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RESEARCH

Effectiveness and safety of pegylated filgrastim (Pelgraz®) for the prevention of febrile neutropenia during cancer chemotherapy in all-day practice in Germany

Tilman Steinmetz[1,10] · Peter Jungberg[2] · Dagmar Guth[3] · Jan Knoblich[4] · Thomas Fietz[5] · Thomas Göhler[6] · Marcel Reiser[7] · Uwe Totzke[8] · Katharina Bernhardt[9]

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Abstract

Purpose Febrile neutropenia (FN) is a common side effect of chemotherapy. It may be prevented by granulocyte colony-stimulating factors (G-CSF), requiring customization based on patients' risk factors, the type of cancer and chemotherapy, and the formulation used. This observational study investigated all-day use of a pegfilgrastim formulation, also available for self-administration.

Methods In outpatient clinics across Germany, doctors recorded data of adult patients suffering from a malignant disease routinely treated with chemotherapy and pegfilgrastim.

Results Overall, 1636 patients received pegfilgrastim, predominantly women suffering from yet untreated breast cancer, 62% being at moderate and 38% at high risk of FN. In total, 2.5% of patients experienced FN despite treatment with pegfilgrastim, with 52.5% requiring hospitalization; in 40%, subsequent chemotherapy had to be postponed or reduced in dose. FN incidence and hospitalization rates were slightly lower when pegfilgrastim was given for primary versus secondary prophylaxis whereas there was no difference when given on day 1 or any later day following chemotherapy. FN incidence was much higher in patients with hematological as compared to solid tumors, particularly when treated with BEACOPP regimens. By contrast, related hospitalization depended less on cancer type and chemotherapy. Pegfilgrastim counterbalanced patients' risk factors, but a previous FN episode and male sex still increased the risk of hospitalization. Overall, 13.4% of patients experienced infections. The most common side effect of pegfilgrastim was bone-related pain. The syringe and self-injector formulations showed comparable effectiveness and safety.

Conclusions Pegfilgrastim (Pelgraz®) treatment appeared to be effective and safe in all-day practice.

Keywords Pegfilgrastim · Neutropenia · Febrile neutropenia

✉ Tilman Steinmetz
steinmetz@oncokoeln.de

1 Outpatient Clinic in Cologne, Cologne, Germany
2 Outpatient Clinic in Chemnitz, Chemnitz, Germany
3 Outpatient Clinic in Plauen, Plauen, Germany
4 Outpatient Clinic in Lörrach, Lörrach, Germany
5 Outpatient Clinic in Singen, Singen, Germany
6 Outpatient Clinic in Dresden, Dresden, Germany
7 Outpatient Clinic in Frechen, Frechen, Germany
8 Totzke & Dreher Scientific (TDS), Basel, Switzerland
9 Former Accord Healthcare, Munich, Germany
10 MV-Zentrum Für Hämatologie Und Onkologie, Sachsenring 69, 50677 Cologne, Germany

Introduction

Neutropenia is one of the most common side effects of chemotherapy. Due to the decrease in neutrophil granulocytes, patients may develop life-threatening febrile infections requiring hospitalization. Among cancer patients hospitalized for febrile neutropenia (FN), mortality rates of about 6% have been reported independently [9, 11]. In addition, neutropenia may cause delay or dose reduction of chemotherapy, diminishing the efficacy of cancer treatment [33]. Accordingly, chemotherapy-induced episodes of neutropenia are to be avoided.

Prophylactic use of granulocyte colony-stimulating factor (G-CSF) proved to reduce infection-related mortality and to nearly halve the risk of FN in cancer patients undergoing

chemotherapy [15]. Based on guidelines for supportive cancer treatment, the prophylactic treatment with G-CSF should be initiated based on the patient's individual risk of FN and the risk associated with the chemotherapy regimen used [47], although in all-day practice, the former appears to be prioritized [42]. However, the impact of individual risk factors is still unclear, and the list of factors partly varies among guidelines [1, 24, 44, 46]. Consistently cited were elderly age [40], poor performance or nutritional status, active infection, open wounds and/or recent surgery, advanced cancer, different comorbidities, and several preceding lines of cancer treatment, as well as dose-dense chemotherapy [1, 47].

