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Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography: a cross-sectional study in Spain

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ABSTRACT

Objetives: to investigate which sensory component is most affected (i.e. vestibular, visual and somatosensory) in women with fibromyalgia and to evaluate the association between functional independence and balance responses.

Design: A cross-sectional observational study using non-probabilistic sampling of consecutive cases. **Setting:** the study was carried out at Rey Juan Carlos University in Madrid, Spain. **Participants:** Twenty-nine women with fibromyalgia and 20 matched healthy controls were assessed. **Primary and secondary outcome measures:** included the Sensory Organization Test and the Functional Independence Measure. Between-group differences were analyzed with ANOVA and the Spearman's test was used for correlations. **Results:** Significant ($P<0.001$) between-group and between-condition differences were observed for the SOT balance values: fibromyalgia women showed somatosensory dependence in balance. Positive linear correlations were found with function in specific daily activities. **Conclusions:** Women with fibromyalgia exhibited balance deficiencies and used different strategies for maintaining their balance, resulting in a negative impact on functional independence.

KEY WORDS: Postural Balance, Fibromyalgia, Patient Positioning.

Strengths and limitations of this study:

- These findings will inform management interventions focused on improving somatosensory balance conditions as well as improving functioning during activities of daily living.
- This is the first study investigating these relationships: postural balance and activity daily living.
- These findings are valuable for planning proper treatment interventions.
- Small sample size and same regional hospital.
- It was only included women diagnosed with fibromyalgia.

INTRODUCTION

Fibromyalgia (FM) is a chronic pain syndrome that has a considerable functional impact on patients. It is estimated that between 10-15% of the general population are affected by this syndrome, according to a recent European study[1]. The main complaint is generalized long-lasting muscle pain of an insidious and progressive onset. The pain is typically deep and intense, worsening with intense physical exercise, cold and/or emotional mental stress. This widespread pain is accompanied by asthenia, fatigue and poor nighttime resting (or non-restorative sleep) together with other poorly defined symptoms[2]. Additionally, individuals with FM present muscle asymmetry[3] and difficulty in relaxing their muscles, which can induce fatigue and pain, leading to poor posture[4,5]. Also, postural disturbances affecting the vertebral column have been observed[6], as well as lower spatio-temporal parameters of gait[7] and a higher risk of falls [8,9,10]. Therefore, sometimes, this disorder can lead to general inactivity[11] with negative effects on the functional capacity of the upper extremity[12].

On the other hand, postural control requires the appropriate integration of sensory, visual, vestibular and somatosensory information into the central nervous system (mainly integrated by proprioceptive and cutaneous sensitivity). Posturography is a technique that enables a quantitative assessment of postural control by studying the displacements of the center of pressure in different circumstances and by simulating actions from normal daily life[13]. This technique in isolation does not enable patient diagnosis, however provides information regarding functional status and is, therefore, valuable for guiding treatment. Some of the most utilized tests in posturography include the Sensory Organization Test (SOT), the motor control test and the adaptation test[14]. The SOT enables isolation of components from the vestibular, visual and somatosensory systems that participate in the maintenance of postural control, enabling

users to determine the site of the main disorder causing the loss of balance[15]. In fact, some studies have reported the presence of deficits in the sensory organization and postural control of women with FM using some of these equipments[16,17]. However, these previous studies did not investigate which component (vestibular, visual or somatosensory) was causing balance deficiencies in women with FM nor the potential consequences of these deficits on functional independence in activities of daily living (ADLs).

Based on the hypothesis supported by prior studies which states that women with FM have worse postural control than healthy women, the aims of the current study were: 1), to investigate which sensory component is the most affected (vestibular, visual or sensory); and, 2), to evaluate the association between the functional independence measure (FIM) and balance responses in women with FM.

METHODS

Research Design

A cross-sectional study was performed. We conducted non-probabilistic sampling of consecutive cases, where subjects who met the established criteria were included. The study was conducted during the second semester of 2015.

Participants

Advertisements were placed in the local newspapers in order to recruit healthy women from the general population to participate in the control group. The inclusion criteria included: no current spontaneous pain, no history of chronic pain (lasting more than 3 months), no pain experienced during the previous year prior to the study, no pain-related diagnoses and participants who were not taking antidepressant or analgesic medication.

Female participants for the experimental group were recruited from the Department of Rheumatology at the University Foundation Alcorcón Hospital (Spain). An experienced rheumatologist confirmed the FM diagnosis according to the American College of Rheumatology (ACR) criteria[18]. Tender points were tested by digital palpation at the 18 sites according to the ACR protocol. Participants were asked to indicate whether they experienced pain in response to a pressure of approximately 4 kg exerted by the examiner. Further, the presence of fatigue, altered sleep patterns and other sensory symptoms experienced by the patients was also recorded[19]. Face-to-face structured interviews were performed to determine the time of the diagnosis, socio-demographic and clinical data, any medications participants were taking at the time of the study and the existence of psychiatric disorders.

Exclusion criteria for both groups included: 1) co-morbid medical diagnoses, e.g., cardiopulmonary disorders, inflammatory disease, obesity, and other diagnoses; 2) malignancy; 3) psychiatric illnesses such as schizophrenia or substance abuse; 4) depression (Beck Depression Inventory-II >8 points); 5) previous history of surgery of any kind; 6) previous history of whiplash; 7) uncontrolled endocrine disorders (i.e. hyper- or hypo-thyroidism, diabetes); or 8) pregnancy.

Participants were matched on the basis of their age and hand dominance to gain homogeneity in the sample during the performance of ADLs involving the upper extremity. Hand dominance was determined by self-reports regarding the hand used for writing.

Ethical considerations

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was reviewed and approved by the Ethics committee of the

University Hospital of Alcorcón, protocol number FHA-URJC 032. All participants provided written informed consent.

Study procedure

The study protocol was the same for all participants, with the exception of the Fibromyalgia Impact Questionnaire (FIQ), which was administered to women with FM in order to assess FM-related disability[20]. The Spanish version of the FIQ was used[21]. All participants were verbally informed of the study, accepted the informed consent, and were familiarized with the different measurement tools before the commencement of data collection.

First, the SOT protocol was performed and subsequently participants completed the remaining assessments. All assessments were performed at a similar time of the day in the laboratory for movement analysis, biomechanics, ergonomics and motor control (LAMBECOM) at the Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine, Faculty of Health Sciences, Rey Juan Carlos University (Spain).

The Functional Independence Measure (FIM) assessment took place in a suitably equipped apartment of the previously mentioned university department, via observation of participants' functional independence demonstrated during the performance of daily activities contained in the scale. An external evaluator performed assessments, who was blinded to the condition of participants.

Outcome measures

Functional independence measure (FIM)

The FIM provides an assessment of the level of functional independence in daily life activities[22]. Also, it provides information primarily on cognitive and motor performance via 18 items. Scores range from 1-7, with higher scores corresponding to a higher level of functional independence. The possible range of the variable is between 0 and 126. The FIM includes observation and face-to-face interviews. This tool has demonstrated excellent psychometric properties[23-25].

Sensory Organization Test (SOT)

The posturography device used in the current study was the SOT assessment, which belongs to the Smart Balance Master©, by Neurocom® EQ0501, International, Inc (Oregon, USA)[22, 23]. This device consists of a platform connected to four symmetrically placed transducers measuring the horizontal forces exercised through the anterior-posterior axis in the plane parallel to the floor. It is also equipped with a mobile visual surround screen. The visual surround together with the platform are computer controlled and can move simultaneously. This device was connected to a PC Pentium I, with Smart Balance Master 5.0 software and a Samsung monitor. The reports were saved on the computer's hard drive.

To conduct the SOT, an individual's postural sway, and thereby balance, is measured under six different conditions during standing. During these tests, the base of support and the visual surround screen can move according to the patient's balancing responses and the strategy used for maintaining the upright position. The 6 conditions tested are: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the

angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform. Tests were always performed following these steps in order. Each condition was performed 3 consecutive times. In total, the duration of the tests lasted approximately 12 minutes for each patient; therefore, it can be considered a non-fatiguing assessment.

Participants were encouraged to maintain their stability and center of gravity, despite the movement of the visual surround or the base of support. The participant's center of gravity was displayed on the upper half of the assessment screen. The feet were correctly positioned facing the visual surround during the entire test. If the participant fell, took a step or touched the visual surround, the test was interrupted and this was registered. Data assessments were performed automatically and compared with theoretical normative electronic data. This was registered on a bar chart assessing the result from 1-100%.

Statistical Analysis

The SPSS statistical package was used for data analysis (version 19.0). A 2x6 mixed-model analysis of variance (ANOVA) with group (FM patients or controls) as a between-subjects factor and with condition of the SOT (from 1 to 6) as a within-subjects factor was used to analyze differences in the assessments of balance responses and strategies used for maintaining the upright position in the SOT. The hypothesis of interest was the Group * Time interaction with a Bonferroni-corrected alpha of 0.008 (6 independent-samples t tests by condition).

The Spearman's rho (rs) test was used to analyze the association between the clinical variables related to disability, symptoms, and FIM and the conditions of the SOT. A value of less than 0.05 was considered statistically significant for these correlations.

RESULTS

Demographic and clinical data

Twenty-nine (n =29) women with FM were screened for eligibility criteria between January and November 2012. The final sample consisted of 20 women with FM, aged 35-55 years old (mean: 48 ± 6 years) who satisfied the eligibility criteria and agreed to participate. Causes for exclusion were as follows: previous surgery (n=3), whiplash syndrome (n=2), pregnancy (n=2), diabetes (n=1) and litigation (n=1). In addition, 20 matched healthy women; aged 35–56 (mean 47 ± 6 years) were also included. There were no significant differences in age between the two groups (P= 0.909). All the participants were right-handed. Seventeen (85%) women with FM (85%) were regularly taking non-steroidal anti-inflammatory medications.

The FIQ revealed a moderate disability with a mean score of 57.9 (95%CI 53.1-62.6).

All women participating in the study completed the assessments and therefore there were no missing data.

