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Clinically significant fatigue after stroke: A longitudinal cohort study ☆

Fiona Duncan [a,1], Carolyn Greig [a,2], Susan Lewis [a,1], Martin Dennis [b,3], Alasdair MacLullich [a,1], Michael Sharpe [c,4], Gillian Mead [a,*]

[a] Geriatric Medicine, University of Edinburgh, UK
[b] Division of Clinical Neurosciences, University of Edinburgh, UK
[c] Department of Psychiatry, University of Oxford, UK

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ABSTRACT

Objective: Fatigue is often distressing for stroke survivors. The time course of clinically significant fatigue in the first year after stroke is uncertain.
We aimed to determine the frequency, severity and time course of clinically significant fatigue in the first 12 months after stroke onset.
Methods: We recruited patients with a recent acute stroke. At about one month, six months and 12 months, we performed a structured interview to identify clinically significant fatigue (case definition), and assessed fatigue severity (Fatigue Assessment Scale (FAS)).
Results: Of 157 patients who initially consented, 136 attended at least one assessment. At one month, 43/132 (33%) had clinically significant fatigue. Eighty-six attended all three assessments, of whom clinically significant fatigue was present in 24 (28%) at one month, 20 (23%) at six months and 18 (21%) at 12 months; their median (IQR) FAS scores were 23 (18 to 29), 21 (17 to 25) and 22.5 (17 to 28) at one, six and 12 months respectively. Of 101 patients who attended at least the one and six month assessments, fatigue status did not change in 65 (64%), with 9 (9%) fatigued throughout and 56 (55%) non-fatigued throughout; 15 (15%) became non-fatigued, 9 (9%) became fatigued, and in 12 (12%) fatigue status fluctuated across three assessments.
Conclusion: Clinically significant fatigue affected a third of patients one month after stroke. About two thirds of these patients had become non-fatigued by six months, most of whom remained non-fatigued at 12 months. Fatigue persists in a third at 12 months.

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Introduction

Fatigue is a common problem after stroke [1] for which there is currently no effective treatment [2]. Understanding the time course of fatigue after stroke is important, so that healthcare professionals can counsel patients about whether it is likely to improve over time. If fatigue persists in a substantial proportion of patients, this would justify the development of interventions. There is one published systematic review of longitudinal cohort studies of post-stroke fatigue (9 studies reporting on 959 patients) [3] and one further longitudinal study published since that review [4]. These studies determined the presence or absence of fatigue using either a cut-off score on one of several different scales, or a single question. Two studies included in the review used the fatigue severity scale, but used different 'cut-off' points to define fatigue, and it is unclear whether these cut-offs represent fatigue that is clinically important to patients. The review concluded that the proportion of patients with fatigue early after stroke ranged from 35% to 92% and that fatigue remained common in the longer term. The proportion of patients with fatigue declined over time in seven (n = 764) of the studies and increased in two (n = 195) [3]. However, methods used to define fatigue in previous studies do not tell us about fatigue that is perceived as problematic by patients. Previous cross-sectional studies of post-stroke fatigue have also used cut-off points on fatigue scales, and the cut-off points have generally been determined using data from other patient populations [5–7]. These cross sectional studies cannot tell us whether fatigue improves over time.

Fatigue is an experience common to all, so arguably the distinction between 'normal' and 'pathological' fatigue is unavoidably arbitrary. Nevertheless, the concept of physiological (or normal) fatigue (a state

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* Corresponding author at: Geriatric Medicine, University of Edinburgh, Room S1642, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, UK. Tel.: +44 131 242 6369/6481; fax: +44 131 242 6370.
E-mail address: gillian.e.mead@ed.ac.uk (G. Mead).
[1] Geriatric Medicine, University of Edinburgh, Room S1642, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, UK.
[2] MRC-ARUK Centre for Musculoskeletal Ageing Research, School of Sport, Exercise and Rehabilitation Sciences, The University of Birmingham, Edgbaston, Birmingham B15 2TT, UK.
[3] Bramwell Dott Building, Division of Clinical Neurosciences, Western General Hospital, Crewe Road South, Edinburgh EH4 2XU, UK.
[4] Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford OX3 7JX, UK.

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of general tiredness which develops acutely after overexertion and improves after rest) and 'pathological fatigue' ('constant weariness unrelated to previous exertion levels and not usually ameliorated by rest') [8] has been developed in the stroke literature. In neurological diseases including stroke, 'pathological fatigue' is generally considered more prominent than 'physiological' fatigue. [9]. Stroke survivors report that the fatigue experienced after stroke is unlike 'normal' fatigue they had experienced prior to stroke [10], that it starts shortly after the stroke and that they believe that is a consequence of the stroke [11]. Thus, the concept of 'clinically significant fatigue' has face validity. In order to identify 'clinically significant post-stroke fatigue' in practice, we developed a case definition and associated structured interview, based on the definition of post-stroke fatigue proposed by other authors, and qualitative interviews with stroke survivors who had fatigue. We subsequently showed that the case definition was valid and reliable [12]. The case definition requires fatigue to be present for >50% of waking hours on most days, and crucially, the fatigue needs to interfere with activities of daily living [12]. The definition of 'clinically significant fatigue' can be refined by evaluating the severity of fatigue [13]. We have previously shown that the fatigue assessment scale (FAS) [14] is valid and reliable after stroke [13]. Thus, our approach to assessing post-stroke fatigue in research studies is to assess whether the case definition is fulfilled, and also fatigue severity using the FAS.

