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ORIGINAL RESEARCH

Severe forms of fibromyalgia with acute exacerbation of pain: costs, comorbidities, and length of stay in inpatient care

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Background and purpose: As a disease of the musculoskeletal system, fibromyalgia is becoming increasingly important, because of the direct and indirect costs to health systems. The purpose of this study of health economics was to obtain information about staff costs differentiated by service provider, and staff and material costs of the nonmedical infrastructure in inpatient care. Patients and methods: This study looked at 263 patients who received interdisciplinary inpatient treatment for severe forms of fibromyalgia with acute exacerbation of pain between 2011 and 2014. Standardized cost accounting and an analysis of additional diagnoses were performed. Results: The average cost per patient was €3,725.84, with staff and material costs of the nonmedical infrastructure and staff costs of doctors and nurses accounting for the highest proportions of the costs. Each fibromyalgia patient had an average of 6.1 additional diagnoses.

Conclusion: Severe forms of fibromyalgia are accompanied by many concomitant diseases and associated with both high clinical staff costs and high medical and nonmedical infrastructure costs. Indication-based cost calculations provide important information for health policy and hospital managers if they include all elements that incur costs in both a differentiated and standardized way.

Keywords: fibromyalgia, DRG, cost, length of stay, comorbidities, interdisciplinary care, inpatient care, musculoskeletal, pain

Background and purpose

Fibromyalgia is a pain disorder listed as M79.70 in the *International Classification of Diseases* (ICD). Patients with fibromyalgia syndrome (FMS) report diffuse (musculo-skeletal) pain all over their body and many symptoms. These often include muscle and joint pain in all areas of the body, and often also stiffness, poor concentration, mood swings, general exhaustion, chronic fatigue, sleep disorders, irritable bowel syndrome, anxiety, and depression. In addition, patients often have symptoms of cardiovascular dysregulation and dizziness, increased sweating, and cold hands and feet.

Diagnosis is difficult and the cause of fibromyalgia unclear. An increase in systemic proinflammatory cytokines and a potentially hyporeactive hypothalamic–pituitary–adrenal axis are among the causes currently being discussed. With reasons uncertain, there are many varied approaches to treatment. Multimodal treatment under inpatient conditions has proven to be effective for the complex and multilayered pattern of symptoms associated with fibromyalgia. 5-8

Research on fibromyalgia and its treatment is becoming increasingly important, because of the direct and indirect costs incurred by health systems. 9-12 Studies show

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that cases of FMS incur higher costs, eg, than other rheumatic disorders. ^{13,14} Delays in the diagnosis of FMS can increase the economic cost even further. ¹⁵ Studies show that patients with fibromyalgia often face a long road to diagnosis, ^{16,17} even though early diagnosis can reduce the cost to health systems. ¹⁶ The purpose of this study was to calculate and analyze the costs of inpatient treatment using standardized cost accounting and to obtain information about disorders that accompany FMS.

Patients and methods

This study did not use individually identifiable patient data. All primary data presented in the results section were derived from administrative databases. Approval from an Institutional Review Board and patient's written informed consent to conduct this study were not necessary, because the data were collected for administrative or billing purposes and no patient can be identified. In the following sections, we describe how costs were calculated and treatment needs assessed.

Calculating inpatient costs

The Kalkulationshandbuch (calculation manual for use in hospitals, version 3.0 – July 10, 2007) was used to calculate the cost of treating FMS patients. The calculation methods were pretested in German hospitals. Between 2010 and 2014, these methods were then used to calculate the costs of around 20 million hospital cases of different diagnoses in Germany. The calculation of case costs is based on the actual costs shown in the audited annual accounts of the hospital.

