Specificity and sensitivity of objective tests to detect possible malingering in fibromyalgia: a case-control study in 211 Spanish patients

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ABSTRACT

Objective. *To characterise patients diagnosed with fibromyalgia (FM) who present a clinical profile suggestive of simulation.*

Methods. *Observational case-control study of 218 patients who met the classification criteria for FM. The profile supporting simulation was based on the proposed criteria for evaluating disability related to the simulation of pain.*

Results. *Compared with controls (n= 105), patients with suspected simulation of FM (n = 106) had a higher mean age (52.5 vs. 49.2 years, p=0.003), a higher frequency of primary education (88.7% vs. 58.1%; p<0.001), a higher percentage of separated/widowed persons (33.9% vs. 8.6%, p<0.001), a higher frequency of psychiatric disorders (100% vs. 67.6%, p<0.001), a higher mean number of positive "control" tender points (4.5 vs. 1.3, p<0.001), a higher mean FIQ questionnaire score (89.8 vs. 68.8, p<0.001) and a lower mean LHS questionnaire score (41.0 vs. 59.9, p<0.001). Patients with suspected simulation were able to walk a shorter distance in the 6-minute walk test than controls (231.0 vs. 356.3 metres, p<0.001), while the appearance of allodynia was achieved with a significantly lower mmHg pressure (159.8 vs. 229.9 mm Hg, p<0.001).*

Conclusion. *Some physical/functional tests, together with the administration of specific questionnaires, may identify a subgroup of patients with FM with a profile consistent with simulation or malingering; these patients have a differentiated demographic and psychiatric profile in comparison with FM patients without a profile of simulation.*

Introduction

Fibromyalgia (FM) is one of the leading causes of chronic pain. It is characterised by widespread chronic pain that patients locate mainly in the musculoskeletal system, and which presents with exaggerated hypersensitivity at multiple preset points (trigger and tender points) without demonstrable organic changes (1). Typically, FM is associated with a range of non-specific somatic complaints, notably persistent fatigue, restless sleep, joint stiffness, and anxiety-depressive symptoms (2). FM was recognised as a disease by the World Health Organization (WHO) in 1992, and typified in the International Classification of Diseases (ICD-10) manual with the code M79.0 (3). However, given the absence of specific organic pathology, the lack of an objective confirmatory diagnostic test, the frequent association with psychopathological problems and the substantial impact on healthcare resources (4, 5), the diagnosis of FM is often associated with conflictive clinical situations and scientific controversy (6).

The impact of FM on the quality of life causes significant limitations in productive capacity and may result in about 50% of patients being incapable of working (7). However, the lack of diagnostic criteria based on objective data, apart from the history and physical examination, has led some experts to suggest that some patients may mimic the signs and symptoms required for the diagnosis (8) or exaggerate and amplify them (9, 10). Access to new information technologies makes it very easy to accumulate prior knowledge of the signs and symptoms of FM and, more importantly, the way in which physicians make a diagnosis of FM based

on exclusively-subjective clinical data. A common problem for the physician is diagnosing FM in a patient who may benefit financially from the diagnosis. In this situation, it is plausible to suspect possible simulation of the signs and symptoms the patient presents. Although studies have suggested some discriminatory tests when simulation of FM is suspected (11, 12), no studies have evaluated this issue specifically in a multidimensional form in a specialised FM clinic, unlike the approach taken by studies that have evaluated the simulation of pain in clinical practice (13). The aim of this study was to evaluate the characteristics of a group of patients with suspected simulated FM by simultaneous evaluation of physical and functional tests together with the administration of questionnaires.