Meanwhile, various G-CSF formulations have been approved to reduce the duration of neutropenia as well as the frequency of neutropenic fever in cancer patients (except chronic myeloid leukemia and myelodysplastic syndrome) during chemotherapy. Second-generation pegylated formulations (pegfilgrastim) have the advantage of requiring less frequent administration and also showed less frequent FN and FN-related complications as compared to filgrastim in real-world studies [39]. Pelgraz® is such a pegylated biosimilar formulation, to be applied only once after each chemotherapy cycle, ideally within 24 to 72 h from its completion and prior to the chemotherapy-induced nadir of the neutrophil level. As this may still result in cumbersome prolongation of the hospital stay or an additional doctor's visit in outpatients, Pelgraz® has also been made available as a ready-to-use injector for self-administration.

This study aimed to investigate whether Pelgraz® covers the medical need for the prevention of FN in all-day practice. Specific objectives were to evaluate whether the day of administration subsequent to chemotherapy has an impact on the incidence of FN and whether the self-injector, reducing the burden of an additional visit, provides comparable effectiveness and tolerability. Moreover, we aimed to evaluate which of the known individual risk factors of chemotherapy-induced FN may persist under pegfilgrastim treatment.

Patients and methods

This was a prospective, multicenter, open-label, observational study conducted in 74 outpatient clinics across Germany between February 2019 and October 2022. For a maximum of four consecutive visits, physicians recorded predefined pseudonymized data of patients routinely treated with pegfilgrastim.

Patients

Eligible patients had to have an age of ≥ 18 years and a malignant disease requiring cytotoxic chemotherapy, indicated for concomitant treatment with pegfilgrastim to prevent FN. Prior to inclusion, eligible patients consented to participation in the study and to the collection and analysis of pseudonymized data. Patients with hypersensitivity to any of the ingredients of pegfilgrastim, or suffering from leukemia due to severe congenital neutropenia, chronic myeloid leukemia, or myelodysplastic syndrome, or with a recent history of pneumonia or pulmonary infiltrates, were excluded; in addition, women were excluded if they were pregnant or lactating.

Treatment

The decision to treat any eligible patient with pegfilgrastim had to be taken independently from study participation. Pegfilgrastim was provided as Pelgraz® 6 mg/0.6 ml ready-to-use solution for subcutaneous injection by syringe or by pen for self-administration, after the latter had been approved and the protocol amended accordingly. Based on the drug label, Pelgraz® injections were to be given once per chemotherapy cycle, no earlier than 24 h from the end of cytotoxic treatment.

Data collection and analysis

Only data routinely collected in all-day practice had to be recorded, i.e., patient demographics, body weight, nutritional status, vital signs, disease-specific clinical data, comorbidities and medications, Eastern Cooperative Oncology Group (ECOG) and/or Karnofsky index, risk factors of FN and overall risk assignment, and specification of planned chemotherapy, along with treatment line and objective at baseline. During follow-up visits, additionally, the time of pegfilgrastim administration in relation to chemotherapy, any adverse events considered related to pegfilgrastim, routinely measured neutrophil counts and body temperature, the occurrence of FN, defined as neutrophil levels < 500/µl and body temperature measured orally of ≥ 38.3 °C once or ≥ 38.0 °C lasting for at least 1 h or being measured twice within 12 h [21], or any infections, and specifically treatment with anti-infectives or further supportive treatments were recorded. At the final visit, the reason for study discontinuation and the planned further treatment had to be specified, and the effectiveness, tolerability, and handling of pegfilgrastim had to be rated on 4-point Likert scales (as very good, good, moderate, or bad and very simple, simple, cumbersome, or very cumbersome, respectively) [29]. The statistical analysis was mostly descriptive, except for the calculation of odds ratios (OR) [7] for known risk factors under pegfilgrastim treatment using the MedCalc software.

Results

Study population

Overall, 1665 patients were recorded in 74 sites across Germany. Of these patients, four did not meet all eligibility criteria, seven were documented twice, and 18 had not received pegfilgrastim at all, leaving a total of 1636 patients exposed to the drug for the analysis of safety. For the evaluation of effectiveness, a further seven patients were excluded, six as they did not receive concomitant cytotoxic chemotherapy, and one patient who did not receive pegfilgrastim following the first chemotherapy. Accordingly, 1629 patients were included in the analysis of effectiveness, and for 1502 of these, complete datasets were available. Overall, 190 patients exclusively self-administered pegfilgrastim with the self-injector.

