Conversion from Filgrastim to Tbo-filgrastim: Experience of a Large Health Care System

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ABSTRACT

BACKGROUND: In 2008, tbo-filgrastim was approved as a biosimilar in Europe and then approved in the United States by the FDA in 2012 as a biologic product with 1 similar indication to filgrastim. Because tbo-filgrastim was less expensive than filgrastim, and clinical information and expert opinion supported similarity, the Pharmacy & Therapeutics Committee of a large health care system approved tbo-filgrastim as the preferred granulocyte-colony stimulating factor (G-CSF) product in March 2014.

OBJECTIVES: To (a) assess the use of filgrastim and tbo-filgrastim products by comparing baseline characteristics, setting of care, indication for use, and payer type and (b) understand potential barriers of conversion to tbo-filgrastim.

METHODS: A retrospective evaluation of filgrastim and tbo-filgrastim use was conducted on all patients (N=204) who received the drugs between July 2015 and December 2015 at the 2 largest hospitals in the health system. Baseline characteristics, indication requiring use of filgrastim or tbo-filgrastim, setting of care, and payer information were collected from electronic medical records, and descriptive analyses were conducted.

RESULTS: Overall, G-CSFs were administered to 204 patients for 261 episodes of care (filgrastim and tbo-filgrastim were used in 65 and 196 episodes of care, respectively). Baseline characteristics were similar between the 59 patients who received filgrastim and the 174 patients who received tbo-filgrastim. G-CSF was primarily used in the inpatient setting (163 episodes of care, 63%) with 90% of patients using tbo-filgrastim. In the outpatient setting (98 episodes of care, 38%), filgrastim and tbo-filgrastim were each used by 50% of patients. Tbo-filgrastim was the preferred G-CSF by clinical providers for all indications, except for stem cell mobilization, where filgrastim use was higher (55% vs. 45% of 71 episodes of care). In the outpatient setting, analysis by payers showed that the majority of patients on commercial plans were using filgrastim (58%), while half of Medicare patients were using filgrastim (50%, n=12). Twelve patients were self-paid, and all were using tbo-filgrastim. Subgroup analysis by hospital showed differences in utilization patterns.

CONCLUSIONS: Although tbo-filgrastim was the preferred G-CSF in our formulary, 29% of patients continued to receive filgrastim. Conversion to tbo-filgrastim has been largely successful, but extra steps may be needed to achieve full conversion to biosimilars.

J Manag Care Spec Pharm. 2017;23(12):1214-18

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What is already known about this subject

- Studies have shown that conversion to a biosimilar product can result in significant cost savings.
- Tbo-filgrastim, a short-acting granulocyte-colony stimulating factor product approved as a biologic in the United States, has been shown to have a comparable efficacy and safety profile to filgrastim for the prevention of febrile neutropenia in patients with nonmyeloid malignancies treated with myelosuppressive chemotherapy.

What this study adds

- This study described the experience of a health care system in converting from filgrastim to tbo-filgrastim.
- Differences were assessed in the uptake of the 2 agents based on demographics of patients, indication requiring use, setting of care, and payer type.

In the last 3 decades, there has been a tremendous growth and expansion in the use of biologic agents, mainly because of how they have revolutionized the treatment of many life-threatening and chronic conditions. For example, granulocyte-colony stimulating factors (G-CSFs), which have now been available for over 20 years, are widely used to increase the production of neutrophils in a variety of settings, including primary prophylaxis in patients receiving chemotherapy and in the treatment of neutropenic fever, as well as to mobilize peripheral blood progenitor cells in patients undergoing autologous hematopoietic stem cell transplantation.¹⁻³ Filgrastim was the first recombinant human G-CSF approved by the U.S. Food and Drug Administration (FDA) in 1991.⁴ In recent years, follow-on agents with similar indications to filgrastim have also been approved by regulatory authorities.³ One such agent is tbo-filgrastim, a product approved in Europe as a biosimilar but approved as a biologic in the United States.⁵ In 2008, the European Union (EU) approved tbo-filgrastim as a biosimilar to filgrastim based on the results of 3 phase III trials comparing the efficacy and safety of tbo-filgrastim with filgrastim for treating neutropenia in patients with various types of malignancies undergoing chemotherapy.⁶⁻⁹ Based on the regulatory pathway for the approval of biosimilars, the approval of tbo-filgrastim in the EU was extrapolated to all indications for which the reference product filgrastim is approved.^{6,10} The FDA biosimilar

