A Leading Academic Medical Center Monitors Newly Diagnosed Myeloma Patients with Rave eCOA

The Challenges

When oncology patients are at the onset of treatment, they are faced with balancing the daunting reality of their condition with maintaining a good quality of life. There is a direct correlation between a clinical outcome and factors such as sleep, physical fatigue, and mood disturbances. Doctors understand the interdependence between how patients are feeling and their health, and do their best to strike a balance between quality of life and disease control. When these balances are skewed, patients can be left with adverse outcomes such as increased toxicity or residual disease.

It is often difficult for oncologists to fully grasp the quality of life for a patient, because it encompasses so many dimensions including satisfaction, family, education and employment. However, tools have been developed to help measure these quality of life factors; these are known as PROs, or patient reported outcomes. A PRO allows a patient to report their quality of life independently of their oncologist, offering direct insight into the patient’s perspective. Although somewhat subjective, patient reported outcomes offer validated and reliable tools across trials, and their use has been linked to improved outcomes in clinical practice.

Although patient reported outcomes offer several advantages, they have their drawbacks as well. PROs can be subject to under-reporting or over-reporting, and are often difficult to implement into clinical practice. Additionally, the use of a paper patient reported outcome system is cumbersome and can result in data or organizational errors. Consideration of these drawbacks, led a leading academic medical center to use electronic PROs, or ePROs in their study in Multiple Myeloma patients.

The researchers sought an electronic platform which was convenient for their patients, while still offering objective measurements of quality of life. To gain a comprehensive understanding of the lives of cancer patients outside of the chemo unit, they needed to combine the most advanced science with the most advanced data-capture technology. Collaborating with Medidata in their expansion of Mobile Health (mHealth) technology in oncology treatment, Rave eCOA helped to motivate patients and increase engagement around experiences outside of the clinical setting.
the medical team partnered best in class clinical research with an advanced cloud-based ePRO solution. The innovative study included a clinical trial with 40 patients, split into 2 arms, myeloma patients younger than 65 and patients 65 or older, to assess patients’ quality of life.

The Solution

The researchers, using Medidata’s cloud-based Rave Wearable Sensors, were able to analyze activity and sleep trends, identify outliers, and assess patient compliance and data quality. Patients wore activity trackers for 1-7 days before induction chemotherapy treatment to establish a baseline, then were monitored continuously up to completion of six cycles of chemotherapy.

The Medidata Rave eCOA app allowed patients to measure activity level, fatigue, and appetite data on their smartphones. Since the institution was already using Rave EDC as their clinical study platform, its ability to unify with Rave EDC to ingest, store, and summarize data within the Medidata Rave Clinical Cloud™ made it a great candidate for the study.

Researchers found that Rave eCOA helped to motivate patients and increase engagement around experiences outside of the clinical setting, which otherwise may have gone unmentioned. Similarly, many patients reported an increased motivation to report things like activity and sleep, allowing doctors to measure their implications in cases of serious adverse events. An expanded knowledge of patient quality of life empowered doctors to tailor their disease control approach for each patient.

The Results

The use of the Medidata cloud-based platform helped the researchers aggregate and process data in real time over the course of the trial, providing valuable insights into patterns of movement and sleep.

Study of these patterns and baseline measurements for other quality of life measurements allowed the researchers to monitor and identify correlations between fluctuations in these measures and adverse events. For chronic malignancies, it is especially crucial to be able to measure and balance the subjective quality-of-life measures with effective treatment. Mobile wearable monitoring may provide objective data to support clinical decision making and utility of treatments. The researchers believed that electronically-reported patient data held great promise for the future. The use of Rave eCOA illustrated how real time electronic monitoring could improve the clinical outcomes for patients.