The majority of patients were female Caucasians, suffering from a solid tumor, most commonly breast cancer, that had not been treated yet (Table 1). Two-thirds of patients were at moderate risk (10–20%) of FN, and the remaining

Table 1 Patient and disease characteristics at baseline

		All patients ($N = 1636$)	Self-injector users ($N = 190$)
Age (years)		60.2 ± 12.8	59.8 ± 5.7
Sex	Female	1157 (70.7%)	130 (68.4%)
	Male	479 (29.3%)	60 (31.6%)
Ethnicity	Caucasian	1599 (97.7%)	190 (100%)
	Black	1 (0.1%)	0
	Asian	6 (0.4%)	0
	Not reported	30 (1.8%)	0
BMI (kg/cm^2)		26.5 ± 5.5	26.8 ± 3.1
Tumor type	Solid	1394 (85.2%)	178 (93.7%)
	• Breast	841 (65.4%)	113 (63.5%)
	• Lung	163 (12.7%)	19 (10.7%)
	• Prostate	73 (5.2%)	27 (15.2%)
	Hematological	242 (14.8%)	12 (6.3%)
	• Non-Hodgkin lymphoma	158 (65.3%)	9 (75%)
	• Hodgkin lymphoma	45 (18.6%)	2 (16.7%)
Time from diagnosis to baseline (days)		50 (28–122)	61 (32–130)
WHO stage	Missing	364 (22.2%)	35 (18.4%)
	I	125 (7.6%)	33 (17.4%)
	II	427 (26.1%)	42 (22.1%)
	III	583 (35.6%)	73 (38.4%)
	IV	137 (8.4%)	7 (3.7%)
ECOG	Missing	79 (4.8%)	1 (0.5%)
	0	771 (47.1%)	86 (45.3%)
	1	683 (41.7%)	97 (51.1%)
	2	95 (5.8%)	6 (3.2%)
	3	8 (0.5%)	0
Therapy	No prior chemotherapy	1306 (79.8%)	164 (86.3%)
	No prior radiotherapy	1488 (91.0%)	177 (93.2%)
Febrile neutropenia risk[1]	Low (< 10%)	0	0
	Moderate (10 to 20%)	1071 (65.5%)	150 (78.9%)
	High (> 20%)	565 (34.5%)	40 (21.1%)
	Baseline ANC (10^9/L)	5.0 ± 3.6 4.3 (3.0–6.2)	5.6 ± 3.7 4.7 (3.3–6.7)

Values are numbers (%), means ± standard deviation, and/or median (interquartile range), depending on data distribution

[1]As assessed by the investigator at baseline. The distribution of the individual risk factors is given in Supplement 1

third at high risk (> 20%). In 1459 and 170 out of the 1629 patients in whom effectiveness was evaluable, treatment with pegfilgrastim was initiated for primary and secondary prophylaxis, respectively. Self-injector use was more common in patients with solid and yet non-metastatic tumors and less common at higher ECOG and risk of FN (Table 1).

Incidence of FN and infections

In total, 40 out of the 1629 patients with any effectiveness data (2.5%) and 36 out of the 1502 patients with complete effectiveness data (2.4%) experienced chemotherapy-induced FN despite concomitant treatment with pegfilgrastim. Episodes in most patients were short, resolving on average within 2 (range 1–10) days, but in about 40% of the patients who developed FN, the next chemotherapy cycle had to be postponed or reduced in dose. In 21 (52.5%) patients, FN was serious as they were hospitalized, for a median duration of 6.5 (range 3–23) days.

With 1.6%, the incidence of FN was highest after the first pegfilgrastim cycle and decreased to a constant rate of 0.4% in subsequent cycles, which correlated well with the neutrophil levels per cycle measured in the entire study population (Fig. 1).

The incidence of FN as well as the hospitalization rate was slightly lower in patients treated for primary as compared to secondary prophylaxis, i.e., 35/1355 (2.6%) versus 5/157 patients (3.2%) and 18/35 (51.4%) versus 3/5 (60%) patients, respectively.

