Factors Influencing Consent Rates in a Sleep Medicine Randomized Control Trial

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ABSTRACT The success and timeliness of clinical research studies depends on the enrollment of eligible participants. Various demographic factors such as race, education level, socioeconomic status, and gender have been found to influence a person's decision to consent for participation in clinical trials, however, the effect of each of these factors have been found to vary among each study. The purpose of this quality improvement study was to analyze the effect of age and other demographic factors such as gender, race, education level, and insurance type on consent rates in the SAVE CPAP trial, a sleep medicine randomized control trial. We retrospectively reviewed the medical records of 558 patients that had been eligible for SAVE CPAP over a year span. We found that age did not have an effect on consent rate whether it was treated as a categorical or continuous variable, and that the demographic factors that were collected also did not have a statistically significant effect on consent rates. In addition, we collected the reasons why patients did not consent and found that they provide insight on how to remove obstacles that impede consent. Our study also identified that standardizing the consent process across technicians, and changing paperwork delivery may increase patient satisfaction and participation in the SAVE CPAP trial.

Introduction

The success and timeliness of clinical research studies depends on the enrollment of eligible participants. A study conducted in 2010 reviewed 37 studies including approximately 60,000 eligible participants and found that only 32% of people agreed to participate in the randomized control trials (Caldwell et al. 2010). Another study reviewed 122 clinical trials and found that about half the study investigators had to request a time extension due to an inability to recruit the appropriate number of participants (McDonald et al. 2006). Various factors have been found to influence a person's decision to consent for participation in clinical trials, including participant race, education, income level, and age (Gerber et al. 2007; Sala et al. 2012). However, the effect of each of these factors has tended to vary among each study. For example, the Tuskegee Legacy Project survey found that although African Americans have a fear rating that is 1.8X higher than whites when it comes to research studies, they are just as likely to consent as whites (Katz et al. 2006). On the contrary, a study analyzing the effect of race on consenting rates in a cancer clinical trial found that race does have an effect on consenting rates when it is analyzed with age and income levels (Brown et al. 2003).

Furthermore, the age of participants has also been found to have an effect on enrollment rates. In an analysis of seven epidemiological studies with over 25,000 participants, Dunn et al. found that males, younger people, and those reporting the symptom addressed in the study were more likely to give consent (Dunn et al. 2004). On the contrary, in a study analyzing consenting rates for release of patient information, older patients and patients in worst health conditions were more likely to grant consent to access of their medical records (Woolf et al. 2000). While there have been studies conducted on consenting rates in various clinical research studies, there is not much known about consenting rates in clinical trials focusing on sleep medicine in particular.

The SAVE CPAP trial (Sleep Apnea Video Education for CPAP Adherence) is an ongoing study by our group that aims to identify the impact of an educational video about obstructive sleep apnea (OSA) on adherence to continuous positive airway pressure (CPAP) therapy, which is the main treatment for patients with OSA, a condition in which the upper airway collapses during sleep and causes hypoxia, hypertension, and excessive daytime sleepiness, among other comorbidities (Balachandran & Patel 2014). The aim of this quality improvement study is therefore to examine if younger patients (18-44 years) are more likely to consent to participate in the SAVE CPAP Study than middle-aged patients (45-64 years) and senior citizens (≥65 years), with a secondary interest in determining if other factors like

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education, race, gender, insurance type, and technician experience are correlated with likeliness to consent.

Methods

This was a quality improvement study within the ongoing SAVE CPAP trial, which received IRB approval (IRB# 14-0198). Eligible patients were randomly assigned to two groups: education about CPAP via a standard care pamphlet or via a short video. The night of the sleep study after completion of all necessary paperwork for the polysomnogram, technicians approached all eligible patients about participation in the study. Technicians were granted flexibility in the manner they approached patients for consent.

2.1 Participants

Patients scheduled for a sleep study at the University of Chicago Sleep Lab were screened for the following inclusion criteria: 18 years of age or older, no prior contact with the sleep clinic or a sleep physician, and planned for a split-night polysomnogram. These were considered ideal patients for SAVE CPAP due to having minimal prior knowledge about sleep apnea and treatment, thus making the effects from the educational video or pamphlet more pronounced. Exclusion factors included: previous CPAP use, prior contact with the University of Chicago Sleep Disorder Clinic, non-English speakers, illiterate patients, and a sleep study result which showed no obstructive sleep apnea. The primary goal of SAVE CPAP was to observe adherence to CPAP therapy, so it was necessary for patients to need the treatment and to be capable of filling out all paperwork associated with SAVE CPAP. In this quality improvement study, only patients who were eligible for SAVE CPAP were observed for their consent patterns.

