Earthquake vulnerability of fibromyalgia patients: six-month follow-up after the catastrophic disasters in central Italy

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ABSTRACT

Objective. To investigate the 6-month impact of the catastrophic earthquakes that struck central Italy in August and October 2016 on the health-related quality of life (HRQoL) of patients with fibromyalgia (FM).

Methods. We compared a cohort of 55 consecutive FM patients who had been exposed to an earthquake with a control group of 49 FM patients who had not been exposed to it. At each timepoint (baseline, and after one, two, four and six months), the patients completed self-reported electronic versions of the revised Fibromyalgia Impact Questionnaire (FIQR) and the Fibromyalgia Activity Score (FAS) on a web platform.

Results. At baseline, there were no significant between-group differences in the total FIQR score or the scores of its three domains of function, overall impact and symptoms, and no significant differences in the total FAS score or the FAS fatigue, quality of sleep, and Self-Assessment Pain Scale (SAPS) scores. However, after six months of observation, the median total FIOR score was higher in the earthquake-exposed patients (241.00, 95% confidence interval [CI] 230.55-255.35) than in the unexposed patients (177.50, 95% CI 157.30-185.48; p<0.0001), and the same was true of the median total FAS score (26.86, 95% CI 25.78-28.18 vs. 22.76,95% CI 20.92–24.34; p<0.0001). Moreover, there were also significant differences in all of the FIQR and FAS domain scores.

Conclusion. A natural catastrophe such as an earthquake can have a significant impact on the major domains of pain, fatigue, sleep, and the overall quality of life of FM patients.

Introduction

A series of catastrophic earthquakes struck the central Italian regions of Marche, Abruzzo and Umbria between August and October 2016. On 24th

August, a magnitude 6.2 earthquake hit the town of Amatrice, causing more than 290 victims and leaving several thousand homeless. The many aftershocks during the following days continued taking a toll of survivors, leading to the displacement of 2,925 people (970 in Lazio, 1,200 in Marche and 755 in Umbria) and, by 30 August, the Civil Defence Authority reported that 3,554 people were being accommodated in temporary camps. On 26th October, the same area was struck by two powerful earthquakes (one of magnitude 5.5 and the other of magnitude 6.1) within two hours of each other and, although no victims were reported because the first drove most people out of their homes and saved their lives, 25 municipalities were severely damaged. A third earthquake (magnitude 6.6) struck six kilometres north of the town of Norcia on 30 October. These catastrophic events caused extensive destruction, including that of historical buildings such as the Basilica of Saint Benedict in Norcia, and had a profound effect on everyone throughout Italy.

Despite existing evidence of the shortand long-term effects of disaster-related experiences such as post-traumatic stress disorder (PTSD) on physical and psychological health outcomes, the health-related quality of life (HRQoL) of survivors and the factors associated with it is an under-studied area, especially in the case of patients with chronic diseases. The main aim of this study was to investigate the six-month impact of the central Italian earthquakes on the HRQoL of patients with fibromyalgia (FM).

Materials and methods

Study population

Fifty-five patients living in the areas that were most affected by the earthquakes were selected from a large webbased database of FM patients referring to the Rheumatology Department of

the Polytechnic University of Marche in Jesi, Ancona (1, 2) (http://www.fibromialgiaitalia.it). They all satisfied the 2010 American College of Rheumatology (ACR) FM classification criteria (3) and had none of the exclusion criteria, which were the presence of cardiovascular disease, moderate/severe chronic lung disease, uncontrolled hypertension, uncontrolled thyroid disturbances, inflammatory rheumatic conditions (rheumatoid arthritis, systemic lupus erythematosus, and other connective tissue diseases), schizophrenia or other psychoses. The control group consisted of 49 FM patients coming from areas not affected by the earthquakes, and matched for age, gender, symptom duration and socio-demographic characteristics, was selected from the same database.

The study was approved by the hospital Ethics Committee and conducted between September 2016 and April 2017 in accordance with the Helsinki Declaration.

