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Pain Medication and Pain Intensity Following Hip Fractures—Analyses Based on the ProFem Cohort Study

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ABSTRACT

Purpose: Pain is a common symptom following proximal femoral fractures (PFF), however, information on its treatment in terms of agents and type of use (scheduled vs. pro re nata [PRN]) is scarce. The main objective of this study was to examine pain medication regimens according to pain intensity following PFF. Furthermore, we explored the utilization of medication plans.

Methods: The "ProFem"-study on healthcare provision, functional ability, and quality of life after PFF is a German population-based prospective cohort study based on statutory health insurance data and individually linked survey data from different time points including information on the currently used medication. This present analysis refers to the participants' baseline interviews (about 3 months following PFF) conducted from 2018 to 2019 in the participants' private surroundings.

Results: The study population comprised 444 participants (mean age: 81.2 years, 71.0% female). Half of them reported high intensity pain, and the mean value for the EuroQol visual analogue scale was 50.8. Most commonly used analgesics were metamizole and tilidine/naloxone. Among participants with high intensity pain, 21.9% received only PRN pain medication and 17.2% no pain medication at all. Overall, 61.5% of participants presented any (printed) medication plan and only 25.2% a "federal standardized medication plan" (BMP).

Conclusion: As a substantial number of patients reports high intensity pain about 3 months following a PFF, the large proportion of those receiving no or only PRN pain medication raises questions regarding the appropriateness of the therapy. The overall low utilization of the BMP indicates potential for improvement.

1 | Introduction

Proximal femoral fractures (PFF) are among the most frequent fracture types in older adults [1]. A PFF is an incisive event, which is associated with an increased mortality [2–4] or permanent disabilities [5–7], it can result in care dependency [8] or lead to an institutionalization [9]. A review found that among those patients who recover walking ability and activities for

Summary

- About 3 months after a proximal femoral fracture, 50% of participants reported high intensity pain and an overall comparatively low self-rated health status.
- Almost 40% of participants with high pain intensity received only "pro re nata" pain medication or no pain medication at all raising the question whether this group might have benefited from a closer assessment of pain and its therapy.
- Overall, the analgesic spectrum was dominated by nonopioids.
- Although more than three-quarters of participants fulfilled the criteria for a "federal standardized medication plan" only every fourth participant had a respective plan.

daily living after PFF most do so within 6 months after hospital discharge [6]. In a recent Norwegian study, the largest improvement with respect to health-related quality of life (HRQoL) and function was observed within the first 3 months following hip fracture [10] indicating that the first months after discharge are a crucial time period.

Pain is one of the most common symptoms after PFF and it often leads to impaired recovery, mobility, functioning [11–13], and quality of life [14, 15]. Therefore, an effective pain management can help gain mobility and maintain independence. However, pain therapy in frail older adults is complicated by, among others, physiological changes, multimorbidity and multimedication [16, 17], and some studies hint at an undertreatment following fractures in patients with cognitive impairment [18, 19]. Pain therapy has to be adapted to the individual patient depending on indication, effectiveness, and tolerability. The analgesic spectrum covers different drug classes including nonopioids and opioids as categorized by the World Health Organization's (WHO) pain ladder [20]. Potential treatment regimens comprise scheduled medication, that is, the administration on a fixed schedule irrespective of the currently perceived pain and pro re nata (PRN)/as needed medication, which can be used by the patient within a certain range depending on their symptoms, or a combination of both. However, the schedule and complexity of pain medication regimes in the context of PFF has been rarely investigated. Yet, for other pain conditions, treatment deficits in older persons have been shown in studies contrasting pain intensity and the schedule of pain medication [21, 22]. Further, previous studies assessing pain management following PFF included large time frames [15] or focused on opioids only [23–25].

Given the variability and also potentially time-varying conditions, clear instructions to the patients are important to insure an effective and safe pain therapy. Dosages and schedules can be written on the packages and/or provided on patient owned medication lists or plans [26]. In Germany, the so called federal standardized medication plan ("Bundeseinheitlicher Medikationsplan," BMP), was introduced in October 2016. Since then every person insured with a statutory health insurance (SHI) is entitled to a BMP if he or she receives three or more systemic drugs reimbursed by the SHI for at least 28 days. The BMP should be kept up-to-date and cover a patient's complete medication including over-the-counter (OTC) drugs. Early studies examining the prevalence, quality, and completeness of the BMP show potential for improvement in terms of availability and correctness [27, 28]. So far, the use of the BMP has not been analyzed in the context of (specific) pain conditions such as post-fracture pain.

Against this background, the primary objective of this study was to examine pain medication regimens with respect to schedules and the used agents according to pain intensity about 3 months following a PFF. A secondary objective was to determine whether in this population the BMP or other medication plans were used.

2 | Methods

2.1 | Study Design and Study Population

The "ProFem"-study on healthcare provision, functional ability, and quality of life after PFF is a population-based prospective cohort study based on SHI data and individually linked survey data. The overall study design, the inclusion criteria, the recruitment process, and all examined variables have been described in detail in the study protocol [29]. In brief, from January 2018 to September 2019 persons aged at least 60 years and resident in North Rhine-Westphalia, Germany, who had been continuously insured for at least 1 year with the AOK Rheinland/Hamburg and experienced a PFF, were consecutively included in the study. The fracture event was defined according to the 10th revision of the International Classification of Diseases (ICD-10) codes S72.0 (fracture of head and neck of femur), S72.1 (pertrochanteric femoral fracture) and S72.2 (subtrochanteric femoral fracture), and selected surgical and procedural keys [29]. A subgroup of the people with PFF identified in the SHI data was invited to additionally participate in a survey. Eligible participants received an invitation letter signed by the SHI and the project lead. Nonresponders were reminded once in writing after approximately 2 weeks and contacted by telephone in a further step [30].

