Visual Outcomes of Cataract Surgery in the United States, Canada, Denmark, and Spain

Report From the International Cataract Surgery Outcomes Study

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Objective: To compare visual outcomes obtained following cataract surgery in 4 sites in North America and Europe where considerable differences in the organization of care and patterns of clinical practice have been previously described.

Methods: Patients scheduled for first eye-cataract surgery and aged 50 years or older were enrolled consecutively in a prospective multicenter study that collected clinical and patient interview data preoperatively and postoperatively. From the United States, 772 patients were enrolled; from the Province of Manitoba (Canada), 159; from Denmark, 291; and from the City of Barcelona (Spain), 200. Preoperative and 4- month postoperative visual acuity was obtained for 92% of the patients (n = 1291).

Results: The mean 4-month postoperative visual acuity of eyes operated on varied significantly across the 4 sites ($P<.001$) and had the following Snellen decimal fraction measurements: 0.49 in Barcelona, 0.65 in Denmark, 0.66 in Manitoba, and 0.74 in the United States. However, while crude visual acuity outcome figures varied significantly, no significant difference was observed across the 4 sites regarding the risk of poorer visual outcome after controlling for differences in age, preoperative visual acuity, and general health status for patients with no ocular comorbidity. Older age, poorer preoperative visual acuity, poorer preoperative general health status, and coexisting ocular comorbidity were predictors of a poorer visual outcome.

Conclusion: A previously identified variation in treatment modalities across the 4 sites did not seem to affect patients' visual acuity outcomes.

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TO INVESTIGATE the effect of alternative treatment modalities on health outcomes, the US National Cataract Patient Outcomes Research Team (PORT) studied variation in preoperative, intraoperative, and postoperative cataract surgical management. The study showed that, in the United States, the identified variation in treatment modalities only moderately affects patient outcomes.[1-4] The International Cataract Surgery Outcomes Study was established in 1992 to assess the impact of variation in the management of cataract on patient outcomes across health care systems in 4 sites: the United States, Denmark, the Province of Manitoba (Canada), and the City of Barcelona (Spain). In the 4 sites, instruments developed by the US National PORT were used for the primary data collection. Patients were observed for at least 4 months postoperatively.

The present article compares visual outcomes obtained in the 4 sites where differences in organization of care and in predominant surgical technique have been described previously.[5,6] To adjust for differences in the case mix of patients, we identified patient characteristics of potential importance with regard to visual outcomes, and included these as explanatory variables in a regression model.

RESULTS

In the United States, 772 of 888 eligible patients met initial enrollment criteria and agreed to participate (response rate, 87%). In Canada, 159 of 226 eligible patients agreed to participate (response rate, 70%), and in Barcelona, 200 of 219 eligible patients agreed to participate (response rate, 91%). In Denmark, 291 of 311 eligible patients met enrollment and eventually participated (response rate, 93.6%).

Of the total cross-national sample of 1422 patients, preoperative interviews as well as preoperative and intraoperative clinical data were available for 1349 patients (95%). Four-month clinical data were obtained for 1311 (92%). The 38 pa-

PATIENTS, MATERIALS, AND METHODS

DESIGN

Patients were eligible for inclusion in the study if they were scheduled for cataract surgery and were 50 years of age or older. Patients were excluded if they had previously undergone cataract surgery or if the planned cataract surgery was a combined procedure involving glaucoma or corneal or vitreoretinal surgery. Further exclusions were made if patients were not living within specified recruitment areas, did not speak the primary language of the area, were deaf or confused, or did not have access to a telephone. Contributing ophthalmologists were recruited as follows:75 ophthalmology practices from the United States; 12 ophthalmology practices from Manitoba; all 17 ophthalmology departments at public hospitals from Denmark; and 4 public sector and 6 private sector practices from Barcelona .

In the United States, 3 cities were selected as recruitment areas based on the annual rate of cataract surgery performed on Medicare beneficiaries.[2] These cites were Columbus, Ohio (low rate), St Louis, Mo (medium rate), and Houston, Tex (high rate). Ophthalmologists in each site were categorized into strata based on annual volume of cataract surgery (0-50, 51-200, 201-399, and >400 surgeries per year). A random sample of ophthalmologists who performed more than 50 surgeries per year was recruited from each of the 3 strata. In all, 75 ophthalmologists were recruited. The ophthalmologists were asked to refer patients consecutively when they were scheduled to undergo cataract surgery. Patients were recruited from July 15, 1991, to December 15, 1991, or until 14 patients had been enrolled.

