

Racial Variation in Treatment Preferences and Willingness to Randomize in the Spine Patient Outcomes Research Trial (SPORT)

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Study Design. Analysis of baseline data for patients enrolled in Spine Patient Outcomes Research Trial (SPORT), a project conducting three randomized and three observational cohort studies of surgical and nonoperative treatments for intervertebral disc herniation (IDH), spinal stenosis (SpS), and degenerative spondylolisthesis (DS).

Objective. To explore racial variation in treatment preferences and willingness to be randomized.

Summary of Background Data. Increasing minority participation in research has been a priority at the NIH. Prior studies have documented lower rates of participation in research and preferences for invasive treatment among African-Americans.

Methods. Patients enrolled in SPORT (March 2000 to February 2005) that reported data on their race ($n = 2,323$) were classified as White (87%), Black (8%), or Other (5%). Treatment preferences (nonoperative, unsure, surgical), and willingness to be randomized were compared among these groups while controlling for baseline differences using multivariate logistic regression.

Results. There were numerous significant differences in baseline characteristics among the racial groups. Following adjustment for these differences, Blacks remained less likely to prefer surgical treatment among both IDH (White, 55%; Black, 37%; Other, 55%, $P = 0.023$) and SpS/DS (White, 46%; Black, 30%; Other, 43%; $P = 0.017$) patients. Higher randomization rates among Black IDH patients (46% vs. 30%) were no longer significant following adjustment (odds ratio [OR] = 1.45, $P = 0.235$). Treatment preference remained a strong independent predictor of randomization in multivariate analyses for both IDH (unsure OR = 3.88, $P < 0.001$ and surgical OR = 0.23, $P < 0.001$) and SpS/DS (unsure OR = 6.93, $P < 0.001$ and surgical OR = 0.45, $P < 0.001$) patients.

Conclusions. Similar to prior studies, Black participants were less likely than Whites or Others to prefer surgical treatment; however, they were no less likely to agree to be randomized. Treatment preferences were strongly related to both race and willingness to be randomized.

Key words: spinal stenosis, degenerative spondylolisthesis, intervertebral disc herniation, treatment preference, willingness to be randomized, racial variation, surgical treatment, clinical trial. **Spine 2006;31:2263–2269**

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This study is dedicated to the memory of Brianna Weinstein.

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Ten years ago, legislation was passed that mandated the inclusion of women and minorities in NIH-funded biomedical and behavioral research with human subjects.¹ For Phase III clinical trials, women and minorities are supposed to be enrolled in adequate numbers to ensure valid analyses of differences in intervention effects.¹ Few studies are able to fulfill this mandate, and concerns have been raised that the NIH policy may be ineffective or even that it may be doing more harm than good.²

Recruiting large numbers of minorities into research studies is complicated because these groups by definition comprise a minority of the population. In addition, lower rates of willingness to participate in medical research studies among minority groups have been reported.^{3,4} Some possible reasons underlying these differences include: distrust of medical research due to the history of racially biased/unethical studies^{3,5–7}; the belief that racial minorities have borne a disproportionate share of the burden for testing new treatments; preferences to-

ward risk^{4,5}; perceptions of traditional and alternative treatment methods⁴; and socioeconomic barriers to participation.⁶⁻¹³

The Spine Patient Outcomes Research Trial (SPORT) is an NIH-funded study that is being conducted at 11 clinical centers around the United States. It involves the simultaneous conduct of three randomized clinical trials comparing surgical and nonoperative treatments for patients with intervertebral disc herniation (IDH), spinal stenosis (SpS), or degenerative spondylolisthesis (DS). Patients who meet the eligibility criteria but decline to be randomized are invited to participate in a parallel observational cohort study. Details of the design of the project, including recruitment, eligibility criteria, treatment, and follow-up procedures have been published previously.¹⁴ In this study, we used data collected from SPORT participants at baseline to explore racial variation in treatment preferences and willingness to be randomized.

■ Materials and Methods

Patient Population. This analysis includes a total of 2,323 subjects that were enrolled in SPORT between March 2, 2000 and February 28, 2005 and who provided data regarding their race/ethnic background. Other baseline characteristics that we examined in this analysis include: age; sex; body mass index (BMI); education; income; work/legal status; smoking history; comorbidity; back-related symptoms (*frequency* or how often the symptom recurs; *duration* or length of time the symptom persists once it begins; and *bothersomeness* or troublesomeness of the pain); Oswestry Disability Index (ODI) score; Health Utilities Index (HUI) score; and physical (PCS) and mental (MCS) component summary scores for the SF-36.

