Burden of Illness Due to Fibromyalgia in a Neurology Clinic

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Abstract

Background Fibromyalgia (FM) is a common disorder in general population and it causes an increased patient load in hospitals and specialty clinics. FM attendance will be high in clinics dealing with neuropathic pain and other pain syndromes. Though prevalence of FM has been studied in community and pain clinics in other countries, it has not so far been studied in India. So, a study is relevant and hence it was planned in neurology clinic of a teaching government hospital. At present, they are treated mainly by nonsteroidal anti-inflammatory drugs (NSAIDs) which are public health hazard.

Methods Using 2016 revision of 2010/2011 American College of Rheumatology criteria of FM, patients were screened in neurology OPD. Proportion and clinical profile were noted. Study was continued for 6 months till the sample size was met.

Results A total of 2,300 patients were screened. Two hundred and ninety-eight FM patients were identified among them. Proportion was 12.96%. Delayed diagnosis of more than a year occurred in 55%. Only 29.2% were treated, but none was offered cognitive behavioral therapy (CBT) before. NSAIDs for pain were given for 51.01%.

Conclusion Proportion of FM detected is considerable. Affection of homemakers and manual laborers, delayed diagnosis, coexisting comorbid illness, and treatment of pain with NSAIDs are causes of concern. Clinicians should be sensitized to clinical profile and criteria of FM. Patients should be diagnosed and treated by CBT at the earliest and NSAIDs should be avoided as far as possible.

Introduction

Fibromyalgia (FM) is a common disorder, characterized by widespread pain, fatigue, and sleep disturbances. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition categorized it as a mental disorder, called somatic symptom disorder.1,2 FM is diagnosed by specialists and usually missed by primary care physicians (PCPs). Based on guidelines, FM could be diagnosed with confidence at primary care level and specialty help is needed when mental illness or somatic disease needs exclusion. Criteria put forward from 1990, 2010, and 2016 revision of 2010/2011 are useful to diagnose FM.3,4 Diagnostic delay of mean period of 2.3 years is common. FM does not have a definite objective evidence and diagnosis is based on clinical criteria.4 Hence, classification is feasible by categorizing into a psychiatric disorder. FM is a spectrum of disorders, for diagnostic and research purposes based on clinical criteria.4,5 There are 1,990 American College of Rheumatology (ACR) criteria and 2010 criteria,6 the 2016 revision of 2010/2011 ACR criteria is more refined for diagnosis by excluding regional pain syndromes.

The knowledge gap is large for FM, compared with other chronic illnesses such as diabetes, asthma, etc. Early diagnosis, cognitive behavioral therapy (CBT), and drug treatment
with education of both patient and health care provider should be the aim. FM patients should be followed up and all FM features should be addressed simultaneously. Realistic decisions regarding who takes long-term care of FM patients should be made. Thus, FM should be normalized as a chronic illness.8,9

Prevalence of FM has been studied in community and in pain clinics in most countries. But in Indian hospital clinics which deal with neuropathic pain and other pain syndromes, prevalence of FM has not so far been studied. The burden of illness due to FM in our society and in our tertiary hospital clinics is not available as there are no published prevalence studies. So, a prevalence study is relevant and hence this study was planned. A qualitative study done in the same clinic earlier found an increased number of FM patients.

Materials and Methods

FM has significant morbidity with respect to quality of life and the unawareness among PCPs led to consequences such as analgesic nephropathy, gastritis, peptic ulcer diseases, and stroke. Hence, it was planned to study the FM prevalence in neurology outpatient department, which also deals with neuropathic pain syndromes.

With the objective of studying the proportion and clinical profile of FM in neurology clinic, a hospital-based observational study was done in neurology outpatient clinic, Government Medical College Hospital, Kottayam. Adult patients attending neurology clinic who are ambulant, conscious, conversing, and cooperative were included. Patients who had any coexisting neurological or psychiatric illness were excluded. As there are no studies available regarding prevalence of FM in India, a pilot study was done which showed proportion of 6%.

Using this, proportion (p) and formula \( N = 4pq/d^2 \), sample size was calculated as 2,256. After getting the Institutional Review Board approval, 2,300 patients were screened. Patients were interviewed by the first author using questionnaire 2016 revision to 2010/2011 FM criteria.4 Patients who satisfied FM criteria were enrolled. The duration, comorbid illness, consultations made, investigations done, and details of drug treatment were recorded. They underwent physical examination and managed with both CBT and drugs other than nonsteroidal anti-inflammatory drugs (NSAIDs). FM patients were followed up for 3 months and referred back to PCP. Those who did not show response were also referred back with a note for later review.