Survey data was collected at three planned time points after hospital discharge: (i) 3 months (baseline, personal interview in the participants' private surroundings) and (ii) 6 and (iii) 12 months. For individuals who could not be interviewed after 3 months (baseline), substitute baseline visits were arranged after 6 months as face-to-face interviews whenever possible. The questionnaire covered various items including patient characteristics and medication (in total: 85 questions). If participants considered themselves only partially or not at all able to take part in the survey, for example, due to dementia or reduced state of health, if possible, a proxy person was interviewed additionally or instead. Pain was not assessed by proxy persons, since no reliable information on pain (intensity) was expected. Therefore, when the questionnaire was answered by proxy persons, pain (intensity) was not recorded. In addition to the questionnaire, participants and proxies were asked whether they were willing to provide information about the currently used medication.

Overall, of 2866 invited persons with PFF, 2819 were eligible to participate in the survey. The reasons for exclusion were incomplete insurance data and no PFF in the relevant timeframe. Of all eligible persons, 515 were willing to participate in the baseline interviews [30]. Among those, 444 (86.2%) agreed to provide additional information about their medication; these constituted the study population for this present study.

2.2 | Included Variables

2.2.1 | Medication

The reconciliation of medication included three steps. First, with the participants' permission, BMPs or other medication plans were photographed. If no plans were available, pictures of the patient's current medication were taken categorized as "scheduled medication" or "pro re nata medication" (using respective paper signs). Recorded medication comprised all drugs and supplements listed on a plan or presented by the patient regardless of whether they had been prescribed by a physician or bought OTC. In a second step, medication and its type of use was recorded electronically and stored in a Microsoft Access database. Each drug was assigned to its anatomical therapeutic chemical (ATC) code based on the available information including agent and brand. For products without an official ATC code (e.g., magnesium effervescent tablets or herbal remedies bought from a drugstore), the most appropriate ATC code was assigned manually. Nutrients such as enteral nutrition (ATC codes V06 or products without an ATC code) were not recorded electronically. The type of a drug's use (scheduled or PRN) was assessed from the plans' dosing schedules. Scheduled medication refers to the administration on a fixed schedule whereas PRN medication can be used by the patient within a certain range depending on their symptoms. When medication was assessed via photographed packages, the information from the arranged paper signs was used. Medication marked as scheduled and PRN (e.g., a further tablet to be used in case of breakthrough pain) was assigned to both categories. The electronic collection of medication (regimens) was done by a pharmacist. Validation was carried out by a second skilled person for a random sample of 20%. This corresponded to medication information from 90 persons and 716 drugs. For those, the second person checked whether (i) the medication and (ii) the type of use (PRN vs. scheduled) were recorded correctly (i.e., in total 1432 items). After validation, one item was corrected (total initial agreement: 99.9%). Third, for the analysis only current medication as documented on the day of the interview was included. This comprised also drugs used for a limited period of time (e.g., thromboprophylaxis or antibiotic therapy). If, according to the information on a medication plan, a therapy was ended before the date of the interview, the respective medication was not considered current and therefore discarded.

Medication use was examined on the seventh level of the ATC code. Pain medication was defined as the ATC codes M01A (anti-inflammatory and antirheumatic products, nonsteroids), M02 (topical products for joint and muscular pain), and N02 (analgesics). All drugs were assigned to the respective step of the WHO pain ladder (i.e., nonopioids [step 1], weak opioids [step 2], and strong opioids [step 3]) [20]. For opioids, we further assessed the mode of release (immediate- vs. extended-release [including transdermal patches]).

2.2.2 | Pain

Overall pain and pain intensity were assessed using the respective questions from the von Korff grading of pain severity [31]. This assessment is part of the German pain questionnaire [32] recommended by the German Society of Pain, that is, the German section of the International Association for the Study of Pain (IASP). Here, pain is recorded threefold: (i) the current level of pain, (ii) the average level of pain during the last 4 weeks, and (iii) the highest level of pain during the last 4 weeks [33]. Each item was rated on a numerical rating scale from 1 (no pain) to 5 (worst imaginable pain), adapted from the original scale (0–10). Using a procedure similar to what was done by von Korff et al. the resulting mean value was multiplied by 5 yielding a 5–25 score (original score: 0–100). Values up to 14 were classified as no/minor pain intensity (corresponding to 49 in the von Korff score) whereas values of 15 and higher were considered as high pain intensity [31, 33].

2.2.3 | Patient-Reported Outcomes (PROs) and Other Variables

The visual analogue scale from the European Quality of Life 5-Dimensions (EQ-5D) questionnaire (EQ VAS) was used as a measure of the patient's self-rated health status with values between 0 (worst imaginable state of health) and 100 (best imaginable state of health) [34]. Activities of daily living (ADL) referring to the last 4 weeks were recorded in the Oxford Hip Score (OHS) with summed up scores running from 0 to 48 with 48 being the best outcome. Last, the subjective social status was assessed using the MacArthur Scale, by asking the patients to place themselves on a 10-rung "social ladder," [35] classified as low (1–4), medium (5), and high (6–10).