Race/Ethnic Categories. Patient race/ethnic background is self-recorded at baseline using categories as specified in the NIH guidelines on inclusion of women and minorities in clinical research.¹ These categories include two ethnic categories and six race categories. Because of small numbers of patients in some of the race/ethnic categories, we grouped patients into the following three categories for this analysis: White (White race/not Hispanic or Latino ethnicity), Black (Black/African American race/not Hispanic or Latino ethnicity), and Other (American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, more than one race/Hispanic or Latino ethnicity). Data on the racial composition of the SPORT site hospital referral regions were obtained from *The Dartmouth Atlas of Health Care*.¹⁵ Data on the racial composition of the U.S. population were obtained from the U.S. Census.¹⁶

Treatment Preferences. SPORT participants are asked about their current treatment preferences (definitely nonoperative, probably nonoperative, not sure, probably surgery, definitely surgery) at baseline. For the purposes of this analysis, we grouped the “definitely” and “probably” response categories to form three treatment preference groups (nonoperative, unsure, and surgical). In addition, participants are asked what factors most influence their treatment preferences. Response categories include:

How my personal physician thinks my spine-related problem should be treated;

How my family thinks my spine-related problem should be treated;

The advice or experience of friends;

My ability to work or go about my usual daily activities;

My ability to participate in and enjoy my usual leisure activities;

Not wanting to be a burden to my family;

Worries about money;

Concerns about the potential risks of surgery;

Worries about potential side effects or risks of addiction with pain medications;

Nonoperative treatment has not been effective for me;

Other.

Willingness to be Randomized. Willingness to be randomized is assessed by the subject’s actual decision to participate in the randomized trial as opposed to the observational cohorts. This decision is made following an informed consent process, which included discussions about: the purpose of the study; any potential benefit from the study; what type of treatment and length of time the study involves; risks associated; patient confidentiality; data collection; withdrawal from the study; patient access to research records; number of participants; contact person; cost of the study; enrollment incentive; and liability of research-related injury or illness. Before being asked to agree to participate, patients are asked to review one of two SPORT shared decision-making videos^{14,17,18} that discuss the possible outcome of surgery and nonoperative treatment of back pain. The SPORT Nurse Coordinator reviews the informed consent with the patient before he/she signs it.

Statistical Analysis. Demographic and health status characteristics were summarized using proportions for categorical variables and medians with interquartile ranges for continuous variables. Unadjusted comparisons were made between racial categories using χ^2 tests for categorical variables and Kruskal-Wallis rank tests for continuous variables.

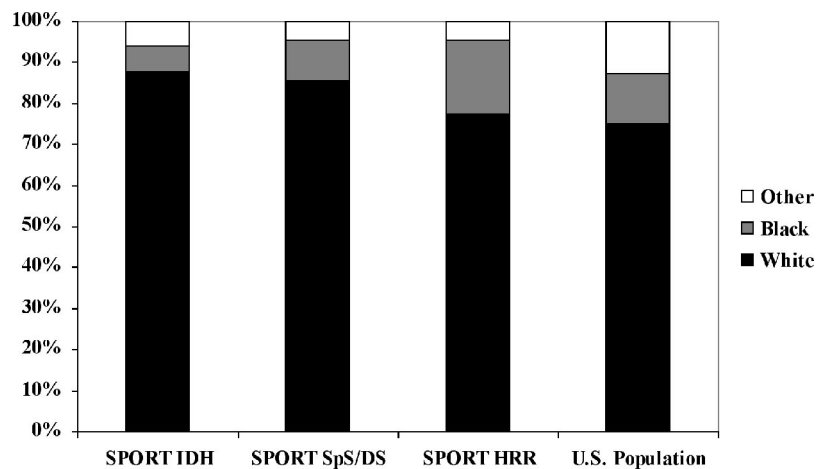
Adjusted analyses for comparing rates of participation in the RCT *versus* the observational cohort, treatment preferences, and factors that influence treatment preferences among racial groups were performed using multiple logistic regression for binary or polytomous categorical data.¹⁹ Variables identified from the initial analyses of the demographic factors were included as covariates in the multiple regression. Logistic regression parameter estimates and covariance matrices for the logistic regression parameters were used to test the global hypothesis of no difference between the odds or cumulative odds associated with the racial categories. Pairwise tests were performed to compare the White category to the Black and Other categories.