Fibromyalgia and balance

We performed an ANOVA test in order to investigate which sensory component determines the poorer postural control of women with FM. This revealed significant differences between groups ($F=37.259$; $P<0.001$) as well as between conditions ($F=71.575$; $P<0.001$) for the balance responses on the SOT: women with FM displayed significantly ($P=0.005$) lower values in all conditions compared to healthy women

(table 1). A significant Group * Condition interaction was also found (F=3.404; P=0.006): the scores of conditions 4-6 were significantly lower (P=0.007) than those for conditions 1-3, particularly within the FM group.

[Insert table 1 about here]

The ANOVA also revealed significant between-group differences (F=12.836; P<0.001) and between-condition differences (F=64.526; P<0.001) for the balance strategies used for maintaining the upright position on the SOT: women with FM displayed significantly lower values (P<0.001) in all conditions when compared with healthy women (table 1). No significant Group x Condition interaction was observed (F=1.170; P=0.325). Values of conditions 4-6 were once more lower (P<0.001) than the values for conditions 1-3.

Correlations between clinical variables and balance in fibromyalgia

Within the group of women with FM, no significant linear correlation was found between the duration (years) of pain nor the intensity of the symptoms with any of the SOT conditions regarding both the balance and strategy sections. Table 2 displays correlation coefficients and the statistical significance for all conditions in the balance section, whereas table 3 displays the same data for each condition within the strategy section.

[Insert table 2 about here]

[Insert table 3 about here]

Correlations between functionality and balance

To assess the association between functionality and balance, the Spearman's test was used. Positive linear correlations between balance and different ADLs variables were found within the group of women with FM (table 4). The balance condition Nº6 (eyes

open, mobile visual surround-mobile platform) was moderately correlated with the bathing activity (r_s=0.541; P<0.001), whereas conditions 2 and 3 were positively and moderately associated with the bed transfers activity (r_s=0.491; P<0.001; r_s=0.510; P<0.001, respectively): the greater the distortion of the postural balance in these conditions, the poorer the function in the respective ADLs.

[Insert table 4 about here]

Similarly, significant positive linear correlations were found between positioning strategy number 6 and the following ADLs: dressing the upper body (r_s=0.530; P<0.001), dressing the lower body (r_s=0.562; P<0.001) and toileting (r_s=0.521; P<0.001). In this manner, the greater the loss of balance, the greater interference there is with functional independence during daily activities.

DISCUSSION

According to these findings, women with FM have poorer balance compared to healthy women, which is in line with previous studies[14,15]. Also, women with FM presented difficulties in all the conditions assessed under the SOT, both in activities with the eyes open as well as closed, as well as with fixed and moving surrounds and surfaces. Furthermore, the strategy used for stabilizing the ankle joint and the hip with the aim of maintaining the upright posture is poorer in women with FM compared to healthy women. These findings further support the need to objectively measure balance and postural deficiencies in women with FM.

Regarding the sensory analysis, both the vestibular as well as the visual quotients were abnormally decreased in FM, however, lower scores were observed in conditions 4 to 6, which are the more challenging conditions, as these correspond with the mobile platform conditions. As suggested by Barona[15], lower values in the last conditions

compared to the first conditions with the fixed platform, suggest a degree of somato-sensory dependence. These observations are in line with those obtained by De Brujin and collaborators [28] who found that in patients with FM, their balance is only optimal on firm and regular floors. Thus, patients with FM are individuals with central nervous system alterations who are clinically disabled. These findings coincide with a pilot study[29] that included 32 women with FM who completed the Smart Balance Master® test by Neurocom®, and found values below the normative population scores in affected subjects, suggesting the presence of deficits in sensory organization and postural control. Further, in the aforementioned study, condition Nº 5 produced markedly lower scores due to a vestibular and visual alteration, similar to the findings of the current study. Other authors have studied postural balance via the Activities-specific Balance Confidence Scale[17] or the Balance Evaluation-Systems Test (BESTest)[16]. In the latter study[16], 34 patients with FM and 32 healthy subjects were analyzed, and a significant decline was found in the patients for all the sections of the BESTest.

Based on the premise that there is no consensus on the effectiveness of rehabilitation for the treatment of this syndrome due to the inconsistency of the published studies[30-32] and considering that the SOT is a reliable and objective tool providing clinically relevant data and measurements, our findings are relevant for the planning of future interventions in order to improve the effectiveness of rehabilitation treatments by considering the somatosensory difficulties when planning rehabilitation treatments. Also, the role of the knee joint in the neurosensory organization of balance control and the generation of postural sensorimotor strategies in this population warrants consideration in future studies, based on reports by Gauchard et al. [33] in osteoarthritis.

Regarding the relation between balance and functional independence in ADLs, the results of the current study point to a positive linear correlation between these factors:

the greater the loss of postural balance, the greater the interference with all activities requiring good postural control and balance, such as bathing and dressing. To our knowledge, this is the first study investigating these relationships. These findings are valuable for planning proper treatment interventions, as the loss of independence in ADLs has a negative impact on quality of life. Our results support previous research by Amris et al.[34] who studied 257 women with widespread chronic pain and reported that FM patients have substantial problems affecting their daily life and are liable to need community support.

This study presents several limitations. First, although significant differences were found between the two study groups, these were based on a small sample size. Furthermore, the population included was recruited from the same regional hospital, which makes generalization of the results to the general population difficult. Consequently, further epidemiological studies with larger sample sizes are needed to enable a more generalized interpretation of the results. Secondly, in the present study, we only included women diagnosed with FM. It is unknown whether men with FM would also exhibit similar deficiencies. Third, as fatigue is a common denominator in patients with FM, it was unknown whether the inclusion of several functional outcomes could be affected by rest-periods. Finally, it is important to note that postural balance may be influenced by the psychological status of the patients. For instance, the presence of depression or anxiety may have affected these results[35] and therefore future studies should include these psychological outcomes into the design.

CONCLUSIONS

Women with FM present lower values in tests for balance and use different strategies for maintaining upright posture compared to healthy women. Furthermore we have

detected that in women with FM, balance depends on somatosensory sensitivity. This finding suggests that treatments for this disorder should specifically target the recovery or compensation of these balance deficits, due to their negative influence upon activities that are seemingly simple and commonplace in patients with high levels of autonomy. Also, these findings demonstrate a relation between the balance difficulties encountered by women with FM and the impact of the same on ADLs. Multidisciplinary treatments directed at improving the problems faced during ADLs may help improve the autonomy of women with FM.

Contributorship Information

- Concept development (provided idea for the research): Marta Pérez de Heredia Torres.
- Design (plane the methods to generate the results): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas, Rosa Martínez Piédrola, Domingo Palacios Ceña, Jorge Alegre Ayala, Montserrat Santamaría Vázquez, César Fernández de las Peñas.
- Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas and César Fernández de las Peñas.
- Datta Collection/processing (responsible for experiments, patient management, organization, or reporting data): Rosa Martínez Piédrola, Domingo Palacios Ceña, and Montserrat Santamaría Vázquez.
- Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas, Domingo Palacios Ceña, Jorge Alegre Ayala, César Fernández de las Peñas.
- Literature search (performed the literature search): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas, Rosa Martínez Piédrola, Domingo Palacios Ceña, and Montserrat Santamaría Vázquez.

- Writing (responsible for writing a substantive part of the manuscript): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas, Rosa Martínez Piédrola, Domingo Palacios Ceña, Jorge Alegre Ayala, Montserrat Santamaría Vázquez, César Fernández de las Peñas.
- Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): Marta Pérez de Heredia Torres, Elisabet Huertas Hoyas and César Fernández de las Peñas.

Competing interests

All authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

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Data sharing statement

No additional data are available.

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TITLES OF TABLES

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

Table 2: Linear correlations between clinical pain variables and the SOT balance values in women with FM

Table 3: Linear correlations between the clinical pain variables and the SOT strategy values in women with FM

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

	Condition 1#	Condition 2#	Condition 3#	Condition 4#*	Condition 5#*	Condition 6#*
	Balance					
Women with FM	93.1 ± 5.4	89.7 ± 4.9	86.3 ± 7.0	76.5 ± 13.4	52.1 ± 18.0	54.7 ± 19.4
Healthy women	95.7 ± 1.3	92.3 ± 3.4	90.7 ± 5.3	86.4 ± 9.3	68.4 ± 12.6	70.8 ± 11.9
	Strategy					
Women with FM	98.5 ± 1.6	97.3 ± 4.4	96.7 ± 3.4	85.7 ± 8.1	76.1 ± 12.0	78.1 ± 7.6
Healthy women	98.8 ± 0.6	98.7 ± 0.7	98.3 ± 1.3	91.9 ± 3.2	81.2 ± 12.7	83.1 ± 11.1

Data are expressed as means ± Standard Deviation

Statistically significant differences between patients and controls (P<0.01; ANOVA test)

* Statistically significant differences between conditions 1-3 (P<0.001; ANOVA test)

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

Table 2: Linear correlations between clinical pain variables and the SOT balance values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = 0.124; P = 0.602	r_s = 0.276; P = 0.239	r_s = 0.242; P = 0.304	r_s = 0.169; P = 0.476
Condition 2	r_s = 0.291; P = 0.213	r_s = 0.051; P = 0.830	r_s = 0.334; P = 0.149	r_s = 0.179; P = 0.450
Condition 3	r_s = 0.310; P = 0.183	r_s = 0.152; P = 0.552	r_s = 0.131; P = 0.581	r_s = 0.127; P = 0.593
Condition 4	r_s = 0.308; P = 0.186	r_s = 0.084; P = 0.736	r_s = 0.076; P = 0.749	r_s = 0.07; P = 0.769
Condition 5	r_s = 0.135; P = 0.571	r_s = 0.111; P = 0.642	r_s = 0.151; P = 0.526	r_s = 0.219; P = 0.354
Condition 6	r_s = 0.123; P = 0.606	r_s = 0.050; P = 0.835	r_s = 0.156; P = 0.511	r_s = 0.156; P = 0.512

r_s = Spearman's correlation test (Spearman's rho)