The Canadian study was conducted in the Province of Manitoba. Of 18 ophthalmologists performing surgery in the province, 12 (67%) agreed to participate in the study. The ophthalmologists were asked to refer eligible patients consecutively as they were enlisted for surgery. The period of inclusion started September 1, 1992, and lasted until an agreed on number of patients from each office were obtained or until February 28, 1993, whichever came first (range, 1-24 patients; mean, 13 patients).

In Denmark, cataract surgery was performed at 17 ophthalmologic departments in public hospitals, all of which agreed to participate in the study. At the time of the data collection, no more than 15% of the total volume of cataract surgery was performed in private surgical clinics.[7] These clinics did not participate in the study. In the Danish public health care system, a patient with cataract is referred by a general ophthalmologist who has a "gatekeeper" function. The referred patient is placed on a waiting list for examination by a hospital surgeon. Beginning in September 1992, patients were enrolled consecutively for this study based on referral notes submitted to the hospitals by general ophthalmologists. Recruitment continued until the required number of patients had been enrolled. The number of enrollees per hospital department depended on the surgical volume of the department (range, 7-26 patients; mean, 17 patients). The last patient was enrolled in March 1993.

In the City of Barcelona, approximately 40% of the cataract surgery is done in the private sector and 60% in the public sector. From the private sector, 12 ophthalmologists were randomly selected and finally 6 agreed to participate. Each ophthalmologist was asked to recruit up to 15 consecutive patients, depending on their surgical volume. From the public sector, 4 of 8 departments providing cataract surgery care in the city were selected after stratification based on the volume of cataract surgery, the average case severity, and financing. Enrollment was conducted between September 1993 and March 1994.

A full preoperative medical history and ophthalmic examination of each patient were obtained that included visual acuity, slitlamp, and fundus examinations. The visual acuity was reported as best-corrected visual acuity on a Snellen chart based on a refraction, obtained by the usual routine of each clinic. The results were reported by the ophthalmologist who performed the examination using a structured data

tients lacking 4-month follow-up information did not differ significantly from the study sample by age, sex, preoperative visual acuity, ocular comorbidity, or perioperative events. (Data not presented.) Complete information on all of the variables examined in this study was available for 1291 patients (91%). These patients composed the basis of the present analyses.

Demographic and clinical characteristics of the patients varied significantly across the 4 sites (**Table 1**). The mean preoperative visual acuity in the eye that was operated on was 0.24 in the United States, 0.16 in Manitoba, 0.17 in Denmark, and 0.07 in Barcelona ($P<.001$). The proportion of eyes that were operated on with ARMD ranged between 14.5% and 20.7% across the 4 sites ($P<.001$). Other kinds of ocular comorbidity were reported for 19.8% of the eyes that were operated on in the total study group. Substantially more comorbidity was observed in Barcelona (33.5%) than in the other sites ($P<.001$). Subanalysis of data showed that the latter was largely due to a greater proportion of patients with myopic degeneration and diabetic retinopathy. (Data not presented.)

The mean 4-month postoperative visual acuity of the eye that was operated on varied across sites as follows: 0.74 in the United States, 0.66 in Manitoba, 0.65 in Denmark, and 0.49 in Barcelona ($P<.001$). Normal or near-normal visual acuity (≥0.67) was reported for 83% of the US patients, 74% of the Manitoba patients, 73% of the Danish patients, and 50% of the Barcelona patients. The 4-month postoperative visual acuity distributed by preoperative visual acuity is shown in **Table 2**. The table shows that most patients end up with a postoperative visual acuity similar to or better than their preoperative visual acuity. Six patients with a preoperative visual acuity of 0.67 or greater obtained a postoperative visual acuity worse than 0.67. The poor outcomes for these patients were reported to be due to postoperative astigmatism (n = 2), posterior capsular opacification (n = 2), glaucoma (n = 1), and optic nerve atrophy (n = 1).