No significant difference, neither in the incidence nor in the hospitalization rate, was observed between groups given pegfilgrastim on day 1 or on a later day following chemotherapy in any cycle. Patients with hematological malignancies, in particular with Hodgkin lymphoma (17.9%), were way more often affected by FN than patients with solid tumors (6.2% versus 1.8% under primary prophylaxis patients), and the dose of the next chemotherapy cycle was also reduced more frequently (53.3% versus 28.0%). By contrast, the hospitalization rate due to FN did not depend on the type of cancer.

In addition, treatment of Hodgkin lymphoma with BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, prednisone, procarbazine) regimens caused the highest rate of FN despite pegfilgrastim prophylaxis (Table 2). Otherwise, no clustering among chemotherapy regimens could be identified (Table 2). Still noteworthy, no FN at all was observed under regimens of oxali-/carbo-/cisplatin + doce-/pacli/cabazitaxel and folinic acid + 5FU + oxaliplatin ± taxane. The incidence of FN was not higher in patients using the self-injector, i.e., 2.1% (4 out of 190 patients) versus 2.5% in the entire population.

In general, significant risk factors for the occurrence of FN could no longer be identified under pegfilgrastim treatment, although a previous episode of FN and male sex significantly increased the risk of subsequent hospitalization (Table 3).

Overall, 219 patients (13.4%) experienced infections lasting on average 7 (1–52) days. As compared to FN, the rate of infections decreased slowly but steadily during the course of chemotherapy, i.e., from 5.1% during cycle 1, to 4.6% during cycle 2, to 3.6% during cycle 3, and eventually to 2.5% during cycle 4. Use of anti-infectives, given to 303 patients (18.6%) in total, decreased in parallel (cycle 1, 10.1%; cycle 2, 9.5%; cycle 3, 8.6%; cycle 4, 7.1% of patients). As for FN, no significant risk factors for infections could be identified while under treatment with pegfilgrastim (Table 3).

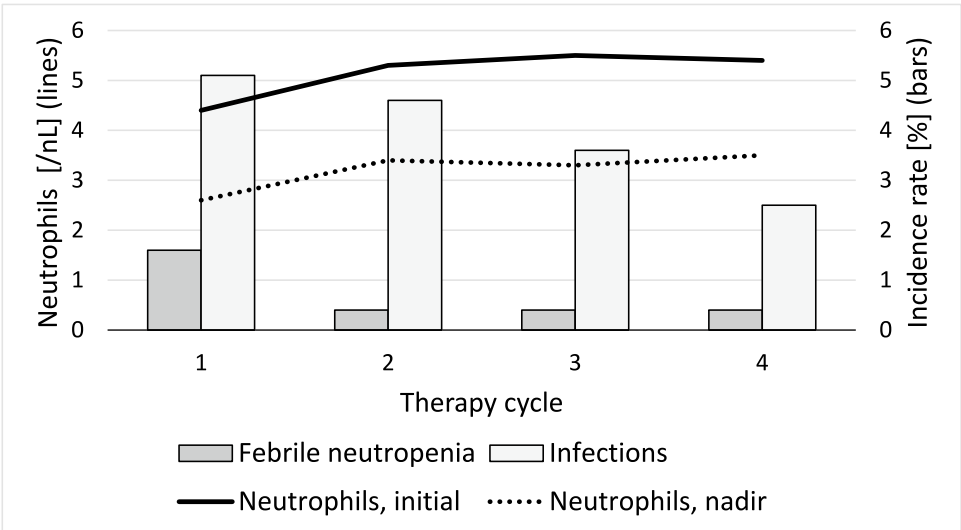

Fig. 1 Incidence rates of febrile neutropenia and infections per pegfilgrastim cycle along with median initial and nadir neutrophil levels

Table 2 Impact of chemotherapy regimen on the incidence of febrile neutropenia and corresponding hospitalization

