PATIENT, NURSE AND PHYSICIAN PREFERENCES:

FINAL RESULTS OF THE CONVENIENCE STUDY EVALUATING PEG-FILGRASTIM PROPHYLAXIS VIA PRE-FILLED SYRINGE OR ON-BODY INJECTOR (OBI) IN CANCER PATIENTS

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INTRODUCTION

The effectiveness of granulocyte colony-stimulating factors (G-CSFs) like pegfilgrastim depends on the optimal timing of administration,[1,2] recommended ≥24 h after chemotherapy (CTx) according to SmPC and guidelines.[3–5] Return visits to the medical office for pegfilgrastim administration, however, may be burdensome and cause additional expenditure of time and costs for both, patients and medical staff. Logistic issues may result in suboptimal timing of pegfilgrastim administration, thus causing an increased risk for patients to develop severe or febrile neutropenia.[6]

The pegfilgrastim On-body injector (OBI) is a small injector automatically delivering a subcutaneous pegfilgrastim dose after 27 h without need of return visit to the medical office. Thus, this alternative application form has the potential to optimize pegfilgrastim prophylaxis by improving administration time point as well as saving time and costs for patients and medical offices.[7,8] The CONVENIENCE study aims to evaluate patient, nurse and physician preference for pegfilgrastim administration via OBI compared to injection via pre-filled syringe (PS).

METHODS

Study design and participants

In this randomized, multicenter, cross-over study 404 patients with early breast cancer (EBC) receiving 2 or 3 weekly anthracycline/cyclophosphamide or 3 weekly taxane-based CTx or patients with Non-Hodgkin lymphoma (NHL) receiving 1st-line R-CHOP-14 or -21 were enrolled at 41 sites in Germany from 06/2018 -06/2019. Patients were observed for 4 CTx cycles supported with pegfilgrastim via OBI or PS in an alternating sequence with 1:1 randomization of the application form to start with (Arm A and B, see **Figure 1**). Preferences of patients, nurses and physicians as well as resource utilization at the site for either application form were evaluated using questionnaires.

Final analysis

In the final analysis the primary endpoint, all secondary and tertiary endpoints were analyzed. The primary endpoint was patient preference at the end of study. McNemar's test was used to test the primary hypothesis that the OBI is more often favored by the patients than the PS. Descriptive statistics were used to analyze the other endpoints. The poster shows patients' preference at the end of the study with reasons for decision and actual timepoint of pegfilgrastim administration (per-protocol analysis). Furthermore, physicians' and nurses' preference after study as well as resource utilization at the sites for either application form are shown (study center set analysis).

Figure 1

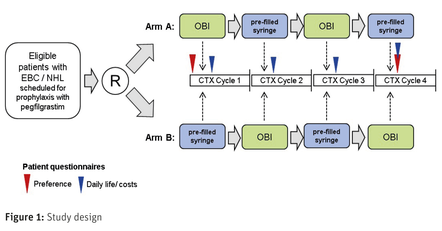

Figure 1: Study design

RESULTS

In the per-protocol population the median age was 56 years (range 28-85 years) and 93.8% of patients were female. 91.2% of patients suffered from EBC and 8.8% from NHL. All patients had an ECOG performance status of 0 or 1. Patient characteristics were well balanced between the study arms (**Table 1**).

Since there were no marked differences in the overall results between the study arms starting with OBI or PS, they will be presented for both arms together.

After end of study 43.2% of patients preferred the OBI and 36.0% of patients preferred the PS (**Figure 2**). Thus, slightly more patients preferred the OBI but this difference was not statistically significant (p=0.159). Of the patients with "no preference" after end of study (20.8%), 57.8% would recommend the OBI to other patients and only 31.3% would recommend the PS.

58.1% of patients injected pegfilgrastim always in a private environment and had no time expenditure for an additional physician visit. Only 22.1% and 4.9% of patients received all PS administrations at the oncological practice or general practitioner. 11.0% of patients received the PS administrations at varying locations. Only patients who received the PS at a general practitioner rather preferred the PS. In all other subgroups slightly more patients preferred the OBI (**Figure 2**).