2.2 Procedure

The medical records of all eligible patients were retrospectively reviewed and the following data was collected to build the database: patient age, gender, insurance type, self-reported education level, self-reported race, body mass index (BMI), technician name, sleep lab location, consent response, and if consent declined, reason why did the patient did not consent. Education level was categorized into "less than 4 years of college" versus "4 years of college or more". Primary insurance type was split into "Medicaid or Medicare" versus "Private Insurance." Race was categorized into "African American" versus "non-African American." Reason why a subject did not consent was categorized into "no reason given", "too tired", "not interested in research", "didn't want to read pamphlets", "did not want to complete more paperwork", "did not want to take the time" and other reasons given were qualitatively collected. A total of 558 patient files were reviewed, which included eligible patients from June 30, 2014 to June 29, 2015.

2.3 Statistical Analysis

The primary hypothesis of the effect of patient age on consent rates was tested in two manners. First, patients were separated into three age groups (18-44 years, 45-64 years, and ≥65 years). Age categories were treated as a categorical variable and a Chi-square analysis was performed. Second, age was also analyzed as a continuous variable via a point biserial correlation test to visualize any correlation among age and likelihood to consent for participation in SAVE CPAP. Logistic regression models were created to explore the secondary aims of the impact of patient education level, patient insurance, patient race, and technician experience. All of these statistical tests were done using Stata 14 (StataCorp, College Station, TX) and a p value <0.05 was considered statistically significant.

Results

Table 1- Characteristics of Study Cohort

Demographic	All Participants (N=558)
Age, years	52 ± 14
Gender	
Male	228 (41%)
Female	330 (59%)
BMI, kg/m^2	36.6 ± 9.5
Education Category*	
Less than 4 years of college	317 (60%)
4 years of college or more	212 (40%)
Race Category	
African American	336 (60%)
Non- African American	222 (40%)
Insurance Category	
Medicare/ Medicaid	270 (48%)
Private	288 (52%)
Sleep Lab Location	
Main Campus	236 (42%)
Satellite Campus	322 (58%)

Data is presented as mean ± SD or No. (%). SD= Standard Deviation. BMI = Body Mass Index. *Data missing on 29 participants.

The overall consent rate to participate in the SAVE CPAP trial, with 558 eligible patients recruited from June 30, 2014 to June 29, 2015, was 47 percent (see Figure 1).

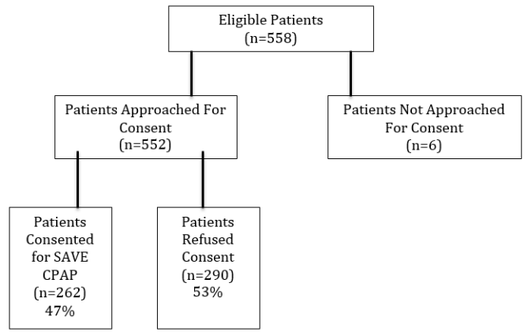

Figure 1- Study Flow Diagram illustrating how the final number of participants were obtained

Demographic data are summarized in Table 1. The majority of the cohort was African American, had less than 4 years of college education, and more than half were women. The mean age of participants was 52±14 years and most were obese with a mean BMI of 36.6 ±9.5 kg/m2. About half of the participants had private insurance, and the other half had Medicare or Medicaid insurance. After discarding 130 patients due to missing consent forms, the largest reason for not consenting was "not interested in research" (21%). Other prevalent reasons included "did not want to complete more paperwork" (13%), "did not want to take the time (11%), and "too tired" (7 %, see Table 2).

Table 2- Reasons why eligible patients did not consent*

Reasons	Participants that refused consent (n=160)
Not interested in research	34 (21%)
No reason given	32 (20%)
Did not want to complete more paperwork	20 (13%)
Did not want to take the time	18 (11%)
Too tired	11 (7%)
Poor vision/ hearing	8 (5%)
Did not want to read pamphlets	8 (5%)
Other	28 (18%)

*Consent form missing for 130 patients.