	N	FN	+ Hospital
CPA + epi-/doxorubicin	586	12 (2.0%)	4 (0.7%)
CPA + epi-/doxorubicin + vinca alkaloids ± etoposide	144	6 (4.2%)	5 (3.4%)
CPA/epirubicin/platin/taxane monotherapy	95	3 (3.2%)	2 (2.1%)
Oxali-/carbo-/cisplatin + doce-/pacli-/cabazitaxel	153	0	0
Oxali-/carbo-/cisplatin + topo-/irinotecan/etoposide	99	3 (3.0%)	3 (3.0%)
Doce-/pacli-/cabazitaxel monotherapy	97	2 (2.1%)	0
Folinic acid + 5FU + irinotecan + oxaliplatin	53	1 (1.9%)	1 (1.9%)
Folinic acid + 5FU + oxaliplatin ± taxane	39	0	0
BEACOPP	22	4 (18.2%)	1 (4.5%)
Other[1]	171	4 (2.3%)	2 (1.2%)

BEACOPP, bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, prednisone, procarbazine; *CPA*, cyclophosphamide; *5FU*, 5-fluorouracil. Only patients treated for primary prophylaxis

[1]Rather heterogeneous group of less common regimens. The 4 patients developing FN received rituximab + polatuzumab + bendamustin; cisplatin + pemetrexed; bevacicumab + paclitaxel; and docetaxel + ramucirumab

Table 3 Risk factors of neutropenic outcome

	Febrile neutropenia	Hospitalization due to FN	Infection
Dose-dense chemotherapy	1.03 (0.54–1.96)	1.07 (0.46–2.53)	0.82 (0.61–1.11)
Age > 65 years	0.97 (0.51–1.86)	1.12 (0.48–2.64)	0.81 (0.60–1.09)
Advanced cancer	0.95 (0.50–1.80)	1.72 (0.74–4.01)	1.19 (0.89–1.59)
Previous FN episode	2.73 (0.63–11.9)	**5.25 (1.17–23.49)**	0.93 (0.32–2.67)
Female sex	0.75 (0.39–1.45)	**0.40 (0.17–0.93)**	1.00 (0.73–1.38)
Reduced general health	0.95 (0.29–3.14)	1.18 (0.27–5.11)	1.56 (0.98–2.50)
Poor nutritional status	1.09 (0.26–4.62)	2.10 (0.48–9.16)	1.25 (0.66–2.35)
Impaired immune function	1.76 (0.73–4.25)	2.21 (0.74–6.6)	0.81 (0.48–1.36)

Presented are odds ratios along with 95% confidence intervals. Significant risk factors in bold. The distribution of the individual risk factors in the study population is given in Supplement 1

Side effects of pegfilgrastim

Overall, 1000 patients (61%) reported a total of 3261 adverse events (AEs), of which 308 in 204 patients (12.5%) were serious. In total, 496 AEs experienced by 202 patients (12.3%) were considered drug-related, i.e., side effects, none of them being serious. The most common were musculoskeletal and connective tissue disorders, followed by gastrointestinal, general, and nervous system disorders. The most common side effects were pain in extremity, bone, and back, nausea, and myalgia (Table 4). AEs and drug side effects were slightly less common in patients treated for secondary prophylaxis as compared to primary prophylaxis (50.6% versus 62.3% and 7.6 versus 12.9%, respectively). There was no increase in the incidence of side effects with the self-injector.

Assessments of effectiveness, tolerability, and drug handling

Physicians rated the effectiveness of pegfilgrastim as good or very good in 94.6%, as moderate in 3.4%, and as bad in 0.6% of patients. Similarly, tolerability was rated as good or very good in 96.0%, as moderate in 2.3%, and as bad in 0.2% of patients.

Handling of the medication was rated by physicians as simple or very simple in 96.3% and as cumbersome in 0.2% of cases. Similarly, 91.7% of patients rated handling of the syringe as simple or very simple, and 0.9% as cumbersome or very cumbersome. Ratings among patients using the self-injector were slightly lower, i.e., 87.1% rated its handling as simple or very simple, and 6.0% as cumbersome or very cumbersome.

