Predicting Early Study Drop-Outs Using Adherence Data from a Mobile Tracking Device

Lia D. Ernst[1], Connie Lau[6], Page B. Pennell[3], Jacqueline French[1], Rutendo Kashambwa[3], Nichelle G. Llewellyn[3], Ashley K. Kniseley[4], Benjamin Kaufman[1], Eyal Bartfeld[5], Cynthia L. Harden[2]

New York University School of Medicine, New York, NY[1]; Hofstra North Shore-Long Island Jewish School of Medicine, Hempstead, NY[2]; Neurology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA[3]; Neurology, University of Pittsburgh, Pittsburgh, PA[4]; Irody, Inc., Lexington, MA[5]; Neurology, North Shore LIJ Health System, Great Neck, NY[6]

Rationale

The WEPOD (Women with Epilepsy: Pregnancy Outcomes and Deliveries) study is a 4-site prospective, observational study evaluating fertility in women with epilepsy (WWE) and healthy controls (HC) as they transition from preconception planning through pregnancy and delivery. This interim analysis assessed the relationship between adherence with daily data tracking and completion of the study.

A customized diary application created for mobile devices (Apple's iPod Touch, iPhone, iPad) tracks fertility information, and in WWE, seizures and daily medication use. The app delivers all patient data to a central database where it can be reviewed and analyzed on a real-time basis. Determining a degree of adherence that is associated with early drop-out would be useful in clinical studies for predicting subject retention or for identifying subjects who need vigilant monitoring.

Methods

Women with epilepsy and healthy controls, ages 18-40 years, seeking pregnancy are enrolled within 6 months of stopping birth control. IRB approval was obtained at all sites. We developed a customized mobile Application (the WEPOD App™) for daily data tracking. The WEPOD App™ is connected to a web-based program that allows for data entry and provides central data monitoring. Data entries by the subjects are time stamped with the time the entry was made. Subjects were given a 4th generation iPod Touch, which they could also use with the web-based program, or choose to use a paper diary. All subjects recorded menstrual bleeding and sexual activity daily. WWE also tracked seizure occurrence and medication adherence. The WEPOD App™ includes a "pop-up" reminder asking the subject to make their daily diary entry. Subjects track fertility data daily until conception or until 12 months elapses, and WWE track medication data potentially until delivery, creating a long duration for study participation. Only the women with epilepsy were included in this analysis as the population of interest. Daily diary adherence was calculated as the percent of potential tracking days since study enrollment until study completion or drop-out that subjects entered data for all required fields.

Figure 1: WEPOD application

Epilepsy Group Diary
Menses
Sexual Activity
Seizures
Medications
Mood (optional)

Medication Data Entry:
Subjects indicate whether or not medications were taken at prescribed times

Results

Demographics: 61 WWE were enrolled by Dec 01, 2012 and began daily diary tracking. All subjects used the WEPOD app and/or the web; no subjects chose paper diaries. Demographics for all WWE are listed in Table 1.

Table 1: Demographic characteristics of WWE in the WEPOD study

	Total Subjects (n=61) % (n); mean ± std dev
Age (years)	32.33 ± 5.73
Race	
American Indian or Alaska native	1.64 (1)
Asian	6.56 (4)
Pacific Islander/Native Hawaiian	1.64 (1)
African American/ Black	0 (0)
White	83.61 (51)
Other/ Mixed	4.92 (3)
Missing	1.64 (1)
Ethnicity	
Hispanic or Latino	16.39 (10)
Not Hispanic or Latino	83.61 (51)
Education	
High School	9.84 (6)
Some College	13.11 (8)
Bachelor's Degree	34.43 (21)
Advanced Degree	39.34 (24)
Missing	3.28 (2)
Employment	
Student	3.28 (2)
Unemployed	21.31 (13)
Part-time	13.11 (8)
Full time	57.38 (35)
Missing	4.92 (3)

Figure 2: 2x2 Table of Specificity and Specificity of 87% Daily Diary Adherence as Predictor of Dropout

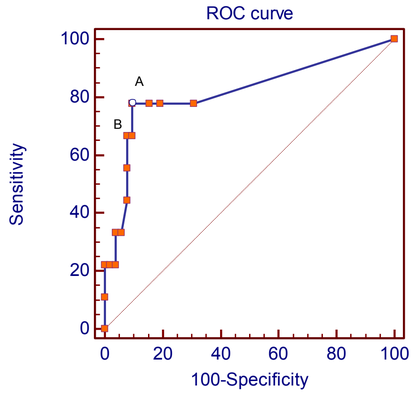
		Condition: Positive Drop-out	Condition: Negative Complete study	
Test Outcome	Positive ≤ 87% diary compliant	6 (True Positive)	4 (False Positive)	Positive predict value= 60%
	Negative >87% diary compliant	3 (False Negative)	48 (True Negative)	Negative predic value= 94.11%
		Sensitivity = 66.67 %	Specificity = 92.30 %	

Electronic Daily Diary Adherence in WWE:

- Of 61 WWE who enrolled before 12/1/12 and tracked data, 9 subjects dropped out and 52 continued in the study.
- The overall mean daily diary adherence was 92.3%; 36/61 had 100% adherence. Mean percent adherence of the 52 completed subjects was 96.1% (median 100, range 33-100). Of the 9 subjects who dropped out, percent adherence was 6, 22, 25, 55, 77, 86, 97, 100 and 100 for a mean of 63.1% (median 77).
- Only 4 subjects were less than 87% tracking adherent and completed the study.
- The optimal percent adherence cut-point for association with dropping out of the study was 96% which had a sensitivity of 77.8% and a specificity of 90.4% (point A – see Figure 3).
- Given that the cut point of 96% adherence is higher than the overall mean adherence, a more reasonable cut point may be a cut point of ≤ 87% adherence, which has a sensitivity of 66.7% and a specificity of 92.3% (point B – see Figure 3).

Results

Figure 3: ROC curve for % daily diary adherence for study subjects who dropped out versus completed



Conclusions

- Less than 87% adherence with tracking daily data may be a useful measure for predicting early drop-outs in a prospective study.
- The 9 subjects with less than 87% adherence dropped out within three months of starting the study. This is a period consistent with the prospective baseline of many interventional trials.
- Since percent adherence is easily determined using electronic data capture devices, this information may be useful at the onset of clinical studies for predicting subject retention or for identifying subjects who need vigilant monitoring.

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