A Time-Motion Observational Study of Clinic Staff: Administration of Pegfilgrastim Primary Prophylaxis via Next-Day Manual Injection and On-body Injector

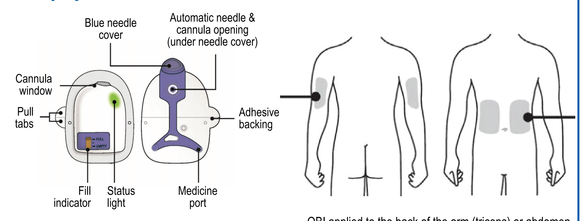
Mark D. Hatfield,[1] Susan Reitan,[2] Lea Moser,[3] David Chandler,[1] Maureen Reiner,[1] John Reitan,[2] Mark Bensink[1]

[1]Amgen Inc., Thousand Oaks, CA; [2]RJM Group, LLC., Crown Point, IN; [3]South Carolina Oncology Associates, Columbia, SC

INTRODUCTION

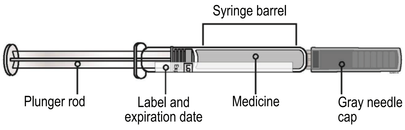
- Febrile neutropenia (FN) is a common and potentially life-threatening side effect of myelosuppressive chemotherapy[1]
- Pegfilgrastim prophylaxis reduces the incidence of FN and should be administered at least 24 hours after myelosuppressive chemotherapy[2]
- Pegfilgrastim can be administered using
  1. On-body injector: applied to the patient's skin (abdomen or back of arm) at the end of chemotherapy, and pegfilgrastim is automatically administered approximately 27 hours later
  2. Prefilled syringe: patient returns to the clinic the day after chemotherapy for a manually administered subcutaneous injection
- Use of the on-body injector versus a prefilled syringe is potentially more convenient for patients;[3-5] however, little is known about the time required for clinic staff to administer pegfilgrastim using the on-body injector versus the prefilled syringe
- We conducted a time-motion study to explore the practical implementation of each device in the clinic setting

On-body Injector[2]



OBI applied to the back of the arm (triceps) or abdomen

Prefilled Syringe[2]



Abbreviations: OBI, on-body injector.

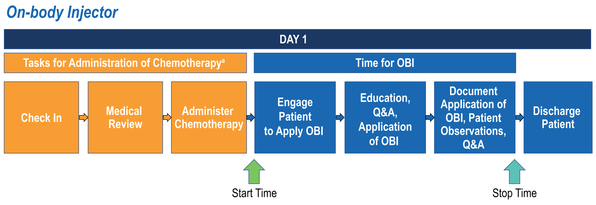
METHODS

Study Design

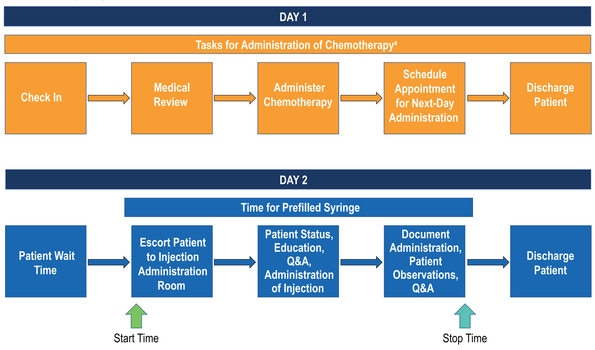
- Prospective time-motion observational study of staff administering pegfilgrastim primary prophylaxis to patients receiving myelosuppressive chemotherapy
- Data on time required for pegfilgrastim administration-related activities were collected from community-based oncology centers located in the US that administer pegfilgrastim primary prophylaxis via on-body injector and prefilled syringe as part of routine clinical practice
- Data were collected between May and October 2017
- Pegfilgrastim administration-related activities were included for patients ≥ 18 years old receiving myelosuppressive chemotherapy
- Pegfilgrastim administration-related activities were excluded if patients had complications, such as uncontrolled vomiting, hypotension, fever, or dehydration
- Trained data collectors observed clinic processes and staff time associated with pegfilgrastim administration via on-body injector and prefilled syringe, and study monitors captured notes on the overall process
- Planned sample size was 10 centers; however, the study was stopped early due to accrual challenges, and only two centers participated in the study

Pegfilgrastim Administration-Related Activities With On-body Injector and Prefilled Syringe

On-body Injector



Prefilled Syringe



[a]Not recorded.

Abbreviations: OBI, on-body injector; Q&A, questions and answers.