Discussion

The efficacy of pegfilgrastim for the prevention of chemotherapy-induced FN is well established as globally reflected in treatment guidelines [1, 17, 21, 24, 44, 46] and was initially demonstrated in well-controlled randomized phase III trials in breast cancer patients, in whom the incidence of FN, corresponding hospitalizations, and the use of anti-infective

Table 4 Most frequently experienced* side effects

Primary system organ class • Preferred term	All patients ($N = 1636$)	Self-injector users ($N = 190$)
Patients with drug-related adverse events (AE)	202 (12.3%)	7 (3.7%)
Musculoskeletal and connective tissue disorders	**156 (9.5%)**	**5 (2.6%)**
• Pain in extremity	76 (4.6%)	0
• Bone pain	59 (3.6%)	5 (2.6%)
• Back pain	16 (1.0%)	0
• Myalgia	10 (0.6%)	0
• Arthralgia	8 (0.5%)	0
Gastrointestinal disorders	**20 (1.2%)**	**1 (0.5%)**
• Nausea	11 (0.7%)	0
• Abdominal pain	5 (0.3%)	0
• Diarrhea	4 (0.2%)	1 (0.5%)
General disorders and admin. site conditions	**18 (1.1%)**	**0**
• Chest discomfort	6 (0.4%)	0
• Fatigue	5 (0.3%)	0
• Pain	4 (0.2%)	0
Nervous system disorders	**15 (0.9%)**	**1 (0.5%)**
• Headache	8 (0.5%)	1 (0.5%)
• Dizziness	4 (0.2%)	
Blood and lymphatic system disorders	**10 (0.6%)**	**1 (0.5%)**
• Leukocytosis	6 (0.4%)	1 (0.5%)
Respiratory, thoracic and mediastinal disorders	**7 (0.4%)**	**1 (0.5%)**
• Dyspnea	3 (0.2%)	1 (0.5%)
Skin and subcutaneous tissue disorders	**5 (0.3%)**	**0**
• Erythema	3 (0.2%)	0
Vascular disorders	**5 (0.3%)**	**0**
• Hypotension	3 (0.2%)	0
Ear and labyrinth disorders	**4 (0.2%)**	**0**
• Vertigo	3 (0.2%)	0
Reproductive system and breast disorders	**4 (0.2%)**	**0**
• Breast pain	3 (0.2%)	0
Cardiac disorders	**3 (0.2%)**	**0**

*By at least 3 patients (> 0.1%) of the total population

treatments could be reduced multiple times as compared to placebo to about 1% of patients only [25, 48]. After approval of pegfilgrastim, an integrated analysis of individual data from > 2000 breast cancer patients enrolled in 11 clinical trials and observational studies still revealed superiority of pegfilgrastim primary prophylaxis as compared to the practice of neutropenia management at the time regarding FN incidence, related hospitalization, and chemotherapy dose reductions [49]. The external validity of results from controlled clinical trials is limited due to high standardization and potentially biased patient selection and should therefore be assured by observational studies. These are more likely to reflect real-life conditions, but are uncontrolled and therefore limited in the use of inferential statistics; in addition, they need to be of large scale to be representative. Over the last 20 years, a wealth of real-life data on prophylactic FN treatment has accumulated; however, many originate from rather small retrospective studies, in addition to often varying definitions of FN [12].

The observational study reported here was among the largest prospective studies in Europe, comparable to the pan-European MONITOR-GCSF [10] and the French ZOHé study [16, 42], likely being representative of all-day practice in Germany. The revealed incidence of FN under pegfilgrastim is among the lowest reported under real-life conditions in retrospective studies [12], also in Germany [30], and much lower than reported so far in most smaller prospective studies dedicated to certain cancer types, i.e., late-stage NSCLC [3], early-stage breast cancer [8, 13], head and neck cancer [14], urological malignancies [38], lymphoma [41] or non-Hodgkin lymphoma (NHL) [43]. While our incidence was also lower compared to (a) the

prospective MONITOR-GCSF study (5.9% of 1447 patients overall [18] and 9.1 and 5.0% for hematological and solid tumors, respectively [31]) and (b) a prospective biosimilar postmarketing surveillance study (6.88% of 654 patients) [22], our results are in good accordance with (c) the ZOHé study (4.9% in 633 patients with hematological [16] and 3.5% in 1179 patients with solid tumors [42]); (d) two studies with predominantly breast cancer patients in the USA (< 2% of 2730 patients) [27] and in Europe (1.7% of 654 patients) [43], respectively; and (e) a large, retrospective cohort study in over 2000 patients with various cancers comparing pegfilgrastim biosimilars to the originator product [50]. Our incidences were higher than in several German observational studies in lung cancer patients (below 2%) [19, 20, 26].