In a structured cost calculation, service and structural data are collected in accordance with the German Hospital Remuneration Act. Cost data are also collected and broken down into cost center, unit, and case-based service data. In this cost analysis, this included German nursing staff regulation minutes. These distinguish among different care categories based on age and level of care. The levels of care are general care (A) and special care (S), which then are further subdivided into degrees. A1 covers all services for patients with no particular care needs. A2 indicates patients who need help in at least two areas, eg, help with standing up, going to the toilet, and cutting food. A3 patients need full care in at least three areas, eg, full body wash, positioning, incontinence care, and supervision when disoriented. S1 covers minor additional-care services that are not covered by S2 or S3 (eg, daily blood pressure measurement). Having to supervise only one more complexcare service is classed as S2 (dressing change, supervising the taking of medication). A case is categorized as S3 if at least one complex-care service is provided (eg, monitoring patients with side effects of medication).

Costs that are not relevant are not included in the cost calculation, ie, costs that are not linked to the German Diagnosis-Related Group (G-DRG) system are deducted from the total costs of the hospital for both cost-unit and cost-center accounting. This is done on a cost-unit basis by deducting costs relating to other periods. Deductions are also made at cost-center level, eg, the corresponding proportion of a cost center is deducted if outpatients or external patients were also treated there. In this cost calculation, a distinction is made between direct and indirect cost centers. Direct cost centers provide their services directly to the patient. These are mainly examination and treatment services. Indirect cost centers provide their services to direct cost centers rather than individual patients, eg, bed preparation, business and supply services, and administration. The costs of these indirect cost centers are allocated to direct cost centers using allocation keys based on causation. Individual costs are assigned directly to the relevant case in the calculation and thus taken out of cost-center accounting, in order to avoid duplication.

The in-house service-allocation system is used for cost-center accounting. Ultimately, the allocated costs of the medical and nonmedical infrastructure are shown in every direct cost center and then assigned to individual treatment cases using the corresponding case-based reference values.

Need for inpatient treatment

Patients were referred to inpatient treatment by a specialist or general practitioner when unimodal approaches to the treatment of FMS pain were no longer yielding results. The need for inpatient treatment was then assessed by rheumatologists, specialists in general medicine, and specialists in specific pain therapy at the time of admission to hospital.

Furthermore, the Gerbershagen et al classification system (Mainz Pain Staging System [MPSS]), ¹⁹ which is a questionnaire for the patient, was used to assess the need for inpatient treatment. It consists of five different axes, each divided into three stages. Stage I shows the best prognosis, whereas stage III covers the most severe pain disorders. In the questionnaire, patients are asked about temporal aspects of the pain. This includes the frequency and duration of the pain and changes in intensity. Spatial aspects of the pain, eg, location, are also ascertained. In addition, the classification is influenced by information about the use of medication. If a patient has chronic pain classified as stage II or III in the MPSS, an inpatient stay lasting at least 2 weeks is considered constructive. The aim of the MPSS is to identify the stage

of chronicity that the patient has reached and the treatment that is needed. In their study on the operationalization of the MPSS, Gerbershagen et al concluded that in stages II and III, neither monodisciplinary medical nor monodisciplinary psychological treatment is useful.¹⁹ In summary, this system for classifying the chronicity of pain is a multidimensional one from which both the symptoms and how the patient handles the disease can be deduced.

Patient-related assessments were also performed and the results fed into the specialists' decision-making process. A visual analog scale was used to measure, among other things, pain,²⁰ well-being,²¹ and sleep disorders caused by pain.²² To measure the psychological comorbidity of FMS, the Patient Health Questionnaire 9 score of every patient was used as a psychodiagnostic tool.²³ Functional limitations were ascertained using the Hannover Functional Ability Questionnaire.^{24,25} Finally, all patient data relating to the case are recorded. This includes changes in personal physician, pain-related hospital stays and operations, and pain-related rehabilitation received. All tests and data used for assessing acute inpatient-treatment needs are shown in Figure 1.

