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Trial Participation and Outcomes Among English-Speaking and Spanish-Speaking Patients With Appendicitis Randomized to Antibiotics

A Secondary Analysis of the CODA Randomized Clinical Trial

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This study describes trial participation and compares clinical and patient-reported outcomes among Spanish-speaking and English-speaking participants randomized to antibiotics.

Key Points

Question

Are there differences in trial participation, clinical outcomes, and patient-reported outcomes between Spanish-speaking and English-speaking participants with acute appendicitis randomized to antibiotics?

Findings

In this cohort study, which is a secondary analysis of the Comparison of Outcomes of Antibiotic Drugs and Appendectomy trial that included 1552 participants (776 randomized to antibiotics), 476 Spanish speakers agreed to randomization. Spanish speakers missed 6.69 days of work on average, while English speakers missed 3.76 days; clinical and other patient-reported outcomes were similar among Spanish-speaking and English-speaking participants.

Meaning

These findings suggest that antibiotic management of acute appendicitis does not lead to worse clinical outcomes in Spanish-speaking patients who received culturally sensitive, language concordant care at the participating sites.

Abstract

Importance

Spanish-speaking participants are underrepresented in clinical trials, limiting study generalizability and contributing to ongoing health inequity. The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) trial intentionally included Spanish-speaking participants.

Objective

To describe trial participation and compare clinical and patient-reported outcomes among Spanish-speaking and English-speaking participants with acute appendicitis randomized to antibiotics.

Design, Setting, and Participants

This study is a secondary analysis of the CODA trial, a pragmatic randomized trial comparing antibiotic therapy with appendectomy in adult patients with imaging-confirmed appendicitis enrolled at 25 centers across the US from May 1, 2016, to February 28, 2020. The trial was conducted in English and Spanish. All 776 participants randomized to antibiotics are included in this analysis. The data were analyzed from November 15, 2021, through August 24, 2022.

Intervention

Randomization to a 10-day course of antibiotics or appendectomy.

Main Outcomes and Measures

Trial participation, European Quality of Life–5 Dimensions (EQ-5D) questionnaire scores (higher scores indicating a better health status), rate of appendectomy, treatment satisfaction, decisional regret, and days of work missed. Outcomes are also reported for a subset of participants that were recruited from the 5 sites with a large proportion of Spanish-speaking participants.

Results

Among eligible patients 476 of 1050 Spanish speakers (45%) and 1076 of 3982 of English speakers (27%) consented, comprising the 1552 participants who underwent 1:1 randomization (mean age, 38.0 years; 976 male [63%]). Of the 776 participants randomized to antibiotics, 238 were Spanish speaking (31%). Among Spanish speakers randomized to antibiotics, the rate of appendectomy was 22% (95% CI, 17%-28%) at 30 days and 45% (95% CI, 38%-52%) at 1 year, while in English speakers, these rates were 20% (95% CI, 16%-23%) at 30 days and 42% (95% CI 38%-47%) at 1 year. Mean EQ-5D scores were 0.93 (95% CI, 0.92-0.95) among Spanish speakers and 0.92 (95% CI, 0.91-0.93) among English speakers. Symptom resolution at 30 days was reported by 68% (95% CI, 61%-74%) of Spanish speakers and 69% (95% CI, 64%-73%) of English speakers. Spanish speakers missed 6.69 (95% CI, 5.51-7.87) days of work on average, while English speakers missed 3.76 (95% CI, 3.20-4.32) days. Presentation to the emergency department or urgent care, hospitalization, treatment dissatisfaction, and decisional regret were low for both groups.

Conclusions and Relevance

A high proportion of Spanish speakers participated in the CODA trial. Clinical and most patient-reported outcomes were similar for English- and Spanish-speaking participants treated with antibiotics. Spanish speakers reported more days of missed work.

Trial Registration

ClinicalTrials.gov Identifier: [NCT02800785](https://clinicaltrials.gov/ct2/show/study/NCT02800785)

Introduction

In the US, 25 million people (8.4% of the population) have limited English proficiency (LEP).¹ Spanish is the second most common language spoken in US households and 40% of Spanish-speaking individuals have LEP.^{1,2} The growing population of patients with LEP requires health care systems to provide accessible, culturally and linguistically sensitive, high-quality care. Failure in fulfilling this requirement limits access to care for patients with LEP³ and may contribute to the higher rate of adverse hospital events,⁴ longer hospital stays,⁵ higher odds of readmission,⁶ and lower patient satisfaction⁷ in this population. While higher rates of appendiceal perforation have

been observed in children whose parents have LEP,⁸ the association between preferred language and both clinical and patient-reported outcomes in adults with appendicitis has not been studied, to our knowledge.

