Leitthema

Z Rheumatol 2019 · 78 (Suppl 2):S73–S79 https://doi.org/10.1007/s00393-019-0669-9 Published online: 24 July 2019 © The Author(s) 2019

Redaktion

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Currently, about 90% of people in Germany are insured by the statutory health insurance. Due to the large amount of routinely collected health data, the claims data of the statutory health insurance represent an important source for health care research. They include prescribed drugs, therapies, aids, data on sick leave, inpatient care and benefits according to the uniform assessment standard (EBM), such as the basic sum payed for rheumatological treatment. In recent years, the number of publications based on claims data has increased sharply [11].

When analysing claims data for statutory health insurance, it is important to note the limitations of these data [8]. Nevertheless, there are questions that can be examined very well with claims data. A particular strength lies in the fact that data are available for all insured persons of the respective health insurance. In particular, it also reaches people who live in a nursing home, for example, or who are not in specialist medical care. Therefore, the supply of disease-specific medication

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Reality of care for musculoskeletal diseases at the population level

Results of the PROCLAIR collaborative project

(e.g. disease-modifying anti-rheumatic drugs [DMARDs]) or vaccinations can be well investigated. The frequency of certain diseases can also be analysed. However, it should be noted that claims diagnoses should not be equated with clinically confirmed diagnoses. Patientreported parameters such as disease burden, pain or functional limitations cannot be described with claims data either.

In order to counter these limitations, the idea was born for the collaborative project PROCLAIR (Linking Patient-Reported Outcomes with CLAims data for health services research In Rheumatology). In this research consortium funded by the German Federal Ministry of Education and Research, the claims data of a large German statutory health insurance (BARMER) were linked with guestionnaire data of the insured persons. The main objective of the project was to obtain knowledge about the care of people with musculoskeletal diseases on the population level. Partners in the joint project were the German Rheumatism Research Centre, the University of Oldenburg, BARMER statutory health insurance, the University of Dresden and the Charité University Medicine Berlin.

In the following, the methodology and results of the network are presented. They are representative for the range of possibilities of such a combined data set.

Methods of data collection

In PROCLAIR, the three diseases rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) and hip/knee/polyarticular osteoarthritis (OA) were investigated. A sample stratified by age, sex and diagnosis (seropositive/negative in RA, hip/ knee/polyarticular osteoarthritis) was drawn. The BARMER sent questionnaires to the persons in the samples (cross-sectional survey). The number of persons contacted ranged from 4500 for axSpA to 9000 for osteoarthritis. Of the respondents, 51% responded for RA, 47% for axSpA and 42% for OA. These response rates are relatively high compared to surveys of other diseases [5] and sufficient to make reliable analyses.

In the three questionnaires developed in the project for each diagnosis, we asked about the diagnosis, the specialist care, the status of the joint disease and about health, occupational and social restrictions. The information was linked to the claims data of the BARMER. From this data, ICD-10 codes for diagnoses, physicians' medical specialty, prescriptions of drugs (Anatomical Therapeutic Chemical Classification [ATC] codes), assistive devices, vaccinations and operative measures were included in the analysis. The items from claims and survey data are summarised in **Table 1**.

The German version of this article can be found under https://doi.org/10.1007/s00393-019-0664-1

Table 1 Linked data sources by disease					
	Rheumatoid arthritis	Axial spondyl- arthritis	Polyarticular/hip/knee osteoarthritis		
Claims data					
ICD-10-GM diagnosis	M05, M06	M45	M15, M16, M17		
Number of cases in the total insurance data	100,000	22,000	600,000		
Questionnaire data					
Number of sampled per- sons	6195	4471	8995		
Response rate	51%	47%	42%		
Number of persons who confirmed the diagnosis	2535	1776	2499 with symptomatic osteoarthritis		
Disease-specific instru- ments	RAID, FFbH	BASDAI, BASFI	WOMAC		
Interdisciplinary instru- ments and further infor- mation	WHO-5 index of well-being, occupational situation, household income, size of the city of residence, treating physician, school education, height, weight, number of persons in household				