Other participant characteristics included age and sex, the duration of the PFF hospital stay and the highest care grade in the period before the hospital stay (provided by SHI data). In Germany, care-dependent persons are eligible to one of five long-term care grades reflecting their individual ability to manage considering their physical, cognitive, or psychological impairments [36]. In this study, a person's care need was classified as none (no care grade), low (grade 1/2), medium (grade 3/4), and high (grade 5) [37]. From the survey, we further included questions regarding a participant's height and weight, used for the calculation of the body mass index (BMI) [38], and whether the current fracture was the first respective event.

2.3 | Statistical Analysis

Descriptive statistics (mean, standard deviations, median, quartiles (Q1–Q3), and percentages) were used. First, patients' characteristics including demographics and PROs were presented overall and stratified by (i) the origin of the survey information (proxy person vs. participant) and (ii) the reported pain intensity (no/minor vs. high pain intensity). Second,

treatment characteristics were displayed overall and stratified by the use of pain medication (no pain medication vs. only PRN pain medication vs. scheduled pain medication [+/-PRN]). Using the information on the participants' overall medication and the type of use, we assessed whether patients were eligible to a BMP. We displayed (i) overall medication, (ii) scheduled medication, and (iii) scheduled medication reimbursed by the SHI and we examined the use of medication plans including BMPs using the origin of the medication assessment ("BMP," "other (printed) medication plan," "photos of package(s)" and "other"). Third, we displayed the top 10 drugs used PRN and in a scheduled manner, respectively. Forth, the proportion of patients treated with pain medication (overall, by WHO step and drug) were reported by type of medication use (PRN vs. scheduled). Last, for pain medication we displayed the most common treatment regimens (including the analgesic and its type of use). For all analyses regarding the use of medication, we relied on the information provided by the patients ("intention to treat").

Statistical analyses were performed using SAS, Version 9.4 (SAS Institute Inc).

The study was approved by the responsible ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (6128R). All participants provided written informed consent.

3 | Results

3.1 | Baseline Characteristics of the Study Population

In the study population of 444 participants, the mean age was 81.2 years, 71.0% were female, 41.2% had no care grade, and 51.9% normal weight (BMI: 18.5–<25 kg/m^2, Table 1). More than half (54.5%) assigned themselves to a medium social status whereas 22.4% and 23.1% chose places on the ladder referring to high and low status, respectively (mean value: 5.0). The mean duration of the PFF hospital stay was 22 days and the mean time since discharge was 102.1 days with 377 (84.9%) of all interviews being conducted after 3 months following PFF. For 92.4% of patients this was the first hip fracture. The mean values for the EQ VAS were 50.8 and for the OHS 20.2.

For 140 participants, survey data were mainly assessed from proxy persons, whereas 304 participants responded themselves. Participants for whom proxy persons answered were older (mean age: 85.7 vs. 79.2 years) and far more often had a care grade of three or higher (63.6% vs. 19.1%). They also had lower values of the EQ VAS and OHS than those responding themselves (mean values: 40.4 vs. 55.5 and 15.0 vs. 22.6, respectively).

Among the 304 participants responding themselves, 153 (50.3%) had no or minor pain (including 17 persons with no pain) and for 151 participants (49.7%) high intensity pain was recorded. Participants reporting high pain intensity were more often female (72.9% vs. 67.3%), had a medium or high care grade (22.6% vs. 15.7%) and a BMI of 25 or higher (44.9% vs. 40.5%) compared with those reporting no or minor pain. The former also far more frequently assigned themselves to a low social status (30.7% vs. 16.8) and the present PFF was more often not the first event (8.8% vs. 4.7%). With respect to the EQ VAS, the mean score was far lower in patients with high pain intensity (48.2 vs. 62.8). Accordingly, the disease specific function according to the OHS was lower in patients with high intensity pain (17.4 vs. 27.7).

3.2 | Medication Plan and Overall Medication

In the questionnaire, 327 of all participants (73.6%) stated that a medication plan was available (data not shown), and the most common reason for not having a respective plan was that the person used only a few drugs. When asked to show their medication plans, 273 of all participants (61.5%) presented any (printed) plan and 112 (25.2%) provided a BMP (Table 2).

Participants received a median of eight drugs (Q1–Q3: 5–11), with 7 (5–10) referring to scheduled medication. Overall 86.0% received at least three scheduled drugs and 84.5% had at least three scheduled drugs reimbursed by the SHI. At least one PRN drug was used by 247 persons (55.6%). Among the top 10 PRN medications, five were analgesics whereas other commonly used PRN drugs were macrogol and salbutamol (Supporting Figure 1). Pantoprazole was the most often reported scheduled medication and overall six of the 10 drugs could be attributed to the cardiovascular spectrum.

3.3 | Pain Medication and Differences According to the Schedule of Use

Use of any pain medication about 3 months following PFF was documented for 337 (75.9%) of all participants. For five persons the type of use for their pain medication was not specified. Among the 439 participants with a specified type of use, 191 (43.5%) reported at least one PRN and 216 (49.2%) at least one scheduled drug, respectively (Table 2). More than one third of participants received two or more different analgesics; 41.2% used only nonopioids, 7.7% only opioids, and 27.0% were treated with nonopioids and opioids, respectively.