Spanish speakers are underrepresented in clinical trials.^{9,10,11} Patients with LEP may have different experiences and barriers that may influence clinical trial participation and follow-up.¹² Inclusion of this population in clinical research is necessary to better understand differential outcomes, which may be related to treatment, care delivery, and/or structural processes that include discrimination and racism.¹³ The CODA trial was a pragmatic, randomized trial of appendectomy vs antibiotics performed at 25 centers across the US.¹⁴ It included 1552 randomized participants with 476 participants reporting Spanish as their preferred language (31%). Since LEP and speaking a primary language other than English are associated with poor access to care,^{3,15} Spanish-speaking patients with appendicitis who are initially treated with antibiotics may experience structural barriers accessing health care after their index encounter. These barriers may be attenuated when treatment is completed within a randomized clinical trial that provides access to standardized, culturally sensitive, language-concordant care for participants who speak Spanish as their preferred language.

In this secondary, exploratory analysis of the Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) trial data, we aim to describe trial participation in the combined treatment arms and treatment adherence in the antibiotic group based on preferred language. We also aim to compare clinical and patient-reported outcomes by preferred language among participants randomized to antibiotics.

Methods

The research protocol for the CODA trial¹⁴ was approved by the institutional review boards at the 25 participating clinical sites (eAppendix 2 in [Supplement 1](#)). The study population consisted of English- and Spanish-speaking adults (18 years or older) presenting to the emergency department (ED) with imaging-confirmed appendicitis. Exclusion criteria have been previously described in detail.^{14,16} Participants were randomly assigned to a 10-day course of antibiotics or appendectomy. Written informed consent was obtained and questionnaires were conducted in the participant-identified preferred language (English or Spanish). Participants received \$125 for completing study surveys, prorated over 1 year. This study followed the Consolidated Standards of Reporting Trials ([CONSORT](#)) reporting guidelines.

Data Description

Individual Participant Characteristics During the screening process, people were asked about the language in which they would be most comfortable communicating: English, Spanish, or both English and Spanish. The Spanish language arm includes participants who reported a preference to have all materials in Spanish. Participants who reported being equally comfortable with both languages were included in the English language arm in this analysis. Sociodemographic characteristics were measured at baseline.¹⁶ Health literacy, employment status, and level of activity at work were assessed following previously described methods.¹⁷

Study Participation Willingness to randomize was described by examining the number eligible and the number who declined to randomize. Twenty-eight people were excluded from this analysis due to missing preferred language. Among those who were randomized, participation was described using the proportion who returned 30-day and 1-year surveys.

Symptom Management and Treatment Adherence Participants reported whether they were still taking antibiotics, and if so, the number of antibiotic pills they had taken on average at 7 days. Participants also reported whether they had taken “pain medication for abdominal pain related to your appendicitis” in the past week.

Outcome Measures Health status was assessed with the European Quality of Life–5 Dimensions (EQ-5D) questionnaire (scores range 0 to 1; higher scores indicate better health status).¹⁸ Symptom resolution was defined as absence of fever, pain, and abdominal tenderness. Participants reported whether they had an appendectomy or additional visits to the hospital, ED, or urgent care. High decisional regret was defined as a score of more than 50 on the decisional regret scale.¹⁹ The EQ-5D questionnaire^{20,21} and the decisional regret scale²² have been previously validated in Spanish. Participant satisfaction with treatment was assessed using a Likert scale ranging from very dissatisfied to very satisfied. Participants who were employed reported days of work missed since they presented to the ED, including day of presentation. Responses were capped at 30 days.

Statistical Analysis

Information about participation, baseline characteristics, symptom management, and treatment adherence for Spanish and English speakers were described using mean and SD for continuous measures, and count (n) and percentage for categorical variables. Outcomes were described using the same methods and 95% CIs were used to summarize uncertainty around means and percentages.