In the final regression model, the dummy variable contrasting Manitoba, Denmark, and Barcelona with the United States was nonsignificant ($P = .59$, $P = .28$, and $P = .76$, respectively) (**Table 3**). This indicates that the risk of having a postoperative visual acuity worse than

sheet. Intraoperative techniques and 4-month postoperative clinical outcomes were also reported in structured data sheets.

Each patient was interviewed preoperatively by telephone. General health status was assessed by application of the Sickness Impact Profile (SIP).[8] This questionnaire is a valid and reliable measure of self-reported general health status.[8,9] The SIP score ranges from 0 (indicating absence of dysfunction) to 100 (indicating the maximum level of dysfunction). A translation/backtranslation technique[10] was used to develop a Danish version of the SIP. A previously adapted and validated Spanish version of the SIP was used for the Barcelona site.[11]

The data sheets were translated for the European sites from original US versions. Through close collaboration among the researchers in the participating sites, a common concept for each question in the data sheets was established, emphasizing similarities in the meaning of questions rather than exact linguistic equivalence.[12] For most clinical diagnosis a definition was given in the data sheets as a checklist. The intention of these procedures was to minimize potential bias because of differences in data collection across sites.

STATISTICAL ANALYSIS

Differences in demographic and clinical characteristics across sites were tested using χ^2 tests for categorical variables, and Kruskal-Wallis tests for continuous variables. A nonparametric method was used as the distributions of most variables were skewed. Mean visual acuity was calculated as the geometric mean.[13] All visual acuity measurements in this article are presented as Snellen decimal fractions. Visual outcome was dichotomized as 0.67 or better vs worse than 0.67.

Multiple logistic regression was used to compare visual outcomes of surgery in the 4 sites and to identify categories of patients and factors related to surgery associated with obtaining a poor visual outcome. Model reductions were tested by the likelihood ratio test.[14] By means of logistic regression, the odds ratio could be estimated between the United States and the other 3 sites for achieving a subnormal postoperative visual acuity (<0.67). To adjust for any differences in case mix among sites, a number of patient characteristics were included in the analysis. Factors of potential importance were identified based on previous reports.[15-18] Age and sex were included as demographic factors. Preoperative visual acuity was included and categorized in 4 groups (<0.10; 0.10 to <0.20; 0.20 to <0.33; and ≥ 0.33). The Sickness Impact Profile score was included as an indicator of general health. As age-related macular degeneration (ARMD) was the predominant ocular comorbidity observed in the samples, this condition was included as absent, present, or not assessable. The presence of other kinds of ocular comorbidity was represented by a single dichotomous variable (comorbidity vs no comorbidity) since the sample size did not allow for meaningful analysis of other single diagnoses of ocular comorbidity. Surgical technique was included as standard extracapsular vs phacoemulsification.

As a first step, regression models were fitted for each site separately. These regression models showed no significant difference across study sites in the association between postoperative visual acuity on the one hand and age, sex, preoperative visual acuity, general health status, or surgical technique on the other (data not presented). On the basis of this analysis, each of these factors could be included in the final model as a single variable. However, for the presence of ARMD, of unassessable macular status, and of ocular comorbidity, there were significant differences across sites in the association with postoperative visual acuity. In the final model, 2 dummy variables were created for these factors; one variable contrasted patients with ARMD or unassessable macular status with patients with normal macular status from the same site; and one variable contrasting patients with other comorbidity with patients with no comorbidity from the same site. A third dummy variable contrasted Manitoba, Denmark, and Barcelona with the United States.

The studies were approved by the local Committees on Human Research in each study site.

0.67 was not significantly different ($P = .13$) across sites for patients with no ocular comorbidity after controlling for differences in age, general health status, and preoperative visual acuity.

The impact of some patient characteristics as predictors of subnormal outcome was similar across all 4 sites (Table 3). The risk of having a postoperative visual acuity worse than 0.67 increased with age in all sites. Having poorer preoperative general health, as defined by the Sickness Impact Profile score, also increased the risk of a poor visual outcome. The risk of a poor outcome was higher among those with poorer preoperative visual acuity, with the highest risk observed in the 0.10 to less than 0.20 group.