Description of the data used in the collaborative project. *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *BASFI* Bath Ankylosing Spondylitis Function Index, *FFbH* "Funktionsfragebogen Hannover" (Hannover Functional Questionnaire), *ICD-10-GM* International Classification of Diseases, 10th revision German Modification, *RAID* Rheumatoid Arthritis Impact of Disease, *WHO-5* World Health Organisation Five Well-being index, *WOMAC* Western Ontario and McMaster Universities Osteoarthritis Index

Table 2	Overview of the main analysis topics			
Data source	Rheumatoid arthritis	Axial spondylarthritis	Polyarticular/hip/knee osteoarthritis	
Claims data only	Prevalence [7] Vaccination status [13]	Costs of TNF-alpha inhibitor therapy	Prevalence in the elderly [16] Physical therapy before surgery [12]	
Claims and ques- tion- naire data	Provision of health services [4] Comorbidity [14] Physical therapy [9] Income and burden of disease[6]	Depressive symptoms and burden of disease [19] Diagnostic delay [18] Provision of health services Extra-articular manifestations Comorbidity	Self-paid health services Desire and recommenda- tion for endoprosthetic treatment Disease burden Physical therapy	
TNF tumour necrosis factor				

The claims data were analysed not only for the PROCLAIR respondents (linking claims and survey data), but also for all insured persons who had one of the three diagnostic codes. Therefore, some analyses refer to the total data set of BARMER insurants (e.g. 100,000 insured persons with RA diagnosis) while the linked analyses refer only to the surveyed insured persons (e.g. 2500 surveyed persons with RA).

The claims data were also available for persons who did not return the questionnaire. It was found that women and older people responded somewhat more frequently. In addition, respondents were more likely to have anti-inflammatory medication, and the proportion of people with specialist contact (rheumatologist/ orthopaedic specialist) was higher. We therefore assume a selection of persons who are more strongly affected in the survey data.

For 80% of respondents with RA and 85% of those with axSpA, the information provided by respondents on their diagnosis was in agreement the claims diagnosis. In most other cases another inflammatory rheumatic disease was present (e.g. psoriasis arthritis).

Results from PROCLAIR

Table 2 provides an overview of the publications and analyses produced by the project to date (1 March 2019). Important results are summarised below.

Prevalence estimation with claims data

Prevalence of rheumatoid arthritis

In this retrospective secondary data analysis we estimated the prevalence of RA diagnosis in Germany [7]. Of BARMER's 7 million insured persons, 28,000 had an M05 (seropositive RA) and 87,000 an M06 (seronegative RA) diagnosis in at least two quarters in 2013. This corresponds to a prevalence of 1.4% standardised to the German population. Under the assumption that a measurement of erythrocyte sedimentation rate or C-reactive protein must be performed at least once a year in clinically manifest RA, the prevalence was reduced to 1.0% in consideration of this additional criterion, and to 0.8% in consideration of the additional conditions that antiinflammatory therapy (disease modifying antirheumatic drugs [DMARD], non-steroidal anti-inflammatory drugs [NSAIDs] or glucocorticoids) had to be prescribed. We conclude from this that a prevalence calculation based exclusively on outpatient diagnoses is very likely to lead to an overestimation of the frequency. We therefore estimate the prevalence of clinically relevant RA in the range between 0.8 and 1%. The proportion of seronegative RA was surprisingly high. Among the insurants with contact to a rheumatologist, the proportion of the M06 diagnosis (58%) was still significantly higher than in the rheumatological cohorts with 28-36%, so that we have to account for a selection of seropositive patients in rheumatological centres in addition to incorrect coding in health insurance data.

Prevalence of osteoarthritis in the elderly

Claims data also enable analyses for very old people, regardless of whether they

Abstract · Zusammenfassung

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Reality of care for musculoskeletal diseases at the population level. Results of the PROCLAIR collaborative project

Abstract

Background. The objective of the research consortium PROCLAIR was to gain population level knowledge on the treatment of patients with rheumatoid arthritis (RA), axial spondylarthritis (axSpA) and osteoarthritis (OA) in Germany.