Patients and methods
Design
We carried out an observational case-control (1:1) study in 218 consecutive patients of both sexes referred from primary healthcare centres and attended for the first time between January 2009 and August 2012 by the FM Unit of the Hospital 9 d'Octube (Valencia, Spain). The inclusion criteria were: i) age between 18 and 65 years of age, ii) fulfilment of the FM classification criteria proposed by the American College of Rheumatology (14), and iii) written, informed consent to participate in the study. Exclusion criteria were i) permanent disability, ii) refusal to participate in the study and iii) physical and/or mental incapacity to complete self-administered questionnaires. The study was approved by the Clinical Research Committee of the Hospital 9 d'Octube, and complied with the ethical standards of the Helsinki Declaration of 1975 (revision of October 2000).

Measurements
At enrolment, all patients were assessed by the principal investigator (RBP). After fulfilment of the inclusion criteria, patients were examined to determine whether they presented a profile suggesting simulation (15) according to the criteria proposed by

Bianchini *et al.* in 2005 (16) for the assessment of disability related to the simulation of pain:
1. Patient-reported symptoms substantially divergent from those normally corresponding to FM, with vocalisation of an unusual pattern of clinical intensity and variety.
2. Evidence of possible significant external incentives (request for permanent disability) at the first visit.

Patients who met these two criteria were classified as cases (suspected simulation). Each case was matched with a control patient who was assessed for FM on the same day and did not meet the criteria for simulation. After the initial assessment visit, the patient was escorted to another room where two investigators (RMMG and JFPO), who were blinded to the initial assessment by RBP, administered the following examinations and self-reported questionnaires that are used in the evaluation of patients with FM:
1. Assessment of" control" or "false" fibromyalgic points (11, 12), which are not usually more than 2-3 in patients with FM.
2. Six-minutes walk test (in metres). Patients with FM normally walk a shorter distance than patients without FM (17).
3. Allodynia test, induced by sphygmomanometer (18). The induction of pain or myalgia after the application of the sphygmomanometer is achieved with a lower pressure (in mmHg) in patients with FM than in those without (17).
4. *Fibromyalgia Impact Questionnaire* (FIQ). We used the translated and validated Spanish version of the FIQ (19). The theoretical range of the instrument is between 0 (minimum impact of the disease) and 100 (maximum impact).
5. *London Handicap Scale* (LHS). We used the translated and validated Spanish version of the LHS (20). The scale value corresponds to residual function, and the theoretical range of the instrument is between 0 (maximum handicap) and 100 (normal function).

In addition, two investigators (CGG and ASC) collected the following vari-

ables from the medical record of each patient: epidemiological and sociodemographic data (age, sex, ethnicity, marital status and educational level), and psychiatric disorders (DSM-IV-AP classification (ICD-9-CM)). After the publication of a new proposed classification criteria for FM in 2010 (21), we contacted all patients in order to retrospectively apply these criteria, including the *Widespread Pain Index* (WPI), which comprises a 19-item checklist; the patient marks the number of body parts where they have experienced pain during the last week, and the *Symptom Severity Score* (SSSC), which comprises unrefreshing sleep, fatigue, and cognitive issues - three hallmarks of fibromyalgia, with symptoms rated on an ascending scale of severity from 0 to 3.

Statistical analysis
Categorical variables were expressed as absolute frequencies (%). Continuous variables were expressed as means and standard deviations. Possible associations between categorical variables were measured using Fisher's exact test. Normally distributed continuous variables were assessed using the Student t-test and continuous variables with skewed distributions were measured using the non-parametric Mann-Whitney U-test. The sensitivity, specificity and area under the ROC curve (AUC) were calculated for the diagnosis of suspected simulation according to the questionnaires and examinations administered. A value of $p \leq 0.05$ was considered statistically significant. The 95% confidence intervals (CI) were calculated. The statistical analysis was made using the R v2.15.1 for Windows statistical package.

Results
Description of the sample
Of the 218 patients evaluated during the study period, 5 (2.3%) declined to participate and 2 (0.9%) were excluded due to incomplete questionnaires (1) or physical limitations to completing the questionnaires autonomously (1).
Therefore, 211 patients, aged 25–65 years, mean age 50.9 years, 204 female (96.7%), all self-described as

White European, were included in the final analysis. The criteria of Bianchini *et al.* (16) for simulation were met by 106 patients, and 105 patients were assigned to the control group.