For some patient characteristics, the relative impact varied across sites. In Manitoba, Denmark, and Barcelona, a significantly higher risk of a visual outcome worse than 0.67 was observed for patients with ARMD as compared with patients with a normal macula. A similar but nonsignificant association was observed in the United States (Table 3). In the United States, Manitoba, and in Denmark, the risk of a poor visual outcome was not significantly ($P = .61$, $P = .23$, and $P = .95$, respectively) different for patients whose macular status could not be assessed preoperatively, compared with patients with a normal macula. However, in Barcelona, these patients had a significantly higher risk of a poorer visual outcome. In all sites, the risk of a visual outcome worse than 0.67 was significantly higher for patients with other ocular comorbidity compared with patients with no ocular comorbidity. For ARMD, unassessable macular status, and comorbidity, the highest odds ratio was observed in Barcelona as compared with the other sites. Sex and surgical technique were of no significant importance as predictors of visual outcome.

COMMENT

Previously, differences have been reported across the 4 sites studied in the organization of care, and in anesthetic and surgical technique.[5,6] In Denmark, cataract extractions are mainly performed in public hospitals, while in North America and Barcelona, extractions are performed both in hospitals and in private clinics. Ophthal-

Table 1. Distribution of Demographic and Clinical Characteristics of 1291 Patients Undergoing Cataract Surgery in the United States, Manitoba, Canada, Denmark, and Barcelona, Spain*

Characteristics	United States (n = 722)	Manitoba, Canada (n = 138)	Denmark (n = 270)	Barcelona, Spain (n = 161)	Total (n = 1291)	P†
Preoperative						
Female sex	62.7	69.6	67.0	57.8	63.7	>.05‡
Age, y						
<60	6.5	10.1	5.2	13.0	7.4	. . .
≥60 to <70	26.0	24.6	25.9	38.5	27.4	. . .
≥70 to <80	50.0	45.7	47.0	37.9	47.4	. . .
≥80	17.5	19.6	21.9	10.6	17.7	. . .
Median	73	72	74	69	72	<.001§
Median SIP score	4.4	5.2	4.3	10.7	5.0	<.001§
Macula						
Normal	77.1	68.8	60.4	59.0	70.5	<.001‡
ARMD	17.2	14.5	20.7	16.1	17.5	
Not assessable	5.7	16.7	18.9	24.8	12.0	
Ocular comorbidity, other						
Absent	82.4	73.9	85.6	66.5	80.2	<.001‡
Present	17.6	26.1	14.4	33.5	19.8	
Visual acuity						
<0.10	9.6	18.8	16.7	41.0	16.0	. . .
≥0.10 to <0.20	9.7	19.6	17.4	29.8	14.9	. . .
≥0.20 to <0.33	27.6	26.1	30.4	21.7	27.3	. . .
≥0.33	53.2	35.5	35.6	7.5	41.9	. . .
Mean	0.24	0.16	0.17	0.07	0.18	<.001§
Intraoperative						
Surgical technique						
Extracapsular extraction	32.7	37.0	66.7	97.5	48.3	<.001‡
Phacoemulsification	67.3	63.0	33.3	2.5	51.7	
Postoperative						
Visual acuity						
<0.10	0.7	2.2	1.5	6.8	1.8	. . .
<0.10 to <0.20	0.7	2.9	4.1	5.0	2.2	. . .
≥0.20 to <0.33	2.9	3.6	5.6	6.2	4.0	. . .
≥0.33 to <0.67	13.1	17.4	15.5	32.3	16.4	. . .
≥0.67	82.5	73.9	73.3	49.7	75.6	. . .
Mean	0.74	0.66	0.65	0.49	0.68	<.001§

*Values are percentage unless otherwise indicated. SIP indicates Sickness Impact Profile; ARMD, age-related macular degeneration; and ellipses, data not available.

†For difference across site.

‡χ^2 Test.

§Kruskal-Wallis test.

mologic and medical preoperative testing, as well as intraoperative monitoring, is much more intensive in North America and Barcelona than in Denmark. In Barcelona, phacoemulsification is very infrequently performed compared with the other sites, and there is a significantly greater use of general anesthesia in Barcelona.

These reported variations in the management of cataract raises the question of potential differences in the surgical outcomes across the 4 sites. In this study, we have examined one aspect of cataract surgery outcome. We found that the risk of a visual outcome worse than a Snellen value of 0.67 was not significantly different across the 4 sites for patients with comparable preoperative characteristics and no comorbidity.