Table 3: Linear correlations between the clinical pain variables and the SOT strategy values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = - 0.088; P = 0.713	r_s = 0.076; P = 0.749	r_s = 0.204; P = 0.388	r_s = 0.047; P = 0.846
Condition 2	r_s = 0.124; P = 0.602	r_s = - 0.032; P = 0.894	r_s = - 0.399; P = 0.082	r_s = - 0.210; P = 0.613
Condition 3	r_s = 0.123; P = 0.604	r_s = - 0.073; P = 0.759	r_s = - 0.040; P = 0.867	r_s = - 0.022; P = 0.926
Condition 4	r_s = - 0.069; P = 0.772	r_s = - 0.161; P = 0.498	r_s = - 0.118; P = 0.621	r_s = - 0.130; P = 0.585
Condition 5	r_s = 0.036; P = 0.879	r_s = 0.046; P = 0.848	r_s = - 0.140; P = 0.555	r_s = 0.380; P = 0.098
Condition 6	r_s = - 0.097; P = 0.685	r_s = - 0.086; P = 0.718	r_s = - 0.010; P = 0.966	r_s = - 0.151; P = 0.525

r_s = Spearman's correlation test (Spearman's rho)

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

	Balance						Strategy					
	1	**2**	**3**	**4**	**5**	**6**	**1**	**2**	**3**	**4**	**5**	**6**
Eating	.280	.179	.246	.251	.246	.350*	.175	.258	.185	.222	.154	.222
Grooming	.316*	.288	.308*	.375**	.428**	.451**	.002	.108	.154	.423**	.252	.423**
Bathing/showering	.314*	.469**	.481**	.429**	.491**	.541***	.256	.434**	.436**	.427**	.402*	.427**
Dressing upper body	.311*	.323*	.301	.458**	.343*	.307*	.136	.232	.313*	.530**	.450**	.530***
Dressing lower body	.401**	.448**	.336*	.373**	.351*	.438**	.100	.237	.336*	.562***	.469**	.562***
Toileting	.251	.376**	.258	.259	.251	.483**	.055	.223	.273	.521**	.430**	.521***
Bowel management	-.165	-.020	-.131	.062	.187	-.165*	-.212	-.076	-.221	.141	.030	.141
Bladder management	.064	-.051	-.002	.204	.083	.064	.087	.061	.099	.086	.303	.086
Chair-bed transfers	.325*	.491***	.510***	.433**	.451**	.441**	.220	.456**	.378**	.389**	.422**	.389**
Toilet transfers	.195	.223	.282	.453**	.255	.197	.145	.318*	.377**	.452**	.418**	.452**
Bath transfers	.417*	.441	.354	.321	.257	.405	.257	.314*	.351**	.558***	.407**	.558***
Locomotion	.110	-.172	-.039	-.009	-.158	-.192	.105	.132	.141	-.133	.000	-.133
Stairs	.365*	.238	.079	.164	.212	.164	.159	.154	.050	.176	.173	.176
Comprehension	.205	.264	.311*	.407**	.270	.281	.180	.375**	.254	.364**	.250	.364**
Expression	.097	.095	.113	.477**	.247	.372*	-.187	-.108	-.144	.306*	-.061	.306*
Social interaction	.285	.220	.303	.212	.005	.088	.239	.398**	.424**	.269	.158	.269
Problem solving	.192	.220	.245	.307*	.364*	.261	-.018	.033	-.006	.197	-.008	.197
Memory	.311*	.340*	.384**	.468**	.396**	.449**	.069	.156	.314*	.393**	.267	.393**

* P<0.05; ** P<0.01; *** P<0.001

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

STROBE Statement—checklist of items that should be included in reports of observational studies

Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography: a cross-sectional study in Spain

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Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography: a cross-sectional study in Spain

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ABSTRACT

Objectives: Our aims were: 1) to compare the sensory organization of balance control and balance strategies between women with fibromialgia (FM) and healthy women; 2) to investigate which sensory component, i.e., vestibular, visual or somato-sensory, is the most affected in FM; and, 3), to determine the associations between the functional independence measure (FIM) and balance responses in FM. **Design:** Cross-sectional observational study. **Setting:** Urban regional hospital and university (Universidad Rey Juan Carlos, Madrid, Spain). **Participants:** Twenty women with FM and 20 matched healthy women. **Primary/secondary outcome measures:** The Sensory Organization Test (SOT) was used to determine postural sway and balance during six different conditions with subjects in a standing position. The Functional Independence Measure (FIM) was used to determine the level of functional independence in daily life activities. Between-group differences were analyzed with ANCOVA and the Spearman's test was used for correlations. **Results:** Significant between-groups and between-conditions differences were found for all SOT conditions (all, $P<0.001$): women with FM showed lower scores being the vestibular score the most affected. Different correlations between SOT conditions and some specific daily life activities were observed in the FM group: bathing activity and balance condition 6 ($r_s=0.541$; $P<0.001$), bed transfers activity and conditions 2 ($r_s=0.491$; $P<0.001$) and 3 ($r_s=0.510$; $P<0.001$), positioning strategy 6 and dressing the upper ($r_s=0.530$; $P<0.001$) or lower ($r_s=0.562$; $P<0.001$) body, and toileting ($r_s=0.521$; $P<0.001$): the greater the loss of balance, the greater the interference on some daily life activities. **Conclusions:** Women with FM exhibited balance deficiencies and used different strategies for maintaining their balance in standing which was associated with a negative impact on functional independence.

KEY WORDS: Postural Balance, Fibromyalgia, Patient Positioning.

Strengths and limitations of this study:

- This is the first study investigating the association between postural balance and functional interference with activity daily living.
- The sample size was relatively small and from the same regional hospital.
- We only included women, but not me, diagnosed with fibromyalgia.

INTRODUCTION

Fibromyalgia (FM) is a chronic syndrome that has a considerable functional impact on patients. It is estimated that between 10-15% of the general population is affected by this syndrome in Europe[1]. The main complaint is generalized long-lasting muscle pain which is typically described as deep and intense and worsening with intense physical exercise, cold and/or emotional mental stress. This widespread pain is accompanied by other symptoms including asthenia, fatigue and non-restorative sleep together with other poorly defined symptoms[2]. Individuals with FM can also present muscle asymmetry[3] and difficulty for relaxing the muscles[4] which can contribute to fatigue and pain, leading to posture and balance deficit. In fact, balance problems are among the most debilitating symptoms reported by patients with FM.[5,6] Additionally, postural disturbances affecting the vertebral column have been also found[7] as well as lower spatio-temporal parameters during gait[8] and a higher risk of falls[9-11]. Finally, FM can be associated with general inactivity[12] which can lead to negative effects on the functional capacity of the patient.

Postural control requires the appropriate integration of sensory, visual, vestibular and somatosensory information into the central nervous system (mainly integrated by proprioceptive and cutaneous sensitivity). Posturography is a technique that enables a quantitative assessment of postural control by studying the displacements of the center of pressure in different circumstances simulating actions from normal daily life[13]. This technique itself does not enable a diagnosis; however, it provides information regarding functional status and is can be of value for guiding treatment.

Some of the most utilized tests in posturography include the Sensory Organization Test (SOT), the motor control test and the adaptation test[14]. The SOT enables isolation of components from the vestibular, visual and somatosensory systems that participate in the maintenance of postural control, enabling users to determine the site of the main

disorder causing the loss of balance[15]. Some previous studies have reported the presence of balance and postural control deficits in women with FM using different procedures[16-18]. Muto et al[17] observed that patients with FM exhibited impaired postural control, e.g., increased speed of oscillation of the center of gravity and lower balance self-efficacy as assessed with the modified clinical test of sensory interaction on balance (mCTSIB) and the balance self-efficacy (ABC scale). In this study, impaired postural control and low balance self-efficacy were associated with pain severity and muscle strength[17]. Jones et al[16] found that FM patients showed lower scores in almost all conditions of the SOT and an increased number of falls. In this study, postural stability was associated to related disability, cognitive impairment and body mass index, but not to medication intake, pain severity or muscle strength[16]. In a pilot study using the SOT, Russek and Fulk[18] reported that 34% of FM subjects scored below the fifth percentile for population normative data in some SOT conditions. These authors also found a negative association between the somato-sensory score of the SOT and FM-related disability[18]. Although these studies support the occurrence of balance problems in patients with FM using the SOT, they did not investigate the association of balance disturbances with functional independence in activities of daily living (ADLs). The identification of an association between balance problems and ADL disturbances can help clinicians for developing specific therapeutic strategies for patients with FMS. To the best of the author's knowledge, no study has previously investigated this association in patients with FM.

Therefore, the aims of the current study were: 1) to compare sensory organization of balance control and balance strategies between women with FM and healthy controls; 2) to investigate which sensory component (vestibular, visual or somato-sensory) is the most affected in FM women; and, 3), to determine the potential association between the functional independence measure (FIM) and balance responses in women with FM.

METHODS

Research Design

A cross-sectional study was performed. We conducted non-probabilistic sampling of consecutive cases, where subjects who met the established criteria were included. The study was conducted during the second semester of 2015.

Participants

Advertisements were placed in local newspapers in order to recruit healthy women from the general population for acting as control group. Participants were considered as healthy controls if they reported: no spontaneous pain symptoms at the moment of the study, no history of chronic pain (lasting more than 3 months), no pain experienced during the previous year prior to the study, no pain-related diagnoses and participants who were not taking antidepressant or analgesic medication.

Women with diagnosis of FM were recruited from the Department of Rheumatology at the Hospital Fundación Alcorcón (Spain). An experienced rheumatologist confirmed the FM diagnosis based on a combination of both American College of Rheumatology criteria (1990/m2010)[19,20]. It has been suggested that a combination of 1990 and m2010 criteria is recommended since it had the best diagnostic features[21,22]. Tender points were tested by digital palpation at the 18 sites according to the ACR protocol[19]. Participants were asked to indicate whether they experienced pain in response to a pressure of approximately 4 kg exerted by the examiner[19]. Further, the presence of fatigue, altered sleep patterns and other sensory symptoms self-perceived by the patient was recorded[20]. Face-to-face structured medical interviews were performed to determine the time of the diagnosis, socio-demographic and clinical data, current medication intake and presence of psychiatric disorders.