TABLE 1 Baseline Characteristics of Patients on Filgrastim and Tbo-filgrastim (N=204)

Baseline Characteristics	Hospital A & B (N=203)			Hospital A (n=103)			Hospital B (n=100)		
	Filgrastim	Tbo-filgrastim	P Value ^a	Filgrastim	Tbo-filgrastim	P Value ^a	Filgrastim	Tbo-filgrastim	P Value ^a
Number of patients ^b	59	174	–	10	97	–	49	77	–
Age (years), mean (SD)	54.7 (17)	57.8 (13)	0.146	46.6 (30)	56.7 (14)	0.060	56.3 (12)	59 (12)	0.221
Female, n (%)	26 (44)	81 (47)	0.741	3 (30)	39 (40)	0.529	23 (47)	34 (44)	0.760
Race, n (%) ^c									
Black	3 (5)	12 (7)	0.801	1 (10)	10 (10)	0.623	2 (4)	2 (3)	0.771
White	48 (81)	142 (82)		6 (60)	76 (78)		42 (86)	66 (86)	
Others	4 (7)	16 (9)		2 (20)	11 (12)		2 (4)	5 (7)	

^aP value is based on a chi-square test for the categorical variables and a 2-sample t-test for the continuous variables.

^bThe sum of patients taking tbo-filgrastim and filgrastim is greater than the total number of patients (N=204) in the study because some patients took different G-CSF within the time frame of analysis.

^cAbout 3% of patients did not provide their race.

*Number of episodes of care with CSF within the time frame of analysis: Average episodes of care was 1.3 per patient.

G-CSF=granulocyte-colony stimulating factor; SD=standard deviation.

approval pathway did not exist at the time of the tbo-filgrastim application in the United States; consequently, tbo-filgrastim was approved in 2012 as a biologic product for only 1 indication for which filgrastim is approved, rather than as a biosimilar.^{4,6} More recently, filgrastim-sndz was approved in 2015 as the first U.S. biosimilar for all filgrastim indications.¹¹

These follow-on drugs are typically priced lower than the original filgrastim product and represent an opportunity for cost savings. In the United States, the wholesale acquisition cost (WAC) of tbo-filgrastim is approximately 20% less than filgrastim,¹² offering significant cost savings.^{13,14} In March 2014, based on clinical and expert opinion from hematologists, oncologists, oncology clinical pharmacists, and oncology nurses, the Pharmacy & Therapeutics (P&T) Committee of a large health care system in eastern Massachusetts with 14 hospitals approved tbo-filgrastim as the preferred formulary G-CSF for all indications of filgrastim, with anticipated drug cost savings of over half a million dollars. The purpose of this analysis is to describe the conversion of filgrastim to tbo-filgrastim and to understand any potential barriers to conversion.

Methods

Following the P&T Committee decision, tbo-filgrastim was added to the formulary and listed as the preferred G-CSF product. Each hospital in the health care system was responsible for implementing the conversion from filgrastim to tbo-filgrastim. This conversion included changing existing order sets and therapy plans and the purchase of the new product. In some cases, pharmacists would contact clinicians to convert to the filgrastim product. We conducted a retrospective evaluation of the use of filgrastim and tbo-filgrastim in 2 hospitals within the health care system. This study was approved by Partners Healthcare Office for Human Research Studies.