■ Results

Racial/Ethnic Composition of the SPORT Population

The SPORT population includes 2011 (86.5%) Whites, 182 (7.8%) Blacks, and 130 (5.6%) Others (50 Hispanic/Latino, 11 American Indian/Alaska Native, 25 Asian, 6 Native Hawaiian/Pacific Islander, 38 More Than One Race). The SPORT population (Figure 1) has a smaller proportion of Blacks (6.13% IDH/9.57% SpS/DS) compared with that of the Hospital Referral Regions (HRRs)

Figure 1. Racial/ethnic composition of the SPORT population compared to the hospital referral region (HRR) population and U.S. population overall (Pearson $2(2) = 8.2898$; $Pr = 0.016$). Racial composition of the 10 HRRs from which SPORT patients are drawn weighted according to site-specific enrollment rates. Adapted from the U.S. Census.



from which SPORT patients are drawn (17.8%) or the U.S. population as a whole (12.3%). The proportion of patients in the Other category (6.13% IDH/5.13% SpS/DS) is slightly higher than that of the hospital referral population (4.7%) but considerably lower than that of the U.S. population as a whole (12.6%).

Characteristics at Baseline

The demographic and medical history characteristics of the SPORT population are compared among the three racial groups in Table 1. Age, sex, BMI, education, income, marital status, and work/legal status were significantly associated with racial group. Mean age was lower ($P = 0.014$) for Others (49 years) compared with Whites and Blacks (both 54 years). A lesser proportion of Blacks were male (36.8%) than were Whites (52.8%) and Others (51.5%, $P < 0.001$). Median BMI was higher ($P < 0.001$) among Blacks (28.8) and Others (27.4) than among Whites (26.8). Blacks were less likely to have a college or graduate degree (Black: 60.2%, White: 70.6%, Other: 70.0%, $P = 0.014$), more likely to have no job (Black: 40.7%, White: 34.5%, Other: 34.6%), and more likely to earn less than \$20,000 per year if they did have a job than Whites and Others (Black: 24.2%, White: 16.2%, Other: 13.8%, $P < 0.001$). Black subjects were more likely ($P < 0.001$) to report having hypertension (51.1%) compared with Whites (28.8%) and Others (24.6%) and were more likely ($P < 0.001$) to report having diabetes (17.0%) than Whites (8.2%) or Others (10.0%). Blacks were also more likely ($P = 0.01$) to have joint problems (46.2%) than Whites (36.6%) and Others (34.6%). Other subjects were more likely ($P = 0.024$) to report stomach problems (25.4%) than either Whites (16.6%) or Blacks (19.8%).

Diagnosis and quality of life characteristics are compared among the racial groups in Table 1. There were significant differences in diagnosis among the racial/ethnic categories, with 50.8% of Whites diagnosed with IDH, 25.5% with SpS, and 23.8% with DS compared with 39.0% IDH, 29.1% SpS, 31.9% DS for Blacks, and 54.6% IDH, 27.7% SpS, 17.7% DS for Others ($P = 0.011$). Back symptoms were less bothersome ($P =$

0.001) and less frequent ($P < 0.001$) among White subjects compared with Blacks and Others. Whites had higher median SF-36 physical ($P = 0.001$) and mental ($P = 0.001$) component summary scores and lower median ODI scores ($P = 0.016$) than Blacks or Others. (Note: The lower score on ODI indicates less disability, whereas a higher score on the SF-36 means less pain, less mental distress, *etc.*)

Having a Workers' Compensation claim, time since quitting smoking, history of stroke, osteoporosis, cancer, fibromyalgia, migraine headaches, chronic fatigue syndrome, depression, anxiety/panic disorder, PTSD, alcoholism, drug dependency, heart problems, lung problems, stomach problems, bowel/intestinal problems, liver problems, kidney problems, blood vessel problems, nervous system problems, and duration of low back/leg pain were not significantly associated with racial groups.