Exclusion criteria for both groups included: 1) co-morbid medical diagnoses, e.g., cardiopulmonary disorders, inflammatory disease, obesity, and other diagnoses; 2) malignancy; 3) psychiatric illnesses diagnosis, e.g. schizophrenia or substance abuse; 4) depression (Beck Depression Inventory-II >8 points); 5) previous history of surgery; 6) previous history of whiplash; 7) uncontrolled endocrine disorders (i.e. hyper- or hypo-thyroidism, diabetes); or 8) pregnancy.

Participants were matched on the basis of their age and hand dominance to gain homogeneity in the sample during the performance of those ADLs involving the upper extremity. Hand dominance was determined by self-reports regarding the hand used for writing.

Ethical considerations

The current study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was reviewed and approved by the Ethics committee of the Hospital Fundación Alcorcón (protocol FHA-URJC 032). All subjects provided written informed consent.

Study procedure

The study protocol for the SOT was the same for all participants. In addition, women with FM also fulfilled the Spanish version of the Fibromyalgia Impact Questionnaire (FIQ)[23] to assess FM-related disability[24]. All participants were verbally informed of the study, accepted the informed consent, and were familiarized with the different outcomes before starting data collection.

First, the SOT protocol was performed and subsequently participants completed the remaining assessments. All assessments were performed at a similar time of the day in the LAboratory for Movement analysis, Biomechanics, Ergonomics and MOtor Control

(LAMBECOM) located at the Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos (Spain).

The Functional Independence Measure (FIM) assessment took place in a suitably equipped apartment, via observation of subject's functional independence demonstrated during the performance of ADL contained in the scale. An external evaluator, blinded to the participant's condition, performed the assessments.

Outcome measures

Functional independence measure (FIM)

The FIM provides an assessment of the level of functional independence in daily life activities[25]. It also provides information primarily on cognitive and motor performance via 18 items. Scores range from 1-7, with higher scores corresponding to a higher level of functional independence. The possible score ranges from 18 to 126 points. The FIM includes observation and face-to-face interviews. This tool has demonstrated excellent psychometric properties[26-28].

Sensory Organization Test (SOT)

The posturography device used in the current study was the SOT assessment, which belongs to the Smart Balance Master©, by Neurocom® EQ0501, International, Inc (Oregon USA)[29,30]. The device consists of a platform connected to symmetrically placed transducers measuring the vertical and horizontal shear forces exercised through the anterior-posterior axis in the plane parallel to the floor. It is also equipped with a mobile visual surround screen. Both the visual surround and platform are computer-controlled and can move simultaneously. This device was connected to a PC Pentium I, with Smart Balance Master 5.0 software and a Samsung® monitor. The reports obtained for each participant were saved on the computer's hard drive.

To conduct the SOT, an individual's postural sway, and thereby balance is measured under 6 different conditions during standing. During these tests, the base of support and the visual surround screen can move according to the patient's balancing responses and the strategy used for maintaining an upright position. For instance, no altered stimuli are given in condition 1; whereas visual information is removed in condition 2, by asking the participant to close the eyes. In condition 3, the visual surround is moving with the subject's anterior-posterior body sway, whereas in condition 4, the platform rotates with the subject's anterior-posterior body sway. In condition 5, subjects close their eyes and the platform moves with the subject anterior-posterior body sway. Finally, in condition 6, the visual screen and the platform are moved with the subject's anterior-posterior body sway. Briefly, the 6 conditions can be resumed as follows: 1) eyes open, fixed surround and support platform; 2) eyes closed, fixed surround and support platform; 3) eyes open, moving surround (moving proportional to the angle of anterior-posterior body sway) and fixed support platform; 4) eyes open, fixed surround and moving support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, fixed surround and moving support platform; and 6) eyes open, moving surround and support platform. Tests were always performed following these steps in order. Each condition was performed 3 consecutive times and the mean was considered in the analysis. In total, the duration of the tests lasted approximately 12 minutes for each patient; therefore, it can be considered a non-fatiguing assessment. This procedure has shown good test-retest reliability in healthy people[31].

Participants were encouraged to maintain their stability and center of gravity, despite the movement of the visual surround or the base of support. The participant's center of gravity was displayed on the upper half of the screen. The feet were correctly positioned facing the visual surround during the entire test. If the participant fell, took a step or

touched the visual surround, the test was interrupted and the fall was registered. Data assessments were performed automatically and compared with theoretical normative electronic data. The score of each condition consist of a percentage that compares the subject anterior-posterior center of pressure sway with the theoretical limits of stability. The score is registered on a bar chart ranging from 0% to 100% where 0% represents the least stable (fall) and 100% indicates perfect stability[29].

In addition, combination of the results obtained in the different conditions provides a ratio score of each sensory system (somato-sensory, vestibular, or visual). The somato-sensory ratio (condition 2/condition 1) determines how successfully a person uses input from the somato-sensory system for balance; the visual ratio (condition 4/condition 1) determines how successfully a person uses visual system for balance; and the vestibular ratio (condition 5/condition 1) determines how successfully a person uses input from the vestibular system for balance.

Finally, a strategy score for each SOT condition is also calculated with scores near 100 indicating use of an ankle strategy and scores near 0 indicating a hip strategy

Sample Size Calculation

The sample size was calculated using the Ene 3.0 software (Autonomic University of Barcelona, Spain). The sample calculation was based on detecting significant moderate correlations (r=0.60) between the SOT conditions and FIM variables with an alpha level (α) of 0.05, and a desired power (β) of 90%. This generated a sample size of at least 19 subjects.

Statistical Analysis

The SPSS statistical package was used for data analysis (version 19.0, SPSS Inc, Chicago, IL, USA). The Kolmogorov-Smirnov test was used to analyze the normal distribution of the variables (P>0.05). Quantitative data without a normal distribution

(clinical data and FIM scores) were analyzed with non-parametric tests and those data with a normal distribution (SOT conditions) were analyzed with parametric tests. A 2x6 analysis of variance (ANCOVA) with group (FM or controls) as a between-subjects factor and with condition of the SOT (from 1 to 6) as a within-subjects factor was and body mass index as covariate used to analyze differences in the assessments of balance responses and strategies used for maintaining the upright position in the SOT. The main hypothesis of interest was the Group * Condition interaction. Further, unpaired Student t-tests were also conducted to determine between-groups difference for the ratio score of each sensory system (somato-sensory, vestibular, or visual). Finally, the Spearman's rho (rs) test was used to analyze potential associations between the clinical variables related to symptoms, disability, FIM and SOT conditions in the FM group. The statistical analysis was conducted at a 95% confidence level; but, we corrected for multiple comparisons using the Holm-Bonferroni adjustment[32] assuming a significant alpha level of 0.008 (6 independent-samples t-tests by condition).

RESULTS

Demographic and clinical data

Twenty-nine (n =29) women with FM were screened for eligibility criteria between January and November 2015. Nine women were excluded as follows: previous surgery (n=3), whiplash syndrome (n=2), pregnancy (n=2), diabetes (n=1) and litigation (n=1). The final sample consisted of 20 women with FM aged 35-55 years old (mean: 48±6 years) who satisfied all the eligibility criteria and agreed to participate. In addition, 20 matched healthy women; aged 35-56 years old (mean: 47±6 years) were also included. There were no significant differences in age (P=0.909) or body mass index (control: 23.8 ±1.3; FM: 24.2±1.5, P=0.508) between both groups. All participants were right-

handed. Seventeen (85%) women with FM (85%) were regularly taking non-steroidal anti-inflammatory medications. The FIQ revealed a moderate disability with a mean score of 57.9 (95%CI 53.1-62.6). All participants completed the assessments and therefore there were no missing data.

Fibromyalgia and SOT

The ANCOVA revealed significant differences between groups (F=21.634; P<0.001) and conditions (F=45.164; P<0.001) for the balance responses on the SOT: women with FM displayed significantly (P=0.005) lower values in all SOT conditions than healthy women and scores of conditions 4-6 were significantly lower (P=0.007) than those for conditions 1-3 (table 1). A significant Group * Condition interaction was also observed (F=3.404; P=0.006): differences between conditions 4-6 scores and conditions 1-3 were significantly more pronounced within the FM group. No effect of the body mass index was observed (F=1.144; P=0.338).

We found significant (t=2.901; P=0.006) lower vestibular ratio score in women with FM (mean: 0.55±0.2) as compared to healthy women (mean: 0.72±0.15). No significant differences in somato-sensory (t=0.011; P=0.989) and visual (t=1.900; P=0.065) ratios between women with FM (somato-sensory: 0.95±0.03; visual: 0.82±0.15) and healthy women (somato-sensory: 0.96±0.03; visual: 0.90±0.1) were observed.

[Insert table 1 about here]

The ANCOVA also revealed significant between-groups (F=10.456; P<0.001) and between-conditions (F=35.301; P<0.001) differences for the balance strategies used during the SOT conditions: FM women displayed significantly lower values (P<0.001) in all conditions than healthy women (table 1) suggesting a greater use of the hip instead the ankle. Again, scores on conditions 4-6 were lower than those values for conditions

1-3 (P<0.001). No significant Group x Condition interaction (F=1.170; P=0.325) or effect of the body mass index (F=0.608; P=0.770) was observed.

Correlations between clinical variables and SOT conditions in fibromyalgia

Within the group of women with FM, no significant correlation was found between the duration (years) of neither pain nor the intensity of the symptoms with any of the SOT conditions. Table 2 displays correlation coefficients and the statistical significance for all conditions in the balance section, whereas table 3 displays the same data for each condition within the strategy section.

[Insert table 2 about here]

[Insert table 3 about here]

Correlations between functionality and SOT conditions

Positive correlations between different SOT conditions and different ADLs variables were found in the group of women with FM (table 4). The balance condition Nº6 (eyes open, mobile visual surround-mobile platform) was moderately associated with bathing activity (r_s=0.541; P<0.001) whereas conditions 2 and 3 were positively and moderately associated with bed transfers activity (r_s=0.491; P<0.001; and r_s=0.510; P<0.001, respectively): the lower the score balance in these conditions, the poorer the function in the respective ADLs.

