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Characteristics of participants consenting versus declining follow-up for up to ten years in a randomized clinical trial

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Abstract

Background—With patients living a decade or longer postprocedure, long-term data are needed to assess the durability of carotid artery stenting versus carotid endarterectomy. Identifying characteristics of those consenting or declining to continue in longterm follow-up may suggest strategies to improve retention in clinical trials.

Purpose—This report describes differences between patients choosing or declining to continue follow-up for up to ten years in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST).

Methods—Following completion of the primary outcome, patients who were in active CREST follow-up were asked to continue beyond their original four-year commitment for a maximum of ten years. The characteristics of those who consented were compared with those who declined. Univariate and multivariable logistic regression were used for analysis, and backwards stepwise logistic regression (the most parsimonious model) was used to determine the factors associated with continuation.

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Results—Of the 1921 active CREST participants for whom consent to extend follow-up was requested, 1695 (88%; mean age 68.4) consented; 226 (12%; mean age 69.6) declined. Of those who did not consent versus those who consented, 66% vs. 48% were symptomatic at baseline (p<0.0001), at follow-up 28% vs. 20% were smokers (p=0.009), 85% vs. 90% were hypertensive (p=0.01) and 84% vs. 94% were dyslipidemic (p<0.0001). Additional factors that differed between those who did not consent and those who consented included the mean number of years in the study at time of consent (4.8 years vs. 3.7 years (p=<0.0001)) and patients from sites that enrolled <30 patients compared to sites randomizing ≥30 or more (70% vs. 52% (p<0.0001). Multivariable logistic regression indicated that those with lesser odds of consenting to the extended follow-up were older (OR 0.80; 95% CI 0.67, 0.96), more likely to be symptomatic (OR 0.58; 95% CI 0.42, 0.80) smokers (OR 0.48; 95% CI 0.34, 0.70), were in the study 5+ years vs. < 3 (OR 0.21; 95% CI0.13, 0.34) and at a site that randomized <30 patients (OR 0.46; 95%, CI 0.33, 0.63), while patients with dyslipidemia at follow-up had increased odds of consenting (OR 2.28 (1.47, 3.54).

Conclusions—Symptomatic status, increasing age, randomized at lower volume centers and longer time in follow-up, were associated with reduced odds of consenting to long-term follow-up. Identifying factors associated with reduced willingness to extend participation long-term can suggest targeted strategies to improve retention in future clinical trials.

Keywords

Randomized clinical trial; retention; patient characteristics; long-term follow-up; carotid endarterectomy; carotid stenting; stroke; elderly participants

Introduction

Retention of participants in randomized clinical trials (RCT) is a recognized challenge that can threaten both the internal and external validity of its results.[1–5] Often, extended follow-up is necessary to compare longer term effects of the treatment groups. A review of 19 government-funded trials transitioning from an average 3–4 years' follow-up to extended follow-up studies found transitioning usually necessitates reconsent and depends upon participants' willingness to continue.[6]

Retention of frail elderly participants can be particularly difficult.[1, 2, 7–9] Poor health and mobility were common problems. Investigators state there is a need to know more about factors impeding participation to design effective retention strategies.[2]

Other studies have identified factors related to participant retention.[7–13] However, these factors can differ. One trial identified characteristics associated with the participation and non-participation of older (65-plus) stroke survivors.[1] Participants were younger, received less help in the home, and had significantly poorer self-reported physical health. Conversely, in four HIV prevention trials, those characteristics (younger age and poorer health) were associated with non-participation.[14] We may thus conclude that reasons for non-participation may be specific to a particular cohort, disease or treatment.[15]

For carotid revascularization, with patients living many years post-procedure, long-term data are needed to assess the durability of stenting versus surgery. Other carotid RCTs have been

able to recruit and retain the elderly,[16, 17] but few have reported results on a large cohort of elderly patients willing to continue participation for up to ten years. Only the Asymptomatic Carotid Surgery Trial (ACST-1) and the International Carotid Stenting Study (ICSS) of symptomatic patients extended follow-up to ten years.[18, 19] However, these studies have not published trial management analyses of patients continuing in follow-up and the role of the clinical sites and study design in promoting retention. Identifying patient characteristics of those choosing or declining long-term follow-up may suggest mechanisms to improve retention in future clinical trials.[7, 8, 15, 20, 21]

Funded by the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS) to assess the safety and efficacy of carotid stenting (CAS) versus endarterectomy (CEA), the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) is a large multicenter RCT in patients with symptomatic and asymptomatic carotid disease.[22] From December 21, 2000 to July 18, 2008, CREST randomized 2502 patients at 117 clinical sites in the United States and Canada.[23] Following completion of the primary outcome, randomized patients who were still in active follow-up were asked to continue beyond their original four-year commitment for a maximum of ten years. In this report, we identify characteristics of CREST participants who did and did not agree to extended long-term follow-up.