Comparative statistical analysis

Table I summarises the main epidemiological and sociodemographic variables and the DSM-IV diagnosis of psychiatric disorders in the two groups. Patients classified as suspected simulation had a higher mean age (52.5 *vs.* 49.2 years, *p*=0.003), but no differences were found with respect to sex (97.2% female *vs.* 96.2% female, *p*=0.721).

Patients suspected of simulation had a higher prevalence of primary education only (88.7%), while controls had a higher prevalence of secondary or university education (58.1%, *p*<0.001). The percentage of separated/widowed status was higher in patients with suspected simulation (33.9% *vs.* 8.6%, *p*<0.001).

All patients suspected of simulation had some type of psychiatric involvement according to DSM-IV codes, compared with 71 controls (100% *vs.* 67.6%, *p*<0.001). There were no differences in the percentage of patients categorised as having mild/severe anxiety (25.5% *vs.* 25.7%) but there was a higher frequency of adjustment disorder (34.9% *vs.* 21%) and mild/severe depression (39.6% *vs.* 20.9%) in patients suspected of simulation.

Characterisation of fibromyalgia

Table II shows the results of the physical and functional tests and the answers to the questionnaires.

On physical examination, patients suspected of simulation had a mean of 17 painful points compared with 13.8 in controls (*p*<0.001). Patients suspected of simulation had a mean of 4.5 positive control or false painful points compared with 1.3 in controls (*p*<0.001). Patients suspected of simulation had significantly higher scores in the WPI index (16.9 *vs.* 12.9, *p*<0.001) and the SSSC index (9.6 *vs.* 6.8, *p*<0.001).

Patients suspected of simulation had a significantly higher mean score in the FIQ questionnaire (89.8 *vs.* 68.8, *p*<0.001), and a significantly lower

Table I. Sociodemographic characteristics and classification of psychiatric involvement: comparison between patients suspected of simulation and control patients.

	Suspected simulation (n=106)	Control FM (n=105)	*p*-value
Age, years	52.5 ± 7.1	49.2 ± 8.6	0.003
Sex, female	103 (97.2%)	101 (96.2%)	0.721
Educational level			<0.001
- No education	0 (0%)	1 (0.9%)	
- Primary	94 (88.7%)	43 (41.0%)	
- Secondary	12 (11.3%)	48 (45.7%)	
- University	0 (0%)	13 (12.4%)	
Marital status			<0.001
- Single	6 (5.7%)	8 (7.6%)	
- Separated/divorced	31 (29.2%)	7 (6.7%)	
- Widowed	5 (4.7%)	2 (1.9%)	
- Married	64 (60.4%)	88 (83.8%)	
DSM-IV-AP (ICD-9-CM) diagnosis			<0.001
- None	0 (0%)	34 (32.4%)	
- Mild depression	34 (32.1%)	14 (13.3%)	
- Severe depression	8 (7.5%)	8 (7.6%)	
- Mild anxiety	25 (23.6%)	21 (20.0%)	
- Severe anxiety	2 (1.9%)	6 (5.7%)	
- Adjustment Disorder	37 (34.9%)	22 (21.0%)	

Table II. Application of the classification criteria for FM, physical and functional tests and questionnaires: comparison between patients suspected of simulation and control patients.

	Suspected simulation (n=106)	Control FM (n=105)	*p*-value
Number fibromyalgic points	17.0 ± 1.3	13.8 ± 1.6	<0.001
Number control points	4.5 ± 0.8	1.3 ± 1.5	<0.001
WPI index score	16.9 ± 1.4	12.9 ± 1.7	<0.001
SSSC index score	9.6 ± 0.8	6.8 ± 1.0	<0.001
FIQ score	89.8 ± 4.7	68.8 ± 10.9	<0.001
LHS questionnaire score	41.0 ± 6.3	59.9 ± 9.1	<0.001
6-minute walk test (metres)	231.0 ± 38.9	356.3 ± 78.4	<0.001
Allodynia (mmHg)	159.8 ± 19.2	229.9 ± 31.0	<0.001

Values expressed as mean ± standard deviation.

mean score in the HSL questionnaire (41.0 *vs.* 59.9, *p*<0.001).