[Insert table 4 about here]

Similarly, significant positive correlations were found between positioning strategy number 6 and the following ADLs: dressing upper body (r_s=0.530; P<0.001), dressing the lower body (r_s=0.562; P<0.001) and toileting (r_s=0.521; P<0.001): the worse the balance strategy, the greater interference with functional independence in these ADL.

DISCUSSION

The current study found that women with FM exhibit worse balance scores compared to healthy women as assessed with the SOT, in agreement with previous studies[16,18]. In fact, differences were higher with the eyes closed and moving surroundings surfaces. Further, the strategy used for stabilizing the ankle joint was poor in women with FM. Nevertheless, the most significant contribution of the current study was the association of balance scores with functional independence during ADL.

Women with FM exhibited lower scores in all SOT conditions compared to healthy women suggesting poor balance. Our results agree with those previously observed by Jones et al[16] and Russek and Fulk[18] who also reported significantly lower scores in all SOT conditions in individuals with FM. It is interesting to note that the scores observed in our study were similar to those reported in these previous studies[16,18]. Current and previous evidence would suggest that subjects with FM exhibit poor general balance as compared to healthy women. Nevertheless, although all SOT conditions showed lower scores in FM, the vestibular ratio was the most significantly impaired in our sample of women with FM. This may be related to the fact that scores in the last SOT conditions (4 to 6) were significantly much lower in the FM group than in the healthy group. As previously suggested, lower scores in conditions 4 to 6 compared to conditions 1 to 3 suggest a degree of somato-sensory dependence[15]. This hypothesis is in line with the study by De Brujin et al[33] who found that balance in patients with FM was more optimal on firm and regular surfaces. In fact, Russek and Fulk[18] and the current study did not find significant differences within the somato-sensory system ratio between individuals with FM and healthy people, suggesting that it is the vestibular, and probably the visual, system[16,18] the most affected in this population.

To determine the mechanisms related to poor balance in patients with FM is beyond the scope of the current study, but some hypotheses have been proposed. Since FM is characterized by abnormal nociceptive processing, it is possible that multiple processing disturbances may lead to poor balance. Additionally, other processing abnormalities of the central nervous system, e.g., cognitive dysfunction, could also contribute to postural instability. In fact, Bayazit et al[34] suggested that women with FM have neural brainstem disintegration which could lead to abnormal perception of audio-vestibular inputs and to abnormal auditory brainstem response. Current and previous finding demonstrating that the vestibular system was the most affected in individuals with FM would support this hypothesis. Nevertheless, since we did not specifically evaluate the function of the vestibular system in our sample of women with FM, the current results do not permit to determine whether the low scores on the vestibular component of the SOT were due to peripheral or central deficits.

Additionally to lower balance scores, we also observed that our sample of women with FM also used different strategy than healthy women for maintaining their balance. The SOT strategy scores indicate that woman with FM use a hip strategy to maintain their balance whereas healthy women use a more ankle strategy. Some possible reasons for these changes in balance strategy can be the presence of muscle trigger points in the gastrocnemius and tibialis anterior muscles[16] or the greater muscle fatigue in the tibialis anterior muscle[35] observed in FM. Future studies should investigate neurophysiological mechanisms related to changes in balance strategy in subjects with FM.

The most relevant result of our study was the positive association between balance scores and functional independence during ADL since the greater the loss of postural balance, the greater the interference with those ADL activities requiring proper postural control and balance, e.g., bathing and dressing. These findings are valuable for planning

proper treatment interventions, since deficits or loss of independence in these ADLs has a negative impact on the quality of life of the patients. Our results agree with the study by Amris et al[36] who investigated women with widespread chronic pain symptoms and observed that patients with FM have substantial problems affecting their daily life and are liable to need community support. Therefore, current findings can help for planning multidisciplinary interventions for individuals with FM. For instance, balance strategies and postural control can be treated with physical therapy whereas therapeutic strategies for improvement of ADL efficacy should be applied by occupational therapists. Further, cognitive behaviors or fear to movement can be benefit from psychological approaches.

Finally, this study presents several limitations. First, although significant differences were found between groups, these were based on a small sample size. Nevertheless, we believe that a large sample size would not alter the direction of our findings. Further, the population included was recruited from a regional hospital, which makes generalization of the results to the general population difficult. Consequently, further epidemiological studies with larger sample sizes are needed to enable a more generalized interpretation of the results. Second, we only included women diagnosed with FM. It is unknown whether men with FM would also exhibit similar results. Third, we excluded women with FM and comorbid depressive symptoms, so extrapolation of our results to this subgroup of patients with FM should be considered with caution. Although it seems that depression or anxiety may affect balance[37]; we do not known the effect of depression in the outcomes included in our study, particularly those related to the FIM. Fourth, as fatigue is a common denominator in individuals with FM, it was unknown whether the inclusion of several functional outcomes could be affected by rest-periods.

CONCLUSIONS

Women with FM exhibit poor balance and use different strategies for maintaining upright posture as compared to healthy women which may be associated to disturbances of the vestibular system. Additionally, balance deficits are associated with a negative impact on functional independence in ADL. Multidisciplinary treatments directed at improving the problems faced during ADLs may help improve the autonomy of women with FM.

Competing interests

All authors declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

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No additional data are available.

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TITLES OF TABLES

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

Table 2: Correlations between clinical pain variables and the SOT balance values in women with FM

Table 3: Correlations between the clinical pain variables and the SOT strategy values in women with FM

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

	Condition 1#	Condition 2#	Condition 3#	Condition 4#*	Condition 5#*	Condition 6#*
	Balance					
Women with FM	93.1 ± 5.4	89.7 ± 4.9	86.3 ± 7.0	76.5 ± 13.4	52.1 ± 18.0	54.7 ± 19.4
Healthy women	95.7 ± 1.3	92.3 ± 3.4	90.7 ± 5.3	86.4 ± 9.3	68.4 ± 12.6	70.8 ± 11.9
	Strategy					
Women with FM	98.5 ± 1.6	97.3 ± 4.4	96.7 ± 3.4	85.7 ± 8.1	76.1 ± 12.0	78.1 ± 7.6
Healthy women	98.8 ± 0.6	98.7 ± 0.7	98.3 ± 1.3	91.9 ± 3.2	81.2 ± 12.7	83.1 ± 11.1

Data are expressed as means ± Standard Deviation

Statistically significant differences between patients and controls (P<0.01; ANOVA test)

* Statistically significant differences between conditions 1-3 (P<0.001; ANOVA test)

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

Table 2: Correlations between clinical pain variables and the SOT balance values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = 0.124; P = 0.602	r_s = 0.276; P = 0.239	r_s = 0.242; P = 0.304	r_s = 0.169; P = 0.476
Condition 2	r_s = 0.291; P = 0.213	r_s = 0.051; P = 0.830	r_s = 0.334; P = 0.149	r_s = 0.179; P = 0.450
Condition 3	r_s = 0.310; P = 0.183	r_s = 0.152; P = 0.552	r_s = 0.131; P = 0.581	r_s = 0.127; P = 0.593
Condition 4	r_s = 0.308; P = 0.186	r_s = 0.084; P = 0.736	r_s = 0.076; P = 0.749	r_s = 0.07; P = 0.769
Condition 5	r_s = 0.135; P = 0.571	r_s = 0.111; P = 0.642	r_s = 0.151; P = 0.526	r_s = 0.219; P = 0.354
Condition 6	r_s = 0.123; P = 0.606	r_s = 0.050; P = 0.835	r_s = 0.156; P = 0.511	r_s = 0.156; P = 0.512

r_s = Spearman's correlation test (Spearman's rho)

Table 3: Correlations between the clinical pain variables and the SOT strategy values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = - 0.088; P = 0.713	r_s = 0.076; P = 0.749	r_s = 0.204; P = 0.388	r_s = 0.047; P = 0.846
Condition 2	r_s = 0.124; P = 0.602	r_s = - 0.032; P = 0.894	r_s = - 0.399; P = 0.082	r_s = - 0.210; P = 0.613
Condition 3	r_s = 0.123; P = 0.604	r_s = - 0.073; P = 0.759	r_s = - 0.040; P = 0.867	r_s = - 0.022; P = 0.926
Condition 4	r_s = - 0.069; P = 0.772	r_s = - 0.161; P = 0.498	r_s = - 0.118; P = 0.621	r_s = - 0.130; P = 0.585
Condition 5	r_s = 0.036; P = 0.879	r_s = 0.046; P = 0.848	r_s = - 0.140; P = 0.555	r_s = 0.380; P = 0.098
Condition 6	r_s = - 0.097; P = 0.685	r_s = - 0.086; P = 0.718	r_s = - 0.010; P = 0.966	r_s = - 0.151; P = 0.525

r_s = Spearman's correlation test (Spearman's rho)

