CHARACTERISTICS OF PARTICIPANTS AGREEING TO LONG-TERM (UP TO TEN YEARS) FOLLOW-UP IN A LARGE RANDOMIZED CLINICAL TRIAL

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For the CREST Investigators

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for the CREST Investigators

CHARACTERISTICS OF PARTICIPANTS AGREEING TO LONG-TERM (≤ 10 YEARS) FOLLOW-UP IN A LARGE RANDOMIZED CLINICAL TRIAL

- Retention in clinical trials -- a CHALLENGE!
- Long term data needed to assess durability of carotid revascularization
- Patients live a decade or longer post-procedures
- Identifying patient and site characteristics of those re-consenting and refusing long term follow-up may improve retention in long term studies

CHARACTERISTICS OF PARTICIPANTS AGREEING TO LONG-TERM (≤ 10 YEARS) FOLLOW-UP IN A LARGE RANDOMIZED CLINICAL TRIAL

CREST = CAS vs CEA

117 sites in US & Canada

- **2000: Randomization**
- **2008: 2502 Enrollment achieved**
- **2009: Protocol and consents for up to 10 years follow-up sent to sites**
- **2016: End of Follow-up (≤ 10 Years)**

Methods

- Characteristics of 1869 (75%) surviving active participants and their sites were investigated to compare the characteristics of those who consented long-term (5 - 10 years) with those who refused.
- Patients who were alive and had not withdrawn from the study were considered eligible.
- Eligible patients were grouped by whether they had or had not agreed/consented to participate in long-term follow-up

Methods

- Univariate and multivariable logistic regression were used to look at baseline demographic and clinical characteristics associated with willingness to participate
- Backwards logistic regression was used to determine the factors significantly associated with participation (most parsimonious model)

Baseline Patient Characteristics

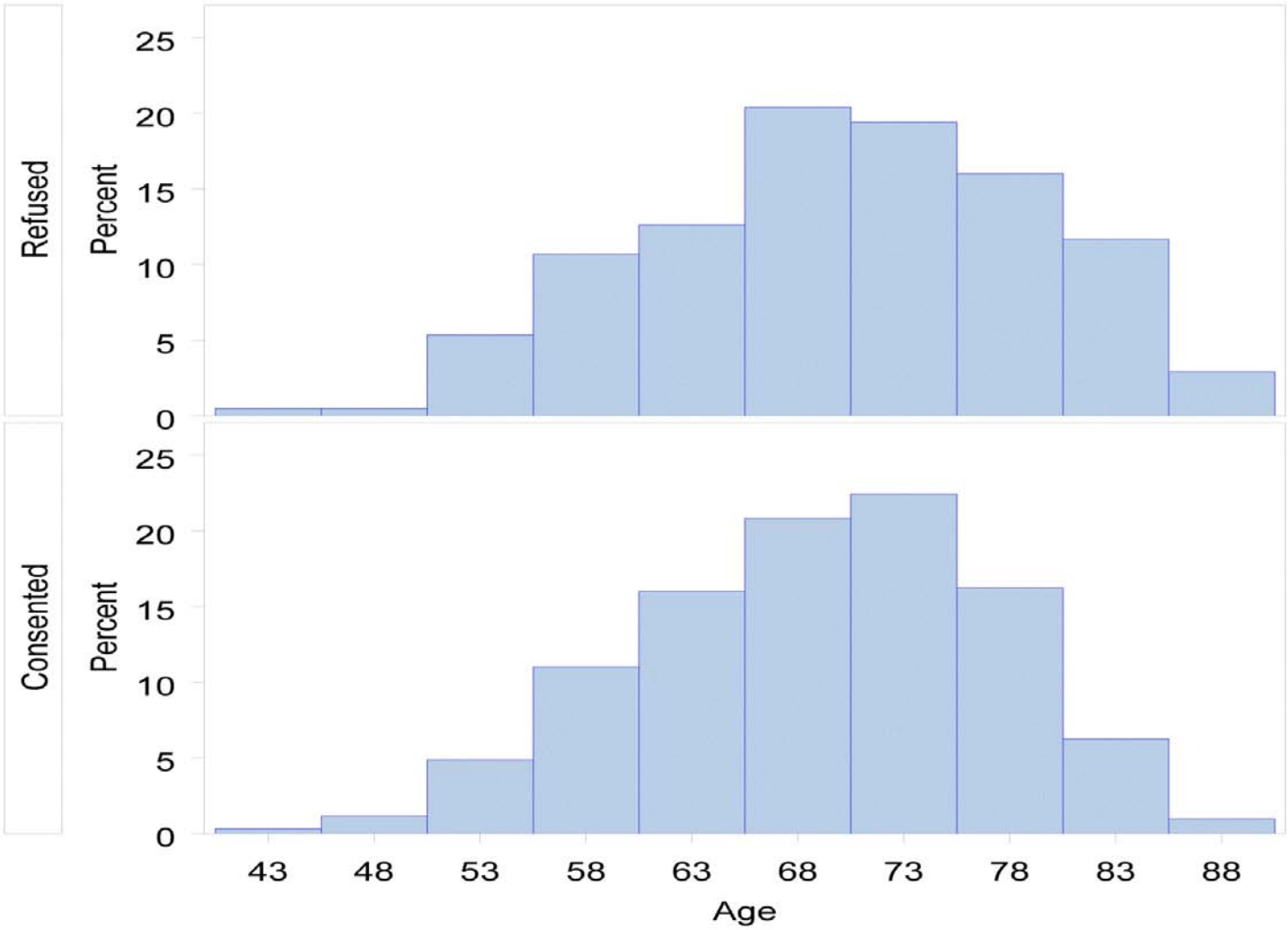
	Consented to Long-term Follow-up (n=1663) (%)	Did not Consent (n=206) (%)	p-value
Age (mean+SD)	68.4 + 8.4	69.8 + 9.2	**0.048**
Assigned to CAS	51.4	49	0.55
Female	34	39.3	0.13
White	94.6	92.2	0.17
Symptomatic	48.5	65.1	**<0.0001**
Hypertension	84.8	87.3	0.34
Dyslipidemia	86.7	81	**0.03**
Diabetes	29.1	36.6	**0.03**
Current smoker	24.7	35	**0.02**
History of CVD or CABG	43.6	44.2	0.87
Severe Stenosis ≥70%	86.4	82.5	0.14
Larger randomizing site (30+ patients randomized)	61.3	46.6	**<0.0001**