Patients suspected of simulation walked a significantly shorter distance in the 6-minute walk test (231.0 *vs.* 356.3 m, *p*<0.001), while allodynia was achieved with a significantly lower sphygmomanometer pressure in patients suspected of simulation (159.8 *vs.* 229.9 mm Hg, *p*<0.001).

Predictive model to identify suspected simulation

We analysed the diagnostic capacity of each test using the AUC and the maximum/altered value from which suspected simulation could be identified with the best combination of sensitivity and specificity (Table III). All tests had a high sensitivity and specificity. Figure 1 shows the distribution of the two groups in the diagnostic tests administered. The SSSC index (AUC = 0.963, sensitivity = 97.2, specificity = 88.6), the FIQ score (AUC = 0.961, sensitivity = 97.2, specificity = 86.7) and the allodynia test (AUC = 0.958, sensitivity = 96.2, specificity = 89.5) had the greatest sensitivity and specificity for suspected simulation (Fig. 2).

Discussion

We analysed a subgroup of patients who met the qualifying criteria for FM (both existing and newly proposed) (14, 21) but whose vocalisation of symptoms and demand for permanent disability at the first visit were suggestive of simulation. This subgroup had a different demographic profile and widely divergent

Table III. Cut-off points for each of the tests applied which obtained the maximum AUC, with the respective sensitivity and specificity.

	Cut-off	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	AUC
Number fibromyalgic points	≥16	92.4 [85.6 - 96.1]	84.8 [76.7 - 90.4]	0.918
Number control points	≥4	96.2 [90.7 - 98.5]	87.6 [80.0 - 92.6]	0.940
WPI index score	≥15	94.3 [88.2 - 97.4]	82.9 [74.5 - 88.9]	0.946
SSSC index score	≥9	97.2 [92.0 - 99.0]	88.6 [81.1 - 93.3]	0.963
FIQ questionnaire score	≥80	97.2 [92.0 - 99.0]	86.7 [78.9 - 91.9]	0.961
LHS questionnaire score	≤47	89.6 [82.4 - 94.1]	89.5 [82.2 - 94.1]	0.924
6-minute walk test (metres)	≤287	95.3 [89.4 - 98.0]	87.6 [80.0 - 92.6]	0.951
Allodynia (mmHg)	≤181	96.2 [90.7 - 98.5]	89.5 [82.2 - 94.1]	0.958

values in the objective tests performed with respect to the normal values observed in patients with FM.

The diagnosis of FM is based on the fulfilment of subjective self-reported criteria, including the physical examination, where the existence of pain is also self-reported.

In 1990, the American College of Rheumatology (ACR) sponsored a multicenter study to unify and standardise the classification criteria for FM, in order to differentiate it from other syndromes with similar symptoms (14). The first classification criterion is the same as that used to identify patients with chronic widespread pain. Coster *et al*. (22) detected a prevalence of chronic widespread pain of 4.5% in the general population, of whom more than half (2.5%) met the ACR criteria for FM. The difficulty in distinguishing between chronic pain states according to their cause has recently been evaluated by Provenzano *et al*. (23), who suggested that, although there were differences in the expression of pain in patients with different diseases (FM, rheumatoid arthritis or neuralgia), there were difficulties in discriminating the type of pain according to the underlying pathology. Therefore, the decision as to whether a patient has chronic widespread pain, which in itself is highly prevalent, heterogeneous and controversial, or FM, is based only on fulfilment of the second criterion, namely pain when pressure is applied to tender points. However, studies have raised significant doubts about the diagnostic utility of tender points (24).