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

	Balance						Strategy					
	1	**2**	**3**	**4**	**5**	**6**	**1**	**2**	**3**	**4**	**5**	**6**
Eating	.280	.179	.246	.251	.246	.350*	.175	.258	.185	.222	.154	.222
Grooming	.316*	.288	.308*	.375**	.428**	.451**	.002	.108	.154	.423**	.252	.423**
Bathing/showering	.314*	.469**	.481**	.429**	.491**	.541***	.256	.434**	.436**	.427**	.402*	.427**
Dressing upper body	.311*	.323*	.301	.458**	.343*	.307*	.136	.232	.313*	.530**	.450**	.530***
Dressing lower body	.401**	.448**	.336*	.373**	.351*	.438**	.100	.237	.336*	.562***	.469**	.562***
Toileting	.251	.376**	.258	.259	.251	.483**	.055	.223	.273	.521**	.430**	.521***
Bowel management	-.165	-.020	-.131	.062	.187	-.165*	-.212	-.076	-.221	.141	.030	.141
Bladder management	.064	-.051	-.002	.204	.083	.064	.087	.061	.099	.086	.303	.086
Chair-bed transfers	.325*	.491***	.510***	.433**	.451**	.441**	.220	.456**	.378**	.389**	.422**	.389**
Toilet transfers	.195	.223	.282	.453**	.255	.197	.145	.318*	.377**	.452**	.418**	.452**
Bath transfers	.417*	.441	.354	.321	.257	.405	.257	.314*	.351**	.558***	.407**	.558***
Locomotion	.110	-.172	-.039	-.009	-.158	-.192	.105	.132	.141	-.133	.000	-.133
Stairs	.365*	.238	.079	.164	.212	.164	.159	.154	.050	.176	.173	.176
Comprehension	.205	.264	.311*	.407**	.270	.281	.180	.375**	.254	.364**	.250	.364**
Expression	.097	.095	.113	.477**	.247	.372*	-.187	-.108	-.144	.306*	-.061	.306*
Social interaction	.285	.220	.303	.212	.005	.088	.239	.398**	.424**	.269	.158	.269
Problem solving	.192	.220	.245	.307*	.364*	.261	-.018	.033	-.006	.197	-.008	.197
Memory	.311*	.340*	.384**	.468**	.396**	.449**	.069	.156	.314*	.393**	.267	.393**

* P<0.05; ** P<0.01; *** P<0.001

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

STROBE Statement—checklist of items that should be included in reports of observational studies

Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography: a cross-sectional study in Spain

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Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography: a cross-sectional study in Spain

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ABSTRACT

Objectives: Our aims were: 1) to compare the sensory organization of balance control and balance strategies between women with fibromialgia (FM) and healthy women; 2) to investigate which sensory component, i.e., vestibular, visual or somato-sensory, is the most affected in FM; and, 3), to determine the associations between the functional independence measure (FIM) and balance responses in FM. **Design:** Cross-sectional observational study. **Setting:** Urban regional hospital and university (Universidad Rey Juan Carlos, Madrid, Spain). **Participants:** Twenty women with FM and 20 matched healthy women. **Primary/secondary outcome measures:** The Sensory Organization Test (SOT) was used to determine postural sway and balance during six different conditions with subjects in a standing position. The Functional Independence Measure (FIM) was used to determine the level of functional independence in daily life activities. Between-group differences were analyzed with ANCOVA and the Spearman's test was used for correlations. **Results:** Significant between-groups and between-conditions differences were found for all SOT conditions (all, $P<0.001$): women with FM showed lower scores being the vestibular score the most affected. Different correlations between SOT conditions and some specific daily life activities were observed in the FM group: bathing activity and balance condition 6 ($r_s=0.541$; $P<0.001$), bed transfers activity and conditions 2 ($r_s=0.491$; $P<0.001$) and 3 ($r_s=0.510$; $P<0.001$), positioning strategy 6 and dressing the upper ($r_s=0.530$; $P<0.001$) or lower ($r_s=0.562$; $P<0.001$) body, and toileting ($r_s=0.521$; $P<0.001$): the greater the loss of balance, the greater the interference on some daily life activities. **Conclusions:** Women with FM exhibited balance deficiencies and used different strategies for maintaining their balance in standing which was associated with a negative impact on functional independence.

KEY WORDS: Postural Balance, Fibromyalgia, Patient Positioning.

Strengths and limitations of this study:

- This is the first study investigating the association between postural balance and functional interference with activity daily living.
- The sample size was relatively small and from the same regional hospital.
- We only included women, but not me, diagnosed with fibromyalgia.

INTRODUCTION

Fibromyalgia (FM) is a chronic syndrome that has a considerable functional impact on patients. It is estimated that between 10-15% of the general population is affected by this syndrome in Europe[1]. The main complaint is generalized long-lasting muscle pain which is typically described as deep and intense and worsening with intense physical exercise, cold and/or emotional mental stress. This widespread pain is accompanied by other symptoms including asthenia, fatigue and non-restorative sleep together with other poorly defined symptoms[2]. Individuals with FM can also present muscle asymmetry[3] and difficulty for relaxing the muscles[4] which can contribute to fatigue and pain, leading to posture and balance deficit. In fact, balance problems are among the most debilitating symptoms reported by patients with FM.[5,6] Additionally, postural disturbances affecting the vertebral column have been also found[7] as well as lower spatio-temporal parameters during gait[8] and a higher risk of falls[9-11]. Finally, FM can be associated with general inactivity[12] which can lead to negative effects on the functional capacity of the patient.

Postural control requires the appropriate integration of sensory, visual, vestibular and somatosensory information into the central nervous system (mainly integrated by proprioceptive and cutaneous sensitivity). Posturography is a technique that enables a quantitative assessment of postural control by studying the displacements of the center of pressure in different circumstances simulating actions from normal daily life[13]. This technique itself does not enable a diagnosis; however, it provides information regarding functional status and is can be of value for guiding treatment.

Some of the most utilized tests in posturography include the Sensory Organization Test (SOT), the motor control test and the adaptation test[14]. The SOT enables isolation of components from the vestibular, visual and somatosensory systems that participate in the maintenance of postural control, enabling users to determine the site of the main

disorder causing the loss of balance[15]. Some previous studies have reported the presence of balance and postural control deficits in women with FM using different procedures[16-18]. Muto et al[17] observed that patients with FM exhibited impaired postural control, e.g., increased speed of oscillation of the center of gravity and lower balance self-efficacy as assessed with the modified clinical test of sensory interaction on balance (mCTSIB) and the balance self-efficacy (ABC scale). In this study, impaired postural control and low balance self-efficacy were associated with pain severity and muscle strength[17]. Jones et al[16] found that FM patients showed lower scores in almost all conditions of the SOT and an increased number of falls. In this study, postural stability was associated to related disability, cognitive impairment and body mass index, but not to medication intake, pain severity or muscle strength[16]. In a pilot study using the SOT, Russek and Fulk[18] reported that 34% of FM subjects scored below the fifth percentile for population normative data in some SOT conditions. These authors also found a negative association between the somato-sensory score of the SOT and FM-related disability[18]. Although these studies support the occurrence of balance problems in patients with FM using the SOT, they did not investigate the association of balance disturbances with functional independence in activities of daily living (ADLs). The identification of an association between balance problems and ADL disturbances can help clinicians for developing specific therapeutic strategies for patients with FMS. To the best of the author's knowledge, no study has previously investigated this association in patients with FM.

Therefore, the aims of the current study were: 1) to compare sensory organization of balance control and balance strategies between women with FM and healthy controls; 2) to investigate which sensory component (vestibular, visual or somato-sensory) is the most affected in FM women; and, 3), to determine the potential association between the functional independence measure (FIM) and balance responses in women with FM.

METHODS

Research Design

A cross-sectional study was performed. We conducted non-probabilistic sampling of consecutive cases, where subjects who met the established criteria were included. The study was conducted during the second semester of 2015.

Participants

Advertisements were placed in local newspapers in order to recruit healthy women from the general population for acting as control group. Participants were considered as healthy controls if they reported: no spontaneous pain symptoms at the moment of the study, no history of chronic pain (lasting more than 3 months), no pain experienced during the previous year prior to the study, no pain-related diagnoses and participants who were not taking antidepressant or analgesic medication.

Women with diagnosis of FM were recruited from the Department of Rheumatology at the Hospital Fundación Alcorcón (Spain). An experienced rheumatologist confirmed the FM diagnosis based on a combination of both American College of Rheumatology criteria (1990/m2010)[19,20]. It has been suggested that a combination of 1990 and m2010 criteria is recommended since it had the best diagnostic features[21,22]. Tender points were tested by digital palpation at the 18 sites according to the ACR protocol[19]. Participants were asked to indicate whether they experienced pain in response to a pressure of approximately 4 kg exerted by the examiner[19]. Further, the presence of fatigue, altered sleep patterns and other sensory symptoms self-perceived by the patient was recorded[20]. Face-to-face structured medical interviews were performed to determine the time of the diagnosis, socio-demographic and clinical data, current medication intake and presence of psychiatric disorders.

Exclusion criteria for both groups included: 1) co-morbid medical diagnoses, e.g., cardiopulmonary disorders, inflammatory disease, obesity, and other diagnoses; 2) malignancy; 3) psychiatric illnesses diagnosis, e.g. schizophrenia or substance abuse; 4) depression (Beck Depression Inventory-II >8 points); 5) previous history of surgery; 6) previous history of whiplash; 7) uncontrolled endocrine disorders (i.e. hyper- or hypo-thyroidism, diabetes); or 8) pregnancy.

Participants were matched on the basis of their age and hand dominance to gain homogeneity in the sample during the performance of those ADLs involving the upper extremity. Hand dominance was determined by self-reports regarding the hand used for writing.

Ethical considerations

The current study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was reviewed and approved by the Ethics committee of the Hospital Fundación Alcorcón (protocol FHA-URJC 032). All subjects provided written informed consent.

Study procedure

The study protocol for the SOT was the same for all participants. In addition, women with FM also fulfilled the Spanish version of the Fibromyalgia Impact Questionnaire (FIQ)[23] to assess FM-related disability[24]. All participants were verbally informed of the study, accepted the informed consent, and were familiarized with the different outcomes before starting data collection.

First, the SOT protocol was performed and subsequently participants completed the remaining assessments. All assessments were performed at a similar time of the day in the LAboratory for Movement analysis, Biomechanics, Ergonomics and MOtor Control

(LAMBECOM) located at the Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos (Spain).

The Functional Independence Measure (FIM) assessment took place in a suitably equipped apartment, via observation of subject's functional independence demonstrated during the performance of ADL contained in the scale. An external evaluator, blinded to the participant's condition, performed the assessments.

Outcome measures

Functional independence measure (FIM)

The FIM provides an assessment of the level of functional independence in daily life activities[25]. It also provides information primarily on cognitive and motor performance via 18 items. Scores range from 1-7, with higher scores corresponding to a higher level of functional independence. The possible score ranges from 18 to 126 points. The FIM includes observation and face-to-face interviews. This tool has demonstrated excellent psychometric properties[26-28].