Since Spanish speakers were mostly concentrated in 5 sites, we performed a subset sensitivity analysis using only data from Spanish speakers and English speakers from those 5 sites. Due to the limited sample size, we were not able to include all outcomes. Among those who agreed to randomize, there was no missing data on preferred language. Information about missing baseline characteristics and outcomes is presented in eAppendix 1 in [Supplement 1](#). Analysis was conducted November 15, 2021, through August 24, 2022, using R version 4.2 (The R Project).

Results

Trial Recruitment and Follow-up

Among eligible individuals, 476 of 1050 of Spanish speakers (45%) and 1076 of 3982 of English speakers (27%) agreed to randomization. Five of the 25 participating sites recruited 442 of 476 Spanish-speaking participants (93%) (Olive View-UCLA Medical Center, Harbor-UCLA Medical Center, Columbia University Medical Center, Lyndon B. Johnson Hospital, and Boston University

Medical Center). Among eligible individuals at these 5 sites, 442 of 891 Spanish speakers (50%) and 268 of 757 English speakers (35%) agreed to randomization. Among the participants recruited at these sites, the proportion of Spanish speakers ranged from 48% to 72%. A total of 399 of 476 Spanish speakers (84%) and 534 of 1076 of English speakers (50%) were recruited from safety net hospitals (eFigure in [Supplement 1](#)). The 30-day survey was returned by 427 of 476 of Spanish speakers (90%) and 970 of 1076 English speakers (90%). The 1-year survey was returned by 379 of 476 Spanish speakers (80%) and 845 of 1076 English speakers (79%).

Sociodemographic Characteristics

Of the CODA participants who were randomized to antibiotics or appendectomy, 476 of 1552 were Spanish speaking (31%). The distribution of demographic characteristics varied by language group ([Table 1](#); eTable 1 in [Supplement 1](#)). Among Spanish-speaking participants, 403 of 465 had an education of high school or less (87%) and 189 of 460 reported needing help reading health-related instructions and materials sometimes or more (41%). Among English-speaking participants, 230 of 1065 had an education of high school or less (22%) and 95 of 1031 needed help with health literacy sometimes or more (9%). The most common insurance category for Spanish speakers was no insurance (211 of 458 [46%]) and most of those insured had public insurance (eTable 1 in [Supplement 1](#)). Among English-speaking participants, 143 of 1056 were uninsured (14%) and commercial insurance was the most common (610 of 1056 [58%]). An income that was below the federal poverty level was reported by 233 of 282 of Spanish speakers (83%) and 179 of 810 of English speakers (22%).

Baseline Clinical Characteristics

Spanish and English speakers both had low Charlson scores (mean [SD] of 0.25 [SD, 0.51] in Spanish speakers and 0.24 [SD, 0.54] in English speakers). Symptom duration of 1 or more day(s) was reported by 82% of Spanish speakers and 72% of English speakers. The distribution of baseline diagnostic characteristics associated with appendicitis was similar in both groups (eTable 1 in [Supplement 1](#)). Among Spanish speakers, the mean (SD) Alvarado score was 6.81 (SD, 1.58) and white blood cell count was 13.61 (SD, 4.05) μL . Among English speakers, the mean Alvarado score was 6.54 (SD, 1.69) and white blood cell count was 12.82 (SD, 4.05) μL . Radiographic appendicolith was present in 118 of 476 of Spanish speakers (25%) and 296 of 1076 of English speakers (28%). Mean appendiceal diameter was 11.27 (SD, 2.74) among Spanish-speaking participants and 11.44 (SD, 2.92) among English-speaking participants. Radiographic evidence of perforation was identified in 6 of 461 Spanish speakers and 11 of 989 English speakers (1% in each group).

Symptom Management and Treatment Adherence in Antibiotics Arm

At 7 days, among those who had filled a prescription, 170 of 189 Spanish speakers (90%) and 384 of 437 English speakers (88%) reported still taking at least 1 antibiotic. Among those who were still taking antibiotics, 132 of 150 Spanish speakers (88%) and 327 of 373 English speakers (88%)

reported taking all their prescribed antibiotic pills daily. In the first week after randomization, 123 of 219 participants in the Spanish-speaking group and 276 of 493 participants in the English-speaking group had taken pain medications for their appendicitis (56% for each group).