Results

Out of 2,300 consecutive patients screened, 298 patients satisfied 2016 revision of 2010/2011 ACR criteria. The proportion was 12.96%. Females formed 93.6%. The majority were between ages 40 and 60 years. Ninety-three per cent had only school education. Homemakers and unskilled laborers formed 86%. Patients with residence in rural area formed 95%. Comorbid illnesses such as hypertension, diabetes, and hypothyroidism were seen in 41.9%. Diagnostic delay of more than a year occurred in 55% FM was present in 45% for less than 1 year, while 25% suffered more than 5 years (∼Tables 1 and 2).

Seventy per cent patients did not have any treatment, while amitriptyline was prescribed for 16% and 51.01% were given NSAIDs. Sixty-six per cent did not have any

| Table 1 Baseline data of FM patients |
|-------------------------------------|
| Subdivisions | Number | Percentage |
|---------------|--------|------------|
| Age           |        |            |
| Below 40      | 42     | 14.1       |
| 40–60         | 184    | 58.7       |
| Above 60      | 85     | 28.5       |
| Sex           |        |            |
| Male          | 19     | 6.4        |
| Female        | 279    | 93.6       |
| Education     |        |            |
| Illiterate    | 4      | 1.3        |
| Less than 10th standard | 149 | 50      |
| 10th–12th standard | 128 | 43      |
| Degree, PG    | 10     | 3.4        |
| Professional education | 7  | 2.3    |
| Occupation    |        |            |
| Homemakers    | 174    | 58.4       |
| Unskilled work| 82     | 27.5       |
| Skilled work  | 16     | 5.4        |
| Professional  | 24     | 8.1        |
| Others        | 2      | 0.67       |
| Residential status | | |
| Rural         | 283    | 95         |
| Urban         | 15     | 5          |

Abbreviations: FM, fibromyalgia; PG, postgraduation.
prior consultations, while 21% had single and 13% had more than one consultations for FM. Patients were kept under follow-up for 3 months and later referred to PCP. Patients were treated with either drug therapy with duloxetine or pregabalin or CBT. Majority showed good response.

**Discussion**

The prevalence of FM in the community varies from 1.1 to 6.4%. In clinics, it is having an increased prevalence, 11 to 13.8% in various pain clinics of Korea. In Tel-Aviv Medical Center, it was found that the prevalence is 41.2% (another pain clinic). Many studies regarding FM are published, but its prevalence has not been looked into teaching hospital clinic till now. In the present study, it was found to be 12.96%. FM has an increased prevalence in specialty clinic when compared with general population.

FM is found to have an association with small fiber neuropathy. All subjects under study had various types of pain, some were disabling impairing quality of life. Author was questioned regarding etiology of pain by all patients, revealing knowledge gap. Patients were satisfied when explained regarding small fiber neuropathy and altered pain processing mechanisms, reduced connectivity between pain appreciated areas and other cerebral regions causing increased pain appreciation. Multifactorial theory of FM with oxidative stress and reactive oxygen species also came to help.

In addition to pain, patients reported neurological symptoms such as cognitive abnormalities, headache, vertiginous sensation, subjective unsteadiness, numbness, tingling, sway, giddiness, falls, and fatigue. Cranial nerve symptoms such as photophobia, tinnitus, and dysphagia were also seen. This could be the reason why patients chose to visit neurology clinic even before attending PCP. Dysuria, pelvic pain, and odynophagia were rarely encountered. Gastrointestinal motility disorders were common.

Many neurological patients have FM symptoms. FM patients with neurological illness were not included in the present study. It was found that among neurological patients, prevalence of FM is high. Conversely, FM patients had more neurological symptoms such as poor balance, photophobia, sensory and motor symptoms (tingling, numbness, and weakness), dysphagia, etc. than the control group in published studies. An increased rate of falls were found in FM patients compared with normal controls but was not addressed in the present study.