The most commonly used analgesic was metamizole (reported by overall 54.1% of patients), followed by tilidine/naloxone (18.2%) and ibuprofen (14.6%, Supporting Table 1). Metamizole was slightly more often used as scheduled medication (31.0% vs. 27.8%) whereas other nonopioids were more often used PRN. Opioids were far more often used as scheduled than as PRN medication (WHO step 2: 16.6% vs. 4.3% and WHO step 3: 13.2% vs. 2.5%) and about 90% of all opioids were extended-release preparations. Almost all analgesic regimens included metamizole with 71.2% of analgesic users receiving this drug. Metamizole + tilidine/naloxone were the single most frequent combination (Figure 1).

Participants with scheduled pain medication more often had a medication plan (any plan: 72.7%, BMP: 31.0%) than those with PRN pain medication only (any plan: 52.6%, BMP: 19.0%) or those without pain medication (any plan: 50.5%, BMP:

TABLE 1 | Baseline characteristics of the study population.[a]

		Information assessed from		Pain intensity ($N=304$)	
	Overall ($N=444$)	Proxy persons ($N=140$)	Participants ($N=304$)	No or minor ($N=153$)[b]	High ($N=151$)
Sex (0 missings)					
Female	315 (71.0%)	102 (72.9%)	213 (70.1%)	103 (67.3%)	110 (72.9%)
Male	129 (29.0%)	38 (27.1%)	91 (29.9%)	50 (32.7%)	41 (27.2%)
Age (years) (0 missings)					
Mean (SD)	81.2 (8.4)	85.7 (7.8)	79.2 (7.8)	79.0 (8.0)	79.3 (7.6)
Median (Q1–Q3)	81.9 (76.0–86.9)	86.3 (82.5–91.2)	80.2 (74.0–84.6)	80.0 (73.6–84.4)	80.5 (74.4–84.7)
Care need preceding PFF (0 missings)					
None	183 (41.2%)	18 (12.9%)	165 (54.3%)	93 (60.8%)	72 (47.7%)
Low (grade 1/2)	114 (25.7%)	33 (23.6%)	81 (26.6%)	36 (23.5%)	45 (29.8%)
Medium (grade 3/4)	134 (30.2%)	77 (55.0%)	57 (18.8%)	24 (15.7%)	33 (21.9%)
High (grade 5)	13 (2.9%)	12 (8.6%)	1 (0.3%)	0 (0.0%)	1 (0.7%)
First hip fracture? (8 missings)					
Yes	403 (92.4%)	127 (90.7%)	276 (93.2%)	141 (95.3%)	135 (91.2%)
Duration of PFF hospital stay (days) (0 missings)					
Mean (SD)	22.0 (12.1)	23.0 (12.6)	21.6 (11.8)	20.5 (10.2)	22.6 (13.1)
Median (Q1–Q3)	20.0 (13.0–28.5)	22.0 (13.0–30.0)	19.0 (12.5–28.0)	18.0 (12.0–27.0)	20.0 (13.0–29.0)
Visit (0 missings)					
Baseline (after 3 months)	377 (84.9%)	116 (82.9%)	261 (85.9%)	130 (85.0%)	131 (86.8%)
Substitute baseline visit (after 6 months)	67 (15.1%)	24 (17.1%)	43 (14.1%)	23 (15.0%)	20 (13.3%)
Person(s) answering the questionnaire (0 missings)					
Participant	283 (63.7%)	3 (2.1%)	270 (88.8%)	146 (95.4%)	134 (88.7%)
Participant + proxy person	29 (6.5%)	5 (3.6%)	24 (7.9%)	7 (4.6%)	17 (11.3%)
Proxy person only	132 (29.7%)	132 (94.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Body mass index (kg/m^2) (12 missings)					
0 to <18.5	33 (7.6%)	16 (11.7%)	17 (5.8%)	10 (6.8%)	7 (4.8%)
18.5 to <25	224 (51.9%)	72 (52.6%)	152 (51.5%)	78 (52.7%)	74 (50.3%)
25+	175 (40.5%)	49 (35.8%)	126 (42.7%)	60 (40.5%)	66 (44.9%)
Subjective social status (ladder) (7 missings)					
Mean (SD)	5.0 (1.5)	5.0 (1.5)	5.0 (1.5)	5.2 (1.5)	4.7 (1.5)
Median (Q1–Q3)	5.0 (5.0–5.0)	5.0 (5.0–6.0)	5.0 (5.0–5.0)	5.0 (5.0–5.0)	5.0 (4.0–5.0)
High	98 (22.4%)	36 (26.1%)	62 (20.7%)	35 (23.5%)	27 (18.0%)
Medium	238 (54.5%)	72 (52.2%)	166 (55.5%)	89 (59.7%)	77 (51.3%)
Low	101 (23.1%)	30 (21.7%)	71 (23.7%)	25 (16.8%)	46 (30.7%)

(Continues)

TABLE 1 | (Continued)

		Information assessed from		Pain intensity ($N=304$)	
	Overall ($N=444$)	Proxy persons ($N=140$)	Participants ($N=304$)	No or minor ($N=153$)[b]	High ($N=151$)
Time since discharge (days) (0 missings)					
Mean (SD)	102.1 (39.1)	104.3 (42.1)	101.1 (37.7)	102.2 (39.7)	99.9 (35.7)
Median (Q1–Q3)	91.0 (79.0–107.0)	91.0 (81.0–107.0)	91.0 (78.0–106.0)	92.0 (77.0–107.0)	91.0 (79.0–106.0)
EuroQol visual analogue scale (EQ VAS) (2 missings)					
Mean (SD)	50.8 (21.6)	40.4 (21.0)	55.5 (20.2)	62.8 (19.6)	48.2 (18.0)
Median (Q1–Q3)	50.0 (30.0–70.0)	35.0 (25.0–55.0)	50.0 (40.0–70.0)	62.5 (50.0–80.0)	50.0 (35.0–60.0)
Oxford hip score (7 missings)					
Mean (SD)	20.2 (10.9)	15.0 (8.2)	22.6 (11.2)	27.7 (10.8)	17.4 (8.9)
Median (Q1–Q3)	19.0 (12.0–27.0)	14.0 (10.0–19.0)	22.0 (13.0–31.0)	28.0 (20.0–35.0)	17.0 (10.0–23.0)

Abbreviations: PFF: proximal femoral fracture; SD: standard deviation.
[a]Percentages are column percentages (missings of the respective variable removed).
[b]Seventeen patients reporting no pain and 136 reporting minor pain.