Aims. A main question of the consortium was whether it is possible to identify groups of people who were exposed to a particular risk of undersupply or oversupply of treatment. In addition, the study investigated the validity of claims data for these diseases as a basis for further studies.

Patients and methods. Cross-sectional surveys were carried out among insurees of the BARMER statutory health insurance fund whose claims data included RA, axSpA and OA diagnoses. The questionnaire data were linked with the claims data of the insured persons if they agreed.

Results. In all three diseases risk groups for care deficits could be identified. Persons with RA who are not treated by a specialist have less access to drug treatment. Physical therapy is prescribed for all three diagnoses at a low level, even for people undergoing joint replacement surgery. A connection between depressive symptoms and disease activity or function in axSpA was shown. In addition to the results relevant to care, the PROCLAIR network has also made contributions to critically assess the quality of health insurance data.

Discussion. The combination of billing data with survey data enables a comprehensive description of the treatment of musculoskeletal diseases. Particularly relevant factors are the specialization of the physician, sociodemographic parameters of the patients and the region of residence. In particular, access to treatment cannot be investigated in randomized clinical trials.

Keywords

Inflammatory rheumatic diseases · Treatment · Disease burden · Billing data · Treatment deficits

Versorgungswirklichkeit muskuloskeletaler Erkrankungen auf Bevölkerungsebene. Erkenntnisse aus dem Verbundprojekt PROCLAIR. Englische Version

Zusammenfassung

Hintergrund. Der Forschungsverbund PROCLAIR (Linking Patient-Reported Outcomes with CLAims data for health services research In Rheumatology) hatte die Zielsetzung, bevölkerungsbezogene Erkenntnisse zur Versorgung von Patienten mit rheumatoider Arthritis (RA), axialer Spondyloarthritis (axSpA) oder Arthrose in Deutschland zu gewinnen.

Ziel der Arbeit. Zu den Fragestellungen des Verbundes gehörte es, ob sich Personengruppen identifizieren lassen, die einem besonderen Risiko für Unter- oder Fehlversorgung ausgesetzt sind. Außerdem sollten Erkenntnisse über die Validität von Abrechnungsdiagnosen zu diesen Erkrankungen als Basis für weitere Studien gewonnen werden. Patienten und Methoden. Es wurden Querschnittbefragungen bei Versicherten der BARMER Krankenversicherung durchgeführt, in deren Abrechnungsdaten sich die Diagnosen RA, axSpA oder Arthrose fanden. Die Fragebogenangaben wurden bei vorliegendem Einverständnis der Versicherten mit deren Abrechnungsdaten verknüpft. Ergebnisse. In allen 3 Krankheitsbildern wurden Risikogruppen für Versorgungsdefizite identifiziert. Personen mit RA, die nicht fachärztlich versorgt werden, haben geringeren Zugang zu medikamentöser Therapie. Physikalische Therapie wird für alle 3 Diagnosen auf niedrigem Niveau verordnet. Ein Zusammenhang von depressiven Symptomen und Krankheitslast bei axSpA wurde aufgezeigt. Neben den versorgungsrelevanten Ergebnissen hat der PROCLAIR-Verbund auch methodenkritische Beiträge zur Qualität von Krankenkassendaten geleistet. **Diskussion.** Die Verknüpfung von Abrechnungs- mit Befragungsdaten ermöglicht eine umfassende Beschreibung der Versorgung muskuloskeletaler Erkrankungen. Besonders relevante Einflussgrößen sind die Fachrichtung des Arztes, soziodemografische Parameter der Patienten oder Wohnregion. Insbesondere der Zugang zu Versorgung lässt sich in randomisierten klinischen Studien nicht untersuchen.