Our study revealed no significant risk factors of FN to persist while under pegfilgrastim treatment (although male sex and a previous FN episode still rendered patients at higher risk of hospitalization) and confirmed a significant decrease in the incidence of FN after the first chemotherapy cycle [16, 28, 34]. Both results do not support the requirement for any risk re-evaluation prior to each chemotherapy cycle, as recommended by EORTC guidelines [1, 2, 10]. That 127 patients (7.8%) in our study dropped out after the first treatment cycle may indicate that G-CSF treatment was not continued beyond the first cycle, although this has been mandated by controlled clinical trials [5] and meta-analyses [49]. A study on daily use of G-CSF in the USA revealed a similar discontinuation rate after the first cycle which was shown to result in a significantly increased FN risk during subsequent cycles [52]. Even if the risk of FN might be highest during the first chemotherapy cycle, clinically continuous G-CSF treatment remains mandated, beyond considerations of cost-effectiveness [4, 5].

Due to the generally low incidence of FN and the reassuringly great majority of pegfilgrastim administrations within 1–3 days from completion of chemotherapy, our data is inconclusive regarding the impact of any time lag beyond on the effectiveness of pegfilgrastim. No difference between day 1 and day 2 administration has previously been reported, also in all-day practice [23, 32, 36]. In a large, retrospective analysis in the USA, 8% of over 50,000 patients received G-CSF on day 0 and 1% later than day 4 from completion of the first chemotherapy cycle; the risk of FN in these patients indeed increased by 40% and 90%, respectively [51]

The hospitalization rate due to FN is known to vary among chemotherapy regimens, with major differences reported in real life as compared to clinical trials though [11]. Again, our rates were generally low, to which here also underreporting may add, as the reason for hospitalizations might not always be followed up in outpatient clinics. However, our data confirm the real-life studies that consistently reported low risk associated with the combination of carboplatin and paclitaxel and the highest risk to be associated with multidrug regimens containing cyclophosphamide, doxorubicin, vincristine, and etoposide [11, 16]. In particular, under BEACOPP, the FN incidence remained rather high, despite prophylactic pegfilgrastim treatment.

Our study has also been among the first reporting real-life experience with a G-CSF self-injector, supposed to reduce the treatment burden associated with an additional doctor's visit following chemotherapy. It appeared to be user-friendly and manageable and comparable to the syringe in effectiveness and tolerability, though routinely used in patients with apparently rather low disease burden. These results are in line with previous reports of comparable effectiveness of self-injectors [35, 37], although in these studies, they were more commonly used in patients of older age, higher baseline ANC, and white race [35]. In a retrospective real-world data analysis of over 1000 matched patients with either breast cancer or NHL, there was either no significant difference in economic outcomes as compared to the prefilled syringe [37].

Finally, our study confirmed the safety profile of pegfilgrastim, with bone pain as the most common side effect in all-day practice [6]. AE incidence was again lower than reported in several prospective real-life studies [18, 22], although not lower than those reported in lymphoma [41] and Japanese patients [45].

In conclusion, our study showed treatment with the pegfilgrastim biosimilar Pelgraz® in all-day practice to meet expectations regarding effectiveness and safety. The reason for the dropout rate of 7.8% of patients after only one chemotherapy cycle despite the general recommendation for continuous treatment throughout chemotherapy is within published data, but the reasons still warrant further investigation.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00520-026-10354-1.

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Data availability The anonymized data collected are on file at Accord Healthcare, Munich, Germany.

Declarations

Ethics approval This observational study complied with the principles set out in the current version of the Declaration of Helsinki and was approved by the ethical committee of the Ärztekammer Nordrhein (ID 2018375). It was registered in the German Clinical Trial Register (ID DRKS00017218).

Competing interests T Steinmetz received research funding from Accord Healthcare, Amgen, Celgene/BMS, is a member of the board of directors, speaker's bureau or advisory committee of Accord Healthcare, Amgen, BMS/Celgene, Hexal/Sandoz, Janssen-Cilag, Novartis and Pfizer. P Jungberg, D Guth, J Knoblich, T Fietz, T Göhler, M Reiser; U Totzke received honoraria by Accord Healthcare GmbH; K Bernhardt was former employee of Accord Healthcare GmbH. All remaining authors declare they have no financial interests.

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