Sensory Organization Test (SOT)

The posturography device used in the current study was the SOT assessment, which belongs to the Smart Balance Master©, by Neurocom® EQ0501, International, Inc (Oregon USA)[29,30]. The device consists of a platform connected to symmetrically placed transducers measuring the vertical and horizontal shear forces exercised through the anterior-posterior axis in the plane parallel to the floor. It is also equipped with a mobile visual surround screen. Both the visual surround and platform are computer-controlled and can move simultaneously. This device was connected to a PC Pentium I, with Smart Balance Master 5.0 software and a Samsung® monitor. The reports obtained for each participant were saved on the computer's hard drive.

To conduct the SOT, an individual's postural sway, and thereby balance is measured under 6 different conditions during standing. During these tests, the base of support and the visual surround screen can move according to the patient's balancing responses and the strategy used for maintaining an upright position. For instance, no altered stimuli are given in condition 1; whereas visual information is removed in condition 2, by asking the participant to close the eyes. In condition 3, the visual surround is moving with the subject's anterior-posterior body sway, whereas in condition 4, the platform rotates with the subject's anterior-posterior body sway. In condition 5, subjects close their eyes and the platform moves with the subject anterior-posterior body sway. Finally, in condition 6, the visual screen and the platform are moved with the subject's anterior-posterior body sway. Briefly, the 6 conditions can be resumed as follows: 1) eyes open, fixed surround and support platform; 2) eyes closed, fixed surround and support platform; 3) eyes open, moving surround (moving proportional to the angle of anterior-posterior body sway) and fixed support platform; 4) eyes open, fixed surround and moving support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, fixed surround and moving support platform; and 6) eyes open, moving surround and support platform. Tests were always performed following these steps in order. Each condition was performed 3 consecutive times and the mean was considered in the analysis. In total, the duration of the tests lasted approximately 12 minutes for each patient; therefore, it can be considered a non-fatiguing assessment. This procedure has shown good test-retest reliability in healthy people[31].

Participants were encouraged to maintain their stability and center of gravity, despite the movement of the visual surround or the base of support. The participant's center of gravity was displayed on the upper half of the screen. The feet were correctly positioned facing the visual surround during the entire test. If the participant fell, took a step or

touched the visual surround, the test was interrupted and the fall was registered. Data assessments were performed automatically and compared with theoretical normative electronic data. The score of each condition consist of a percentage that compares the subject anterior-posterior center of pressure sway with the theoretical limits of stability. The score is registered on a bar chart ranging from 0% to 100% where 0% represents the least stable (fall) and 100% indicates perfect stability[29].

In addition, combination of the results obtained in the different conditions provides a ratio score of each sensory system (somato-sensory, vestibular, or visual). The somato-sensory ratio (condition 2/condition 1) determines how successfully a person uses input from the somato-sensory system for balance; the visual ratio (condition 4/condition 1) determines how successfully a person uses visual system for balance; and the vestibular ratio (condition 5/condition 1) determines how successfully a person uses input from the vestibular system for balance.

Finally, a strategy score for each SOT condition is also calculated with scores near 100 indicating use of an ankle strategy and scores near 0 indicating a hip strategy

Sample Size Calculation

The sample size was calculated using the Ene 3.0 software (Autonomic University of Barcelona, Spain). The sample calculation was based on detecting significant moderate correlations (r=0.60) between the SOT conditions and FIM variables with an alpha level (α) of 0.05, and a desired power (β) of 80%. This generated a sample size of at least 19 subjects.

Statistical Analysis

The SPSS statistical package was used for data analysis (version 19.0, SPSS Inc, Chicago, IL, USA). The Kolmogorov-Smirnov test was used to analyze the normal distribution of the variables (P>0.05). Quantitative data without a normal distribution

(clinical data and FIM scores) were analyzed with non-parametric tests and those data with a normal distribution (SOT conditions) were analyzed with parametric tests. A 2x6 analysis of variance (ANCOVA) with group (FM or controls) as a between-subjects factor and with condition of the SOT (from 1 to 6) as a within-subjects factor was and body mass index as covariate used to analyze differences in the assessments of balance responses and strategies used for maintaining the upright position in the SOT. The main hypothesis of interest was the Group * Condition interaction. Further, unpaired Student t-tests were also conducted to determine between-groups difference for the ratio score of each sensory system (somato-sensory, vestibular, or visual). Finally, the Spearman's rho (rs) test was used to analyze potential associations between the clinical variables related to symptoms, disability, FIM and SOT conditions in the FM group. The statistical analysis was generally conducted at a 95% significance level; but, we corrected for multiple comparisons using the Holm-Bonferroni adjustment[32] assuming a significant alpha level of 0.008 (6 independent-samples t-tests by SOT condition).

RESULTS

Demographic and clinical data

Twenty-nine (n =29) women with FM were screened for eligibility criteria between January and November 2015. Nine women were excluded as follows: previous surgery (n=3), whiplash syndrome (n=2), pregnancy (n=2), diabetes (n=1) and litigation (n=1). The final sample consisted of 20 women with FM aged 35-55 years old (mean: 48±6 years) who satisfied all the eligibility criteria and agreed to participate. In addition, 20 matched healthy women; aged 35-56 years old (mean: 47±6 years) were also included. There were no significant differences in age (P=0.909) or body mass index (control: 23.8 ±1.3; FM: 24.2±1.5, P=0.508) between both groups. All participants were right-

handed. Seventeen (85%) women with FM (85%) were regularly taking non-steroidal anti-inflammatory medications. The FIQ revealed a moderate disability with a mean score of 57.9 (95%CI 53.1-62.6). All participants completed all assessments and there were no missing data.

Fibromyalgia and SOT

The ANCOVA revealed significant differences between groups (F=21.634; P<0.001) and conditions (F=45.164; P<0.001) for the balance responses on the SOT: women with FM displayed significantly (P=0.005) lower values in all SOT conditions than healthy women and scores of conditions 4-6 were significantly lower (all, P<0.01) than those for conditions 1-3 (table 1). A significant Group * Condition interaction was also found (F=3.404; P=0.006): differences between conditions 4-6 scores and conditions 1-3 were significantly more pronounced within the FM group. No effect of the body mass index was observed.

We found significant (t=2.901; P=0.006) lower vestibular ratio score in women with FM (mean: 0.55±0.2) as compared to healthy women (mean: 0.72±0.15). No significant differences in somato-sensory (t=0.011; P=0.989) and visual (t=1.900; P=0.065) ratios between women with FM (somato-sensory: 0.95±0.03; visual: 0.82±0.15) and healthy women (somato-sensory: 0.96±0.03; visual: 0.90±0.1) were observed.

[Insert table 1 about here]

The ANCOVA also revealed significant between-groups (F=10.456; P<0.001) and between-conditions (F=35.301; P<0.001) differences for the balance strategies used during the SOT conditions: FM women displayed significantly lower values (P<0.001) in all conditions than healthy women (table 1) suggesting a greater use of the hip instead the ankle. Again, scores on conditions 4-6 were lower than those values for conditions

1-3 (P<0.001). No significant Group x Condition interaction (F=1.170; P=0.325) or effect of the body mass index was observed.

Correlations between clinical variables and SOT conditions in fibromyalgia

Within the group of women with FM, no significant correlation was found between the duration (years) of neither pain nor the intensity of the symptoms with any of the SOT conditions. Table 2 displays correlation coefficients and the statistical significance for all conditions in the balance section, whereas table 3 displays the same data for each condition within the strategy section.

[Insert table 2 about here]

[Insert table 3 about here]

Correlations between functionality and SOT conditions

Positive correlations between different SOT conditions and different ADLs variables were found in the group of women with FM (table 4). The balance condition Nº6 (eyes open, mobile visual surround-mobile platform) was moderately associated with bathing activity (r_s=0.541; P<0.001) whereas conditions 2 and 3 were positively and moderately associated with bed transfers activity (r_s=0.491; P<0.001; and r_s=0.510; P<0.001, respectively): the lower the score balance in these conditions, the poorer the function in the respective ADLs.

[Insert table 4 about here]

Similarly, significant positive correlations were found between positioning strategy number 6 and the following ADLs: dressing upper body (r_s=0.530; P<0.001), dressing the lower body (r_s=0.562; P<0.001) and toileting (r_s=0.521; P<0.001): the worse the balance strategy, the greater interference with functional independence in these ADL.

DISCUSSION

The current study found that women with FM exhibit worse balance scores compared to healthy women as assessed with the SOT, in agreement with previous studies[16,18]. In fact, differences were higher with the eyes closed and moving surroundings surfaces. Further, the strategy used for stabilizing the ankle joint was poor in women with FM. Nevertheless, the most significant contribution of the current study was the association of balance scores with functional independence during ADL.

Women with FM exhibited lower scores in all SOT conditions compared to healthy women suggesting poor balance. Our results agree with those previously observed by Jones et al[16] and Russek and Fulk[18] who also reported significantly lower scores in all SOT conditions in individuals with FM. It is interesting to note that the scores observed in our study were similar to those reported in these previous studies[16,18]. Current and previous evidence would suggest that subjects with FM exhibit poor general balance as compared to healthy women. Nevertheless, although all SOT conditions showed lower scores in FM, the vestibular ratio was the most significantly impaired in our sample of women with FM. This may be related to the fact that scores in the last SOT conditions (4 to 6) were significantly much lower in the FM group than in the healthy group. As previously suggested, lower scores in conditions 4 to 6 compared to conditions 1 to 3 suggest a degree of somato-sensory dependence[15]. This hypothesis is in line with the study by De Brujin et al[33] who found that balance in patients with FM was more optimal on firm and regular surfaces. In fact, Russek and Fulk[18] and the current study did not find significant differences within the somato-sensory system ratio between individuals with FM and healthy people, suggesting that it is the vestibular, and probably the visual, system[16,18] the most affected in this population.