Web-based patient reported outcomes

Upon recruitment to the on-line followup, all of the patients received a secure username/password combination to log into the specifically developed study website. Consent was obtained electronically and consenting patients were asked to complete electronic versions of the revised Fibromyalgia Impact Questionnaire (FIQR) (4, 5) and the Fibromyalgia Activity Score (FAS) (6) at least once a month. The questions were displayed using radio buttons, and check boxes and drop-down menus were used for the responses. Each question had to be completed before the software continued to the following page. The two questionnaires took approximately 10 minutes to complete. The FIQR was developed by Bennett et al. in an attempt to address the limitations of the original FIQ (4). The Italian version (5) has 21 items that are rated using an 11-point numerical scale (0-10, with 10 being the worst), and cover the three domains of function, overall impact and symptoms with a recall period of seven days. The total maximum score is 100: the total score for the 9-item function domain (range 0-90) is divided by three; the total score for the

Table I. Demographic characteristics of the study patients.

Characteristics	1	ke survivors n=55)	Controls (n=49)		
Women, n. (%)	49	(89.1)	46	(93.8)	
Mean age, years (SD)	50.1	(10.3)	51.4	(9.8)	
Mean disease duration, years (SD)	4.9	(3.8)	5.1	(4.2)	
Education					
Primary school, n (%)	13	(23.6)	11	(22.5)	
Middle school, n (%)	30	(54.5)	28	(57.1)	
High school/university, n. (%)	16	(21.9)	10	(20.4)	
Employment status					
Employed, n (%)	31	(56.4)	29	(59.2)	
Work-disabled, n (%)	12	(21.8)	10	(20.4)	
Other (student, full-time homemaker, other), n (%)) 12	(21.8)	10	(20.4)	
Marital status					
Married, n (%)	32	(58.2)	28	(57.1)	
Divorced/separated, n (%)	13	(23.6)	10	(20.4)	
Single, n (%)	5	(9.1)	6	(12.2)	
Widowed, n (%)	5	(9.1)	5	(10.3)	
Mean BMI, kg/m ² (SD)	27.7	(5.1)	28.1	(6.4)	

2-item overall impact domain (range 0-20) remains as it is; and the total score for the 10-item symptom domain (range 0-100) is divided by two. The patients' total scores were used to classify the severity of FM as mild (from 0 to <39), moderate (from 39 to <59), or severe (59–100).

The FAS is a valid, reliable and responsive disease-specific composite measure for patients with FM (1,6) that combines scores relating to fatigue (range 0-10) and the quality of sleep (range 0-10) with scores obtained using the Self-Administered Pain Scale (SAPS) in order to provide a single measure of disease activity (range 0-10). The SAPS asks patients to classify pain (0=none, 1=mild, 2=moderate, and 3=severe) in 16 non-articular sites, and the final total score of 0-48 is transformed into a scale of 0-10.

At the end of the study, the electronically collected raw HRQoL data (including the number, age and gender of the patients, the duration of the assessments, and their results) were extracted and made anonymous.

Statistical analysis

Depending on their distribution (tested using the Kolmogorov-Smirnov test), the continuous data are presented as mean values and standard deviations (SD) or median values with their 95% confidence intervals (95% CIs). The demographic and clinical measures were compared using the Mann-Whitney Utest for the continuous variables and the chi-squared test for the discontinuous variables. Serial measurement analysis was used to compare the area under the curve (AUC) between the two FM groups. The serial measurements diagram plotted the serial data of every case consecutively. Although the use of summary measures to analyse serial measurements is not new, it is simple and potentially useful for medical research (7).

All of the data were entered into a Microsoft Excel database developed for the management of prospective multicentre studies, and were analysed using MedCalc[®], v. 15.0 (MedCalc Software, Mariakerke, Belgium).

Results

The 55 earthquake-exposed patients were compared with the 49 unexposed controls. Most of the patients were women (89.1% in the earthquakeexposed group vs. 93.8% in the unexposed group) and middle-aged (mean 50.1±10.3 years in the earthquake-exposed group vs. 51.4±9.8 years in the unexposed group); disease duration was respectively 4.9±3.8 and 5.1±4.2 years. Most of the patients in both groups had received a secondary school education, and the majority were employed. There were no significant differences in the demographic characteristics of the two groups (Table I).



Fig. 1. Total FIQR (a) and FAS score trajectories (b) of each patient during the 6-month follow-up.