Univariate Analyses

In univariate analyses (Table 2), treatment preferences varied significantly among the racial groups overall ($P = 0.008$). Blacks were less likely to prefer surgical treatment (33.0%) compared with Whites (46.6%) and Others (43.8%). These relationships persisted within each of the diagnosis groups but were less statistically significant. Overall, Others were the group most willing to be randomized (47.7%) compared with Whites (42.9%) and Blacks (45.1%), but this difference was not statistically significant ($P = 0.50$). Among patients diagnosed with SpS/DS, Others were the group most willing to be randomized (54.2%) compared with Whites (46.6%) and Blacks (42.3%), while among patients diagnosed with IDH, Black subjects were more willing to be randomized (49.3%) than Whites (39.3%) or Others (42.3%). None of these differences reached statistical significance.

Multivariate Analyses

Treatment preferences adjusted for baseline differences are compared among the racial groups. Black subjects were less likely than Whites or Others to prefer surgical treatment among both IDH (White = 51.0%, Black =

Table 1. Patient Characteristics by Racial Group

Characteristic	White (N = 2011)	Black (N = 182)	Other (N = 130)	P
Demographics				
Age (yr)	54.0 (40.0, 68.0)	54.0 (43.0, 65.0)	49.0 (36.0, 61.0)	0.014
Sex (male)	1062 (52.8%)	67 (36.8%)	67 (51.5%)	<0.001
BMI	26.8 (23.7, 30.4)	28.8 (25.6, 33.1)	27.4 (24.0, 29.8)	<0.001
Education				
Less than high school	590 (29.4%)	72 (39.8%)	39 (30.0%)	0.014
Some college	1419 (70.6%)	109 (60.2%)	91 (70.0%)	
Marital status				
Married/living with significant other	1444 (71.8%)	95 (52.2%)	84 (64.6%)	<0.001
Divorced	181 (9.0%)	37 (20.3%)	20 (15.4%)	
Widowed	163 (8.1%)	22 (12.1%)	5 (3.8%)	
Single	223 (11.1%)	28 (15.4%)	21 (16.2%)	
Personal income				
No job	693 (34.5%)	74 (40.7%)	45 (34.6%)	<0.001
<\$20,000/yr	325 (16.2%)	44 (24.2%)	18 (13.8%)	
\$20,000–49,999/yr	458 (22.8%)	38 (20.9%)	43 (33.1%)	
≥\$50,000/yr	535 (26.6%)	26 (14.3%)	24 (18.5%)	
Work/legal status				
Legal case	71 (3.5%)	20 (11.0%)	22 (16.9%)	<0.001
Medical history				
Smoking status				
Yes	332 (16.5%)	41 (22.5%)	21 (16.2%)	0.067
Not now, but in past	724 (36.0%)	62 (34.1%)	36 (27.7%)	
Never smoked	955 (47.5%)	79 (43.4%)	73 (56.2%)	
Comorbidity				
Hypertension	579 (28.8%)	93 (51.1%)	32 (24.6%)	<0.001
Diabetes	164 (8.2%)	31 (17.0%)	13 (10.0%)	<0.001
Stomach problem	333 (16.6%)	36 (19.8%)	33 (25.4%)	0.024
Joint problem	736 (36.6%)	84 (46.2%)	45 (34.6%)	0.031
Back-related				
Diagnosis				
DS	478 (23.8%)	58 (31.9%)	23 (17.7%)	0.011
IDH	1021 (50.8%)	71 (39.0%)	71 (54.6%)	
SPS	512 (25.5%)	53 (29.1%)	36 (27.7%)	
Duration				
6 wk or less	161 (8.0%)	10 (5.5%)	7 (5.4%)	0.35
7–12 wk	290 (14.4%)	17 (9.3%)	19 (14.6%)	
3–6 mo	758 (37.7%)	74 (40.7%)	54 (41.5%)	
7–12 mo	374 (18.6%)	43 (23.6%)	21 (16.2%)	
1–2 yr	224 (11.1%)	16 (8.8%)	17 (13.1%)	
2–3 yr	95 (4.7%)	7 (3.8%)	6 (4.6%)	
3 yr+	109 (5.4%)	15 (8.2%)	6 (4.6%)	
Health-related quality of life				
Bothersomeness	19.0 (14.0, 24.0)	19.0 (15.0, 25.0)	22.0 (15.0, 26.0)	0.001
Frequency	19.0 (14.0, 24.0)	20.0 (15.0, 25.0)	22.0 (16.0, 27.0)	<0.001
ODI	44.0 (31.0, 60.0)	49.0 (35.0, 64.0)	49.0 (33.0, 65.0)	0.016
SF-36				
Physical component summary	29.3 (24.1, 35.2)	27.2 (22.5, 32.5)	27.9 (23.9, 33.8)	<0.001
Mental component summary	49.1 (38.6, 57.2)	45.7 (36.8, 55.8)	43.2 (34.8, 54.1)	0.001

