

# Outpatient Administration of Granulocyte-Colony Stimulating Factor Following Autologous Stem Cell Transplantation

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## Background

- Granulocyte-colony stimulating factor (G-CSF) administration following autologous stem cell transplantation (ASCT) is a common practice
- Routine administration of G-CSF following ASCT in hospitalized patients reduces time to neutrophil engraftment, documented infection, time to hospital discharge, and may result in net cost savings
- Few studies evaluate G-CSF administration following ASCT in the outpatient setting
- In one study, routine G-CSF administration following outpatient ASCT was associated with increased hospitalizations
- Cost savings from reduced duration of hospitalization may not apply when ASCT conducted in the outpatient setting
- No benefit observed in overall survival, therefore use of G-CSF is controversial

## Objectives

- To evaluate outpatient administration of G-CSF compared to no G-CSF following ASCT in the Vancouver General Hospital (VGH) Outpatient Leukemia Bone Marrow Transplant (LBMT) Clinic
- Primary Outcome:**
  - Hospitalization within 30 days
- Secondary Outcomes:**
  - Outpatient clinic visits, days to neutrophil engraftment, days of neutropenia and severe neutropenia, number of febrile neutropenic episodes, days to platelet engraftment, days of IV antibiotics, positive blood cultures within 30 days, early mortality (within 30 and 100 days), hospitalization characteristics and G-CSF indication.

## Methods

- Design** - Retrospective chart review
- Study Dates** - April 1, 2012 and March 31, 2014
- Inclusion Criteria** - Patients receiving ASCT with melphalan conditioning for treatment of multiple myeloma
- Exclusion Criteria** - Patients where documentation of outpatient G-CSF administration was not clear
- Patients** - 180 included, 9 excluded (total N=171)
  - No G-CSF: N=91; G-CSF: N=80
- Statistical Analysis**
  - Nominal data was compared using the Chi-Squared Test
  - Continuous data was compared using the Wilcoxon Rank Sum Test

Table 1: Baseline Patient Characteristics

(Reported as median with interquartile range, or number with percentage)

| Patient Characteristic                     | No G-CSF (N=91)  | G-CSF (N=80)     |
|--|------------------|------------------|
| Age (years)                                | 61 (55-65)       | 60 (55-65)       |
| Males                                      | 57 (63%)         | 51 (64%)         |
| Weight (kg)                                | 75.7 (66.8-89.5) | 76.5 (65-88.4)   |
| Body Mass Index                            | 27.5 (24.9-30.3) | 27.5 (24.6-29.9) |
| CD34+ cells infused (x10 <sup>6</sup> /kg) | 4.15 (3.14-6.08) | 3.88 (3.02-5.90) |
| <b>International Staging System</b>        |                  |                  |
| I  | 25 (27.5%)       | 17 (21.3%)       |
| II   | 28 (30.8%)       | 23 (28.8%)       |
| III  | 8 (8.8%)         | 11 (13.8%)       |
| Unknown                                    | 30 (33%)         | 29 (36.3%)       |
| <b>Melphalan Dose</b>                      |                  |                  |
| 140 mg/mm <sup>2</sup>                     | 5 (5.5%)         | 9 (11.3%)        |
| 200 mg/mm <sup>2</sup>                     | 82 (94.5%)       | 75 (88.8%)       |

Table 2: Outcome Results

(Reported as median with interquartile range, or number with percentage)

| Primary Outcome   | No G-CSF (N=91) | G-CSF (N=80) | P-value |
|---|-----------------|--------------|---------|
| Hospitalization within 30 days                            | 29 (31.9%)      | 20 (25%)     | 0.32    |
| <b>Secondary Outcomes</b>                                 |                 |              |         |
| Outpatient clinic visits                                  | 13 (10-15)      | 14 (12-14)   | 0.009   |
| Days to neutrophil engraftment                            | 15 (13-17)      | 13 (12-14)   | <0.001  |
| Days of neutropenia (ANC <0.5 x10 <sup>9</sup> /L)        | 8 (6.5-10)      | 6.5 (6-8)    | <0.001  |
| Days of severe neutropenia (ANC <0.1 x10 <sup>9</sup> /L) | 6 (5-8)         | 6 (5-6)      | 0.007   |
| Febrile neutropenic episode                               | 63 (69.2%)      | 73 (91.3%)   | <0.001  |
| Days to platelets >20 x10 <sup>9</sup> /L                 | 13 (12-14)      | 13 (12-15)   | 0.073   |
| Days to platelet >50 x10 <sup>9</sup> /L                  | 14 (13-16)      | 15 (13-17)   | 0.061   |
| Duration of IV antibiotics                                | 5 (1-7)         | 5 (4-7)      | 0.13    |
| Positive blood culture within 30 days                     | 8 (8.8%)        | 7 (8.8%)     | 0.99    |
| Mortality at 30 days                                      | 1 (1.1%)        | 0 (0%)       | 0.34    |
| Mortality at 100 days                                     | 1 (1.1%)        | 0 (0%)       | 0.34    |

