

The Effect of Alarms on Completion of Electronic Diaries in Patients with Inflammatory Bowel Disease

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BACKGROUND

- Clinical trials have contributed substantially to the development of novel therapies for inflammatory bowel disease, including Crohn's disease (CD) and ulcerative colitis (UC).
- The Food and Drug Administration (FDA) recommends the use of the Crohn's Disease Activity Index (CDAI) and the modified Mayo Score (mMS) to measure primary endpoints in CD and UC trials, respectively.
 - Both assessments are composite scores and require the completion of a daily diary by subjects to report on disease symptoms, including stool frequency, rectal bleeding, abdominal pain, and general well-being.
 - To facilitate the timely completion of diaries, and to limit missing entries, it has been recommended to implement device alarms or reminders.

OBJECTIVE

- The objective of this study was to determine the impact of device alarms and/or reminders on the completion times of daily electronic diaries (eDiaries) in CD and UC studies.

METHODS

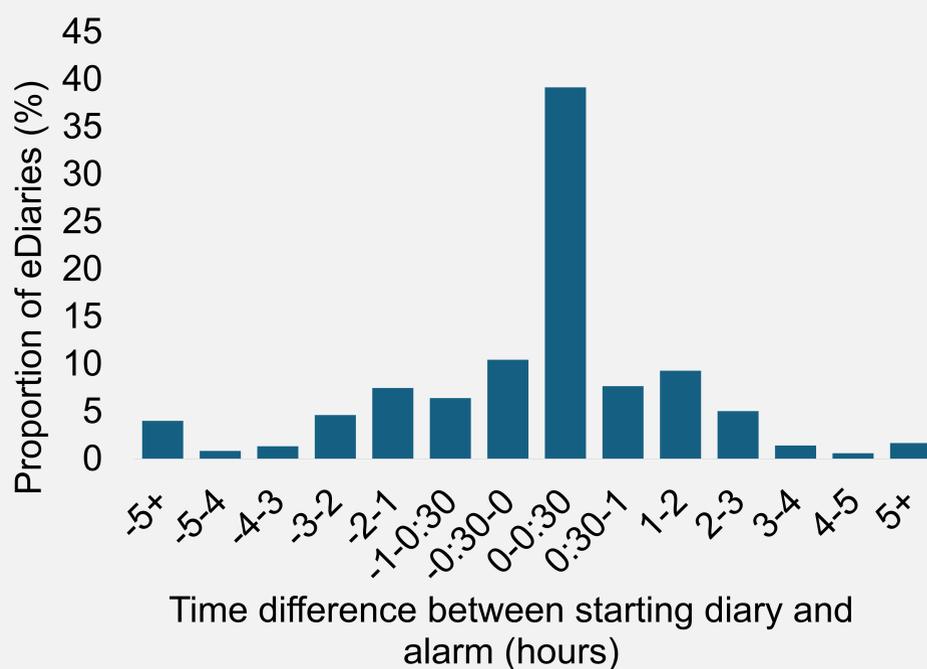
- This analysis included more than 3.7 million eDiary entries from 12 153 patients across 11 studies in CD and UC.
- Patients were required to complete eDiaries daily, either on their personal smartphone or on an equivalent provisioned device, throughout their participation in the specific study.
 - On device-notifications and alarms were programmed to remind patients to complete their eDiary.
- Only completed eDiary entries were included.
- For this analysis, the difference between the patient's eDiary alarm time and the time that the eDiary was first opened was determined.

RESULTS

Analysis of eDiary completion times for patients with CD:

- 65% (n = 1 079 823) of eDiaries were opened after the programmed alarm time (**Figure 1**).
- 39% (n = 652 138) were answered 30 minutes after the alarm time.
- 8% (n = 127 711) were answered between 30 minutes and one hour after the alarm time.

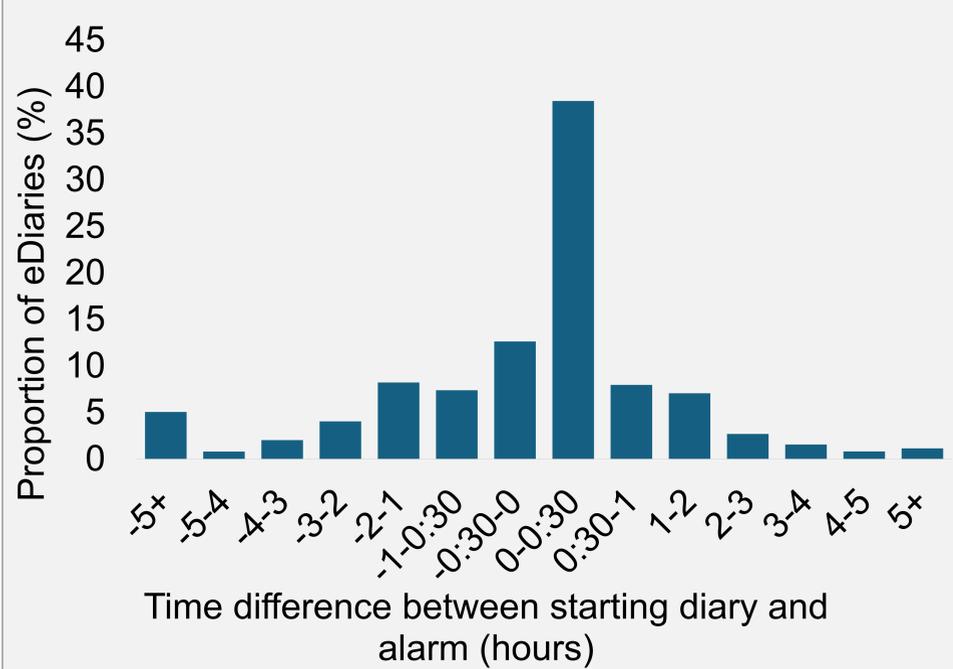
Figure 1. Timeframe in which CD patients completed eDiary in relation to alarm time.



Analysis of eDiary completion times for patients with UC:

- 60% (n = 1 277 090) of eDiaries were opened after the programmed alarm time (**Figure 2**).
- 38% (n = 822 552) were answered 30 minutes after the alarm time.
- 8% (n = 170 433) were answered between 30 minutes and one hour after the alarm time.

Figure 2. Timeframe in which UC patients completed eDiary in relation to alarm time.



CONCLUSION

- The implementation of eDiary alarms appears to be a significant factor driving positive compliance.
- The analysis carried out here suggests that eDiary alarms encourage completion of the eDiary within an hour reporting window of their scheduled alarm time.
- Nevertheless, sites and study teams should continue to educate patients on the importance of eDiary completion.