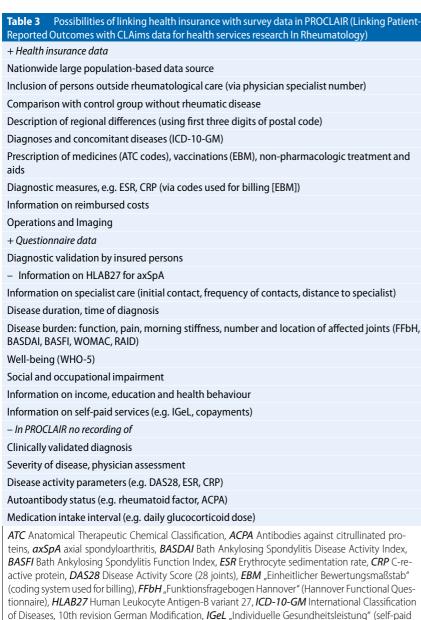
Schlüsselwörter

Entzündlich rheumatische Erkrankungen · Therapie · Krankheitslast · Abrechnungsdaten · Versorgungsdefizite

live in their own homes or in nursing homes. Postler et al. [16] examined the prevalence of the diagnosis of hip and/or knee OA in persons over 60 years of age on the basis of the claims data. The frequency of hip and/or knee OA was highest in the group of 80–89 year olds (31%) and decreased again for older insured persons, also with increasing care level (31% for patients with care level 0 or 1 and 19% for patients with care level 3). An underreporting in old age and with an increasing level of care may indicate the lower relevance of osteoarthritis in bedridden old people compared to other diagnoses.

Comorbidity

All diagnoses and prescribed medications are recorded in health insurance data. In the overall data set, Ramos et al. [14] compared the prevalence of concomitant diseases in insured persons with RA diagnosis (defined as ICD-10 coding of M05 or M06 in at least two quarters in 2013) with an age- and gender-matched control group without RA. All comorbidities considered were more frequent in RA. Among the five most common comorbidities were hypertension (63%), osteoarthritis (44%), hyperlipidaemia (40%), depression (32%) and osteoporo-



of Diseases, 10th revision German Modification, *IGeL* "Individuelle Gesundheitsleistung" (self-paid health services), *RAID* Rheumatoid Arthritis Impact of Disease, *WHO-5* World Health Organisation Five Well-being index, *WOMAC* Western Ontario and McMaster Universities Osteoarthritis Index

sis (26%). The prevalence clearly exceeds the data from the rheumatological cohorts, e.g. depression is documented much less frequently here [1]. The codes in the claims data recorded in the Elixhauser Comorbidity Index [17] are very broad and include, for example, episodic depression states. However, if we consider the prescribed medication, 13% of those with RA still had depression treated with antidepressants.

Utilisation of care

Specialist medical care and drug therapy

In addition to the information available in the claims data, the survey provided us with information on specialist medical care [4]. In the case of rheumatologists or specialists in internal medicine, this can only be depicted to a limited extent in the claims data via the physician specialty numbers. Two thirds of the respondents with RA stated that they were currently receiving internistic rheumatological care. Patients having only contact to general practitioners had a comparably high burden of disease as patients cared for by specialists. Nevertheless, 63% of the specialist patients were prescribed a conventional synthetic DMARD, but only 18% of the non-rheumatologically treated patients. Almost only rheumatologically treated patients received a biological DMARD: 18% vs. 2% in the primary care sector. Older and seronegative patients were less well supplied with medication. They also had less access to rheumatologic care. The results indicate that the internistic rheumatological care of RA patients is crucial for demandoriented care.

Prescription of physical therapies

Jacobs et al. [9] evaluated the prescriptions of physical therapies in respondents with RA. In contrast to drug therapy, physiotherapy, massages, thermotherapy and manual therapy are primarily prescribed by the general practitioner. Only every second RA patient surveyed received physical therapy within the last 12 months; those with severe functional impairment received it somewhat more frequently.

