

Impact of Long- versus Short-Acting Growth Factors on Staff Time Consumption and Utilization: A Multi-Center Study (P-5R)

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Background

Fatigue is among the most commonly reported symptoms of cancer patients, and is often attributed to anemia.¹ The European Cancer Anemia Survey² indicates:

- 39% of cancer patients are anemic, with significant variation by tumor type, disease status, and treatment approach
- among patients not anemic at baseline, 63% develop anemia while undergoing chemotherapy

Patients often regard fatigue more detrimental to their daily lives than other cancer- or treatment-related complications.³ Epoetin alfa (EPO) and darbepoetin alfa (DARB) are each used to treat anemia in patients with cancer. Clinical trials have demonstrated that both agents:

- significantly improve hemoglobin levels
- reduce transfusion requirements, and
- improve quality of life⁴

Rationale

DARB is a modified recombinant form of EPO with a longer half-life, allowing it to be dosed less frequently.⁵ The frequency of laboratory monitoring (CBCs) may also be reduced versus EPO. Thus, DARB may be associated with reductions in clinic visits and staff time, and these savings may offset – in whole or in part – the EPO advantage in terms of drug acquisition cost.⁶

To our knowledge, only a single (2-center) study has assessed the impact of long acting growth factors on oncology practice dynamics, finding they lead to significant reductions in health care utilization.⁷ We sought to determine whether similar results would be found in a multi-center study.

Objectives

The study was designed to assess:

- staff time requirements for various aspects of oncology clinic visits during which CBCs are obtained and/or growth factor is administered
- the number of clinic visits, and services provided during these visits, during chemotherapy cycles in which patients received EPO versus DARB

Methods

The study was conducted at 7 oncology centers located in LA, MA, NJ, NM, PA, UT and VA during January - March 2006. The protocol was approved by Western Institutional Review Board.

Time-Motion Assessment

Staff time devoted to laboratory activities and growth factor administration were assessed by direct observation of patients visiting each study center by trained nurses. Consecutive patient visits were observed until the desired sample size was obtained. Stopwatch timings were made to measure the staff time required to conduct each of 6 distinct events:

| | Measurement Commenced | Measurement Terminated |
|------------------------------|--------------------------------|----------------------------------|
| Patient Check-In | Patient presents at reception | Patient departs for waiting area |
| Phlebotomy | Receipt of requisition | Patient leaves phlebotomy area |
| Laboratory | Computer entry of patient data | Laboratory report available |
| Pharmacist Monitoring | Blood drawn or results ready | Deliver medication to nurse |
| Growth Factor Administration | Gather required materials | Dose given & documented |
| Scheduling | Obtain patient calendar | Provide patient his/her schedule |

We sought to obtain 10 time measurements of each event at each center. Because some centers combined tasks, pharmacist monitoring could not be timed at 3 centers, and patient scheduling could not be timed at 4 centers.

Medical Records Review

At each center, patient records were reviewed in reverse chronological order. Chemotherapy cycles meeting each entry criteria and no exclusion criteria were enrolled.

Entry Criteria

- age 18 years or older
- solid tumor, including lymphoma
- chemotherapy cycle duration 14-28 days
- at least 1 EPO or DARB dose administered by center staff
- complete documentation of laboratory testing and growth factor administration available

Exclusion Criteria

- self-administration of EPO or DARB
- receipt of G-CSF or GM-CSF during cycle
- receipt of EPO and DARB during the same cycle

The unit of analysis was an individual chemotherapy cycle, and patients could be enrolled multiple times. We sought to enroll 20 EPO and 20 DARB cycles from each center, but 2 centers provided slightly larger sample sizes, and these additional patients were included in the analysis.

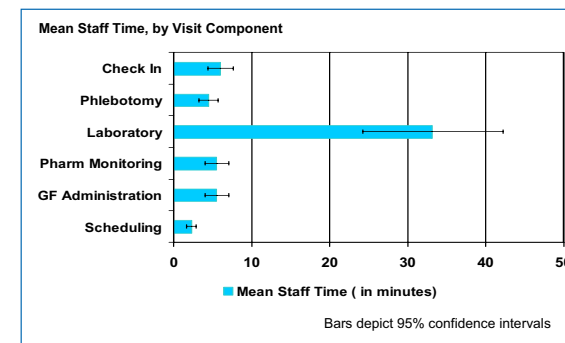
Statistical Analysis

For the time-motion assessment, the mean time required for each event, and associated 95% confidence intervals, were calculated. For the medical records assessment, baseline characteristics of DARB versus EPO patients were compared using Chi Square and Student's t. Mean numbers of CBCs, growth factor doses and non-chemotherapy visits were compared using Student's t.