21.5%, Table 2). Participants with scheduled pain medication also used a higher number of different drugs (median: 9) than those with no or only PRN pain medication (5) and 96.8% had at least three scheduled drugs reimbursed by the SHI. Nearly half (49.5%) of those using scheduled pain medication received any PRN medication and 34.7% had at least one PRN pain medication.

Among participants with no pain medication, 31.7% reported high pain intensity. The respective proportions were higher in those using PRN pain medication only (39.8%) and participants treated with scheduled pain medication (66.1%). This corresponds to 17.2% of participants with high pain intensity receiving no pain medication whereas 22.1% were treated with PRN pain medication only, respectively (Supporting Table 2).

4 | Discussion

In this study, we found that about 3 months following PFF 50% of participants reported high pain intensity displaying a reduced self-rated health status. Almost 40% of participants with high pain intensity received only PRN pain medication or no pain medication at all. About 85% of all participants fulfilled the criteria for a BMP although its actual use was far lower.

4.1 | Baseline Characteristics of the Study Population Compared to the Literature

With respect to demographics, our study population was comparable with other German studies examining hip fracture patients [8, 15]. The overall subjective social status seemed in line when compared with the oldest age group of the "German Health Update" (GEDA) study [35].

OHS and EQ VAS scores were with 20.2 and 50.8 comparatively low. A UK cohort study following hip fracture patients (mean age 83.6 years, 75% female) found mean OHS scores of 29.1 (after 4 weeks) and 35.5 (after 4 months) and also substantially higher EQ VAS values (62.6 after 4 weeks and 65.4 after 4 months, respectively) [39]. Similarly, a Norwegian study (mean age: 82.6, 76.8% female) reported an EQ VAS of 64.1 3 months after a hip fracture operation [10]. A recent German study examining the impact of hip fractures on patient-reported HRQoL in an overall younger study population (mean age: 75.8, 67.2% female) reported EQ VAS values of 69.9 shortly after the PFF and of 59.4 after 6 months [4].

Less than 6% of the participants answering themselves reported no pain about 3 months following PFF whereas half of them stated high pain intensity. Although a comparison with other studies is hampered by differences in the assessment of pain, the prevalence in our study seemed high. Based on the 3-level version of the EQ-5D, a study from the Netherlands (mean age: 80.3 years, 70.4% female) found that about 20% of frail and 30% of nonfrail patients reported no general problems with pain/discomfort 3 months after hip fracture [40]. Similarly, in the Norwegian Hip Fracture Register (mean age 77.3 years, 72.4% female) 25.3% of patients had no pain or discomfort 4 months after the fracture with the highest proportion among those aged 80+ [41].

With respect to the OHS and EQ VAS, persons reporting high pain intensity in our study scored lower than those with no or minor pain, which is plausible given that both PROs are either associated with pain or specifically address pain-related topics. However, also the group with no or minor pain scored lower than the overall groups in the other aforementioned studies [10, 39] suggesting a comparatively poor health status according to the EQ VAS and disease specific function according to the OHS in our cohort about 3 months after PFF.

TABLE 2 | Characteristics of patients by use of pain medication.[a]

	Overall ($N=444$)	No pain medication[b] ($N=107$)	Only PRN pain medication[b] ($N=116$)	Scheduled pain medication[b,c] ($N=216$)
Medication assessed from (0 missings)				
Federal standardized medication plan (BMP)	112 (25.2%)	23 (21.5%)	22 (19.0%)	67 (31.0%)
Other (printed) medication plan	161 (36.3%)	31 (29.0%)	39 (33.6%)[g]	90 (41.7%)
Photos of packages only	91 (20.5%)	30 (28.0%)	28 (24.1%)	30 (13.9%)
Other	80 (18.0%)	23 (21.5%)	27 (23.3%)	29 (13.4%)
Overall medication[d] (0 missings)				
Median number of different drugs (Q1–Q3)	8 (5–11)	5 (3–8)	7 (4–10.5)	9 (7–12)
Scheduled medication				
Median number of different drugs (Q1–Q3)	7 (5–10)	5 (3–8)	5 (3–9)	9 (6–11)
3+ different drugs	382 (86.0%)	81 (75.7%)	90 (77.6%)	211 (97.7%)
5+ different drugs	325 (73.2%)	68 (63.6%)	61 (52.6%)	196 (90.7%)
Scheduled reimbursed medication[e]				
Median number of different drugs (Q1–Q3)	6 (4–9)	5 (2.5–7)	4.5 (3–7)	8 (6–10)
3+ different drugs	375 (84.5%)	78 (72.9%)	88 (75.9%)	209 (96.8%)
5+ different drugs	304 (68.5%)	59 (55.1%)	58 (50.0%)	187 (86.6%)
PRN medication				
At least one PRN drug	247 (55.6%)	24 (22.4%)	116 (100%)	107 (49.5%)
Pain intensity (0 missings)				
Information assessed from proxy persons[f]	$N=140$	$N=25$	$N=33$	$N=80$
Information assessed from participants	$N=304$	$N=82$	$N=83$	$N=136$
No pain or minor pain intensity	153 (50.3%)	56 (68.3%)	50 (60.2%)	46 (33.8%)
High pain intensity	151 (49.7%)	26 (31.7%)	33 (39.8%)	90 (66.1%)
Pain medication[d,g] (0 missings)				
Any analgesic drug	337 (75.9%)	—	116 (100%)	216 (100%)
1 analgesic drug	183 (41.2%)	—	93 (80.2%)	85 (39.4%)
2 analgesic drugs	131 (29.5%)	—	20 (17.2%)	111 (51.4%)
3 or more analgesic drugs	23 (5.2%)	—	3 (2.6%)	20 (9.3%)
Any nonopioid	303 (68.2%)	—	108 (93.1%)	192 (88.9%)
Any opioid	154 (34.7%)	—	15 (12.9%)	137 (63.4%)
Only nonopioids	183 (41.2%)	—	101 (87.1%)	79 (36.6%)
Only opioids	34 (7.7%)	—	8 (6.9%)	24 (11.1%)
Nonopioids and opioids	120 (27.0%)	—	7 (6.0%)	113 (52.3%)