>> The provision of physical therapy for RA and for OA requiring surgery is inadequate

Lange et al. [12] identified all persons with hip or knee OA in the claims data who received endoprosthetic treatment from 2011-2013. The proportion of patients who were prescribed physical therapies and analgesics in the year prior to joint replacement surgery was investigated. On average, only about half of the patients received at least one prescription for physical therapy. In all, 13% of the patients did not receive conservative therapy in the year prior to surgery. In national and international recommendations, however, unsuccessful conservative therapy is a prerequisite for elective joint replacement. One in four of the patients who underwent surgery had no

specialist outpatient contact in the year prior to the operation.

Both analyses indicate a deficit in physical therapy for RA as well as OA requiring surgery.

Use of self-paid health services, measures and preparations outside the practice for osteoarthritis patients

Jacobs et al. (in review) analysed the use of IGeL (self-paid health services) and variables associated with their use in a survey of a total of 2363 insured persons diagnosed with hip, knee or polyarticular OA. Of the respondents, 39% used at least one IGeL in the last 12 months (the highest proportion for knee OA with 45%). These were predominantly performed by orthopaedists (in 86% of the respondents). In a relatively large number of patients, medication was injected into the affected joint during the period in question (knee OA 25%, hip OA 10%, polyarticular OA 13%). Associated with more frequent use of self-paid therapies overall were female gender, higher income, west German residential area, higher burden of disease and lower overall satisfaction with the health care system.

Regional differences in care

Several analyses showed regional differences in the service provided. Vaccination rates against influenza were lowest among patients diagnosed with RA in southern Germany and highest in eastern Germany [13]. Physical therapy was prescribed less frequently in OA [12] and RA [9] in the West than in the East. Reasons for these regional differences can be assumed at several levels. Differences in the occurrence of risk factors, historical differences in vaccination policy, medical education and in the coding of claims are some examples.

Disease burden in inflammatory rheumatic diseases and arthrosis: questionnaire data

The survey data of persons with symptomatic knee (n = 1130), hip (n = 538),

combined knee/hip (n=131) or polyarticular OA (n=700) (Callhoff et al., in review) showed that simultaneous presence of knee and hip OA is associated with the most severe impairment of algofunction (average Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] score of 51), frequent incapacity to work (66%), impairment of personal life (87%) and high consumption of analgesics (60% NSAIDs, 25% opioids).

Risk factors for higher disease burden

An analysis of the combined questionnaire and claims data of respondents with RA showed a strong association of income with parameters of disease burden and physical function [6]. Callhoff et al. considered 1492 patients who were of working age (<65 years) and had a patient confirmed RA diagnosis. On average, insured persons with a low income had the highest functional impairment according to the Hannover Functional Questionnaire (FFbH) and the highest burden of disease, measured by Rheumatoid Arthritis Impact of Disease (RAID) and the number of affected joints. This correlation shows that rheumatologists should increasingly deal with the burden of disease and functional limitations in people with low incomes.

In persons with OA, an association of overweight and personal well-being (World Health Organisation Five Wellbeing Index [WHO-5]) with increasing limitation of algofunction was found. This connection is independent of the painful joint.

>> Patients with severe pain had depressive symptoms significantly more often

A screening tool for depressive symptoms, the WHO-5 questionnaire, was used in all three surveys. In the respondents with RA, Jobski et al. [10] showed a correlation between pain, depressive symptoms and the use of painkillers. Patients with severe pain had significantly more depressive symptoms than patients with moderate or mild to no pain (75% vs. 53% and 21%).

Redeker et al. [19] investigated the variables associated with depressive symptoms in respondents with axSpA. In all, 42% of the patients reported good well-being, but 28% showed mild symptoms and 31% moderate to severe depressive symptoms. Of the patients with moderate to severe symptoms, only one third had a medical diagnosis of depression documented in the claims data. Moderate to severe depressive symptoms were associated with higher disease activity according to the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and more severe functional impairment as measured by the Bath Ankylosing Spondylitis Functional Index (BASFI). The age group of 40-59 year olds had depressive symptoms most frequently.