Results

Time Motion Assessment

Our time-motion assessment indicates that a mean of 61 staff minutes is devoted to each visit at which a CBC is obtained and a growth factor is administered. The largest component of staff time is associated with the laboratory processing component:



Medical Records Review

DARB and EPO patients were comparable on the basis of age, gender, health insurance status and chemotherapy cycle duration. The EPO group contained more patients with breast cancer, while the DARB group included more lung cancer patients:

Results (cont'd)

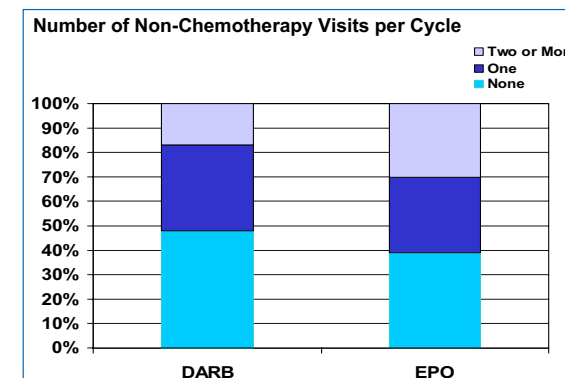
| Baseline Characteristics | DARB (n=156) | EPO (n=155) | p < |
|----------------------------------|--------------|-------------|------|
| Mean (SD) Age in Years | 67 (10) | 65 (14) | 0.11 |
| N (Pct) Female | 86 (55) | 89 (57) | 0.68 |
| Cancer Site - N (%) | | | |
| Genitourinary | 14 (9) | 14 (9) | |
| Breast | 19 (12) | 35 (23) | |
| Gastrointestinal | 52 (33) | 49 (32) | |
| Lung | 44 (28) | 22 (14) | |
| Other | 27 (34) | 35 (32) | 0.02 |
| Primary Insurer - N (%) | | | |
| Medicaid | 14 (9) | 9 (6) | |
| Medicare | 70 (45) | 76 (49) | |
| Private Insurance | 68 (44) | 61 (39) | |
| Self Pay | 4 (3) | 9 (6) | 0.30 |
| Mean (SD) Cycle Duration in Days | 20 (5) | 20 (5) | 0.48 |

On a per-cycle basis, the mean (SD) DARB dose was 331 mcg (144 mcg). The most common DARB dose was 200 mcg (80% of doses administered). During EPO cycles, the mean (SD) dose was 92,600 units (47,800 units). The most common EPO dose was 40,000 units (79% of doses administered).

Excluding visits during which chemotherapy was administered, DARB patients visited study centers 28% less frequently:

| Utilization per 100 Cycles | DARB (n=156) | EPO (n=155) | p < |
|----------------------------|--------------|-------------|-------|
| CBCs | 190 (127) | 234 (142) | <.01 |
| Growth Factor Doses | 157 (68) | 222 (108) | <.001 |
| Non-chemotherapy Visits | 76 (95) | 106 (109) | .02 |

Nearly half of DARB patients completed their chemotherapy cycle without a non-chemotherapy visit, versus only 39% of EPO patients. EPO patients were nearly twice as likely to require >1 non-chemotherapy visit:



Conclusions

Study Limitations

- Our time-motion assessment does not fully capture all staff time. For example, consultation between staff members was not recorded.
- Due to differences in standard procedures between centers, minor protocol revisions were required to complete the study.
- This study only documents some of the costs of additional clinic visits. For example, patient travel costs and time lost by patients (and in some cases, caregivers) were not considered.

Key Findings

- Patient visits for erythropoiesis stimulating proteins account for considerable staff time. Consequently, additional visits for CBCs and growth factor doses are costly for oncology centers.
- Use of DARB in place of EPO is associated with 19%, 29% and 28% reductions in CBCs, growth factor doses and non-chemotherapy visits, respectively.
- This multi-center study confirms previous findings,⁷ and indicates significant staff time may be saved by substituting DARB for EPO.

References

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Author Disclosure

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