Clinical and Patient-Reported Outcomes in Antibiotics Arm

Outcomes were similar across groups that were randomized to antibiotics ([Table 2](#)). The rate of appendectomy at 30 days was 22% (51 of 230; 95% CI, 17%-28%) for Spanish speakers and 20% (104 of 526; 95% CI, 16%-23%) for English speakers. At 1 year, the rate of appendectomy was 45% (97 of 216; 95% CI, 38%-52%) and 42% (202 of 481; 95% CI, 38%-47%), respectively. At 30 days, 138 of 204 Spanish speakers (68%; 95% CI, 61%-74%) and 324 of 472 English speakers (69%; 95% CI, 64%-73%) had symptom resolution. The proportion of participants who presented to the ED or urgent care within 30 days after index treatment was low for both groups—7 of 200 in the Spanish-speaking group (4%; 95% CI, 1%-7%) and 31 of 463 in the English-speaking group (7%; 95% CI, 5%-9%). In the 30 days after index treatment, 30 of 204 of Spanish speakers (15%; 95% CI, 10%-20%) and 81 of 469 of English speakers (17%; 95% CI, 14%-21%) had been hospitalized overnight.

At 30 days, EQ-5D scores were 0.93 (95% CI, 0.92-0.95) for Spanish speakers and 0.92 (95% CI, 0.91-0.93) for English speakers. Treatment dissatisfaction (somewhat dissatisfied or very dissatisfied) was reported by 19 of 204 Spanish speakers (9%; 95% CI, 6%-14%) and 36 of 466 English speakers (8%; 95% CI, 5%-11%). High decisional regret was reported by 25 of 190 Spanish speakers (95% CI, 9%-19%) and 60 of 468 English speakers (95% CI, 10%-16%) (13% of participants for each group). On average, Spanish speakers missed 6.69 (95% CI, 5.51-7.87) days of work within 30 days while English speakers missed 3.76 (95% CI, 3.20-4.32) days of work. Among those reporting to be active at work, Spanish-speaking participants missed 7.27 (95% CI, 5.53-9.02) days of work while English-speaking participants missed 4.88 (95% CI, 3.70-6.06) days. Among those who reported being less active, Spanish-speaking participants missed 7.04 (95% CI, 5.17-8.91) days of work while English-speaking participants missed 3.83 (95% CI, 3.07-4.59) days. In the surgery arm, Spanish-speaking participants missed 14.19 (95% CI, 12.55-15.83) days and English-speaking participants missed 5.67 (95% CI, 4.91-6.43) days.

Subset Analysis

Participant characteristics and outcomes for the subset of participants that were recruited from the 5 sites with a large portion of Spanish-speaking participants (eFigure in [Supplement 1](#)) are presented in eTables 2 and 3 in [Supplement 1](#). Among Spanish-speaking participants at these sites, 381 of 437 had an education level of high school or less (87%) and 217 of 263 had an income below the federal poverty level (83%). Among English-speaking participants at these sites, 89 of 265 had an education level of high school or less (34%) and 84 of 161 had an income below the federal poverty level (52%). Most outcomes were similar between Spanish and English speakers, with the exception of missed work (eTable 3 in [Supplement 1](#)). In the Spanish-speaking group, 125 of 189 (66%; 95% CI, 59%-73%) of participants had symptom resolution and 49 of 213 (23%; 95% CI, 18%-29%) had an appendectomy within 30 days. Among English speakers, 71 of 106 (67%; 95% CI, 57%-76%) reported symptom resolution and 25 of 126 (20%; 95% CI, 13%-28%) had an

appendectomy within 30 days. At 30 days, the average EQ-5D score was 0.93 (95% CI, 0.92-0.95) and days of work missed were 6.57 (95% CI, 5.37-7.78) among Spanish speakers. The average EQ-5D score was 0.91 (95% CI, 0.89-0.94) and days of work missed were 4.99 (95% CI, 3.50-6.47) among English speakers.

Discussion

In this secondary analysis of the CODA trial, we found a higher frequency of recruitment among Spanish speakers compared with English speakers and similar retention. Among Spanish-speaking participants, there was a higher prevalence of socioeconomic factors that are commonly associated with poor access to health care, such as low income, low educational attainment, and lack of insurance.^{23,24} Nevertheless, treatment adherence and clinical outcomes were similar between randomized English- and Spanish-speaking participants. While the patient-reported outcomes of health status, treatment satisfaction, and decisional regret were similar, Spanish-speaking participants reported more days of missed work. However, English- and Spanish-speaking participants both reported fewer days of missed work in the antibiotic arm than the appendectomy arm. The similar number of days of missed work among Spanish-speaking participants with an active job and Spanish-speaking participants with a less active job suggests that there are factors contributing to the observed differences in days of work missed other than type of work.¹⁷