35.2%, Other = 47.9%), and SpS/DS (White = 42.1%, Black = 31.5%, Other = 39.0%) patients (Table 2). We also examined factors that influenced treatment preferences within diagnosis among the racial groups. In adjusted analyses (not shown), significant differences between the racial groups were observed for the following factors: among the IDH patients, ability to enjoy usual leisure activities (White = 48.0%, Black = 33.6%, Other = 36.2%, $P = 0.027$); worries about money (White = 6.6%, Black = 13.2%, Other = 1.4%, $P = 0.007$); and risks of surgery (White = 23.4%, Black = 33.1%, Other = 39.0%, $P = 0.010$). For SpS/DS patients, advice or experience of friends (White = 5.2%, Black = 12.7%, Other = 10.5%, $P = 0.047$); ability to work (White = 72.2%, Black = 60.5%, Other = 62.6%,

$P = 0.035$); ability to enjoy usual leisure activities (White = 53.9%, Black = 41.6%, Other = 31.4%, $P = 0.007$); risk of surgery (White = 29.1%, Black = 41.7%, Other = 37.3%, $P = 0.034$); and nonoperative treatment being ineffective (White = 25.9%, Black = 15.6%, Other = 21.1%, $P = 0.058$) varied significantly among the racial groups.

Willingness to be Randomized

The results of multivariate analyses designed to assess the independent effects of race and treatment preference on willingness to be randomized while controlling for baseline differences among the race groups is shown in Table 3. In this analysis, race was no longer a significant predictor of willingness to randomize in either IDH

Table 2. Univariate Analysis of Treatment Preferences and Willingness to be Randomized Rates by Diagnosis and Racial Group

Outcome	Racial Group			P
	White (%)	Black (%)	Other (%)	
Willingness to be randomized (% yes)				
Overall	42.9	45.1	47.7	0.50
IDH	39.3	49.3	42.3	0.23
SpS/DS	46.6	42.3	54.2	0.33
Treatment preference (% yes)				
Overall				0.008
Nonoperative	34.7	45.1	33.8	
Unsure	18.7	22.0	22.3	
Surgical	46.6	33.0	43.8	
IDH				0.080
Nonoperative	32.6	46.5	31.0	
Unsure	16.4	18.3	21.1	
Surgical	51.0	35.2	47.9	
SpS/DS				0.30
Nonoperative	36.8	44.1	37.3	
Unsure	21.1	24.3	23.7	
Surgical	42.1	31.5	39.0	

(OR = 1.13 for Blacks compared with Whites, $P = 0.66$; OR = 1.02 for Others, $P = 0.95$) or SpS/DS (OR = 0.71 for Blacks, $P = 0.16$; OR = 1.44 for Others, $P = 0.24$) patients. Treatment preference remained a significant, strong predictor of willingness to randomize in both diagnostic groups. Compared with patients with a baseline preference for nonoperative treatment, those who were unsure were much more likely (odds ratio [OR] = 3.60 for IDH, $P < 0.001$; OR = 5.31 for SpS/DS, $P < 0.001$) to agree to be randomized. Those who preferred surgical

Table 3. Willingness to be Randomized (Adjusted Odds Ratios) by Racial Group and Treatment Preference at Baseline

Diagnosis	Odds Ratio	95% Confidence Interval	P
IDH			
Racial group			
White	Reference		
Black	1.13	0.64–2.00	0.66
Other	1.02	0.58–1.80	0.95
Treatment preference			
Nonoperative	Reference		
Unsure	3.60	2.39–5.42	<0.001
Surgery	0.25	0.18–0.34	<0.001
SpS/DS			
Racial group			
White	Reference		
Black	0.71	0.45–1.14	0.16
Other	1.44	0.79–2.63	0.24
Treatment preference			
Nonoperative	Reference		
Unsure	5.31	3.62–7.80	<0.001
Surgery	0.40	0.29–0.54	<0.001

Model-based estimates are adjusted for: age, gender, BMI, education, income, marital status, legal status, smoking, hypertension, diabetes, stomach problems, joint problems, episode duration, bothersomeness, frequency, ODI, SF-36 PCS, and SF-36 MCS. (These are all variables significant at $P < 0.1$ in the univariate analyses for the overall study population.) The same set of predictors was used for both IDH and SpS/DS analyses.

treatment were much less likely (OR = 0.25 for IDH, $P < 0.001$; OR = 0.40 for SpS/DS, $P < 0.001$) to agree to be randomized compared with those who preferred nonoperative treatment.