An important strength of this study is the incorporation of a common design and use of common instruments for data collection in the 4 sites. Comparable information on patient characteristics allows us to control for differences in the case mix of patients, and the importance of this is clearly illustrated by the current study. When mean postoperative visual acuity or when crude proportions of patients with a visual outcome worse than 0.67 were compared across sites, a much poorer outcome was seen in Barcelona. However, older age, poorer general health status, lower preoperative visual acuity, and presence of ocular comorbidity were found to be significant risk factors associated with increased likelihood of poorer postoperative visual acuity. The proportions of patients with these risk factors varied across sites. After controlling for the different distributions of these factors, no significant difference remains across the 4 sites regarding risk of a poor visual outcome. Such case mix differences were also found to be of importance in a study from the United States.[19]

Older age was a significant predictor of worse visual outcome across all sites, even when controlling for coexisting ocular abnormalities, preoperative visual acuity, and general health status. This association has previously been reported.[20] A marked decline of retinal neural function is associated with age, and this might be an important explanation for this observation.[21]

Across all sites, a higher risk of a visual outcome worse than 0.67 was observed with decreasing preop-

Table 2. Postoperative Visual Acuity Compared With Preoperative Visual Acuity in the Total Sample of 1291 Patients With Cataract*

Preoperative Visual Acuity	Postoperative Visual Acuity				
	<0.10	≥0.10 but <0.20	≥0.20 but <0.33	≥0.33 but <0.67	>0.67
<0.10					
All sites (N = 206)	8	7	6	16	64
United States (n = 69)	4	1	13	12	70
Manitoba, Canada (n = 26)	4	8	0	12	76
Denmark (n = 45)	4	11	0	4	81
Barcelona, Spain (n = 66)	15	9	5	30	41
≥0.10 to <0.20					
All sites (N = 192)	2	5	8	27	58
United States (n = 70)	3	4	6	21	66
Manitoba (n = 27)	0	8	11	26	55
Denmark (n = 47)	2	8	9	21	60
Barcelona (n = 48)	2	2	10	40	46
≥0.20 to <0.33					
All sites (N = 352)	1	1	4	20	74
United States (n = 199)	0	0	1	17	82
Manitoba (n = 36)	6	0	6	25	63
Denmark (n = 82)	1	2	9	20	68
Barcelona (n = 35)	0	3	6	34	57
≥0.33 to <0.67					
All sites (N = 504)	0	0	2	11	87
United States (n = 354)	0	0	1	10	89
Manitoba (n = 47)	0	0	0	11	89
Denmark (n = 91)	0	0	4	13	83
Barcelona (n = 12)	0	0	0	8	92
≥0.67					
All sites (N = 37)	0	0	3	14	83
United States (n = 30)	0	0	3	10	87
Manitoba (n = 2)	0	0	0	0	100
Denmark (n = 5)	0	0	0	40	60
Barcelona (n = 0)	0	0	0	0	0

Values are percentage unless otherwise indicated.

erative visual acuity. This was shown even after controlling for other patient characteristics including ocular comorbidity and age. However, lens opacities might complicate the examination of the internal eye, and the significance of preoperative visual acuity as an indicator of visual outcome might in part be due to undiagnosed ocular comorbidity.

The importance of ocular comorbidity as a predictor of visual outcome was expected and has been reported previously.[15-18] However, in the present study, the magnitude of the effect of ocular comorbidity varied significantly among sites. We observed a significantly higher risk of a poorer visual outcome for patients with ocular comorbidity in Barcelona than for patients in the other sites. One interpretation could be that ocular comorbidity was more severe in Barcelona. The reason for this is unknown, but might be because of a different selection of patients for cataract surgery in the 4 health care systems.

For most patients with cataract, the aim of surgery is to restore normal visual acuity. In the analyses, we use a cut point of 0.67 or higher for a successful or satisfactory postoperative visual acuity. This cut point was chosen based on clinical experience of what might be regarded as a normal visual acuity in the age group

Table 3. Results of a Logistic Regression Showing Associations Between Multiple Preoperative Patient Characteristics and the Risk of Having a Postoperative Visual Acuity Worse Than 0.67*