Logistic Regression Results
Likelihood of Agreeing to Participate

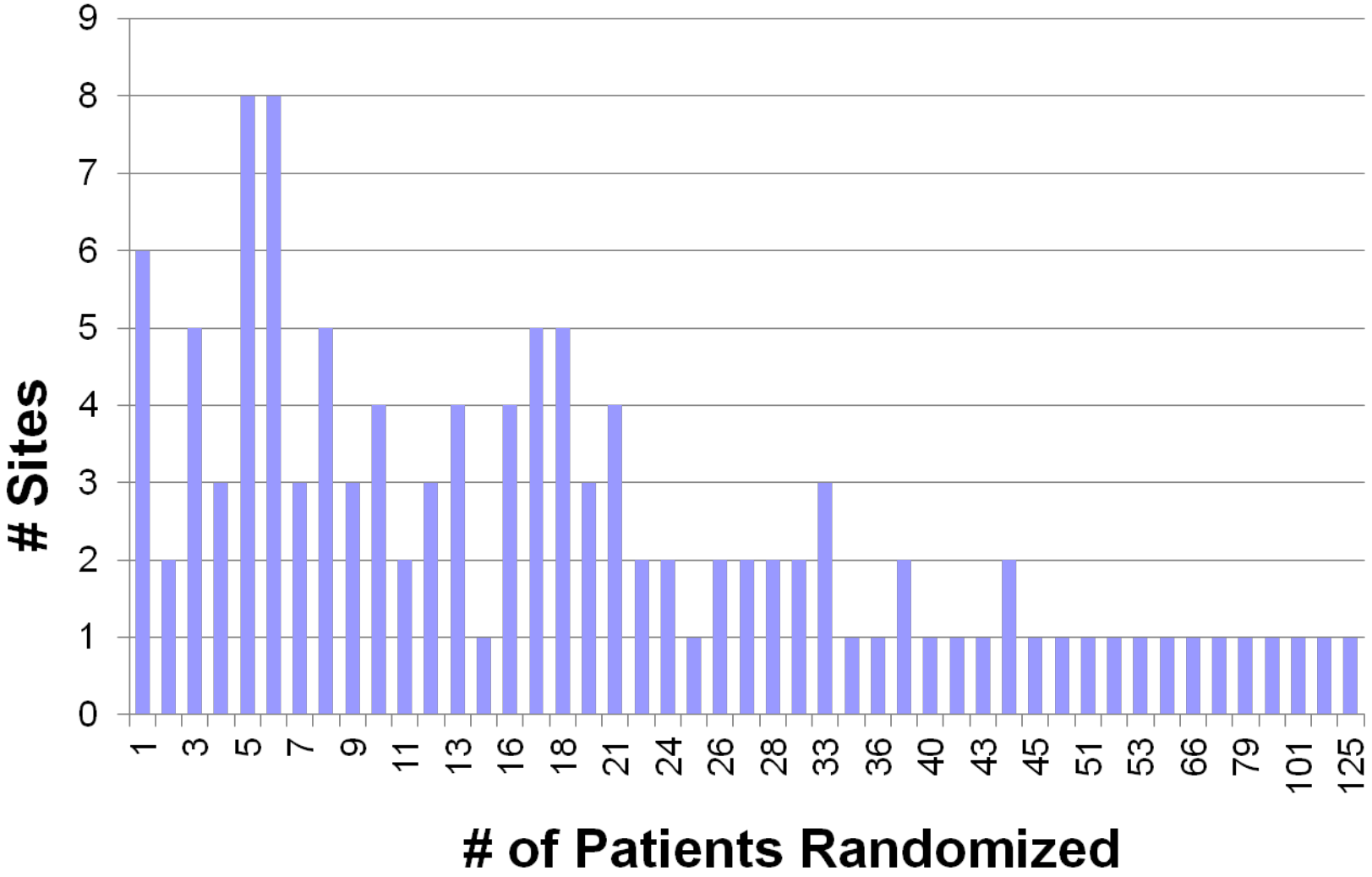
	Univariate Logistic Regression OR (95% CI)	Multivariable * Logistic Regression OR (95% CI)
Age per 10 years	**0.83 (0.69,0.98)**	**0.73 (0.60,0.88)**
Assigned to CAS vs CEA	1.10 (0.82,1.47)	
Female	0.80 (0.59,1.07)	
White	1.47 (0.85,2.56)	
Asymptomatic	**1.97 (1.46,2.67)**	**2.06 (1.51,2.83)**
No Hypertension	1.24 (0.80,1.90)	
No Dyslipidemia	**0.65 (0.45,0.95)**	
No Diabetes	**1.41 (1.04,1.91)**	**1.55 (1.12,2.14)**
Non smoker	**1.64 (1.21,2.24)**	**2.14 (1.50,3.03)**
No History of CVD or CABG	1.03 (0.76,1.38)	
No Severe Stenosis ≥70%	0.75 (0.51,1.10)	
# of Patients Randomized (30+ vs <30)	**1.81 (1.36,2.43)**	**1.92 (1.42,2.61)**

*** Most Parsimonious Model**

Age Distribution by Consent Status



Volume of Randomizations



Results

Of 1869 surviving active subjects,

1663 (89%) consented to continue up to 10 years

206 (11%) refused

There was no significant difference by sex in willingness to participate long term.

Univariate Results

- Factors associated with willingness to Participate
  - Age – for every 10 year increase in age, older patients were 85% less likely to participate
  - Symptomatic status – asymptomatic patients were 97% more likely to participate than symptomatic patients
  - Diabetes – those without diabetes were 41% more likely to participate than those with diabetes
  - Smoking – non smokers were 64% more likely to participate than current smokers
  - Dyslipidemia – patients who did not have high cholesterol were less likely to participate than those with high cholesterol
  - Number of patients randomized – patients randomized at sites with >30 patients were 81% more likely to participate than patients at sites with <30 patients

Multivariable Results
Most Parsimonious Model

- Multivariable factors associated with willingness to participate:
  - Younger age
  - Asymptomatic status
  - Not having diabetes
  - Non smoker
  - Having been randomized at a site that randomized >30 patients

Multivariable Results
Most Parsimonious Model

- Characteristics associated with unwillingness to participate:
  - Older
  - Symptomatic
  - Diabetic
  - Smoker
  - Randomized at a site that enrolled <30 patients

CONCLUSIONS

- Higher volume centers, younger patient age, asymptomatic status and lower levels of risk factors for atherosclerosis were associated with ongoing participation in CREST.
- Knowledge of higher volume centers' patient management techniques may improve retention in long term studies.
- Creative strategies in the management of elderly and sick participants may improve long term retention in clinical trials.