Although there are several published longitudinal cohort studies which have reported the course of fatigue after stroke [3,4] no previous studies have used a case definition approach to identify clinically significant post-stroke fatigue over the first year.

The aim of this longitudinal cohort study was to determine the time course of clinically significant fatigue over the first year after stroke, and changes in its severity. [12]

Methods

Design

A longitudinal cohort study with follow up over 12 months.

Ethical approval

Approval from Lothian Research Ethics Committee was obtained and all participants gave written informed consent

Recruitment

From 1st September 2009 to 30th June 2011, we recruited participants who had been admitted to the Western General Hospital and Royal Infirmary of Edinburgh or seen in an outpatient clinic with a new acute haemorrhagic or ischaemic stroke. Patients had to have postcodes in South Edinburgh or East Lothian to ensure the patients sampled related to a defined population. They could be recruited at any time within the first month of stroke, though in practice most consented a few days after admission to an acute stroke unit.

Patients on the participating acute stroke units were approached face-to-face by the study researcher. Those who had been outpatients were given an information sheet by the clinic doctor and, if they were interested in participating, their details were sent to the study researcher who then contacted them by telephone. Exclusion criteria were: subarachnoid haemorrhage (unless secondary to an intraparenchymal haemorrhage); severe dysphasia or severe cognitive impairment that would prevent completion of the questionnaires; medically unstable and/or considered too unwell by the clinical team to participate.

Baseline measures

Stroke subtype (Oxfordshire Community Stroke Project Classification (OCSP)) and patient characteristics were obtained from medical notes. At recruitment the Mini-mental state examination (MMSE) and National Institute of Health Stroke Scale (NIHSS) were administered.

The National Institutes of Health Stroke Scale (NIHSS) is a 15 item systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit in the early stages after stroke. [16] The maximum possible total score is 42 (representing the most severe neurological deficit), and the minimum possible score is 0 (presenting the least severe neurological deficit).

In order to determine whether fatigue before stroke was likely to influence fatigue after stroke, participants were asked 'Did you have a problem with fatigue before your stroke' (requiring a "yes" or "no" response). Participants were invited to attend follow-up assessments at one month, six months and 12 months after stroke onset.

Follow-up measures

Case definition fulfilment

At each of the follow-up assessments, a structured interview was administered which included seven 'probe' questions to determine whether or not a participant fulfilled our case definition for clinically significant fatigue [3]. Case definition fulfilment required that participants had experienced fatigue, a lack of energy or an increased need to rest, every day or nearly every day for more than 50% of the day, for at least a two week period in the past month; and this fatigue had affected their ability to take part in everyday activities or have been perceived to have been a problem.

The Fatigue Assessment Scale (FAS)

The participant also completed the FAS, a 10 item self-report scale, with each item scored from one to five (1 = never, 2 = sometimes, 3 = regularly, 4 = often, 5 = always). Total scores range from 10 to 50, with a higher score indicating more fatigue. The FAS has been tested for validity and reliability in stroke [13]. A change of four points or more has previously been considered to represent a clinically relevant change in fatigue status [15] in patients with sarcoidosis; and so in this paper we also reported the change in 4 points or more in the FAS.

Analysis

We determined the proportion with clinically significant fatigue and the median (interquartile range) of FAS at each time point using all available data and also for only those patients who attended all three assessments. We also reported changes in fatigue status over time, both according to the case definition and to a change of at least four points in FAS.

Results

Recruitment

We approached a total of 382 eligible patients, of whom 157 agreed to take part. The median time from stroke onset to consent was 5 days (IQR 3–10). Our ethical approval did not allow us to systematically record why patients did not wish to take part; however our impression was that patients who declined were uncertain about availability for follow-up, disliked questionnaires or felt that they already had too much to think about at the time of the stroke.

Of the 157 patients who consented, 21 (13%) did not attend any assessment visits and were excluded from further analyses.

Table 1 compares the demographics of the 86 patients who attended all three assessments with the 44 patients who dropped out or died after one or six months. There were no significant differences between the two groups.

Attendance at assessments

The assessments at one, six and 12 months after stroke onset were attended by 132 (97%), 105 (77%) and 91 (67%) participants respectively. 86 (63%) participants attended all 3 assessments, 29 (21%) dropped out after the one month assessment (including nine who had died), 15 (11%) dropped out after the six month assessment (including three who had died), 3 (2%) attended only the six and 12-month assessments, one (1%)

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