This study provides a valuable perspective on the recruitment and participation of Spanish-speaking participants, a population that is underrepresented in clinical trials.²⁵ The high enrollment and participation rates observed among Spanish speakers in the CODA trial challenge bias that participants from racial and ethnic minoritized groups are more likely to not adhere to a trial protocol,²⁶ be lost to follow-up, or withdraw from a study.²⁷ A study comparing enrollment rate in cancer therapeutic trials by preferred language found similar enrollment rates for English-speaking (13%) and Spanish-speaking participants (11%).²⁸ In our study, the enrollment rate for Spanish-speaking individuals who were eligible to participate in the CODA trial was higher than enrollment rates observed in other clinical trials.^{28,29} While lower item-response rates have been observed among participants with racial and ethnic minoritized identities,³⁰ the proportion of Spanish- and English-speaking participants who completed the 30-day and 1-year survey in the CODA trial was similar.

The recruitment strategy for the CODA trial aimed to provide standardized, culturally sensitive, inclusive, and language-appropriate study materials in both English and Spanish.³¹ This strategy included bilingual, multicultural research staff, and certified interpreters during recruitment and follow-up. Additionally, participants were offered to complete surveys via phone or online and with the assistance of a research coordinator if preferred. It is important to recognize the broader social, cultural, economic, and political context that influence clinical trial participation.³² For example, individuals who have a low educational attainment and limited health literacy might not feel empowered to speak up or ask questions that may inform their decision to participate in a study.³³ Equal financial incentives were distributed to participants. Given that a higher proportion of Spanish-speaking participants in our study reported an income below the federal poverty level,

this equal incentive represents a higher proportion of their income. In addition, for individuals who have experienced barriers in navigating the health care system, the prospect of having direct communication with research staff during their recovery may motivate participation in trials.³⁴

While individuals with a low income may be eligible for health insurance programs, such as Medicaid, immigration-related restrictions prevent some communities from obtaining health insurance and accessing health care services.³⁵ Health research rarely collects data on immigration status due to the sensitive nature of this information and fear of alienating participants or damaging trust³⁶; this study was not the exception. In this study, the sites that recruited the highest proportion of Spanish-speaking participants are located in states that have a large population of Spanish speakers and those with LEP—California, Texas, and New York.¹ Additionally, these sites are located in metropolitan areas with the highest concentrations of both authorized and unauthorized immigrants (Los Angeles, California; New York, New York; Houston, Texas; and Boston, Massachusetts).^{37,38} As a result, these sites have needed to adapt to provide care to immigrant populations and patients that have limited English proficiency. Results from this study may not be generalizable to patients who receive care at hospitals that do not have a strong commitment to or the infrastructure for providing care to all patients regardless of insurance or immigration status.

Indicators of low socioeconomic status tend to be associated with poor health outcomes³⁹ and given that these factors tend to be more prevalent among racial and ethnic minoritized communities, there is concern that patients from these communities would be differentially offered antibiotic treatment and experience worse clinical outcomes as a result.⁴⁰ This was not found in Spanish-speaking participants in the CODA trial treated with antibiotics. However, we cannot extrapolate these findings to other racial and ethnic minoritized communities or to populations that receive care in settings that fall outside the protocolized medical management that occurs in clinical trials. These findings may also not apply to Spanish-speaking patients experiencing communication barriers due to ineffective language services.

Strengths and Limitations

Our study has limitations. English proficiency was not formally assessed.⁴¹ The US Census question to determine limited English proficiency, defined as speaking English less than “very well,” has been shown to have the highest sensitivity for predicting effective communication.⁴² While participants in the Spanish-language cohort are likely to have limited English proficiency, it is possible that some individuals who preferred to communicate in Spanish were also proficient in English. Furthermore, we cannot disentangle limited English proficiency from health literacy or low educational attainment. Notably, existing health literacy questions do not assess verbal communication, health-related decision making, or ability to navigate the health care system.⁴³ It is possible that some participants who reported needing help reading health-related materials required assistance due to limited English proficiency or limited Spanish reading proficiency and not due to limited health literacy. Additionally, we did not adjust our analysis for clinical site. However, recognizing that site differences may lead to differential outcomes, we conducted a subset sensitivity analysis that included only those sites that recruited a high proportion of Spanish-speaking participants. Studies have shown that hospitals that serve a large proportion of non-English speakers are more

likely to offer professional interpreting services,⁴⁴ which is associated with increased patient satisfaction and better clinical outcomes.⁴⁵ The general findings from this sensitivity analysis did not differ from the primary analysis.