All patients who received filgrastim and/or tbo-filgrastim from July 2015 to December 2015 were included in the analysis. The time frame of the analysis was chosen based on the review of monthly purchase trends of both drugs from the date of the Partners P&T Committee decision, March 2014 to December 2015. There was an upward trending in the purchase quantity of tbo-filgrastim and a downward trending in the purchase quantity of filgrastim between March 2014 and June 2015, suggesting an ongoing replacement of filgrastim with tbo-filgrastim. Between June 2015 and December 2015, there was a stabilization in the purchase quantity of both drugs, suggesting a cessation of the switching process.

Patients were identified by querying the pharmacy database at the individual hospitals. Using a data collection tool designed by one of the study authors, information was collected from the electronic medical record for each patient on every episode of care within the analysis time frame. An episode of care was defined as the set of services provided by clinical providers to treat a clinical condition for which filgrastim or tbo-filgrastim was indicated (e.g., administration of a daily dose of filgrastim for 2 weeks or until the absolute neutrophil count has reached 10,000 per mm³ for a patient with febrile neutropenia would be considered an episode of care).

Key variables extracted for an episode of care included G-CSF type (tbo-filgrastim or filgrastim); indication requiring use of G-CSF; setting of care (inpatient or outpatient); and payer type (commercial, Medicare, Medicaid, or self-pay). Demographic information such as age, sex, and race was also collected for each patient. Descriptive statistics of patient characteristics (age, sex, and race); use of filgrastim and tbo-filgrastim in the inpatient and outpatient setting; indication for use of filgrastim and tbo-filgrastim; and payer type were summarized. Subgroup analysis by the 2 hospitals assessed was

TABLE 2 Use of Filgrastim and Tbo-filgrastim by Setting of Care and Indication

	Total Episodes of Care	Filgrastim Use n (%)	Tbo-filgrastim Use, n (%)
Setting of care			
Inpatient	163	16 (10)	147 (90)
Outpatient	98	49 (50)	49 (50)
Indication for use			
Febrile neutropenia	93	16 (17)	77 (83)
Stem cell mobilization	71	39 (55)	32 (45)
Posttransplant support	77	5 (7)	72 (94)
Severe chronic neutropenia	10	2 (20)	8 (80)
Other indications	8	1 (13)	7 (88)

performed. *P* values were reported for the patient characteristics, based on a chi-square test for the categorical variables (race and sex) and on a 2-sample *t*-test for the continuous variable (age). Data were analyzed using STATA 8 (StataCorp, College Station, TX) and Excel software (Microsoft, Redmond, WA).

Results

Of the 204 patients who received filgrastim and tbo-filgrastim between July 2015 and December 2015, 28 received both filgrastim and tbo-filgrastim for different episodes of care. In total, 59 patients (29%) used filgrastim, while 174 patients (85%) used tbo-filgrastim. About a third of patients had greater than 1 episode of care during the analysis time frame, leading to a total of 261 episodes of care (129 at hospital A vs. 132 at hospital B) for all patients in the inpatient and outpatient settings. Of the 261 episodes of care, filgrastim and tbo-filgrastim were used 65 (25%) and 196 (75%) times, respectively. Analysis by hospital showed that filgrastim and tbo-filgrastim were used 10% and 90%, respectively, out of the 129 episodes of care at hospital A, and they were used 39% and 61%, respectively, out of the 132 episodes of care at hospital B.

Baseline characteristics are presented in Table 1. Of the 204 patients, 40% were female, and the average age was 56.8 (± 14.6) years. The majority of patients were white (80%). Although patients who used filgrastim were younger on average than the tbo-filgrastim patient group (mean age: 54.7 years vs. 57.8 years), there was no statistically significant difference between the 2 groups, using a 2-sided *t*-test. All other patient characteristics between the 2 groups were also similar. Subgroup analysis by hospitals showed a similar pattern (Table 1).

Sixty-two percent ($n=163$) of the total episodes of care were conducted in the inpatient setting, while the remaining 38% ($n=98$) were conducted in the outpatient setting. Support care after transplantation (75 episodes of care, 46%) and treatment of febrile neutropenia (72 episodes of care, 44%) were the major indications for use of G-CSFs in the inpatient setting, while they were mainly used for stem cell mobilization

(67 episodes of care, 70%) and febrile neutropenia prophylaxis (20 episodes of care, 20%) in the outpatient setting. Ninety percent of the G-CSF used in the inpatient setting was tbo-filgrastim (147 episodes of care), while filgrastim and tbo-filgrastim were used equally in the outpatient setting (49 episodes of care).