Preoperative Patient Characteristics	No. of Patients	Odds Ratio (95% CI)	*P*
Site			
United States	722	1.00 (. . .)	Ref
Manitoba, Canada	138	0.80 (0.39-1.62)	.59
Denmark	270	1.33 (0.79-2.23)	.28
Barcelona, Spain	161	1.12 (0.55-2.30)	.76
Sex			
Female	823	1.00 (. . .)	Ref
Male	468	1.22 (0.90-1.66)	.20
Age, y			
50 to <60	96	1.00 (. . .)	Ref
60 to <70	354	1.06 (0.51-2.19)	.88
70 to <80	612	2.45 (1.21-4.92)	.01
≥80	229	5.20 (2.48-10.92)	<.001
SIP score (1-U increase)†	. . .	1.03 (1.01-1.04)	<.001
Visual acuity			
≥0.33	541	1.00 (. . .)	Ref
≥0.20 to <0.33	352	1.95 (1.25 - 3.03)	<.001
≥0.10 to <0.20	192	4.32 (2.78-6.72)	<.001
<0.10	206	2.53 (1.52-4.20)	<.001
Macular status			
Normal macula‡	. . .	1.00 (. . .)	Ref
ARMD			
United States	124	1.47 (0.89-2.44)	.13
Manitoba	20	4.60 (1.50-14.14)	.008
Denmark	56	2.29 (1.13-4.65)	.02
Barcelona	26	5.63 (1.67-18.94)	.005
Unassessable			
United States	41	1.25 (0.54-2.86)	.61
Manitoba	23	1.99 (0.64-6.18)	.23
Denmark	51	0.98 (0.43-2.20)	.95
Barcelona	40	6.66 (2.55-17.4)	<.001
Other comorbidity			
None§	. . .	1.00 (. . .)	Ref
Comorbidity			
United States	127	1.78 (1.08-2.93)	.02
Manitoba	36	2.64 (1.04-6.67)	.04
Denmark	39	2.64 (1.20-5.80)	.02
Barcelona	54	5.96 (2.42-14.72)	<.001
Surgical technique			
Extracapsular extraction	624	1.00 (. . .)	Ref
Phacoemulsification	667	1.10 (0.78-1.54)	.58

*The regression model is described in the "Results" section of the text. Ref indicates reference group; SIP, Sickness Impact Profile; ARMD, age-related macular degeneration; and ellipses, data not applicable.

†An increasing SIP score indicates a poorer general health status.

‡Patients with ARMD or unassessable status are contrasted with patients with normal macular status from the same country only.

§Patients with comorbidity are contrasted with patients with no comorbidity from the same country only.

considered. However, even when a less stringent cut point of 0.50 or higher was used, only trivial changes in results were seen. (Data not shown.)

Some limitations in the study must be considered. In Denmark, all hospital clinics performing cataract surgery in the public sector were included, but in the other sites only a selection of clinics participated. It is possible that nonparticipating clinics have clinical practices that differ from those participating. Similarly, some selection bias might also have occurred in the recruit-

ment of patients within each clinic. However, nonresponder analyses in the United States and Denmark did not support the existence of such bias.[2,22] In the instruction for the ophthalmologists, visual acuity was defined as visual acuity obtained on a Snellen visual acuity chart after a refraction. To maximize the rate of participation among the selected ophthalmologists, no attempt was made to change their routine of refraction or the equipment of the clinic. This decision involves a deliberate trade-off between a potential selection bias due to lack of participation on the one hand, and a potential information bias due to lack of standardization on the other. In choosing between the 2 sources of bias, we found that the information bias was potentially of less importance. We believe that refraction and measurement of best-corrected visual acuity is a well-established routine procedure in all of the participating clinics. We have no evidence to support a suspicion that visual acuities were systematically misclassified across the 4 sites. Despite a checklist for most clinical diagnoses on the data sheets, local interpretation of ocular comorbidity, as well as severity of comorbidity, might vary, which could be other sources of bias.

CONCLUSIONS

In this study, we have examined postoperative visual acuity as one measure of visual outcomes for cataract surgery in 4 different health care settings in 4 countries. After controlling for patient case mix, similar visual acuity was found across the sites for patients without comorbidity. This was observed despite previously reported variations in surgical techniques and management of care. Age, preoperative visual acuity, general health status, and coexisting ocular abnormalities were important predictors of visual outcomes. These predictors were identified in all 4 sites, although the magnitude of the effect varied. This consistency supports the validity and generalizability of these findings.

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