Methods

The CREST protocol was approved by the institutional/ethics review boards (IRB/IEC) at all participating sites; all participants provided written informed consent. The study design and primary results have been previously published.[22, 23] CREST was originally designed to include up to four years of patient follow-up; the primary endpoint was any stroke, death, or myocardial infarction up to 30 days and ipsilateral stroke thereafter up to four years. In 2009, the protocol and consents were revised to extend follow-up to a maximum of ten years; the primary endpoint is ipsilateral stroke. Participants were required to provide written informed consent to continue beyond the initial four years of follow-up.

After the clinical site IRB/IECs approved an addendum to the informed consent form which detailed the protocol changes, from February 2009 through May 2014, surviving CREST participants were contacted to complete the consent process for continuation. They were approached at their next scheduled follow-up clinic visit, provided with information about extended follow-up, and asked for consent. If the next scheduled follow-up was a telephone interview, participants were approached via telephone. After an explanation of the changes, if the participant agreed to continue with extended follow-up, the informed consent form was either mailed for signature or signed in-person at the next scheduled clinic appointment. For participants continuing with follow-up through phone interviews only, or unable to return to the clinic because of physical, medical or other limitations, the IRB/IEC approved the use of a verbal consent script, requiring documentation of this in the patient's records.

Additionally, with approval from the IRB/IECs, those who had previously completed the original four years of follow-up were contacted and given the opportunity to reinstate their participation in extended follow-up.

Demographic and clinical characteristics were investigated to compare the characteristics of those who consented with those who declined. Defined in the protocol, symptomatic patients were those with a transient ischemic attack (TIA), amaurosis fugax or non-disabling stroke within 180 days of randomization. Asymptomatic patients had no ipsilateral neurological events within the 180 days preceding randomization. Other variables included sex, age, race, and assigned treatment, as well as the number of years in the study at the time the patient was approached for re-consent (< 3years, 3–4 years, or 5+ years) and the volume of patients enrolled at the randomizing site (<30 patients vs. ≥30 patients). Hypertension, dyslipidemia, diabetes and smoking were updated through January 31, 2010 from the last documented status for each in the primary results dataset.[23] Variables for walking and driving status at one year are from the CREST quality of life assessments.[24]

Univariate logistic regression assessed the association of characteristics with willingness to participate long-term. Backwards stepwise logistic regression was used to determine the factors significantly associated with participation (the most parsimonious model). We included age in the modeling in ten year increments. A sensitivity analysis was conducted, adding variables for walking and driving at one year available from the quality of life sub-study. As this data was missing on 392 subjects (84 refused; 308 consented) for walking status and 416 (83 refused; 333 consented) for driving status, the analysis looking at these factors was limited to this subset of patients and not included in the overall results.

Results

CREST completed enrollment of 2502 patients in July 2008; 1921 (76.8%) completed the consent process for up to ten years' follow-up. The remaining 581 were unreachable for consent (218 deaths, 293 who dropped out of the study prior to the extended consent process, and 70 who officially completed the initial four-year study prior to long-term follow-up). Of the 1921 patients, 1695 (88%) consented to continue up to 10 years; 226 (12%) declined. Demographic and clinical characteristics of those declining and consenting are shown in Table 1. Those refusing to consent were more likely to be symptomatic at baseline (66% vs. 48%; $p<0.01$) and to be smokers at follow up (28% vs. 20%, $p<0.01$) but were less likely to be hypertensive (85% vs. 90%, $p=0.01$) or dyslipidemic (84% vs. 94%; $p<0.0001$). Sites randomizing less than 30 patients had a significantly lower proportion consenting to long-term follow-up than sites randomizing at least 30 patients (70% vs. 52%, $p<0.0001$). Patients who had been in the study longer, more frequently declined to consent compared to those who had been in the study fewer years (mean years in study 4.8 vs. 3.7 $p<0.0001$). Having had a primary endpoint, randomization to CAS versus CEA, age, race, and sex were not significantly associated with willingness to participate.

The results of the univariate and multivariable logistic regression are shown in Table 2. According to the backwards multivariable logistic regression model, the most parsimonious model showed increasing age (OR 0.80; 95% CI 0.67,0.96), symptomatic status (OR 0.58; 95% CI 0.42, 0.80), and smoking (OR 0.48; 95% CI 0.34,0.70), as well as randomized at lower volume enrolling sites (OR 0.46; 95% CI 0.33, 0.63) and longer time in the study at the time of consent (OR 0.43 (0.28, 0.67) 3–4 years vs. < 3 years; OR 0.21 (0.13, 0.34) 5+ years vs. <3 years) were associated with lower odds of agreeing to participate, while having

dyslipidemia at follow-up increased the odds of participating (OR 2.28 (1.47,3.54). The model demonstrated a good fit for the data ($p_{\text{Hosmer and Lemeshow}} = 0.33$). In the subset of patients who had information on walking status and driving status at one year, those who did not consent had significantly lower scores for walking (2.0 vs. 1.7, $p<0.001$) and driving (1.8 vs. 1.4, $P<0.001$) compared to those who consented.