We hypothesized that increasing patient age would be correlated with a lower consent rate. After performing a Chi-square analysis on the three age groups (18-44 years, 45-64 years, and ≥65 years), it was found that these age groups did not predict consent rate (p= 0.06, see Figure 2). A point biserial correlation completed with age as a continuous variable found no relationship between age and consent rate with a coefficient of -0.02 (p=0.5).

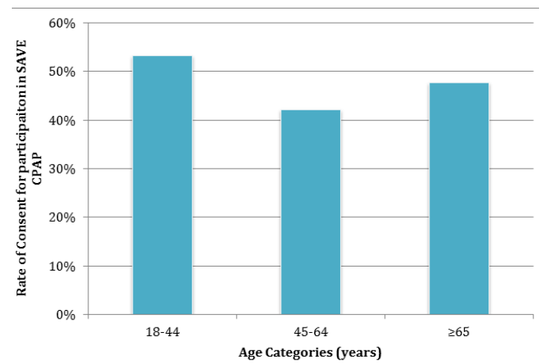

Figure 2- Bar chart of consenting rates for participation in SAVE CPAP according to each age group; (n=558, X2=5.3, p=0.06)

Using Chi-square analyses, we also assessed the effect of various other factors on consent rates and found that none were statistically significant: race (African American vs Non-African American, p=0.24), education (Less than 4 years of college vs 4 years of college or more, p=0.17), insurance (Private vs Medicare or Medicaid, p=0.47), and gender (Male vs Female, p=0.08). A logistic regression model was also created to study the effect of these multiple factors (gender, race, insurance, education, age, BMI, and study location) on consent rates; none were predictive of consent rates (see Table 4).

Table 3- Technicians categorized by years of experience in the field vs. success rate in consenting participants

Technician Experience Conducting Sleep Studies (n=15)	Weighted Mean Success Rate (%± SD)
0-7 years (n=5)	40± 6
8-13 years (n=6)	48± 15
≥14 years (n=4)	52±14

SD= Standard Deviation, p=0.08.

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Table 4- Logistic Regression Results on Demographic Factors

	# Consented (%)	OR, 95% CI P value^
Gender		
Female	165 (50)	1
Male	97 (43)	0.74 (0.53, 1.04) P=0.08
Race		
African American	151 (45)	1
Non-African American	111 (50)	1.23 (0.87, 1.72) P=0.24
Insurance		
Medicare/ Medicaid	131 (49)	1
Private	131 (45)	0.89 (0.63, 1.23) P=0.47
Education		
4 years of college+	107 (50)	1
<4 years of college	141 (44)	0.79 (0.55, 1.11)
Missing	-	- P=0.18
Obese (BMI>=30)		
No	63 (45)	1
Yes	199 (47)	1.09 (0.74, 1.60) P=0.66
Sleep Lab Location		
Campus	114 (48)	1
Satellite Location	148 (46)	0.91 (0.65, 1.27) P=0.58

The effect of technician experience on consenting rates was also analyzed. Technicians were grouped by their years of experience working as sleep technicians (0-7 years, 8-13 years, and ≥14 years) and a weighted average of their success rates was calculated. Table 3 shows that weighted mean success rate increased with technician experience, but was not statistically significant. Figure 3 shows the success rate versus technician acquiring consent, with the size of each circle representing how many participants each of the 15 technicians approached.

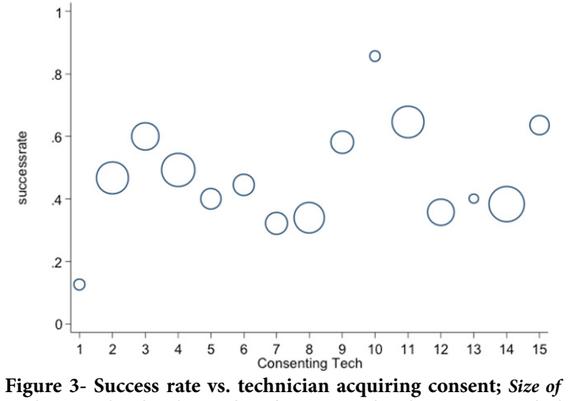

Figure 3- Success rate vs. technician acquiring consent; ***Size of circle is correlated to the number of patients each technician approached for consent.***

Discussion

The aim of this quality improvement study was to examine if younger patients (18-44 years) would be more likely to consent to participate in the SAVE CPAP trial than middle-aged patients (45-64 years) and senior citizens (≥65 years). Whether treated as a categorical or continuous variable, age was not found to be predictive of consent rates. Research studies with larger samples sizes have found a positive or negative correlation between patient ages and consent rates, depending on the study topic, and our cohort may have been too small to demonstrate an effect. Indeed, a post hoc power calculation for our study (assuming an alpha of 0.05 and a beta of 0.95) suggested that a sample size of 1,545 subjects would be needed to detect a 10% effect size of age on consent rate (Faul et al. 2007).