The controversial aspects include the variation over time in the same patient (25), the small differences observed when points, groups of points or areas are tested (26), variations in assessments and outcomes (27, 28), the modest association found between the pain in a specific body segment and a specific pain point located in this segment (29), and the substantial overlap between patients with FM and osteoarthritis (30). It is unclear whether the newly proposed criteria address these questions (31, 32).

In the context of a diagnosis based solely on subjective data, the problem of simulation of the disease arises, especially when possible economic incentives, such as obtaining permanent disability, may be involved. Studies have suggested the influence of somatisation and possible simulation in patients allegedly suffering FM (33-35), but few studies have analysed the problem of deliberate simulation, or malingering. Mittenberg *et al*. (36) found that 35% of patients with chronic fatigue/FM gave diagnostic impressions of probable malingering, while Gervais *et al*. (37) found that a significant percentage of patients with FM presenting for disability-related evaluations failed tests applied to rule out exaggerated memory complaints, and Häuser *et al*. (31) found a greater degree of pain reported by patients requesting permanent work disability compared to those who did not. We have found no study that has proposed protocolised guidelines to identify patients suspected of malingering. Our study protocol includes various tests which, we believe, provide an objective evaluation of measurements, both in the general population and in patients with FM. The extreme values obtained in several of these tests complement the initial clinical suspicion of

malingering in patients attending a first visit who are requesting permanent disability.

The finding of significant differences in epidemiological and sociodemographic characteristics and in the DSM-IV diagnoses confirms previous studies suggesting a possible influence of the epidemiological and psychopathological profile in the simulation of FM (38, 39). Moreover, the finding of extreme values in the validated questionnaires (FIQ and LHS) and abnormally-altered values in physical tests (allodynia and the 6- minute walk tests) suggest a possible psychosomatic component. Studies have identified various psychopathological patterns in patients with FM, some of which resemble somatisation. Giesecke *et al*. (40) were the first to propose a combined evaluation of the psychopathological profile and a personalised assessment of the response to pain (hyperalgesia and perception of pain), and identified three subgroups of patients with a well-defined psychopathological profile, which was clearly related to the way in which each subgroup responded to pain. Muller *et al*. (41) proposed an empirical classification of FM based, especially, on the psychopathological profile, including group 1 (without psychiatric disorders), group 2 (FM with depression), group 3 (depression with FM) and group 4 (FM due to somatisation). The characteristics of patients in group 4 are similar to those of our patients classified as malingering.

Our study has some limitations. The clinical suspicion of malingering was made subjectively, based on the experience of the principal investigator as a clinician and expert witness and the adaptation of the criteria for disability related to the simulation of pain proposed by Bianchini *et al*. (16). Therefore, the diagnostic approach remains as subjective as that normally used for the diagnosis of FM. Moreover, the influence of the psychopathological profile or psychiatric disease cannot be ruled out in some patients (42, 43), as this could influence how these patients experience and express the symptoms evaluated (44). Likewise, extreme personal experiences (45-47) could

