

Increased numbers of concerning symptoms and ePRO survey alert notifications are associated with premature study discontinuation

Association between alert notification intensity during early study participation and time to study discontinuation in the AFT-39 PRO-TECT cluster-randomized clinical trial

Brenda Ginos MS, Amylou C. Dueck PhD, Deborah Schrag MD MPH, Jennifer Jansen MPH, Sydney Henson BS, Angela M. Stover PhD, Philip Carr MPH, Patricia A. Spears BS, Mattias Jonsson, Allison M. Deal MS, Antonia V. Bennett PhD, Gita Thanarajasingam MD, Lauren Rogak MA, Bryce B. Reeve PhD, Claire Snyder PhD, Deborah Bruner PhD, David Cella PhD, Lisa A. Kottschade MSN, Jane Perlmutter PhD, Cindy Geoghegan MA, Barbara Given PhD, Gina L. Mazza PhD, Robert Miller MD, Jon F. Strasser MD, Dylan M. Zylla MD, Anna Weiss MD, Anna P. Wolf, BA, Victoria S. Blinder MD, Ethan Basch MD MSc

BACKGROUND

Nurses received real-time alert notifications when patients reported concerning (i.e., severe or worsening) symptoms via remote symptom monitoring.

OBJECTIVES

Examine whether a high number of concerning symptoms or alert notifications for a patient in a short period of time early in the study signals that patient's early study discontinuation.