(Continues)

TABLE 2 | (Continued)

	Overall ($N=444$)	No pain medication[b] ($N=107$)	Only PRN pain medication[b] ($N=116$)	Scheduled pain medication[b,c] ($N=216$)
Specified type of use[b] (5 missings)				
Any PRN pain medication	191 (43.5%)		116 (100%)	75 (34.7%)
Any scheduled pain medication	216 (49.2%)		—	216 (100%)

Abbreviations: ATC: anatomical therapeutic chemical; PRN: pro re nata/as-needed; SHI: statutory health insurance.
[a]Percentages are column percentages (missings of the respective variable removed).
[b]For five patients, pain medication was recorded without any information regarding its use (PRN/scheduled).
[c]With or without additional PRN medication.
[d]Based on the seventh level of the ATC code.
[e]Excluding products usually not reimbursed by the SHI (vitamins [ATC: A11], mineral supplements [A12], antacids [A02A], topical products for joint and muscular pain [M02A]).
[f]Pain was not assessed externally.
[g]Anti-inflammatory and antirheumatic products, nonsteroids (ATC: M01A), topical products for joint and muscular pain (M02), analgesics (N02).

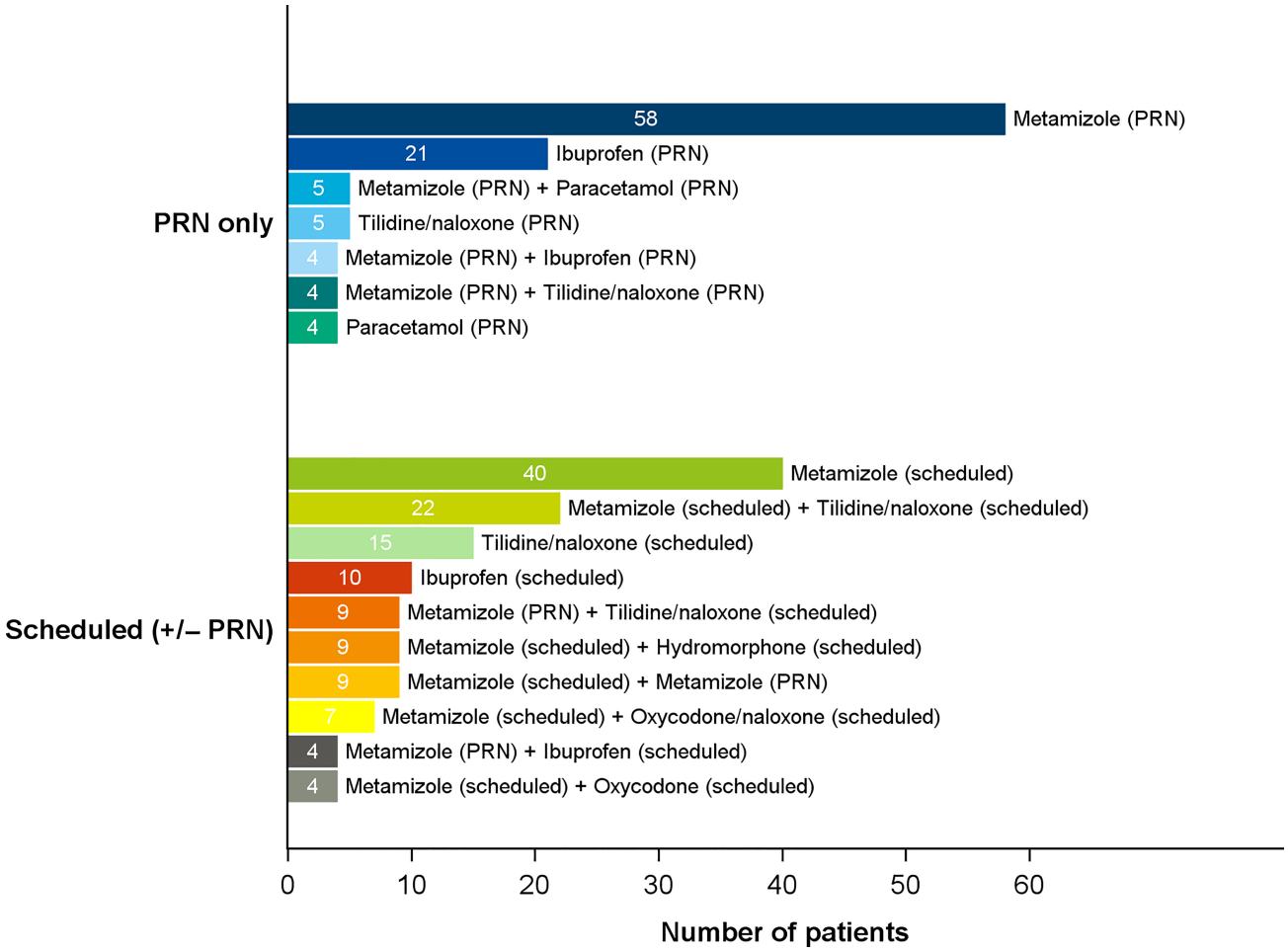

FIGURE 1 | Pain medication regimens recorded for the study population ($N=444$) by type of use. Only one analgesic (combination) was possible per patient. PRN: pro re nata/as-needed.

4.2 | Pain Medication According to Pain Intensity

In our study, 17.2% of participants with high pain intensity had no recorded pain medication and 22.1% received only PRN pain medication. Since our study also included OTC medication such as paracetamol, (low-dose versions of) ibuprofen, and diclofenac or topical treatment, our assessment regarding current analgesic use can be considered rather complete. Overall, these findings are in line with other German studies examining different pain conditions. Among patients with rheumatoid arthritis (RA) reporting severe pain 18.0% received no analgesic reimbursed by the SHI [42]. Among older home-care recipients, 17.5% with current pain and about 11% with severe pain did not receive any pain medication [22, 43].

Most studies examining pain medication in the context of hip fractures focus on opioids and with 34.7% opioid users our results are in line with other analyses at similar time points [44, 45]. Most opioids in our study were extended-release products and about 81% were used in a scheduled manner, which is recommended in the WHO pain ladder [20] and by the German guideline on long-term opioid therapy for chronic noncancer pain [46]. The exception was some patients using extended-release tilidine/naloxone PRN. This seems insufficient in case of acute pain where an immediate analgesic effect is crucial but might be plausible if patients experience pain only in specific (scheduled) situations such as physiotherapy sessions.

In our study, the analgesic spectrum was overall dominated by nonopioids and the mainly used mono and combination therapies were metamizole and the combination of metamizole and tilidine/naloxone. This is in line with the German guideline on the treatment of acute perioperative and posttraumatic pain, which considers several nonopioids such as nonsteroidal anti-inflammatory drugs (NSAIDs) and metamizole equally effective and, for severe and moderate pain, recommends that opioids should be used in combination with