Discussion

In the PROCLAIR joint project, BARMER claims data were supplemented by questionnaire data. Valuable results were obtained on the care and disease burden of patients with RA, axSpA and OA. Even if no clinical validation of the claims diagnoses was possible, the survey of the insured persons on their diagnosis made it possible to verify the reliability of the claims diagnoses. This knowledge is useful for further studies that are carried out exclusively using claims diagnoses. **Table 3** gives an overview of the possibilities of combined survey and claims data. In addition to great synergy effects in methodology, there was also knowledge transfer between the individual analyses in terms of content. The results of the survey helped to better classify the prevalence data of RA and comorbidities. The RA prevalence is certainly overestimated if only the claims diagnosis is considered [7]. But there is also evidence that certain diseases are underdiagnosed. These include OA in people with high levels of care and depression in axSpA patients [16, 19].

In the rheumatological registers and observational studies, patients are recruited via the treating rheumatologists [2, 3, 15, 20]. A particular strength of

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the PROCLAIR project was therefore the availability of data on people who are not in rheumatological care, but who are treated exclusively by general practitioners or another specialist. The evaluation of comorbidity in RA patients showed that individuals with many comorbidities are less frequently treated by a specialist [14] than individuals with few comorbidities. It could be that in view of the multitude of necessary measures and medications the coordinating function of the general practitioner gains priority. It is also possible that the rheumatic disease loses importance in the context of many other chronic diseases.

As the randomly selected insured persons were only interviewed once, longitudinal data were only available for the claims data. With the cross-sectional data from the surveys, it is therefore not possible to investigate courses of events or causal relationships. In principle, only rough temporal relationships can be established from claims data. Many data are only available on a quarterly basis and do not have a specific date. However, it is much more important that no clinical data, e.g. on disease activity, is available from claims data. Claims data are therefore not an alternative to wellconducted observational studies. However, they can be a valuable addition. In particular, claims data can be used to obtain information on unselected groups of people at population level that are not available in the existing cohorts.

The results from PROCLAIR form a valuable basis for targeted measures and projects to address the identified deficits in the care of people with musculoskeletal diseases. Further analyses with the collected data are still in progress. Detailed results on the care of patients with axSpA, disease burden and use of selfpaid health services in osteoarthritis will be published shortly.

Conclusion for the practice

- The linkage of claims data with surveys of insured persons in the PROCLAIR collaborative project provided current population-related findings on the care of patients with musculoskeletal diseases.
- Specific groups of persons and risk factors were identified with regard to undersupply or a high burden of disease for the respective diseases.
- Statutory health insurance claims data offer a wealth of data, which must, however, be interpreted with caution in view of the lack of clinical validity of diagnoses.
- The combination of claims and survey data is suitable for establishing relationships between provision of care and patient-reported variables (disease burden, income, pain, depressive symptoms).

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Acknowledgements. We would particularly like to thank all the authors of the original works on which this review is based. These are H. Haibel, S. Hense, J. Goronzy, H. Jacobs, K. Jobski, J. Klotsche, T. Lange, A. Luque Ramos, K. Minden, A. Postler, I. Redeker, J. Schmitt and J. Sieper. We would like to thank all insured persons who, by agreeing to make their data available to the project and by carefully documenting the guestionnaires, made extensive data analysis possible. Our thanks also go to BARMER, in particular Dr Marschall, Dr Dudey, Ms Schwarz and Mr Saam, for providing the data and for their excellent support during the survey. We would like to thank the patient research partners of the German League against Rheumatism for their cooperation in creating the questionnaires.

The research network on musculoskeletal diseases, PROCLAIR (Linking Patient-Reported Outcomes with CLAIms data for health services Research in rheumatology), was funded by the German Federal Ministry of Education and Research from 2015–2018 (01EC1405).

Compliance with ethical guidelines

Conflict of interest J. Callhoff, K. Albrecht, F. Hoffmann, D. Poddubnyy, K.-P. Günther and A. Zink declare that they have no competing interests.

A positive ethics vote was issued in 2015 by the Ethics Commission of the Charité University Medicine Berlin (EA1/051/15). The investigation was conducted in accordance with national law.

The supplement containing this article is not sponsored by industry.

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