±2.8	ns
Leg	10.7±5.3	7.6±5.6	ns
Knee	14.2±7.5	17.5±6.2	ns
Extremities	4.1±3.0	6.8±5.4	ns
Multiple joints	27.3±13.2	14.4±12.5	ns
Others	16.1±7.9	11.9±7.3	ns

significant increase in the number of patients no longer showing signs of anxiety ($p<0.04$).

Secondary end-point: impact on drug prescription

Except for level 3 painkilling drugs, painkiller prescriptions were similar in both groups at inclusion (Table III). At T1, level 2 painkiller prescriptions significantly decreased in the scale group, as well as within this group between T-1 and T1 ($p=0.035$), and between the 2 groups at T1+7 days ($p=0.003$) (Table V).

Discussion

This study shows that the use of assessment scales for pain evaluation in general practice does not help patients suffering from chronic pain affecting the musculoskeletal system. On the contrary, patients in the scale group were significantly less relieved than patients in the control group. However, this statistical observation does not necessarily have any clinical relevance.

Within the scale group the level 2 painkiller prescriptions decreased, while it did not change in the control group. Between the 2 groups, the scale group significantly decreased its prescription of level 2 painkillers. At inclusion, more patients in the scale group were taking level 3 analgesic drugs suggesting that they were suffering from a more intense pain

Table III. Painkilling treatments prescribed at T-1 (cluster analysis).

	Scale group $n=10$ (%)	Control group $n=9$ (%)	p
Level 1	34.7±10.6	42.9±18.4	ns
Level 2	42.2±5.9	44.1±19.6	ns
Level 3	7.5±5.6	2.5±2.1	0.02
Co-analgesics	46.0±7.6	38.7±7.5	ns
Other drugs	21.6±7.1	27.3±13.5	ns
Non-medicinal treatments	44.3±10.2	44.9±11.1	ns

Table IV. Mean relief at T1+7 days.

	Scale group ($n=10$)	Control group ($n=9$)	p
Mean relief at T1+7 days (%)	41.1±4.6	50.7±4.8	0.0004
Not including patients on Grade 3 analgesics (%)	40.8±4.0	50.7±4.2	0.0001

which could explain why less pain relief was observed in this group. However, the overall number of these patients was very small and the difference in the relief reported by the 2 groups remained unchanged when these patients were excluded from the analysis. Lastly, the high overall patient response rate (94.3%) enhances the validity of the results.

There is no published data available showing the impact of using assessment instruments to evaluate chronic pain in outpatients. One randomized controlled study conducted in French hospitals (7) addressed the efficiency of an educational programme for nurses in surgical units for acute pain. The results showed that nurses who had benefited from such training were more likely to use the VAS, although this did not have a real impact on pain levels for patients.

How can we explain this surprising result which supports routine general practices and goes against published recommendations (1)?

- Perhaps the difference in pain relief observed at the end of the study was already present at baseline. Nevertheless, it was not possible to measure pain relief in the 2 groups at inclusion. This measurement needed to use a pain relief scale in the control group, which could input a big methodological bias. The similarities between the 2 groups according to general patients' characteristics, pain location and treatments are in favour of similar pain level at baseline.
- Introducing a measurement instrument into a long-standing relationship (12 years in average) to evaluate long-lasting chronic pain (9 years) can disturb the patient/physician relationship.
- The use of instruments to provide a more objective evaluation of pain can alter the scale group patients' perception of such pain.
- The use of the scales might lead to improved pain relief and altered prescription of medication over a longer period than 1 month.
- Hypothesizing that at inclusion the pain level was comparable in the 2 groups (VAS = 45.8 mm), physicians in the scale group could consider that this moderate intensity did not justify level 2 painkiller prescriptions. So, they

Table V. Evolution of painkilling prescriptions between T-1 and T1 within group and between groups.

	Scale group T-1 ($n=10$)	Scale groupT1 ($n=10$)	p within scale group	Control group T-1 ($n=9$)	Control group T1 ($n=9$)	p within control group	p between groups
Level 1	34.7±10.6	29.6±9.9	0.17	42.9±18.4	34.2±12.4	0.27	0.38
Level 2	42.2±5.9	35.4±6.3	0.035	44.1± 19.6	47.7±8.8	0.45	0.003
Level 3	7.5±7.6	7.2±4.7	0.73	2.5±2.1	1.8±2.5	0.51	0.007
Co-analgesics	46.0±7.6	38.4±11.4	0.08	38.7±7.5	33.0±15.1	0.22	0.38
Other drugs	21.6±7.1	19.0±5.3	0.27	27.3±13.5	22.9±11.5	0.51	0.34
Non-medicinal treatments	44.3±10.2	33.8±11.8	0.07	44.9±11.1	39.3±12.5	0.19	0.30

significantly decreased their prescriptions of these drugs which can explain a lower relief in this group at the end of the trial.

- Despite training and an attempt to standardize the use of scales, the physicians allocated to this group may not have correctly used these instruments (8).
- In a 9-year long-lasting relationship, two assessments using the scales, at a 1-month interval, may be not sufficient enough to determine their usefulness. The likelihood of detecting a change in these patients could be found with a longer follow-up.
- It is possible that medical practices, patient behaviour and results could have been modified through a Hawthorne effect.
- The results of this study question some main beliefs. It is possible that assessment scales can be useful in managing intense, refractory pain in hospitalized patients or at the first consultation at a pain management centre. In these cases, such assessments can provide accurate, reproducible information for the multiple care providers involved in following the patient. However, such instruments are not necessarily relevant in other contexts. At the general practice level, the relationship between physician and patient is personal and long-lasting.

General practitioners do not see the relevance of scales as their knowledge of the overall situation coupled with their 'empirical' assessment of the patient during the course of the interview allows them to give an accurate evaluation.

Therefore, this study raises the question of the validity of guidelines for outpatient clinical practices (9). The guidelines reflect the recruitment, experience and habits of physicians other than general practitioners. Furthermore, they are based on experimental scientific data taken from studies in secondary or tertiary care (specialized or hospital settings) that are different from general practice.

The patients, health problems, physicians, pain intensity and resistance to treatment, care and social and cultural environment (10,11), are specific factors in primary care. Instruments which could be useful in one context may not be in another (12). Before recommending such instruments to all health care providers, they should be evaluated in the context in which they are to be used. This concept raises the problem of the ranking of clinical practice guidelines according to the level of health care provision. It is difficult to suggest advice on decision making to all physicians regardless of their field of practice.

The results of this study show that, when it comes to managing non-malignant chronic pain in outpatients, a discrepancy exists between the guidelines and daily practice. This discrepancy is associated with inadequate recommendations rather than inappropriate practices. Other studies should be envisaged to confirm this result and should be extended to more specialized medical fields and to countries with different health care systems. To reduce any discrepancies, the guidelines should be tested in the environments in which they are to be applied.

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