After end of study more patients with OBI than PS preference stated that saving time due to the OBI (53.4% vs. 9.9%) and the time expenditure for visiting the medical office for PS administration (46.6% vs. 18.9%) are reasons for their decision that apply completely. In contrast, more patients with PS than OBI preference stated that feeling uncomfortable with the OBI (25.2% vs. 3.0%) and feeling safer when the PS is administered by health care professionals (32.4% vs. 9.0%) are reasons for their decision that apply completely (**Figure 3**). Feeling uncomfortable in the room for OBI administration is not a reason for their decision (does not apply at all: OBI 85.0%, PS 79.3%).

After end of study 58.5% of physicians preferred the PS, whereas only 36.6% of physicians preferred the OBI. The PS was also slightly preferred by the nurses (46.3% vs 43.9%) (**Figure 4**).

78.0% of physicians and 58.5% of nurses stated that the OBI offers more independence for the patients. 51.2% of physicians and 53.7% of nurses answered that the PS allows a better control over administration and possible side effects. Slightly more physicians and more nurses stated that the PS yields labor savings at the medical practice in comparison to the OBI (physicians: 39.0% vs 36.6%, nurses: 48.8% vs 14.6%). None of the application forms was associated with cost savings (no difference: 78.0% and 85.4%) (**Figure 5**).

Nurses were involved in preparation, application and explanation of the OBI for 5-10 min in 48.8% of sites, whereas they needed <5 min for PS administration in 51.2% of sites. Physicians were mostly not involved (OBI: 46.3%, PS: 70.7%) or involved for <5 min (OBI: 29.3%, PS: 9.8%) for any application form. Other staff was mostly not needed for any application form (OBI: 61.0%, PS 75.6%). A consulting room was needed for OBI application for 5-10 min in 26.8% and for <5 min in 14.6% of sites, whereas it was needed for PS administration for 5-10 min in 22.0% and for <5 min in 43.9% of sites. A waiting room or other rooms were mostly not required for any of the application form (waiting room: OBI: 56.1%, PS: 80.5%, other: OBI: 48.8%, PS 65.9%) (**Figure 6**).

With PS, pegfilgrastim was injected between 24 and <72 h after CTx only in 63.1% of administrations. Furthermore, pegfilgrastim was injected <24 h after CTx in 22.1% of administrations via PS and hence not in the time frame recommended by guidelines. In contrast, with the OBI pegfilgrastim was injected between 24 and <72 h after CTx in 97.6% of administrations and hence according to guidelines (**Figure 7**).

CONCLUSION

After study the OBI was slightly preferred by patients. For patients preferring the OBI saving of time was a major reason for their preference. Only patients who received the PS at a general practitioner rather preferred the PS. The PS was physicians' most preferable choice and slightly preferred by nurses. Physicians and nurses stated that the OBI offers more independence for the patients, whereas the PS offers better control over administration and possible side effects. However, the present data show that in routine the PS is often not administered in the recommended time period, whereas at least in this study OBI was almost always applied as specified.

Table 1

	Total (n=308)	Arm A (n=154)	Arm B (n=154)
Age (years)			
Median (min – max)	56 (28-85)	55 (29-85)	57 (28-83)
Gender			
Female	289 (93.8%)	146 (94.8%)	143 (92.9%)
Male	19 (6.2%)	8 (5.2%)	11 (7.1%)
ECOG			
0	245 (79.5%)	127 (82.5%)	118 (76.6%)
1	63 (20.5%)	27 (17.5%)	36 (23.4%)
Tumor entity			
Early breast cancer	281 (91.2%)	141 (91.6%)	140 (90.9%)
Non-Hodgkin lymphoma	27 (8.8%)	13 (8.4%)	14 (9.1%)
Early breast cancer	**n=281**	**n=141**	**n=140**
AJCC Staging			
IA	79 (28.1%)	32 (22.7%)	47 (33.6%)
IIA/IIB	131 (46.6%)	72 (51.1%)	59 (42.1%)
IIIA/IIIB/IIIC	51 (18.1%)	26 (18.4%)	25 (17.9%)
IV	1 (0.4%)	0 (0.0%)	1 (0.7%)
Unknown	19 (6.8%)	11 (7.8%)	8 (5.7%)
Regimen			
Anthracycline-based	16 (5.7%)	9 (6.4%)	7 (5.0%)
Anthracycline/Cyclo-phosphamide-based	228 (81.1%)	115 (81.6%)	113 (80.7%)
Anthracycline/Cyclo-phosphamide/Taxane-based	6 (2.1%)	4 (2.8%)	2 (1.4%)
Taxane-based	31 (11.0%)	13 (9.2%)	18 (12.9%)
Non-Hodgkin lymphoma	**n=27**	**n=13**	**n=14**
Ann-Arbor			
Stage I	4 (14.8%)	2 (15.4%)	2 (14.3%)
Stage II	7 (25.9%)	3 (23.1%)	4 (28.6%)
Stage III	7 (25.9%)	2 (15.4%)	5 (35.7%)
Stage IV	8 (29.6%)	6 (46.2%)	2 (14.3%)
Unknown	1 (3.7%)	0 (0.0%)	1 (7.1%)
Type of lymphoma			
B-cell lymphoma	26 (96.3%)	12 (92.3%)	14 (100.0%)
Other	1 (3.7%)	1 (7.7%)	0 (0.0%)
Regimen			
R-CHOP 14	9 (33.3%)	5 (38.5%)	4 (28.6%)
R-CHOP 21	17 (63.0%)	7 (53.8%)	10 (71.4%)
Other	1 (3.7%)	1 (7.7%)	0 (0.0%)