### Table 2 Clinical and treatment history of FM patients

| Major heading | Subdivisions | Number | Percentage |
|---------------|--------------|--------|------------|
| Duration of symptoms | Less than 1 y | 135 | 45.3 |
| | 1–3 y | 62 | 20.8 |
| | 3–5 y | 27 | 9.1 |
| | More than 5 y | 74 | 24.8 |
| Preconsultations | Nil | 197 | 66.1 |
| | Once | 63 | 21.1 |
| | More than once | 38 | 12.8 |
| Response to treatment | Good response | 274 | 91.1 |
| | Moderate | 22 | 7.4 |
| | Mild | 1 | 0.3 |
| | No | 1 | 0.3 |
| Drugs used | No drugs | 211 | 70.8 |
| | Amitriptyline | 48 | 16.1 |
| | Pregabalin | 3 | 1 |
| | Propranolol | 3 | 1 |
| | Flunarizine | 2 | 0.7 |
| | NSAIDs | 152 | 51.01 |
| | Others and combination | 11 | 3.7 |
| Comorbidities | Nil | 173 | 58 |
| | Hypothyroidism | 25 | 8.4 |
| | Diabetes mellitus | 24 | 8.1 |
| | Hypertension | 39 | 13.1 |
| | Vascular diseases | 3 | 1 |
| | Connective tissue disorders | 4 | 1.3 |
| | Combinations | 22 | 7.3 |

Abbreviations: NSAIDs, nonsteroidal anti-inflammatory drugs; FM, fibromyalgia.
Maximum number of patients were between 40 and 60 years. Patients younger than 40 years were least followed by older than 60 years. Similar finding was reported where younger group (below 29) and older group (above 60) were having reduced prevalence. Another study did not reveal any findings in association with age. Community prevalence may be similar and get reflected in clinics.

Females were represented more by 93.6 versus 6.4% males. This sex ratio is similar to community prevalence, which was reported where it was 2 versus 0.14%. The striking finding was the absence of alcohol use in majority of male FM patients which was found here too. Reason could be that alcohol use will alleviate chronic pain (hypothesis only which needs testing).

Fifty per cent of patients did not complete 10 years of formal schooling, while 43% studied for 12 years. Proportion of illiterate was least, closely followed by professionals. Lower socioeconomic status was associated with increased prevalence and more severe disease.

Occupation-wise homemakers formed greatest (58.4%), followed by unskilled laborers (27.5%). Professionals represented least, 0.7%. Work demanding increased physical exertion was found to aggravate FM. This was found before and there should be careful balance of work for FM patients to function without losing workdays.

Ninety-five per cent of FM resided in rural area, while 5% in urban. This is in contrast to European study where urban FM patients were 0.7 to 11.4%, while rural were 0.1 to 5.2%. This could be due to increased manual work done in rural India than urban.

Comorbid diseases were absent in 58.1%. Hypertension was the commonest coexisting disease in 13.1% followed by hypothyroidism in 8.4%. Diabetes was present in 8.1% and connective tissue disorders were present in 1.3%. Vascular disease was present in 1%. Though many patients had anxiety and depression and quality of life were impaired, they were not measured. Though there was significant association noticed between connective tissue disorders, only 1.3% had it while significant proportion had hypothyroidism.

Diagnostic latency was between 6 months and 1 year in 45.3%, while 24.8% were diagnosed after 5 years. In one study, it was seen that the symptom onset to medical help seeking was 11.1 months and 29% presented after 6 months of illness. Mean time to receive FM diagnosis was 2.3 years. Here, diagnosis was early, probably because FM patients presented directly to neurology clinic.

On clinic visit, 70.8% was not on any specific treatment. NSAIDs were prescribed to 51.01%. In FM, pain is an important symptom and diagnostic delay is common. NSAIDs associated with renal disease and prothrombotic states. Comorbid diseases such as diabetes, hypertension, and hypothyroidism which are prothrombotic were not uncommon among FM. NSAIDs though not useful is widely prescribed for FM, which are associated with analgesic nephropathy and strokes. Majority of FM patients were on amitriptyline, 16.1% and other drugs were duloxetine, milnacipran, and pregabalin. FM patients who consulted one physician were 21.1% and more than one were 12.8%, before presenting to neurology clinic for treatment. Diagnosis was made for 66.1% who came to seek medical help for the diseases for the first time in neurology clinic. It could be inferred that neurology clinic is tuned to FM that primary diagnosis were made in 66.1%. Patients were treated with pharmacotherapy and advised for CBT. On follow-up, 91.9% reported good improvement of their symptoms, while 7.4% moderate and 0.3% mild. No improvement was reported by 0.3%. CBT is the mainstay of treatment and improves by brain connectivity.

Conclusion

The current one is the first study to report the proportion and clinical profile of FM in a hospital clinic from India is considerable. Increased prevalence was associated with manual labor and had latent period of years before arriving at definite diagnosis. Comorbid disorders such as diabetes, hypertension, and hypothyroidism were not uncommon in FM. Treatment with CBT and recommended drug treatment were not offered prior to presentation. NSAIDs were given to significant proportions which may lead to complications especially in the presence of older age and comorbid diseases.

Conflict of Interest

None declared.

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