To determine the mechanisms related to poor balance in patients with FM is beyond the scope of the current study, but some hypotheses have been proposed. Since FM is characterized by abnormal nociceptive processing, it is possible that multiple processing disturbances may lead to poor balance. Additionally, other processing abnormalities of the central nervous system, e.g., cognitive dysfunction, could also contribute to postural instability. In fact, Bayazit et al[34] suggested that women with FM have neural brainstem disintegration which could lead to abnormal perception of audio-vestibular inputs and to abnormal auditory brainstem response. Current and previous finding demonstrating that the vestibular system was the most affected in individuals with FM would support this hypothesis. Nevertheless, since we did not specifically evaluate the function of the vestibular system in our sample of women with FM, the current results do not permit to determine whether the low scores on the vestibular component of the SOT were due to peripheral or central deficits.

Additionally to lower balance scores, we also observed that our sample of women with FM also used different strategy than healthy women for maintaining their balance. The SOT strategy scores indicate that woman with FM use a hip strategy to maintain their balance whereas healthy women use a more ankle strategy. Some possible reasons for these changes in balance strategy can be the presence of muscle trigger points in the gastrocnemius and tibialis anterior muscles[16] or the greater muscle fatigue in the tibialis anterior muscle[35] observed in FM. Future studies should investigate neurophysiological mechanisms related to changes in balance strategy in subjects with FM.

The most relevant result of our study was the positive association between balance scores and functional independence during ADL since the greater the loss of postural balance, the greater the interference with those ADL activities requiring proper postural control and balance, e.g., bathing and dressing. These findings are valuable for planning

proper treatment interventions, since deficits or loss of independence in these ADLs has a negative impact on the quality of life of the patients. Our results agree with the study by Amris et al[36] who investigated women with widespread chronic pain symptoms and observed that patients with FM have substantial problems affecting their daily life and are liable to need community support. Therefore, current findings can help for planning multidisciplinary interventions for individuals with FM. For instance, balance strategies and postural control can be treated with physical therapy whereas therapeutic strategies for improvement of ADL efficacy should be applied by occupational therapists. Further, cognitive behaviors or fear to movement can be benefit from psychological approaches.

Finally, this study presents several limitations. First, although significant differences were found between groups, these were based on a small sample size. Nevertheless, we believe that a large sample size would not alter the direction of our findings. Further, the population included was recruited from a regional hospital, which makes generalization of the results to the general population difficult. Consequently, further epidemiological studies with larger sample sizes are needed to enable a more generalized interpretation of the results. Second, we analyzed around 264 correlations in our study. It is possible that a Type I error would be present. A greater sample size would help to elucidate if the significant association observed in the current study are further significant or not. Third, we only included women diagnosed with FM. It is unknown whether men with FM would also exhibit similar results. Fourth, we excluded women with FM and comorbid depressive symptoms, so extrapolation of our results to this subgroup of patients with FM should be considered with caution. Although it seems that depression or anxiety may affect balance[37]; we do not known the effect of depression in the outcomes included in our study, particularly those related to the FIM. Fifth, as fatigue is a

common denominator in individuals with FM, it was unknown whether the inclusion of several functional outcomes could be affected by rest-periods.

CONCLUSIONS

Women with FM exhibit poor balance and use different strategies for maintaining upright posture as compared to healthy women which may be associated to disturbances of the vestibular system. Additionally, balance deficits are associated with a negative impact on functional independence in ADL. Multidisciplinary treatments directed at improving the problems faced during ADLs may help improve the autonomy of women with FM.

Competing interests

All authors declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

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Data sharing statement

No additional data are available.

Contributor-ship Information

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TITLES OF TABLES

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

Table 2: Correlations between clinical pain variables and the SOT balance values in women with FM

Table 3: Correlations between the clinical pain variables and the SOT strategy values in women with FM

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

Table 1: Differences in the values of the sensory organization test (SOT) between women with FM and healthy women

	Condition 1#	Condition 2#	Condition 3#	Condition 4#*	Condition 5#*	Condition 6#*
	Balance					
Women with FM	93.1 ± 5.4	89.7 ± 4.9	86.3 ± 7.0	76.5 ± 13.4	52.1 ± 18.0	54.7 ± 19.4
Healthy women	95.7 ± 1.3	92.3 ± 3.4	90.7 ± 5.3	86.4 ± 9.3	68.4 ± 12.6	70.8 ± 11.9
	Strategy					
Women with FM	98.5 ± 1.6	97.3 ± 4.4	96.7 ± 3.4	85.7 ± 8.1	76.1 ± 12.0	78.1 ± 7.6
Healthy women	98.8 ± 0.6	98.7 ± 0.7	98.3 ± 1.3	91.9 ± 3.2	81.2 ± 12.7	83.1 ± 11.1

Data are expressed as means ± Standard Deviation

Statistically significant differences between patients and controls (P<0.001; ANCOVA test)

* Statistically significant differences between conditions 1-3 (P<0.01; ANCOVA test)

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

Table 2: Correlations between clinical pain variables and the SOT balance values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = 0.124; P = 0.602	r_s = 0.276; P = 0.239	r_s = 0.242; P = 0.304	r_s = 0.169; P = 0.476
Condition 2	r_s = 0.291; P = 0.213	r_s = 0.051; P = 0.830	r_s = 0.334; P = 0.149	r_s = 0.179; P = 0.450
Condition 3	r_s = 0.310; P = 0.183	r_s = 0.152; P = 0.552	r_s = 0.131; P = 0.581	r_s = 0.127; P = 0.593
Condition 4	r_s = 0.308; P = 0.186	r_s = 0.084; P = 0.736	r_s = 0.076; P = 0.749	r_s = 0.07; P = 0.769
Condition 5	r_s = 0.135; P = 0.571	r_s = 0.111; P = 0.642	r_s = 0.151; P = 0.526	r_s = 0.219; P = 0.354
Condition 6	r_s = 0.123; P = 0.606	r_s = 0.050; P = 0.835	r_s = 0.156; P = 0.511	r_s = 0.156; P = 0.512

r_s = Spearman's correlation test (Spearman's rho)

Table 3: Correlations between the clinical pain variables and the SOT strategy values in women with FM

	Duration of symptoms	Current pain	Best pain	Worse pain
Condition 1	r_s = - 0.088; P = 0.713	r_s = 0.076; P = 0.749	r_s = 0.204; P = 0.388	r_s = 0.047; P = 0.846
Condition 2	r_s = 0.124; P = 0.602	r_s = - 0.032; P = 0.894	r_s = - 0.399; P = 0.082	r_s = - 0.210; P = 0.613
Condition 3	r_s = 0.123; P = 0.604	r_s = - 0.073; P = 0.759	r_s = - 0.040; P = 0.867	r_s = - 0.022; P = 0.926
Condition 4	r_s = - 0.069; P = 0.772	r_s = - 0.161; P = 0.498	r_s = - 0.118; P = 0.621	r_s = - 0.130; P = 0.585
Condition 5	r_s = 0.036; P = 0.879	r_s = 0.046; P = 0.848	r_s = - 0.140; P = 0.555	r_s = 0.380; P = 0.098
Condition 6	r_s = - 0.097; P = 0.685	r_s = - 0.086; P = 0.718	r_s = - 0.010; P = 0.966	r_s = - 0.151; P = 0.525

r_s = Spearman's correlation test (Spearman's rho)

Table 4: Correlations between the SOT balance and strategy values and the FIM in women with FM

	Balance						Strategy					
	1	2	3	4	5	6	1	2	3	4	5	6
Eating	.280	.179	.246	.251	.246	.350*	.175	.258	.185	.222	.154	.222
Grooming	.316*	.288	.308*	.375**	.428**	.451**	.002	.108	.154	.423**	.252	.423**
Bathing/showering	.314*	.469**	.481**	.429**	.491**	.541***	.256	.434**	.436**	.427**	.402*	.427**
Dressing upper body	.311*	.323*	.301	.458**	.343*	.307*	.136	.232	.313*	.530**	.450**	.530***
Dressing lower body	.401**	.448**	.336*	.373**	.351*	.438**	.100	.237	.336*	.562***	.469**	.562***
Toileting	.251	.376**	.258	.259	.251	.483**	.055	.223	.273	.521**	.430**	.521***
Bowel management	-.165	-.020	-.131	.062	.187	-.165*	-.212	-.076	-.221	.141	.030	.141
Bladder management	.064	-.051	-.002	.204	.083	.064	.087	.061	.099	.086	.303	.086
Chair-bed transfers	.325*	.491***	.510***	.433**	.451**	.441**	.220	.456**	.378**	.389**	.422**	.389**
Toilet transfers	.195	.223	.282	.453**	.255	.197	.145	.318*	.377**	.452**	.418**	.452**
Bath transfers	.417*	.441	.354	.321	.257	.405	.257	.314*	.351**	.558***	.407**	.558***
Locomotion	.110	-.172	-.039	-.009	-.158	-.192	.105	.132	.141	-.133	.000	-.133
Stairs	.365*	.238	.079	.164	.212	.164	.159	.154	.050	.176	.173	.176
Comprehension	.205	.264	.311*	.407**	.270	.281	.180	.375**	.254	.364**	.250	.364**
Expression	.097	.095	.113	.477**	.247	.372*	-.187	-.108	-.144	.306*	-.061	.306*
Social interaction	.285	.220	.303	.212	.005	.088	.239	.398**	.424**	.269	.158	.269
Problem solving	.192	.220	.245	.307*	.364*	.261	-.018	.033	-.006	.197	-.008	.197
Memory	.311*	.340*	.384**	.468**	.396**	.449**	.069	.156	.314*	.393**	.267	.393**

* P<0.05; ** P<0.01; *** P<0.001

Footnote: 1) eyes open, fixed visual surround and fixed support platform; 2) eyes closed, fixed support platform; 3) eyes open, mobile visual surround (moving proportional to the angle of anterior-posterior body sway) and the fixed support platform; 4) eyes open, fixed visual surround and mobile support platform (moving proportional to the angle of anterior-posterior body sway); 5) eyes closed, mobile support platform; and 6) eyes open, mobile visual surround and mobile support platform.

STROBE Statement—checklist of items that should be included in reports of observational studies

Balance deficiencies in women with fibromyalgia assessed using computerized dynamic posturography

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	8-9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	9-10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.