Table 1: Patient characteristics

Figure 2

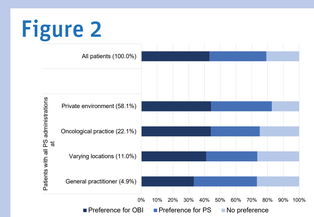

Figure 2: Preference after study of all patients and by location of PS administration.
All patients: n=308. Patients with all PS administrations at private environment n=179, at an oncological practice n=68, at varying locations n=34 or at a general practitioner n=15; Missing: n=12.

Figure 3

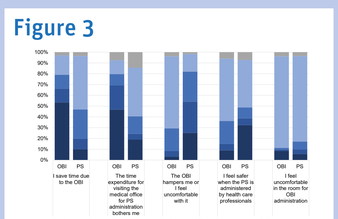

Figure 3: Reasons for patients' preference in patients preferring OBI (n=133) or PS (n=111)

Figure 4

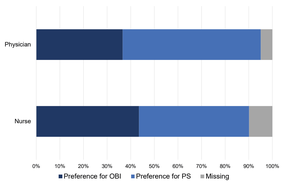

Figure 4: Preference of physician (n=41) and nurse (n=41) after study

Figure 5

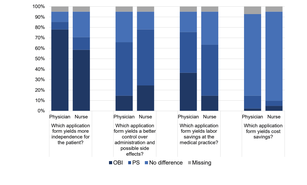

Figure 5: Answers from physician (n=41) and nurse (n=41) about the two application forms.

Figure 6

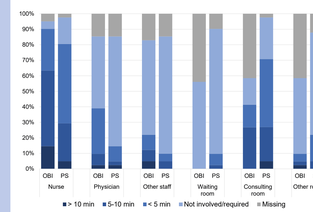

Figure 6: Resource utilization for OBI or PS application at the sites (n=41)

Figure 7

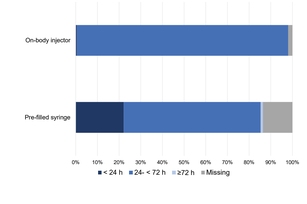

Figure 7: Time interval between chemotherapy and pegfilgrastim administration via OBI (n=616) and PS (n=616)

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Conflicts of Interests:
Metz M.: Officer/Board of Directors: NIO Niedersachsen; Advisory/Consultancy: Novartis, Roche, BMS, Celgene; Shareholder/Stockholder/Stock options: Novartis; Honoraria: Octapharm, Abbvie, Boehringer Ingelheim, Celgene, Amgen, BMS, Hexal

Hielscher C.: Honoraria:Amgen, Pfizer, Celgene, Roche; Travel/Accomodation/Expenses: Celgene, Oncovis

Zahn M.-O.: Leadership Role and Board of Directors: NIO Niedersachsen

D. Semsek, Rogmans, U. Hutzschenreuter, T. Fietz, J. Harde, S. Zacharias, S. A. Lorenz, D. Guth, Grebhardt, C. Fichter, K. Potthoff : No conflicts of interest

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