nonopioids [47]. Although metamizole has good analgesic, antipyretic and spasmolytic efficacy, its risk of agranulocytosis led to its ban in several countries whereas in Germany its use was restricted to a narrow spectrum of indications including postoperative pain [48, 49]. Nevertheless, metamizole has been found as main analgesic in several German studies and various settings [22, 42, 50–52]. An overall very similar utilization of metamizole was found in the aforementioned German study on older home-care recipients mainly suffering from low back pain, osteoarthritis, and neuropathic pain (71.4%) [22].

NSAID use was slightly lower than in our study while opioid use was slightly higher, more often scheduled (88.7%) and more frequently included step 3 opioids [22] probably attributable to the rather chronic conditions in that study. In that study as in ours, paracetamol played a minor role with only about 5% of analgesic users treated with this agent although it is the analgesic of choice in older persons according to German positive or negative lists such as FORTA (Fit fOR The Aged) [53] or PRISCUS (potentially inadequate medications in the elderly) [54]. With respect to potential interactions of analgesics with other drugs (e.g., ibuprofen and low-dose acetylsalicylic acid (ASS) or opioids and central nervous system depressing drugs [46, 47]), paracetamol might be also considered advantageous. However, since it is not effective in many indications [46, 55] and also considered inferior to NSAIDs or metamizole in the context of postoperative pain [47] its wider use in Germany is hampered. Here our findings stand in stark contrast to the aforementioned Swedish study where 82% of patients used paracetamol (61% regularly) 12 weeks after discharge from orthopedic care [44] underlining the differences in cross-country comparisons due to drugs' approvals.

4.3 | Utilization of the Medication Plan

Although three-quarters of patients stated to own a medication plan, only about one in four presented a BMP. Considering that about 85% of participants in our study received three or more scheduled (reimbursed) medications, which means that they were entitled to a BMP, this proportion is considered to be low. This is especially important to be assessed against the background that all participants had experienced an incisive event, which was likely followed by medical treatment or changes thereof. Two other German studies found low proportions of BMPs as well; however, these were conducted in the hospital setting where the (physical) availability of a BMP may be further hampered compared to a patient's private surroundings. In a study examining the prevalence and quality of medication plans at hospital admission in 2017, 56.6% of patients eligible for a BMP presented a medication plan (72.2% reported to own one) with only 13.4% having a BMP [28]. In that study, which, compared to ours, included younger patients (mean age: 65 years) using a lower number of long-term drugs (median: 5) the probability to own a medication plan and to have it present at hospital admission increased with the number of medications and a patient's age [28]. Another study (late 2017 to early 2018) found a BMP proportion of 21.2% among elective surgical patients with three or more scheduled medications [27].