The FIQR and FAS scores were not normally distributed (Kolmogorov-Smirnov test). At baseline, there was no significant between-group difference in the total FIQR score or the scores of its three domains of function, overall impact and symptoms, and no significant difference in the total FAS score or the FAS fatigue, quality of sleep, and Self-Assessment Pain Scale (SAPS) scores. However, during the follow-up, the two groups of patients significantly differed. Figures 1a-b show the total FIQR and FAS score trajectories of each subject. After six months, the median AUC of the total FIQR total score in the earthquake-exposed patients was 241.00 (95% CI 230.55-255.35) and the mean AUC was 243.66±35.69 (95% CI 234.01-253.31); the corresponding figures in the unexposed patients were respectively 177.50 (95% CI, 157.30-185.48; two-tailed Whitney U test, p<0.0001) and 173.84±62.89 (95%) CI 155.77-191.90) (Table II, Fig. 2a). Similarly, after 6-months of observation, the median and mean AUC of the total FAS score was higher in the group of earthquake-exposed patients (median: 26.86, 95% CI 25.78-28.18; mean: 26.62±2.68, 95% CI 25.90-27.35) than in the group of unexposed patients (median: 22.76, 95% CI 22.76-24.38;

mean: 22.29 ± 5.27 , 95% CI 20.77– 23.80, p<0.0001) (Table III, Fig 3a). Moreover, there were significant differences in the 6-month period in all of the FIQR and FAS sub-domain scores between the earthquake-exposed and unexposed patients (Table II, Table III, Figs. 2b-2d, Fig. 3b-3d).

Discussion

Our findings show that a natural catastrophe such as an earthquake can have a significant impact on the major FM domains of pain, fatigue, sleep, and the quality of life. A number of studies have investigated the repercussions of unexpected natural events on the everyday life of healthy survivors, and highlighted the increased risk of developing chronic pain syndromes or psychological distress, but there are no published data concerning patients with pre-existing FM.

A cross-sectional study by Yabuki *et al.* (8) evaluated the impact of the Great East Japan Earthquake on pain thresholds, general health and social functioning in 71 non-FM evacuees 18 months after it struck on 11 March 2011 by administering a numeric rating scale (NRS), the Medical Oycome Study short-form 36-item Health Survey (SF-36) and a pedometer. The authors found

lower pain thresholds (62.0% of the subjects experienced chronic pain with a mean NRS score of 2.74), an impaired quality of life and reduced physical activity, with worse scores in the subjects still living in their homes than in those sheltering in tents.

Physical injury leading to disability may severely affect the quality of life of earthquake survivors, reduce pain thresholds and lead to symptoms of anxiety or depression. Sudaryo et al. found that injured people surviving a 7.6 magnitude earthquake that hit the coast of Padang City in West Sumatra in September 2009 had a worse quality of life than non-injured people (9). Cammack et al. described the cases of two young women surviving a magnitude 6.3 earthquake that struck Christchurch, New Zealand, in February 2011 (10) who suffered severe traumatic injuries involving the lower limbs and pubic rami that required urgent hospitalisation. After surgery and the stabilisation of their global health, they developed chronic pain, allodynia and mood fluctuation requiring opioid analgesics and antidepressants.

Many of these manifestations can be traced back to a PTSD, which shares some of the clinical features of FM, including chronic generalised pain and

Table II. Comparison of the area under curve of total FIQR score and function, overall impact, and symptoms sub-scores in the earthquake survivors and controls after six months' follow-up.

AUC of total FIQR score									
Group	Pts	Mean	95% CI	SD	Median	95% CI			
Controls	49	173.84	155.77 - 191.90	62.89	177.50	157.30 - 185.48			
Earthquake survivors	55	243.66	234.01 - 253.31	35.69	241.00	230.55 - 255.35			
Mann-Whitney test									
Average rank of first group						34.46			
Average rank of second group						68.56			
Mann-Whitney U test						464.00			
Test statistic Z (corrected for ties)						5.75			
Two-tailed probability						<i>p</i> <0.0001			

Group	Pts	Mean	95% CI	SD	Median	95% CI
Controls	49	43.33	36.87 - 49.79	22.48	42.00	36.67 - 51.65
Earthquake survivors	55	67.41	63.93 - 70.90	12.88	65.50	62.38 - 69.94
Mann-Whitney test						
Average rank of first group						35.48
Average rank of second group						67.65
Mann-Whitney U test						514.00
Test statistic Z (corrected for ties)						5.42
Two-tailed probability						<i>p</i> <0.0001