Discussion

Given the prevalence of carotid artery disease in elderly patients, their participation in carotid clinical trials is important in order to generalize results to elderly patients overall.[1, 2, 9, 25, 26] In contrast to several other studies,[1, 2, 7, 13] CREST results indicate that it is possible to retain a large number of elderly patients long-term in a multi-site RCT: 1695 (88%) of active participants with a mean baseline age of 68.4 years consented to be followed for up to ten years (Table 1). Nevertheless, the most parsimonious model (Table 2) showed older patients, symptomatic patients, smokers, as well as patients randomized at lower volume sites and patients who had been in the study longer, had lower odds of agreeing to participate.

Previous studies have associated increased age, poor health and lack of mobility with non-participation.[7, 8, 10–12] We suggest that such patients may have had greater difficulty adhering to protocol visit requirements and infer that mechanisms for retention of such patients be given special early attention in future trials. For example, in the CREST elderly cohort, more than 10% of the patients were unable to drive, and more than 50% had mild or greater difficulty walking at baseline.[24] In the subset of patients who completed the Quality of Life assessment at one year containing walking and driving status, those with lower scores on these two standardized scales were significantly less likely to participate.

Our success in re-consenting the majority of our study participants (88% of those active at the time of re-consent) may be due in part to strategies taken to address patient needs. As in the we with Extremity Constraint Induced Therapy Evaluation (EXCITE) trial, in 2006[27] we provided funds annually for patients' transportation, parking, related costs and, when necessary, the assistance of a caregiver or attendant, for clinic visits. Visits at alternate locations with approved CREST clinical and testing sites were instituted to enable those wintering in warmer climates, moving, or living far from their randomizing sites, to better adhere to their clinic visit schedule. Telephone visits were allowed for those who were homebound and unable to travel. In addition to the CREST website, a patient newsletter with human interest articles about participating patients and scientific summaries of significant trial results was distributed periodically. Respect for patients, their needs, and recognition of significant events (e.g. birthdays) were encouraged with specific suggestions from research coordinators shared at our annual training meetings. These management strategies, also used in other studies,[2, 9, 25, 28] may have contributed to the retention of CREST's aging at-risk population.

Provencher et al.[2] provide a summary of evidence-based strategies to meet consenting and retention challenges that includes financial compensation. While the retention rate for studies using financial incentives can be higher[5] amounts should not be coercive.[3] With

patients volunteering for up to ten years (2000–2014), the CREST IRB of Record and site IRB/IECs approved financial support for final visits and completing the long-term study (2015–2016). During this time period, patients who complete in-person visits and testing receive compensation ($200) for time, transportation, and visit costs. Participants can interact directly with clinical staff, ask questions, and receive information on the latest trial results. Assessing health and long-term effects of the two treatments, inperson visits and testing will benefit patients and the quality of study results, increasing the trial's ability to provide research guidelines for the treatment of carotid disease to the scientific community.

Another significant finding (Table 2) was that, for patients at sites that enrolled less than 30 participants, the odds of consenting to longer follow-up were lower than those at sites with 30 or more patients recruited. One might assume that sites with more patients would have greater difficulty managing and retaining larger numbers of participants; however, this report suggests that those most successful in recruitment may be most successful in other aspects of clinical trial management as well. This agrees with studies[9, 29, 30] that recommend selecting experienced centers with proven track records to maximize participation. Further study of patient management at the high-enrollment clinical sites may identify successful strategies used to promote long-term retention.[29, 30]

Table 2 shows that patients who had been in the study longer had lower odds of agreeing to participate. The Childhood Asthma Management Program (CAMP) trial similarly found a longer time in follow-up increased non-participation.[31] Others have identified study duration with non-participation[25, 32] and advise that trials last the minimum necessary to answer the scientific question. Follow-up in longitudinal studies should be designed to maximize retention of participants at greater risk of dropout.[33]

Interestingly, the multivariable analysis (Table 2) shows those with dyslipidemia had significantly greater odds of participation. This concurs with studies concluding that patients at higher risk may seek the personal attention, frequent visits and medical expertise often offered to trial participants.[2, 26, 27]

A strength of this report is the large number of elderly, in the analysis cohort, contacted for re-consent. Like the Multicenter Uveitis Steroid Treatment (MUST) and Childhood Asthma Management Program (CAMP) prevention and treatment trials[6] CREST investigators were able to design and obtain funding for the follow-up study prior to the end of the trial. As in the Alzheimer's Disease Anti-Inflammatory Prevention Trial (ADAPT), participants were approached before their termination visit to consent to extended follow-up. Active consented participants from the original CREST cohort were followed long-term at their recruiting clinics without interruption. Continuous seamless transition from trial to follow-up study can maximize long-term participation.