Inclusion criteria for interdisciplinary patient-centered care

Decisive for being selected for an interdisciplinary patientcentered treatment for fibromyalgia is the fulfillment of certain inclusion criteria regarding the patient. These are shown in Table 1, and are checked for after being diagnosed with FMS. All patients included in the present study were surveyed as per these criteria to determine the severity of the illness and thus the necessity of inpatient treatment.²⁶ Only patients who fulfilled all criteria, thereby qualifying for inpatient treatment, were included in the standardized cost calculation.

Interdisciplinary patient-centered care for FMS patients can comprise three complex treatments: multimodal complex rheumatologic treatment (OPS 8-983), multimodal pain management (OPS 8-918), and naturopathic complex therapy (OPS 8-975). The codes in parentheses refer to the standards on which these approaches are based (Operationen- und Prozedurenschlüssel [OPS]). All three were applied for FMS patients during the study.

Results

The study included 263 patients who received inpatient treatment in a specialized clinic for the principal diagnosis of fibromyalgia between 2011 and 2014. The inclusion criteria were the criteria described above in the "Patients and methods" section, which indicated a severe form of FMS that was resistant to outpatient treatment. Of all patients included in the study, 247 were female and eleven male. The majority of the patients (about 77%) in this study had an average

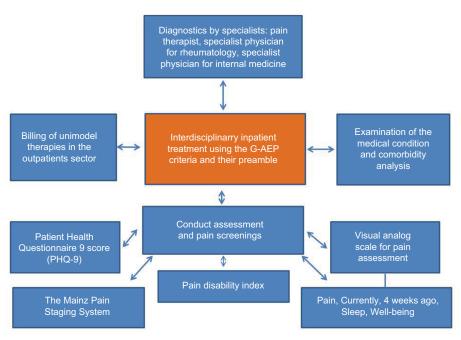


Figure I Acute inpatient treatment: patient-specific examinations.

Abbreviation: G-AEP, German appropriateness-evaluation protocol.

Table I Patient-related inclusion criteria for interdisciplinary patient-centered care

Multimodal complex rheumatologic treatment, OPS 8-983	Multimodal pain management, OPS 8-918	Naturopathic complex therapy, OPS 8-975
Path entry criteria: defined by the hospital	Path entry criteria: defined in German operation and procedure code (Operationen- und Prozedurenschlüssel [OPS])	Path entry criteria: the guidelines ⁴⁶ represent the current state of naturopathic specialist opinion as to which conditions are generally necessary such that a chronically ill patient will be admitted to hospital for inpatient naturopathic complex therapy ⁴⁷
Reduced functional capacity	Manifest or threatening impairment of quality of life and/or ability to work	It must be ensured that it would not be possible to achieve the therapeutic target by means of inpatient rehabilitation
Activity of rheumatic disease	Failure of a previous unimodal pain therapy, a pain-related operative intervention, or a withdrawal therapy	The degree of chronicity must be evaluated analogously to the Mainz stage model of pain chronicity (Mainz Pain Staging System), referring to the individual type and intensity of the symptoms
Manifest or threatening impairment of quality of life and/or ability to work	Existing drug dependence or drug misuse	The symptomatic intensity should be evaluated, eg, analogously to the von Korff model for chronic complaints, referring to the individual type and intensity of the symptoms
Multiple pain	Serious concomitant mental disorder	The clinical picture involves at least three different sections of the International Classification of Diseases
	Serious concomitant somatic disease	

Note: Data from Romeyke and Stummer.²⁶

length of stay of 10-14 days ($\geq 10-<15$). The average age of the patients was 54.78 years.

The assessment results revealed chronicity stages of 2 and 3 (MPSS). All patients were found to have greater (x < 60%) physical limitations, as measured by the Hannover Functional Ability Questionnaire. The well-being of all patients was significantly reduced, and the average intensity of the pain was 7/10 (visual analog scale).

Diagnoses

In accordance with the German coding guidelines, "the diagnosis identified in the analysis as primarily responsible for the patient's inpatient stay" was coded as the principal diagnosis. The phrase "in the analysis" refers to the evaluation of the findings at the end of the inpatient stay, in order to establish which disease was primarily responsible for the inpatient stay. The evaluated findings can include information obtained from the medical and care history, a psychiatric examination, consultations with specialists, a physical examination, diagnostic tests or procedures, surgical procedures, and pathological or radiological examinations.