In a UK analysis of seven studies with over 25,000 participants, Dunn et al. found that people 50 years of age or younger were more likely to give consent for review of their medical records (Dunn et al. 2004). The same trend of younger patients being more likely to consent than older patients (<67±15 years compared to 71±14 years) was found in another study that analyzed participation biases in a patient population with myocardial infraction (Gerber et al. 2007). Conversely, Woolf et al. looked at the correlation of age on consent rates for an American survey study involving review of personally identifiable data. Their study found that older patients were more likely to give consent (Woolf et al. 2000). Thus, the overall effect of age on consent rates appears uncertain, but may depend on both the population demographics, as well as the type of study for which the patient is giving consent.

Secondary aims of this study included determining if other factors like education, race, gender, and technician experience were correlated with likeliness to consent. Again, the effects of these factors may have been found to be non-significant due to a small sample population. Many studies have found that decreased consent rates are correlated with females (Dunn et al. 2004, Gerber et al. 2007, Pirzada et al. 2004, Sala et al. 2012, Woolf et al. 2000,), lower socioeconomic status (Boshuizen et al. 2006, Brown et al. 2003), lower education level (Benfante et al. 1989, Pirzada et al. 2004), and race other than white (Brown et al. 2003, Pirzada et al. 2004, Woolf et al. 2000), so it may be inferred that with a larger sample size our study would have obtained similar results.

Each technician had varying success rates, and although not statistically significant, increasing technician experience showed a trend toward predicting increasing consent rates. This may be because technicians who are more experienced in conducting sleep studies may be better equipped to multi-task consenting patients for the SAVE CPAP study, while also ensuring all patients are hooked up for the polysomnogram in a timely fashion. Another possible explanation for the variability among consent rates between technicians may be that a patient's interpretation of the technician's mannerisms and appearance can influence consent, as previously demonstrated by Felson and colleagues (Felsen et al. 2010). One could speculate that technicians with greater experience might be perceived more favorably since they may seem knowledgeable and trustworthy regarding the study. The patient may also pick up on the technician's attitude toward the study. If the technician views the research study as a work burden and does not have the same opinion of the study as the research team, the potential participant may perceive the negative attitude and choose to refuse consent (Sullivan-Bolyai et al. 2007).

Although patients gave varying reasons as to why they did not want to consent, the responses give insight on how to eliminate certain obstacles that impede consent rate. 21% of patients refused consent because they were "not interested in research." More explicit education on how the study could benefit the patient and the scientific community at large may help in this regard. Another 13% of patients refused consent because they "did not want to complete more paperwork." This may be related to the large amount of paperwork that a patient needs to complete for a standard sleep study. A possible solution and area of further research would be to see if patients are capable and willing to complete a portion of the standard pre-sleep study questionnaires prior to arriving in the sleep lab for the overnight study. This would decrease the amount of paperwork to be completed at night and may increase the likelihood that patients consent for participation in SAVE CPAP.

The main limitation of this study is that it was performed retrospectively. Thus, reasons for not consenting were not structured and there were missing consent files for 130 patients that did not consent. Furthermore, our sample size was limited by the total sample size of the trial so far. Another limitation is that although technicians received training on how to consent patients for SAVE CPAP, the consent process was not structured which may account for the differences in consent rates among technicians. Future research includes performing a subgroup analysis of the effect of age within race categories, insurance types, education groups, and genders. In addition, the influence of technician experience on consent rates should be further studied. Most importantly, since this was a quality improvement study, it is necessary to implement and evaluate quality improvement interventions based on lessons learned. This may consist of standardizing consent delivery to eliminate the effect of technician experience, and of changing the timing of paperwork delivery to reduce the patients' tasks the night of the study.

In summary, this study found that there is no statistically significant relationship between age, education level, insurance type, race, and gender on consent rates in the SAVE CPAP trial. Our study identified that standardizing the consent process across technicians, and adjusting paperwork delivery may increase patient satisfaction and participation in the SAVE CPAP trial.

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