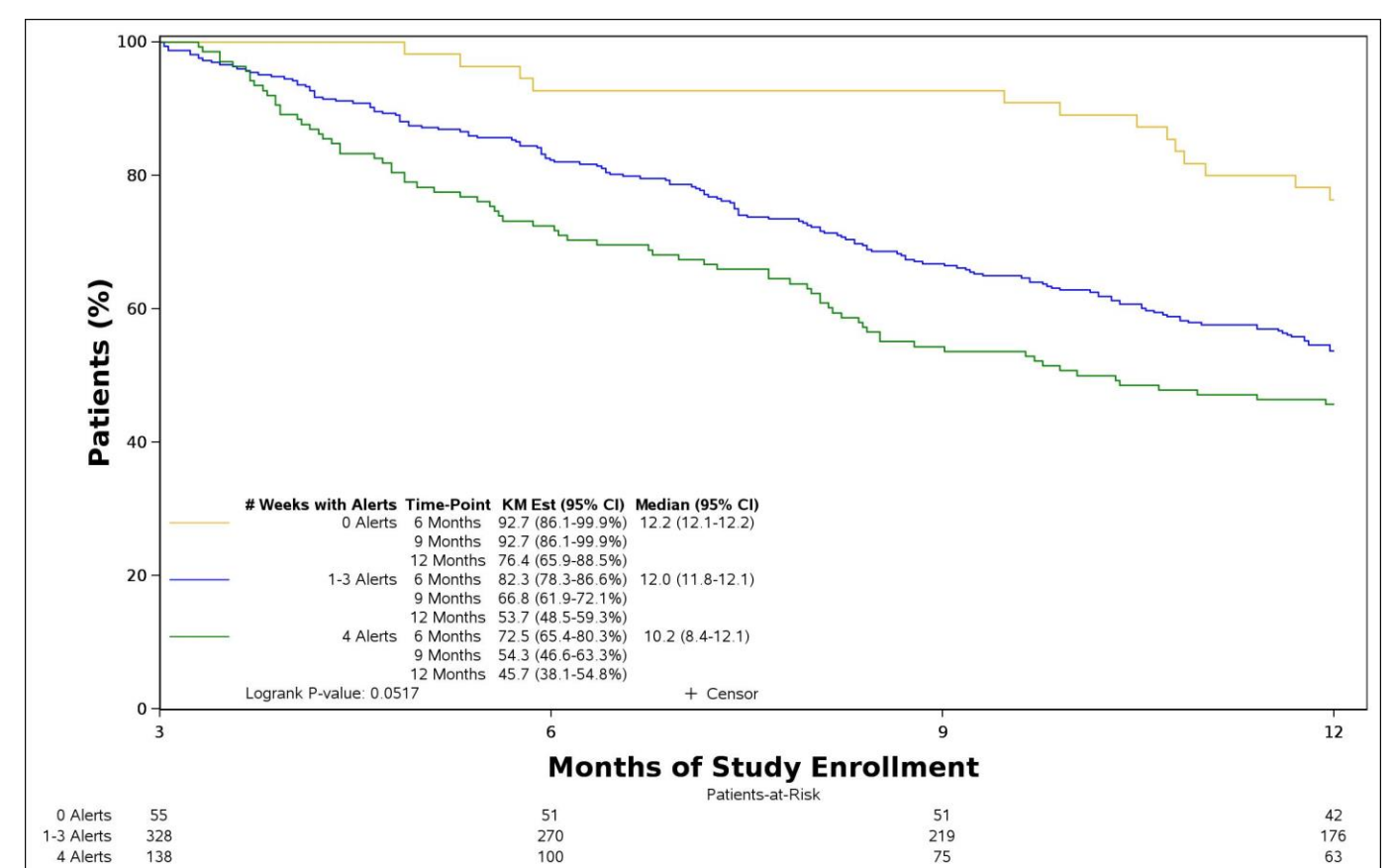
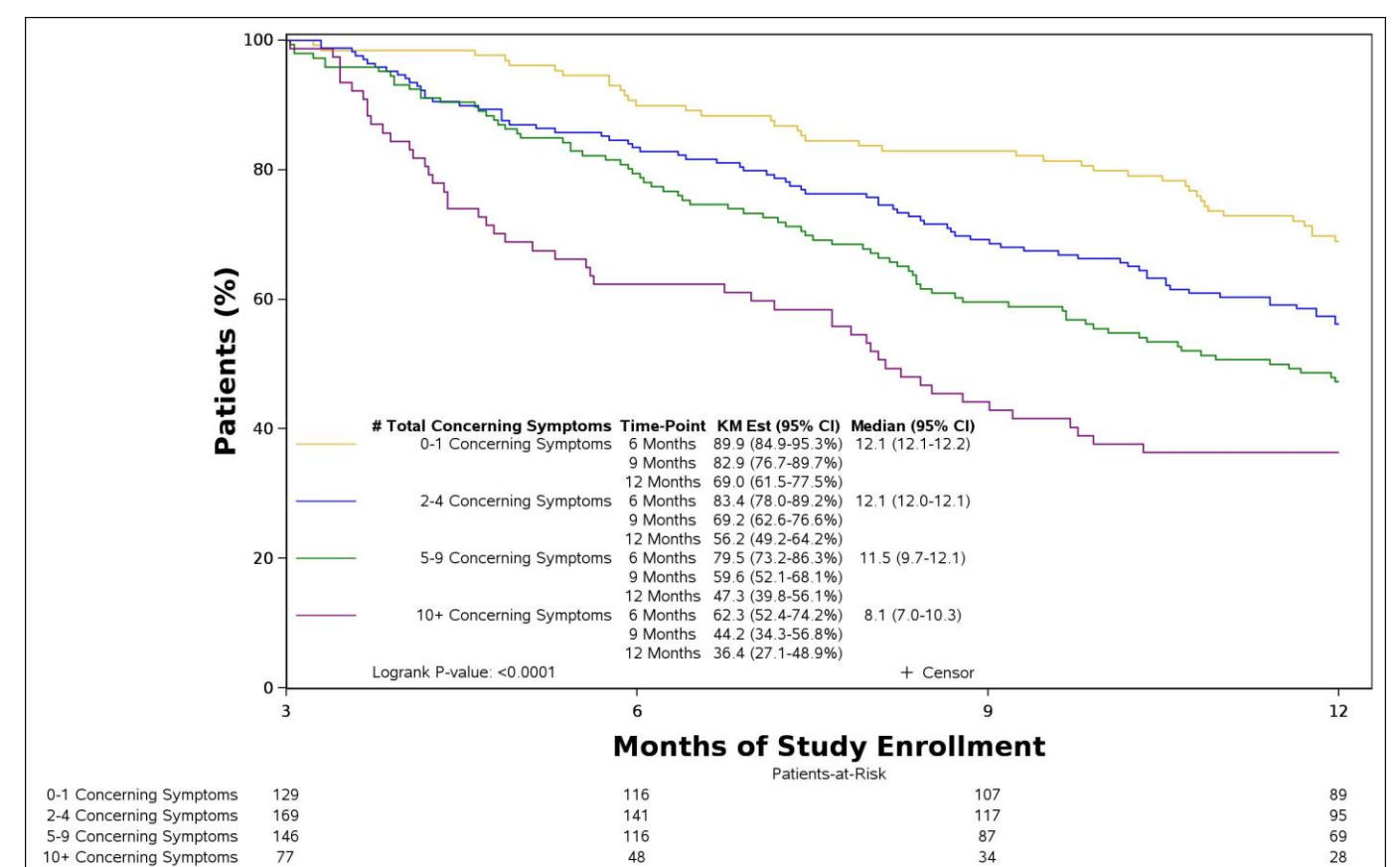
METHODS

- Patients rated 12 symptoms (e.g., pain, nausea, depression) via weekly ePRO surveys through the duration of their study participation, up to 52 weeks. Alerts for concerning symptoms were sent in real-time to nurses based on patient responses.
- A landmark analysis was conducted at three months. Patients were categorized two ways, based on their symptom reports in the first three months:
 - Maximum number of concerning symptoms in any given four-week period.
 - Maximum number of weeks with an alert notification sent to nurses in any given four-week period.

RESULTS

- Nurses received alerts on 6,903/20,565 (33.6%) of completed surveys.
- 521/592 (88.0%) patients were included in the landmark analysis (i.e., were still enrolled on the study at three months).
- Of the patients included in the landmark analysis, patients with the fewest concerning symptoms in the first three months were most likely to still be enrolled at twelve months ($P < 0.001$, top figure).
- Additionally, patients with the fewest alert notifications in the first three months were most likely to still be enrolled at twelve months ($P = 0.05$, bottom figure).

FIGURES: TIME TO OFF-STUDY BY NUMBER OF CONCERNING SYMPTOMS, ALERTS



CONCLUSION

Increased numbers of concerning symptoms and ePRO survey alert notifications, sent to nursing staff during early study participation, are associated with a patient's ultimate premature study discontinuation for any reason.

SUPPORT

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<https://acknowledgments.alliancefound.org>