Study Objectives

- Primary: estimate mean total clinic staff time for administering pegfilgrastim primary prophylaxis via on-body injector and next-day manual injection with prefilled syringe
- Secondary: examine mean total clinic staff time associated with first-time versus subsequent application of the on-body injector

Statistical Analysis

- The mean (95% confidence interval [CI]) total clinic staff time required to administer pegfilgrastim primary prophylaxis via on-body injector and next-day manual injection was estimated
- Descriptive analyses of continuous study outcomes are reported by
  1. On-body injector application and next-day manual injection
  2. First-time and subsequent on-body injector application

RESULTS

- Two sites participated in the study, and a total of 28 nurses were observed
- Total observations:
  - Prefilled syringe: 53 patients (19 first-time patients)
  - On-body injector: 75 patients (16 first-time patients)

Patient Demographics

	First-Time Application/Administration		Subsequent Application/Administration		Overall	
	OBI n = 16	PFS n = 19	OBI n = 59	PFS n = 34	OBI n = 75	PFS n = 53
Age, median (range), years	58 (35–77)	63 (49–86)	61 (28–81)	64 (31–81)	61 (28–81)	63 (31–86)
Sex, n (%)						
Female	13 (81)	11 (58)	41 (69)	25 (74)	54 (72)	36 (68)
Male	3 (19)	8 (42)	18 (31)	9 (26)	21 (28)	17 (32)
ECOG PS, n (%)						
0	14 (88)	9 (47)	38 (64)	20 (59)	52 (69)	29 (55)
1	2 (13)	7 (37)	18 (31)	11 (32)	20 (27)	18 (34)
2	0 (0)	2 (11)	3 (5)	3 (9)	3 (4)	5 (9)
3	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	1 (2)

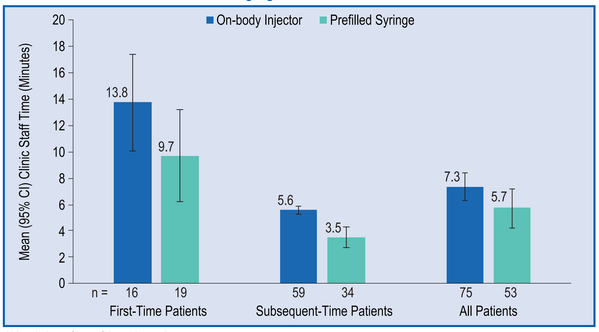
Abbreviations: ECOG PS, Eastern Cooperative Oncology Group performance status; OBI, on-body injector; PFS, prefilled syringe.

Baseline Characteristics of Clinic Staff

	All Staff N = 28
Registered Nurse, n (%)	25 (89)
Licensed Practical Nurse, n (%)	3 (11)
Years of nursing experience, median (range)	19 (4–48)
Years of nursing experience at current site, median (range)	7 (0–31)
Number of on-body injector applications prior to study, median (range)[a]	100 (0–100)

[a]Recorded to a maximum of 100 applications.

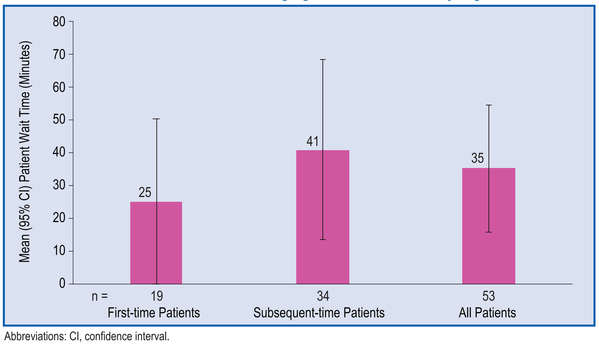
Clinic Staff Time Associated With Pegfilgrastim Administration



Abbreviations: CI, confidence interval.

- Overall mean clinic staff time was 7.3 (95% CI: 6.3–8.4) minutes for on-body injector application and 5.7 (95% CI: 4.2–7.2) minutes for prefilled syringe administration
- Mean clinic staff time for on-body injector application was reduced from 13.8 (95% CI: 10.1–17.4) minutes for first-time application to 5.6 (95% CI: 5.3–5.9) minutes for subsequent applications

Patient Wait Time for Administration of Pegfilgrastim via Prefilled Syringe



Abbreviations: CI, confidence interval.

- After arriving at the clinic, the overall mean patient wait time for next-day prefilled syringe administration was 35.3 (95% CI: 15.9–54.7) minutes

LIMITATIONS

- Only two clinics participated in this study, limiting the generalizability of the conclusions
- The centers had largely converted to the on-body injector, and our descriptive analysis was unadjusted for potential differences in patient characteristics
- Clinic administrative time required to schedule the next-day administration of pegfilgrastim could not be captured

CONCLUSIONS

- From a patient's perspective, on-body injector application occurs at the end of chemotherapy and does not require a next-day visit to the clinic
  - Next-day administration of pegfilgrastim can result in substantial clinic wait time, which is not required for patients who receive pegfilgrastim via the on-body injector
- Most nurses had experience with applying the on-body injector before the study
- There was no difference between time spent applying the on-body injector and use of the prefilled syringe; however, the implied overall burden for patients who received the on-body injector is lower after accounting for patient wait time for next-day injection
- Less time was required for application of the on-body injector to subsequent- versus first-time patients, likely because education about the device was completed at the first on-body injector application
- Taken together with results from a previous study that demonstrated a significant travel burden for next-day clinic visits for granulocyte colony-stimulating factor therapy,[4] use of the on-body injector for pegfilgrastim prophylaxis may reduce the overall time burden for patients, their families, and health care providers

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DISCLOSURES

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SR: No potential conflicts of interest to report.
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