Discussion

The recruitment of minorities into SPORT has been a priority throughout the design and conduct of the project. SPORT clinical sites were selected from a range of geographic locations with a mix of urban, suburban, and rural populations in order to provide a racially/ethnically diverse patient population. In addition, the SPORT protocol requires that all subjects who are eligible for the study be invited to participate regardless of race/ethnic background. Targeted advertisement of the trial was also undertaken on a local level to try to ensure adequate minority enrollment. Despite these efforts, minority groups are underrepresented in SPORT as they have been in many prior clinical trials.^{20–23}

The relative lack of racial/ethnic diversity in the SPORT population may be at least partially attributable to the epidemiology of the conditions that are under investigation. For example, a number of studies have indicated a lower prevalence of low back pain among Blacks compared to Whites.^{24,25} On the other hand, it has been reported that DS occurs more frequently in Blacks than in non-Hispanic Whites.²⁶

Similar to our findings, patient preferences for invasive procedures have been shown to vary according to race for many different medical conditions. Specifically, African-American Blacks have been shown to be less likely than non-Hispanic Whites to prefer invasive treatments for cardiovascular disease,^{27–29} cerebrovascular disease,³⁰ osteoarthritis,^{4,31} and end-stage renal disease.³² Few studies have explicitly investigated the origins of these differences. Some possible explanations include racial differences in how the risks and benefits of invasive treatment are perceived, in predilections for alternative/self-care, and in socioeconomic status/access to health care.^{32,33}

Low rates of minority participation have been documented in clinical trials for numerous conditions such as cardiovascular/cerebrovascular disease,¹¹ cancer,³⁴ and HIV/AIDS.^{35,36} A number of studies have focused on the deleterious effects of prior unethical research studies on rates of minority participation in research. Ironically, the purpose of the informed consent process, which was created to protect the rights and welfare of human subjects, has been reported to discourage minority participation in research. Researchers have found that minorities frequently misinterpret informed consent language as liability protection for the researchers.^{37,38} Other barriers to minority participation in research that have been identified in prior studies and which may contribute to the lack of racial diversity in SPORT include a lack of awareness about clinical trials due to the ineffectiveness/paucity of outreach efforts, socioeconomic/access barriers, and language/cultural issues.¹¹ To their credit, some

investigators made attempts to achieve higher minority enrollment through very localized efforts.

In contrast to the findings of prior studies, Black SPORT participants were not less likely than Whites or Others to agree to be randomized. Indeed, among IDH patients, Blacks showed a trend toward being more willing to be randomized than the other race groups. This effect may have been mediated through treatment preferences. In our study, treatment preferences at baseline were strongly predictive of willingness to randomize. Not surprisingly, patients whose preference was unsure were more likely than those whose preference was non-operative treatment to agree to be randomized. On the other hand, patients whose treatment preference was for surgery were much less likely than those preferring non-operative treatment to agree to be randomized.

One of the strengths of our study is the inclusion of both randomized and observational arms for each of the three diagnoses under investigation in SPORT. Unfortunately, we do not have information about the racial composition of the patients who refused to participate or about perceived discrimination by participants. The racial concordance between research coordinators and subject, subjects' trust in the healthcare system, and their understanding of the consent process was not measured; therefore, the potential influence of these factors on enrollment could not be assessed; this is a limitation of the study.

The results of this study add to the evidence regarding racial differences in treatment preferences. Black participants in SPORT were much less likely to prefer surgical treatment for their back pain. However, in contrast to prior studies, Black participants in SPORT were no less likely than Whites or Others to agree to be randomized. Treatment preferences were strongly related to both race and willingness to randomize.

■ Key Points

- Analyses were performed to explore racial variation in surgical treatment preference and willingness to be randomized for intervertebral disc herniation (IDH), spinal stenosis (SpS), and degenerative spondylolisthesis (DS) patients.
- Blacks were less likely to prefer surgical treatment among the IDH, SpS, and DS patients. There was a higher randomization rate among Black IDH patients.
- After controlling for baseline differences, treatment preferences remained a strong predictor of randomization in IDH, SpS, and DS patients.

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