Based on the ICD, an analysis of the concomitant diseases of each patient revealed 1,572 additional diagnoses for all subjects, ie, an average of 6.1 additional diagnoses per patient, to the principal diagnosis of FMS. The additional diagnoses were coded in accordance with the German coding guidelines for diseases. According to these guidelines,

an additional diagnosis is defined as "a disease or condition that either exists at the same time as the principal diagnosis or develops during the hospital stay". Additional diagnoses were interpreted as diseases that influence patient management in such a way that therapeutic and/or diagnostic measures and higher levels of nursing care are required.

In the analysis of additional diagnoses in accordance with the ICD (Table 2), "diseases of the musculoskeletal system and connective tissue" were the most common. These included low-back pain, low-back pain with sciatica, and spondylosis experienced at the same time as the FMS. There were 285 additional diagnoses among "endocrine, nutritional, and metabolic diseases". These included obesity, diabetes mellitus, and food intolerances, such as fructose and lactose malabsorption. The 225 additional diagnoses in the "mental and behavioral disorders" category included depression, anxiety, dysthymia, and sleep disorders. Diseases of the nervous system were diagnosed 218 times, and included headache, cervicocranial syndrome, and radiculopathy. The 114 diagnoses in the "diseases of the circulatory system" category were dominated by hypertension and cardiovascular diseases (Table 2).

Costs

The average cost of inpatient stay was €3,740.00 per patient. Comprehensive standardized cost accounting was used to allocate costs to cost categories. Eight cost categories were

Table 2 Analysis of additional FMS diagnoses in accordance with the *International Statistical Classification of Diseases and Related Health Problems*, tenth revision

Chapter	Block	n	Title
I	A00-B99	7	Certain infectious and parasitic diseases
II	C00-D48	3	Neoplasms
III	D50-D89	17	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
IV	E00-E90	285	Endocrine, nutritional, and metabolic diseases
٧	F00-F99	225	Mental and behavioral disorders
VI	G00-G99	218	Diseases of the nervous system
VII	H00-H59	11	Diseases of the eye and adnexa
VIII	H60-H95	12	Diseases of the ear and mastoid process
IX	100–199	114	Diseases of the circulatory system
X	J00–J99	39	Diseases of the respiratory system
XI	K00-K93	53	Diseases of the digestive system
XII	L00-L99	10	Diseases of the skin and subcutaneous tissue
XIII	M00-M99	420	Diseases of the musculoskeletal system and connective tissue
XIV	N00-N99	28	Diseases of the genitourinary system
XV	000-099	0	Pregnancy, childbirth, and the puerperium
XVI	P00-P96	0	Certain conditions originating in the perinatal period
XVII	Q00-Q99	3	Congenital malformations, deformations, and chromosomal abnormalities
XVIII	R00-R99	72	Symptoms, signs, and abnormal clinical and laboratory findings not elsewhere classified
XIX	S00-T98	19	Injury, poisoning, and certain other consequences of external causes
XX	V01-Y98	0	External causes of morbidity and mortality
XXI	Z00-Z99	36	Factors influencing health status and contact with health services
XXII	U00–U85	0	Codes for special purposes

Abbreviation: FMS, fibromyalgia syndrome.

analyzed, and their share of the total costs are shown in Figure 2. In cost category 1, an average cost of €822.34 was calculated for the treatment of an FMS patient regarding physician service. This includes the staff costs for doctors, statutory social security contributions and pension contributions, and other staff costs and fees for doctors not employed by the hospital.

Cost category 2 covers nursing-staff costs. This includes statutory social security contributions, pension contributions, and other staff costs. On average, the total cost of nursing for an FMS patient was €739.54. Staff costs for medical technicians/non-ward-based nurses are included in cost category 3. This covers statutory social security contributions, pension contributions, and other staff costs. On average, the total cost of care for an FMS patient was €249.67 in this category.