Future studies would benefit from focusing, as early as possible, on implementing strategies to retain older patients with multiple risk factors and to increase attention to their needs as the study duration increases. This may be especially true at centers with smaller numbers enrolled into the study.

There are limitations to our analyses. The study was post-hoc and serves primarily as hypothesis generating. In addition, other variables could have influenced the likelihood of consent for long-term follow-up. For example, coordinator turnover, ratio of coordinators to number of participants, and how the subject was contacted and consented---by mail, telephone or at clinic visit---were not systematically collected on case report forms.

Conclusions

Patient characteristics that are routinely collected in clinical trials and that may help target those at greater risk of declining extended follow-up include older age, symptomatic status, and smoking. In addition, patients participating longer in a given trial or patients enrolled at centers with lower patient volume are also at greater risk. Mechanisms to engage such participants and keep them returning for visits are important. Creative strategies in their management may improve long-term retention in clinical trials.

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Table 1

Patient characteristics.

Characteristics	Consented to Long-term Follow-up (N=1695) (%)	Did not Consent (N=226) (%)	Total (N=1921) p-value
Age (mean+SD)	68.4 + 8.3	69.6 + 9.3	0.08
Assigned to CAS	51.5	49.1	0.50
Male	65.9	61.1	0.15
White	94.5	92.9	0.35
Symptomatic	48.3	65.5	<0.0001
Hypertension at Follow-up[a]	90.3	84.6	0.01
Dyslipidemia at Follow-up[a]	94.0	84.3	<0.0001
Diabetes at Follow-up[a]	31.3	36.3	0.13
Smoker at Follow-up[a]	20.2	27.8	0.009
Walking status at 1 year[*] **(mean±SD)**	1.7±0.9	2.0±1.1	<0.001
Driving status at 1 year (mean±SD)[**]	1.4±1.1	1.8±1.5	<0.001
Had a stroke endpoint (any stroke within periprocedural period or any ipsilateral stroke out to 4 years)	4.3	5.8	0.32
Smaller randomizing site (<30 patients randomized)	52.3	69.5	<0.0001
Years in study at time of consent(mean±SD)	3.7±1.4	4.8±1.6	<0.0001
Years in study by category			<0.001
< 3years	31.5	12.4	
3–4 years	52.5	47.5	
5+ years	16.1	40.3	

SD: standard deviation; CAS: carotid artery stenting;

[*] missing on 392 (84 refused; 308 consented)

[**] missing on 416 (83 refused; 333 consented)

[a] risk factor status at last time point during the period up until January 31, 2010 (frozen dataset) when question was answered either on telephone contact or clinic visit.

Table 2

Logistic regression results: likelihood of agreeing to participate long-term.

Characteristics	Univariate Logistic Regression OR (95% CI)	Most Parsimonious Model Backwards Multivariable Logistic Regression OR (95% CI)
Age per 10 years	0.85 (0.72,1.002)	0.80 (0.67,0.96)
Assigned to CAS vs. CEA	1.10 (0.83,1.45)	
Male	1.23 (0.93,1.64)	
White	1.30 (0.75,2.25)	
Symptomatic	0.49 (0.37,0.66)	0.58 (0.42,0.80)
Hypertension at follow-up[a]	1.68 (1.13,2.51)	
Dyslipidemic at follow-up[a]	2.90 (1.92,4.39)	2.28 (1.47,3.54)
Diabetes at follow-up[a]	0.80 (0.60,1.07)	
Smoker at follow-up[a]	0.66 (0.48,0.90)	0.48 (0.34,0.70)
Stroke endpoint (any stroke, within periprocedural period or any ipsilateral stroke out to 4 years)	0.74 (0.40,1.35)	
# of Patients Randomized at Site (<30 vs. 30+)	0.48 (0.36,0.65)	0.46 (0.33,0.63)
Years in study at time of consent		
< 3 years	**Reference**	**Reference**
3–4 years	0.44 (0.28, 0.67)	0.43 (0.28, 0.67)
5+ years	0.16 (0.10, 0.25)	0.21 (0.13, 0.34)

OR: odds ratio; CI: confidence interval; CAS: carotid artery stenting;

CEA: carotid endarterectomy; MI: myocardial infarction

[a]Last information available prior to January 31, 2010 as reported in NEJM