Subgroup analysis showed differences in the 2 hospitals. At hospital A, tbo-filgrastim was the major G-CSF type used in the outpatient setting (47 episodes of care; 85%) and inpatient setting (69 episodes of care, 93%), while the major G-CSF used in the outpatient setting and inpatient setting of hospital B was filgrastim (41 episodes of care, 95%) and tbo-filgrastim (78 episodes of care, 88%), respectively.

Table 2 presents data on the indication for use of G-CSFs. Of the 261 episodes of care examined, the major indications for the use of G-CSF were febrile neutropenia (treatment and prophylaxis; 93 episodes of care, 36%), support care after transplantation (77 episodes of care, 30%), stem cell mobilization (71 episodes of care, 27%), and severe chronic neutropenia (10 episodes of care, 4%). Tbo-filgrastim was the preferred G-CSF by clinical providers for all indications: febrile neutropenia (83% of 93 episodes of care); support care after transplantation (93.5% of 77 episodes of care); severe chronic neutropenia (80% of 10 episodes of care); and other indications (87.5% of 8 episodes of care), except for stem cell mobilization (45% of 71 episodes of care). Filgrastim was the preferred choice for stem cell mobilization (55% of 71 episodes of care; Table 2).

Analysis by payers was conducted only in the outpatient setting (98 episodes of care in 88 patients). Results showed that the majority of patients were on commercial plans ($n=45$ patients, 51%) or Medicare ($n=24$ patients, 27%). Twelve patients (14%) were self-paid, while 1 patient was on Medicaid. The payment method of the remaining 6 patients was unknown. Of the 45 patients on commercial plans, 58% were using filgrastim, while 42% were using tbo-filgrastim. Filgrastim and tbo-filgrastim were each used with 50% of patients on Medicare ($n=24$). However, only tbo-filgrastim was used with self-pay patients ($n=12$).

Discussion

Despite its enormous value, like most biologics, filgrastim is expensive, with a single injection costing between \$305 and \$515 (WAC).¹⁵ Thus, the use of biosimilars, or in this case follow-on biologics, represents an important strategy for getting equally safe and effective treatment at a lower cost.¹¹ In this study, we describe a real-world experience of switching from filgrastim to tbo-filgrastim based on an anticipated annual drug cost savings of over half a million dollars in a U.S. health care system. Our estimated cost savings between the time of the P&T Committee decision in March 2014 to September 2015 was \$1.1 million, when adjusted for volume

increase (unadjusted cost savings were \$453K). Despite the cost advantages,^{13,14,16} findings from this study showed that 29% of patients on G-CSF continued to be on filgrastim 2 years after the P&T Committee decision. There were no differences between the demographic characteristics of patients on filgrastim and tbo-filgrastim. However, filgrastim was the preferred choice for patients undergoing stem cell mobilization. Also, we found that all self-paying patients were using tbo-filgrastim.

Tbo-filgrastim was approved by the FDA as a biologic for reducing the duration of febrile neutropenia in patients receiving myelosuppressive chemotherapy, based on studies that confirmed bioequivalence between tbo-filgrastim and filgrastim.⁶ Our findings suggest that physicians were more cautious in the use of tbo-filgrastim for mobilization, an indication for which it is not approved by the FDA. A recent survey conducted among rheumatologists, dermatologists, gastroenterologists, oncologists, and hematologists in New Zealand showed that 32% of clinicians were less confident about indication extrapolation when using biosimilars and reported the need for a high quality clinical trial in the specific condition being treated.¹⁷ Some organizations have adopted similar views on the use of the G-CSF biosimilar. For example, the European Group for Marrow and Bone Marrow Transplantation (2009) and the World Marrow Donor Association Shaw (2011) recommended against the use of the G-CSF biosimilar for mobilization of stem cells in healthy donors.^{10,18} Both organizations cited concern over extrapolation of data from other indications and lack of long-term follow-up studies. However, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Myeloid Growth Factors have incorporated tbo-filgrastim and filgrastim-sndz (the first biosimilar approved in the United States) into its recommendation for all indications, including for use in the mobilization of hematopoietic progenitor cells for transplantation and supportive care after transplantation.³ This recommendation excludes the treatment of febrile neutropenia, where only filgrastim-sndz was incorporated.