Group	Pts	Mean	95% CI	SD	Median	95% CI
Controls	49	28.77	23.65 - 33.89	17.82	28.00	22.26 - 33.00
Earthquake survivors	55	46.49	42.84 - 50.13	13.48	48.00	41.76 - 52.70
Mann-Whitney test						
Average rank of first group						37.11
Average rank of second group						66.20
Mann-Whitney U test						593.50
Test statistic Z (corrected for ties)						4.91
Two-tailed probability						<i>p</i> <0.0001

Group	Pts	Mean	95% CI	SD	Median	95% CI
Controls	49	102.15	94.47 - 109.84	26.74	104.00	95.17 - 110.50
Earthquake survivors	55	129.70	125.28 - 134.11	16.32	130.00	127.52 - 132.09
Mann-Whitney test						
Average rank of first group						35.28
Average rank of second group						67.83
Mann-Whitney U test						504.00
Test statistic Z (corrected for ties)						5.49
Two-tailed probability						<i>p</i> <0.0001

Pts: patients; CI: confidence interval; AUC: area under the curve; FIQR: Revised Fibromyalgia Impact Questionnaire.

somatic symptoms. A German study has demonstrated that FM may follow or accompany the onset of PTSD in predisposed subjects (11), and traumatic events such as natural catastrophes may trigger FM symptoms. Biological and psychological stressors such as family and working life that underlie the onset of the FM model may also provide favourable circumstances in which an unexpected traumatic event can reinforce pain, fatigue, and anxious-hypochondriac or neuro-vegetative symptoms (12).



Fig. 2. Median (\pm standard error) total FIQR (a), function (b), overall impact scores (c), and symptoms (d), as measured by means of time integration (area under the curve) at monthly intervals in the earthquake survivors and controls.

Table III. Comparison of the area under curve (AUC) of total FAS score and fatigue, SASP, and quality of sleep sub-scores in the earthquake survivors and controls after six months' follow-up.

	AUC	of the tota	I FAS scores						
Group	Pts	Mean	95% CI	SD	Median	95% CI			
Controls	49	22.29	20.77 - 23.80	5.27	22.76	20.92 - 24.34			
Earthquake survivors	55	26.62	25.90 - 27.35	2.68	26.86	25.78 - 28.18			
Mann-Whitney test									
Average rank of first group						38.15			
Average rank of second group						65.28			
Mann-Whitney U test						644.50			
Test statistic Z (corrected for ties)						4.57			
Two-tailed probability						<i>p</i> <0.0001			

AUC of the fatigue sub-scores								
Group	Pts	Mean	95% CI	SD	Median	95% CI		
Controls	49	24.98	22.98 - 26.97	6.933	25.50	22.50 - 27.91		
Earthquake survivors	55	30.33	29.33 - 31.34	3.722	30.50	30.00 - 31.61		
Mann-Whitney test								
Average rank of first group						38.87		
Average rank of second group						64.63		
Mann-Whitney U test						680.00		
Test statistic Z (corrected for ties)						4.34		
Two-tailed probability						<i>p</i> <0.0001		

	AUC of the SAPS sub-scores									
Group	Pts	Mean	95% CI	SD	Median	95% CI				
Controls	49	19.05	17.36 - 20.73	5.87	20.00	18.30 - 21.81				
Earthquake survivors	55	22.81	21.81 - 23.80	3.67	23.12	22.24 - 24.39				
Mann-Whitney test										
Average rank of first group						41.00				
Average rank of second group						62.74				
Mann-Whitney U test						784.00				
Test statistic Z (corrected for ties)						3.67				
Two-tailed probability						<i>p</i> =0.0002				

Group	Pts	Mean	95% CI	SD	Median	95% CI
Controls	49	22.71	20.71 - 24.71	6.96	23.00	21.00 - 25.41
Earthquake survivors	55	27.07	25.77 - 28.37	4.80	27.50	25.88 - 29.00
Mann-Whitney test						
Average rank of first group						41.65
Average rank of second group						62.16
Mann-Whitney U test						816.00
Test statistic Z (corrected for ties)						3.46
Two-tailed probability						p=0.0005

Pts: patients; CI: confidence interval; AUC: area under the curve; FAS: Fibromyalgia Activity Score; SAPS: Self-Assessment Pain Scale.