Cost categories 4A and B include material costs for medicinal products, hospital-pharmacy delivery costs, and those relating to medical need for blood, packed red cells, and blood plasma. The average cost in this category was €54.15. Cost categories 6A and B include material costs for "other medical needs". A distinction is made between

A (average cost of €30.19) and B (average cost of €66.80), because 6B includes individual costs in the material costs for other medical needs. Cost categories 6A and B cover dressings, remedies, and aids, medical and nursing consumables, and radiology and nuclear medicine, as well as laboratory services. They also cover tests in external departments, electroencephalography, electrocardiography, ultrasound, physiotherapy, disinfectants, and other medical needs. Cost category 7 covers "staff and material costs of the medical infrastructure", and includes the cost of transporting patients, medical care in the community, maintaining medical technology, and depreciation of replaced medical durables. The average total cost per patient in this group was €340.83.

For cost category 8, the average cost per patient was €1,401.50. This category accounts for the highest proportion of the cost of inpatient care. It includes "staff and material costs of the nonmedical infrastructure", ie, the salaries, statutory social security contributions and pension contributions of clinical hospital staff and staff providing business and supply services, technical services, administrative services, and special services, and staff costs that cannot be allocated

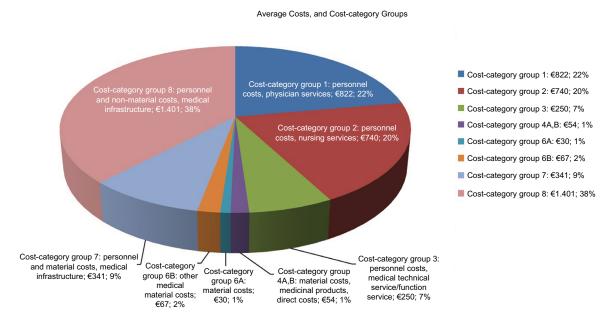


Figure 2 Average costs per cost-category group.

elsewhere. It also includes the cost of food, water, electricity, fuel, materials, cleaning products and disinfectants, linen, laundry cleaning and care, household consumables, crockery, fuel, lubricants, and garden maintenance. Moreover, maintenance cleaning and laundry cleaning by external companies, administrative services, office materials and printing, postage, Post Office box and bank fees, light freight, telephone systems and telex machines, telegrams, radio and television, travel expenses, fares, recruitment costs, consulting fees, audit, court and legal fees, contributions to organizations, hospitality, IT and organizational expenses, central administration, and central personnel management are also included. Category 8 also includes the cost of the central printing service, central technical services, replacing durables (provided fixed values were given), taxes, duties, insurance, interest and similar expenses for operating loans, depreciation of other durables, and ordinary expenditure, such as rent, leases, licenses, carriage for delivery of goods, material expenses for training and development, and renting durables.

The distribution of average total costs on cases is shown in Figure 3. The majority of patients incurred average costs of $\[\in \]$ 4,102.14 $\[\in \]$ 4,664.04, closely followed by a second group incurring $\[\in \]$ 2,995.30 $\[\in \]$ 3,498.44. Patients leaving the hospital earlier than anticipated due to "other reasons" produced costs below $\[\in \]$ 2,987. The most expensive cases, resulting in costs of above $\[\in \]$ 4,674, required more therapies and were longer in hospital, due to lasting pain and relevant functional limitations. These cases were analyzed regarding secondary

diagnoses. We found the following to be the most common: diseases of the musculoskeletal system and connective tissue, endocrine, nutritional, and metabolic diseases, and mental and behavioral disorders. Additional diagnoses are shown in Figure 4, and are coded according to the ICD-10.