Table 3: Hospitalization Characteristics

(Reported as median with interquartile range, or number with percentage)

| Hospitalization Characteristic | No G-CSF (N=29) | G-CSF (N=20) | P-value |
|--------------------------------|-----------------|--------------|---------|
| Days to first hospitalization  | 7 (5-9)         | 11 (9-12.5)  | <0.001  |
| Days of hospital stay          | 8 (4-12)        | 7 (4-9)      | 0.21    |
| Received G-CSF as inpatient    | 22 (75.9%)      | 17 (85%)     | 0.44    |

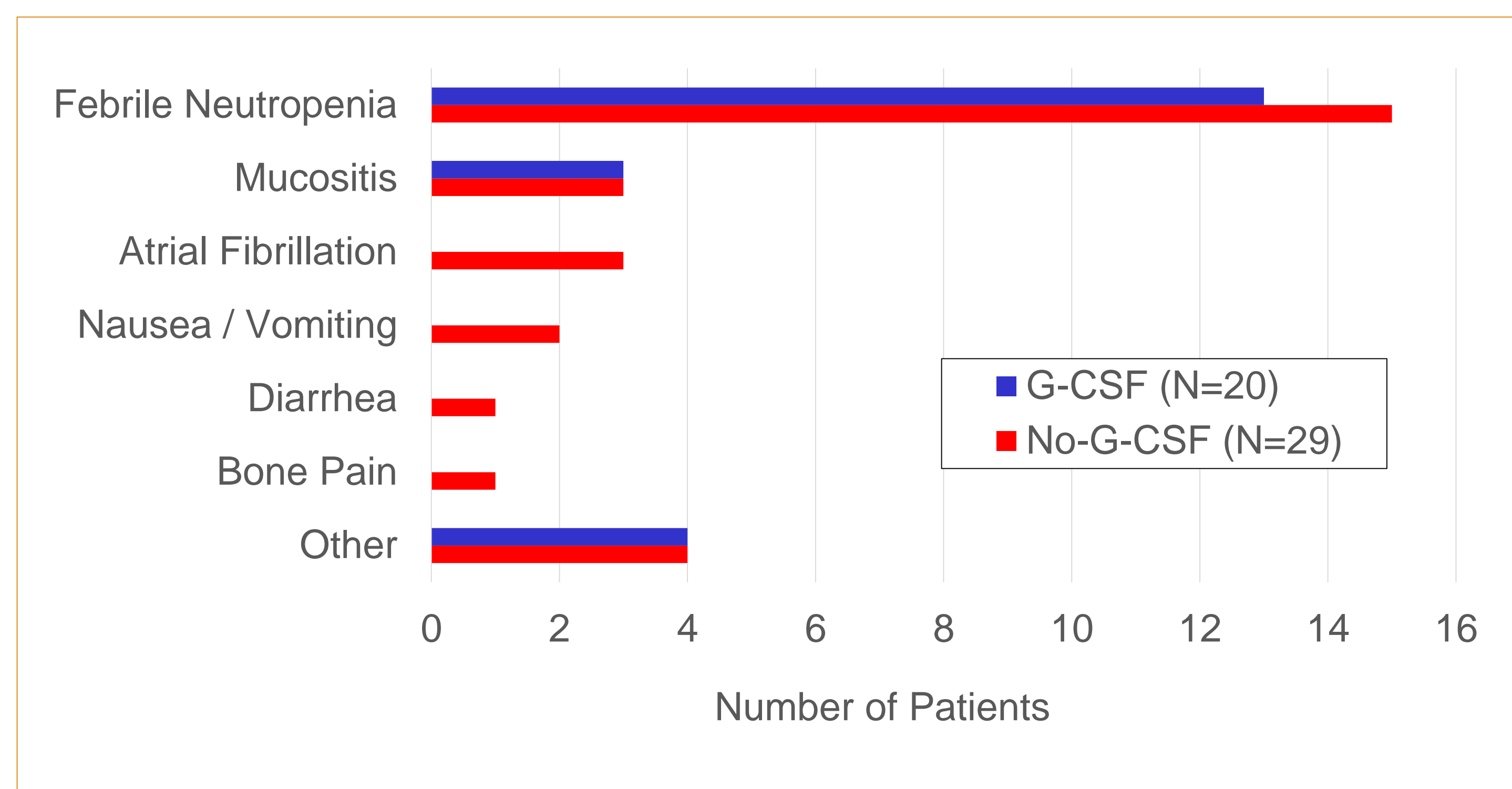


Figure 1: Principal Diagnosis for Hospitalization

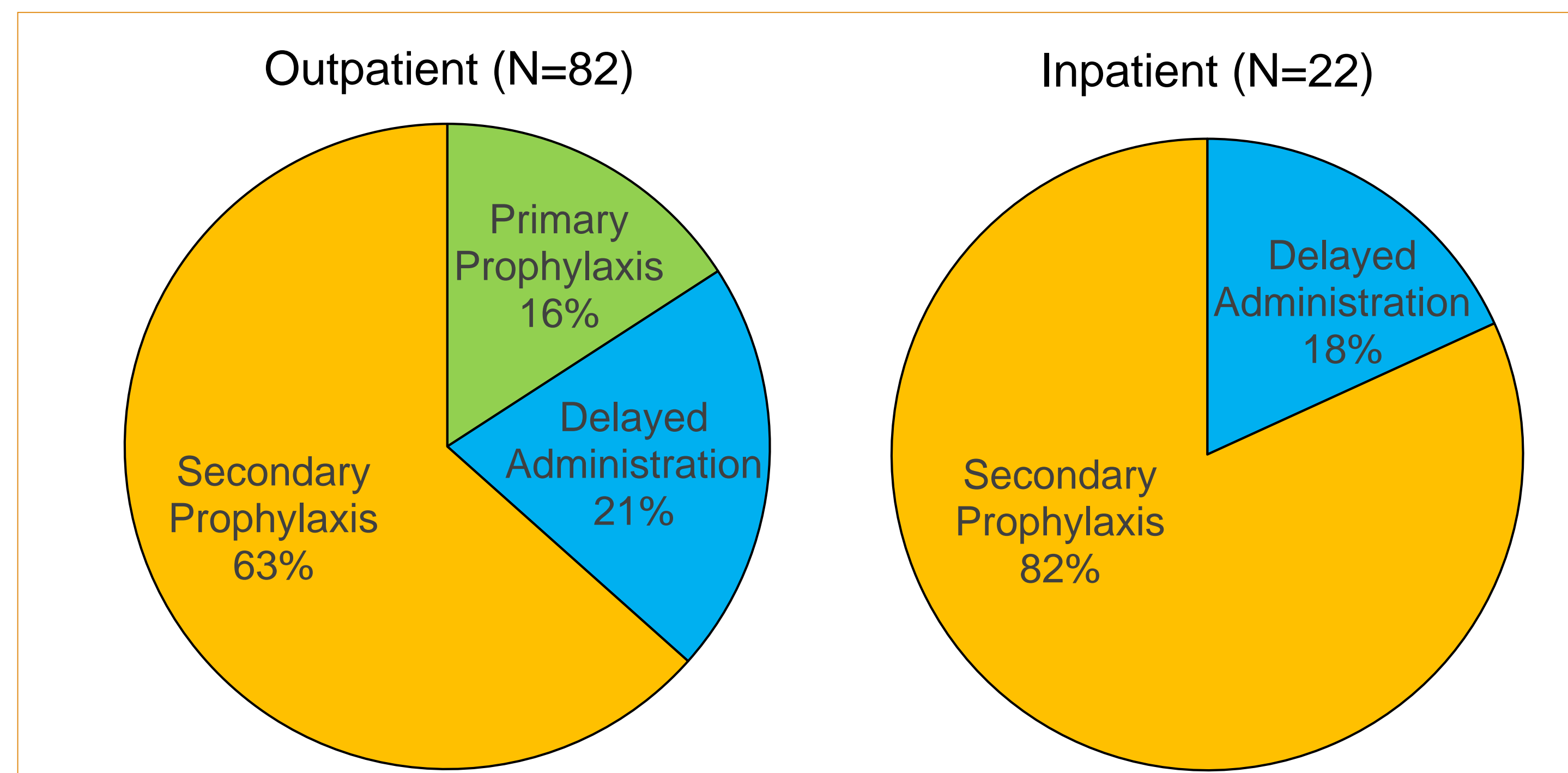


Figure 2: Indications for G-CSF Administration

## Conclusions

- No clinically meaningful benefits observed in patients administered G-CSF following ASCT in the outpatient setting
- The practice of outpatient G-CSF administration following ASCT at VGH warrants re-evaluation
- Further studies needed to identify groups who may benefit from G-CSF