1a
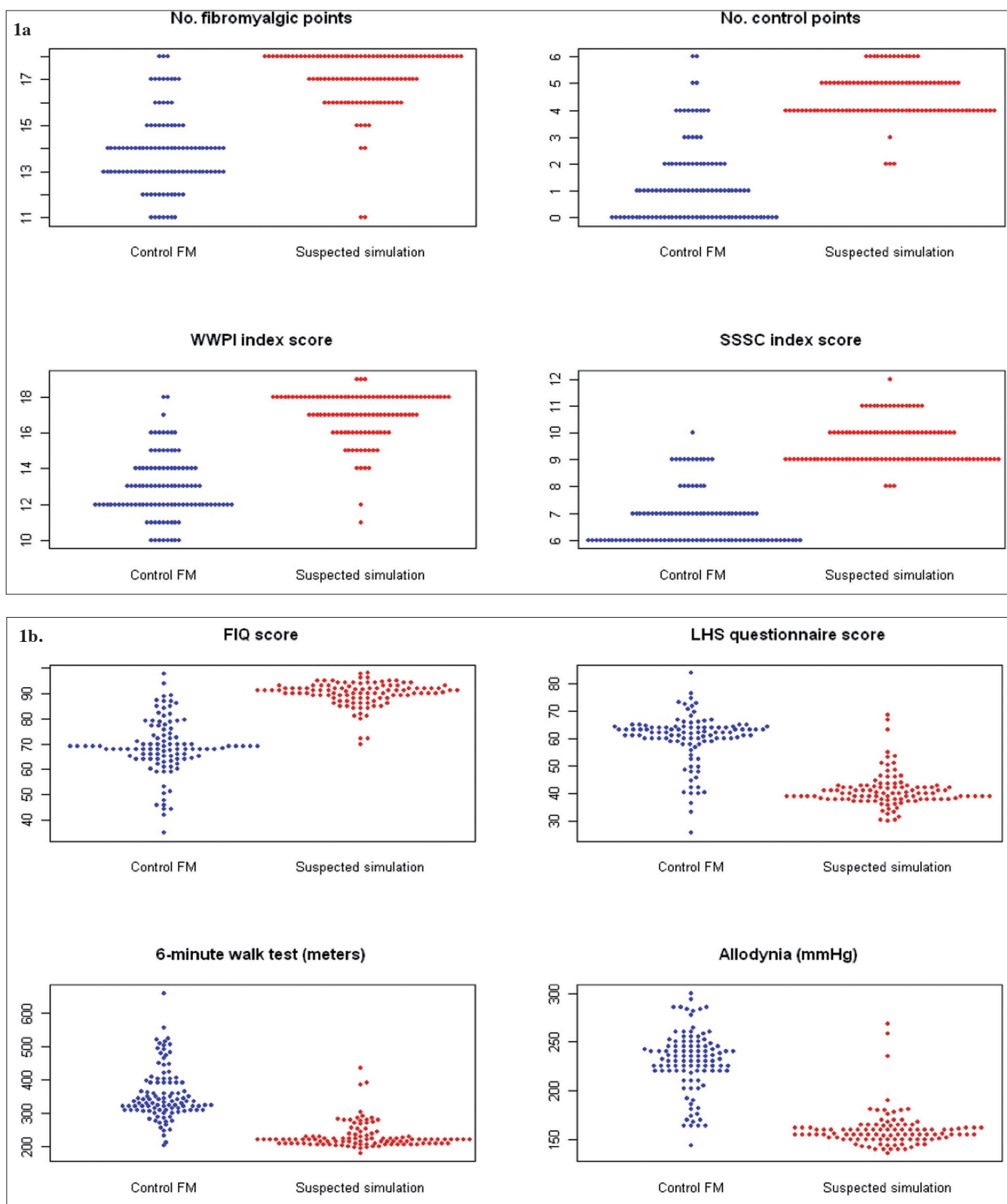
Figs. 1a and **1b.** Distribution of the diagnostic tests administered in the two groups.