In addition, there is a growing body of evidence on the efficacy and safety of tbo-filgrastim in its off-label indications.^{14,19,20} In 1 retrospective study conducted in a U.S. hospital among 185 patients diagnosed with lymphoma or plasma cell disorders undergoing G-CSF mobilization, there was no significant difference seen between filgrastim and tbo-filgrastim in the total collection of CD34(+) cells, which was the primary end point. Furthermore, no clinically meaningful differences were seen in secondary efficacy and safety end points.¹⁴ Findings from another U.S. hospital that had replaced filgrastim with tbo-filgrastim for all on- and off-label indications showed there was no difference in outcome in autologous hematopoietic stem cell transplantation among patients receiving filgrastim and tbo-filgrastim.¹⁹ In a more recent prospective randomized trial, the safety and efficacy of tbo-filgrastim in combination with plerixafor was compared with that of filgrastim in

combination with plerixafor for stem cell mobilization in patients with multiple myeloma and non-Hodgkin lymphoma.²⁰ Tbo-filgrastim was shown to be noninferior in efficacy, with a similar safety profile compared with reference filgrastim.²⁰

Subgroup analysis by hospital showed a lower rate of tbo-filgrastim use in 1 hospital, suggesting differences in the acceptability rate of tbo-filgrastim in the 2 hospitals. Recent research shows that the biggest challenge to acceptability of biosimilars is the significant lack of knowledge among physicians.^{21,22} This knowledge gap may be reduced through targeted communication on biosimilar medicine via professional societies, published literature, and educational events.²² It is also important to note that at the time of formulary addition at our hospitals, tbo-filgrastim was covered by 2 of the 4 major commercial health plans in our area, while it was deemed “new to market” by the remaining ones. However, our most recent review of payer status in 2017 is that tbo-filgrastim is covered by all 4 major health plans, although for 1 health plan filgrastim is at a lower tier than tbo-filgrastim.

With the rising health care costs in the United States, the role of less expensive alternatives, such as biosimilars, becomes more important in the medical community. As reported earlier, our study showed that only tbo-filgrastim was used in self-pay patients (n=12). This finding echoes the importance of cost in the therapeutic choices made among patients and in the medical community. There is a potential for biosimilars to reduce drug expenditure and increase patient access to high-cost medicines.^{23,24}

Limitations

This study is limited by its retrospective nature, which involved reviewing electronic medical record to determine the indication for using G-CSF. It was not possible to ascertain whether the prescriber had other rationales for using the medication beyond the obvious indication stated. Also, this study was focused on 2 tertiary hospitals, so the findings may not be generalizable to other health care systems.

Conclusions

Although tbo-filgrastim was the preferred G-CSF in our formulary, 29% of patients continued to receive filgrastim. Conversion to tbo-filgrastim has been largely successful, but extra steps may be needed to achieve full conversion to biosimilars.

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DISCLOSURES

No outside funding supported this study. Agboola was employed by Partners Healthcare at the time of the study. The authors have nothing to disclose.

Study concept and design were contributed equally by Agboola and Reddy. Agboola collected the data, and data interpretation was performed by both authors. The manuscript was written primarily by Agboola, with assistance from Reddy. Both authors revised the manuscript.

ACKNOWLEDGMENTS

The authors acknowledge Niyati Vakil, Nahal Beik, Lina Alnajjar, Mousa Abdu, and Alex Ulici for their assistance with data collection.

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