Angeletti *et al.* recorded 958 triage documents of patients attending an Emergency Department because of pain following the magnitude 6.3 earthquake that struck L'Aquila, Italy, in 2009 (13), and found that 34.6% of the patients reported pain due to multiple causes (musculoskeletal injuries, wounds, respiratory or cardiocirculatory diseases, neoplasms, headache), 58.8% of whom were affected by severe pain as assessed by means of an 11-point numeric scale, and ten (3%) were classified as having diffuse joint/muscle pain.



Fig. 3. Median (\pm standard error) total FAS (**a**), fatigue (**b**), SASP (**c**), and sleep scores (**d**), as measured by means of time integration (area under the curve) at monthly intervals in the earth-quake survivors and controls.

Zhang et al. investigated the 5-year repercussions of the 2008 Wenchuan earthquake in China on 684 survivors using the civilian version of the PTSD Checklist (PCL-C) (14), and found that the prevalence of PTSD was 9.2%, and that it was significantly associated with female gender, a poor education, and the loss of a family member. Psychological distress following a catastrophic natural event was also investigated in a study by Guimaro et al. that involved 40 people a few months after they had survived a magnitude 7.0 earthquake in Haiti in January 2010 (15). The Hamilton Depression Scale and Beck Anxiety Inventory showed that 55% had symptoms of depression and 40% symptoms of anxiety, which directly correlated with the burden of the loss of a familiar member

A longitudinal study telephonically assessing 58 Norwegian tourists who survived the Khao Lak tsunami in Thailand in 2004 two and six years after the event found an increased prevalence of PTSD, depression and a poorer quality of life, which were partly mitigated by coping strategies and post-traumatic growth behaviours (16).

All of the patients in our cohort had an established and defined diagnosis of FM. They were not assessed for PTSD, which shares some of the features of FM, but the FIQR and FAS questionnaires showed that the patients exposed to the earthquakes had worse scores than those who had not been exposed. A number of studies have described the significant influence of demographic features on patients experiencing traumas. Valenti et al. evaluated the effects of the 2009 L'Aquila earthquake on an adult disease-free population 18 months after it occurred using the Italian version of the World Health Organisation-Quality of Life-BREF assessment instrument (WHOQOL-BREF) (17). Although there as no control group, the authors found that these subjects generally had poor WHOQOL-BREF scores that were considerably influenced by age and education. Similarly, in a study of 349 survivors of the 6.5 magnitude earthquake that struck Ludian, China, in August 2014, Tang et al. found that that physical and mental component summaries varied with education and age (18): the subjects with higher education levels had better coping methods and more social resources, thus minimising the risk of mental health problems. The authors also showed that female gender was associated with a poorer mental component summary, which was perhaps related to a hormone-dictated condition that makes women more vulnerable during stressful events.

Female susceptibility to PTSD following a natural catastrophe was investigated by Takeda et al. in a cross-sectional study of 1,489 female high school students nine months after the Great East Japan Earthquake of March 2011 (19). All of the participants were assessed for PTSD and premenstrual syndrome by means of a premenstrual syndrome questionnaire and the Japanese version of the revised Impact of Event Scale. Of the 1,180 subjects who completed the questionnaires, 10% were classified as having a PTSD, which was also significantly associated with worse premenstrual syndrome questionnaire scores. Following the same event, Yokoyama et al. found that 42.8% of 10,198 people living in the municipalities of Yamada, Otsuchi, and Rikuzentakata were affected by a mental health disturbance as assessed using the K6 Scale; these were mainly women or people with a low socio-economic status (20).

Finally, Khachadourian *et al.* evaluated the impact of the 1988 Spitak earthquake in Armenia on the quality of life of 725 exposed subjects after an interval of 23 years. The people who had suffered severe losses or who had received less social or economic support had the worst scores when assessed using the European Quality of Life-5 Dimensions Questionnaire (21).

In conclusion, our short-term observational study recording the FIQR and FAS scores of FM patients at baseline, and one, two, four and six months after the earthquakes striking central Italy in 2016 demonstrates for the first time that a natural catastrophe such as an earthquake can have a significant impact on the quality of life of FM patients as demonstrated in other countries (22). However, in addition to its short duration, the main limitations of the study are that it did not include an evaluation of PTSD, the use of healthcare resources, or the provision of socio-economic assistance to the earthquake-exposed subjects, and so further studies with a longer follow-up and improved methodology are required in order to collect more data concerning the effects of natural traumatic events on the course of the disease.

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