However, random-sample analyses showed that the number of additional diagnoses of a patient with fibromyalgia was not associated with higher costs. There was no causal relationship between the length of stay in hospital and the number of concomitant diseases either. Instead, physical limitations, high therapy-resistant pain intensity, and progression of chronicity were more likely to have an effect.

Discussion

Patients with severe forms of fibromyalgia are recommended multimodal treatments in an inpatient setting.²⁷ For milder forms, the guidelines state that individual treatment methods in outpatient settings should be administered first.²⁸ The FMS patients included in this study had severe forms, and a multimodal interdisciplinary approach to their treatment involving various specialists, nurses, and therapists was taken.²⁶

Several previous studies have focused on the costs arising from fibromyalgia.^{29–32} Cost comparisons of FMS and other diagnoses, eg, diabetes are available,³³ as is a longitudinal evaluation of health care utilization and costs during the first 3 years after a new diagnosis of fibromyalgia.³⁴ Nevertheless, to date there has been no detailed cost analysis to include all professional groups and material costs³⁵ and differentiate

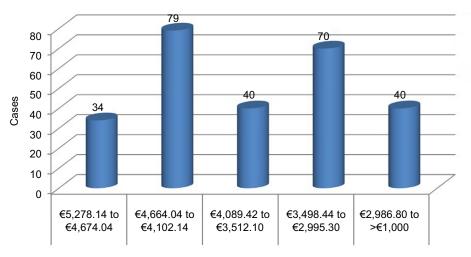


Figure 3 Distribution of average total costs.

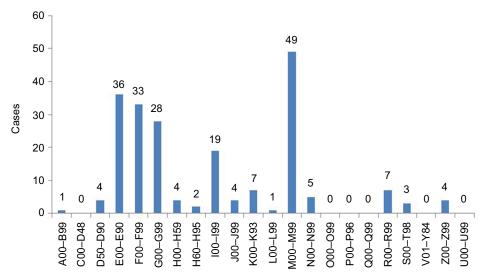


Figure 4 Additional fibromyalgia-syndrome diagnoses in the cost-driving group.

them for the care of FMS patients with severe forms in an acute-inpatient setting with a focus on interdisciplinary care. Berger et al showed that the annual direct cost of FMS patients was about US\$9,573.32.²⁹ However, these results are already old, and more recent information for inpatient and outpatient settings is needed.

As in other studies, women are affected much more often than men. ^{36–39} The average age of the patients in this study also corresponds to the reported results of other investigations. ^{16,40} Length of inpatient stay was dependent on the diagnose(s) and the targets according to the G-DRG, and comparable to those of other studies and those of the calculation institute. ²⁶ As already established in other scientific studies, anxiety and depression are common concomitant diseases. ^{40,41} The most frequent additional diagnosis was "other diseases of the musculoskeletal system", as already reported by Berger

et al in 2007.²⁹ However, we did not find a causal relationship between the number of concomitant diseases and cost,⁴² as was previously assumed in the literature. According to our data, disease activity and physical limitations⁴³ are more likely to influence costs.

Conclusion and limitations

This study includes all of the costs of inpatient care for those with a severe form of FMS. As part of a cost-of-illness study, economic data analysis and its results provide important information for health-policy makers, hospital managers, and the general public. ⁴⁴ Moreover, it can be used as starting point for benchmarking projects and create a basis for process optimization. ⁴⁵ The results of the assessments clearly show, however, that severe forms of FMS are typically associated with a high number of failed treatments. The indication-based

cost calculation can provide information for the financial risk management of an inpatient facility. For doctors, therapists, and nurses, treatment information based on the results of the concomitant disease analysis can also be generated.

Our analysis is limited by the unavailability of comparison data for standardized accounting for interdisciplinary treatment costs depending on and differentiating between intensity of FMS (especially less severe or mild cases, which were excluded here according to the inclusion criteria). Further studies should check for those and also cost related data for the elements of the treatment. In addition, further studies should look more closely at the efficacy of action taken in the context of cost causation.

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Disclosure

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The authors report no conflicts of interest in this work.

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