also modify vocalisation of the main symptoms. However, the main limitation is the inability to attribute extreme results obtained in testing to possible malingering and not to more-severe FM, as many studies use the scores on specific questionnaires (such as the FIQ) to classify FM as mild, moderate or severe, a ranking that has been correlated with health spending (48-51). Therefore, it remains difficult to differentiate between the patient who truly
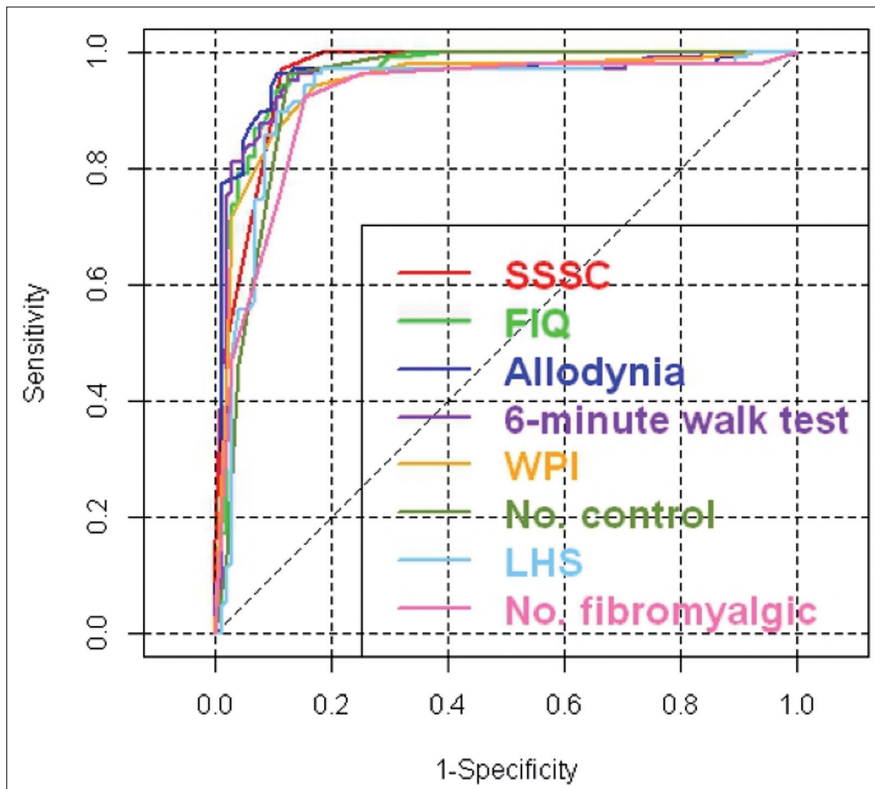
Fig. 2. ROC curves for the diagnostic tests administered.

Table IV. Results obtained in the main tests in patients with FM and suspected malingering compared with the results normally seen in unselected series of patients with FM (52-61).

	Patients with FM and suspected malingering (mean value)	Unselected patients with FM (mean values, range)	Refs.
WPI index score	16.9	8-8.9	59, 60
SSSC index score	9.6	7.4-11.8	59, 60
FIQ questionnaire score	89.8	68-77	57, 58
6-minute walk test (metres)	231	447-511	52-55
Allodynia (% of patients <180 mmHg)	94.3%	69-78%	18, 56

has severe disease and the patient who is simulating severe disease in order to obtain work disability, as the two situations remain completely subjective. However, the results obtained in our patients with suspected malingering are so discrepant from those normally seen in unselected series of patients with FM (Table IV) (18, 52-60) that they are difficult to explain in another way, even if we assume that their true "severity" was greater than that expected in unselected FM patients.

Likewise, even the interpretation of the results of the questionnaires administered is complex when possible incentives are involved, since these questionnaires are also readily available on the internet, and the possibility of malingering cannot be excluded.

In addition, although all patients suspected of malingering had psychological/psychiatric involvement, it is not possible to discern whether this is due to direct malingering or to an inability to face up to life (desperation) that would not include the implication of "malingering" that the patient is somehow cheating. Despite these limitations, we believe that our results may be a useful (although not definitive) clinical approach to the problem of suspected malingering. We recommend that patients consulting for FM who demand permanent disability at the first visit and who presently significantly-altered results in

objective tests (Table III) undergo neuropsychological assessment (36, 61) to rule out fictitious FM.

In conclusion, we describe a subgroup of patients consulting for possible FM who demanded permanent disability at the first visit and reported signs and symptoms suggestive of simulation, with vocalisation of symptoms outside the normal and significantly-altered values in objective tests compared with a control group of patients with FM. The results of our study suggest these tests should be administered in patients consulting for FM in whom simulation is suspected. The high sensitivity and specificity of the battery of objective tests administered may identify a subgroup of patients in whom neuropsychological study is required to rule out malingering.

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