In our study, the highest proportion of BMPs was found in persons with scheduled analgesic treatment. Since these patients received a higher number of drugs this was expected. Further, physicians might be overall more aware of the importance of communicating a drug's use in writing when prescribing analgesics since at least for step 3 opioids written information with respect to dose and schedule were mandatory long before the implementation of the BMP.

However, the proportion of participants using only PRN pain medication and providing neither a BMP nor any other (printed) plan was with 47% surprisingly high. Without clear (written) instructions patients might be undertreated hampering recovery or may use the medication in an uncontrolled manner. According to a recent review patient participation and shared decision-making in PRN medication management was a pillar for safe PRN management [56]. Therefore, the documentation of PRN medication use by the patient for example in a pain diary might be a helpful tool to reflect their needs. Such a documentation aligned with the medication plan could be used by physicians to assess whether a patient's pain medication (schedule) is sufficient, should be intensified or could be tapered. This seems especially important in a situation such as in our study where an optimal treatment is crucial to gain mobility without (automatically) resulting in a long-term analgesic therapy.

4.4 | Strengths and Limitations

The strength of this descriptive study is the drug assessment in the participants' private surroundings including also OTC drugs and medication schedules, which allowed in-depth analyses of current medication and patterns following PFF. Via the questionnaire, we were further able to determine a participant's pain intensity, which allowed pain medication and pain intensity to be contrasted against each other. Additionally, the exploration of the availability and the type of medication plans adds valuable information regarding the (seemingly insufficient) utilization of the BMP in this specific population.

The involvement of proxies allowed the inclusion of information from vulnerable subgroups, such as persons with dementia. Nevertheless, considering the study design and the overall response [57], a selection bias toward healthier study participants cannot be ruled out. This is also suggested by the substantial differences observed between participants responding themselves and those for whom proxy persons answered. However, when considering health status and disease specific function, our overall study population and also the subgroup with no or minor pain intensity scored lower when compared with other studies at similar time points following PFF speaking against a highly selective and particularly healthy group [10, 39]. As a consequence of the inclusion of vulnerable subgroups, information on pain was only available for about 70% of participants (i.e., for those answering themselves), since no reliable information was expected based on a respective assessment by proxy persons.

As another limitation, the assessment of pain in our study referred to pain in general making it impossible to disentangle PFF-related pain and other (possibly chronic) conditions. Accordingly, the analgesic use could not be allocated to specific (pain) indications and it was not possible to verify a person's actual medication use (e.g., in case patients had additional [verbal] information on how and when to use their medication or if they independently decided to deviate from the medication plan). However, patients reporting (any) pain but no pain medication might be considered undertreated irrespective of the pain's origin. In this analysis, we only focused on drug-based pain therapy and did not assess the utilization of for example physical therapy.

Another limitation is that only 444 of overall 515 participants provided information on medication. However, the overall group was very similar in terms of age and sex and also with respect to who was answering the questionnaire. In accordance with the results for those providing information on medication, also in the overall group quality of life and mobility were higher in participants responding themselves than in those for whom proxy persons answered [30].

5 | Conclusions

As a substantial number of patients reports high intensity pain about 3 months following a PFF, the large proportion of those receiving no or only PRN medication raises the question whether this group might have benefited from a closer assessment of pain and its therapy. Given the incisive event and the high number of drugs used, the low utilization of a BMP, especially in the context of PRN pain therapy, is concerning and shows much potential for improvement.

5.1 | Plain Language Summary

Pain is a common symptom following hip fractures. Since pain hinders recovery, an adequate pain therapy is important. The "ProFem"-study examines healthcare provision, functional ability, and quality of life after hip fractures using statutory health insurance data and individually linked survey data including information on the patients' medication. Data were included from 444 participants interviewed about 3 months after hip fracture in 2018–2019. Their mean age was 81.2 years, 71.0% were female. Half of them reported high intensity pain and the scores regarding overall health indicated a comparatively low self-rated health status. Among participants stating high intensity pain, 21.9% received only pain medication to be used "as needed" instead of a scheduled treatment and 17.2% had no pain medication at all. Overall, 61.5% of participants had a (printed) medication plan and only 25.2% the so called "federal standardized medication plan" (BMP). In conclusion, as a substantial number of patients reports high intensity pain after about 3 months after hip fracture, the large proportion of those receiving no or only "as needed" pain medication raises the question whether pain treatment was adequate. The overall low utilization of a BMP shows potential for improvement.

Author Contributions

Silke Andrich, Michaela Ritschel, Marion Baltes, Astrid Stephan, Gabriele Meyer, Andrea Icks, and Falk Hoffmann conceptualized and designed the study. Michaela Ritschel, Katja Pöggel-Krämer, Daniela Anheier, Marion Baltes, and Birgit Klüppelholz were involved in the acquisition of the data. Kathrin Jobski, Burkhard Haastert, Veronika Gontscharuk, and Werner Arend analyzed the data. Kathrin Jobski, Burkhard Haastert, Silke Andrich, Andrea Icks, and Falk Hoffmann interpreted the data. Joachim Windolf, Simon Thelen, and Carina Jaekel provided clinical expertise. The manuscript was initially prepared by Kathrin Jobski and Falk Hoffmann, and critically reviewed by all other authors. All authors have revised and approved the final version of the paper and agree to be accountable for all aspects of their work.

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Ethics Statement

The study was approved by the responsible ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (6128R). All participants provided written informed consent.

Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.