Our findings have important implications for the inclusion of Spanish-speaking participants in clinical trials. The CODA trial demonstrates that enrollment and participation of Spanish-speaking participants is an attainable goal when a study is intentionally designed and resources are allocated to be inclusive of this population. Given that Spanish speakers in the US represent a heterogeneous population, the inclusion of this patient population in clinical trials is important to better understand sources of treatment effect heterogeneity. This is a necessary step to examine disparate outcomes and develop interventions to address health inequity. While our findings do not suggest that preferred language is a source of treatment effect heterogeneity in our study population, Spanish-speaking patients who declined to participate and Spanish-speaking patients seeking care in other health care settings may have different experiences that may manifest as different outcomes. This highlights the need for clinical trials to include participants across diverse geographic, economic, political, social, and health contexts.

Conclusions

In this secondary analysis of the CODA trial, English- and Spanish-speaking participants treated with antibiotics had similar rates of appendectomy at 1 year and reported high EQ-5D scores and low rates of treatment dissatisfaction and decisional regret. Among participants treated with antibiotics, Spanish speakers missed more days of work on average than English speakers. However, participants had fewer days of missed work in the antibiotic arm than the appendectomy arm regardless of preferred language. This is an important difference to highlight during shared decision-making as the inability to miss work can shift the preference toward antibiotics for some patients. The comparable outcomes among English- and Spanish-speaking participants treated with antibiotics challenge the notion that low socioeconomic status may place patients who are treated with antibiotics at higher risk for poor clinical outcomes.

Notes

Supplement 1.

eTable 1. Additional baseline characteristics for participants randomized to antibiotics or appendectomy

eFigure. Description of sites in the CODA trial, ordered by number of participants in each site who were randomized to antibiotics or appendectomy (n)

eTable 2. Baseline characteristics of participants who were randomized to either antibiotics or appendectomy and recruited from the five sites that recruited many Spanish-speaking patients

eTable 3. Outcomes for participants randomized to antibiotics who were recruited from the five sites that recruited many Spanish patients

eAppendix 1. Missing data

eAppendix 2. The CODA Trial Sites and Site Leads

eReferences

Supplement 2.

Trial protocol

Supplement 3.

Nonauthor collaborators

Supplement 4.

Data sharing statement

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Figures and Tables

Table 1.

Baseline Characteristics of Participants Randomized to Either Antibiotics or Appendectomy, by Preferred Language

Characteristic	No. (%)		
	Overall (n = 1552)	English (n = 1076)	Spanish (n = 476)
Race ^a			
Asian	92 (6)	92 (9)	0 (0)
Black	138 (9)	123 (12)	15 (3)
White	910 (59)	687 (64)	223 (48)
Multiple/other ^b	390 (25)	164 (15)	226 (49)
Hispanic ^a			
No	824 (53)	823 (76)	1 (0)
Yes	728 (47)	253 (24)	475 (100)
Age, mean (SD), y	38.0 (13.6)	37.2 (13.7)	40.0 (12.9)
Sex			
Male	976 (63)	666 (62)	310 (65)
Female	576 (37)	410 (38)	166 (35)
Insurance			
Commercial	640 (42)	610 (58)	30 (7)
Medicare or Tricare	178 (12)	118 (11)	60 (13)
Medicaid or state	265 (18)	142 (13)	123 (27)
Other or none	431 (28)	186 (18)	245 (53)
Below federal poverty level			
No	680 (62)	631 (78)	49 (17)
Yes	412 (38)	179 (22)	233 (83)
Education			
Some beyond high school/GED	897 (59)	835 (78)	62 (13)
High school/GED	309 (20)	184 (17)	125 (27)
Less than high school	324 (21)	46 (4)	278 (60)
Health literacy help			
Never or rarely	1207 (81)	936 (91)	271 (59)
Sometimes or more	284 (19)	95 (9)	189 (41)
Employment and activity			

Abbreviation: GED, general educational development.

^a Race and ethnicity were self-reported.

^b Other race includes American Indian, Alaska Native, Native Hawaiian, Pacific Islander, and other/not listed. The most common response for other race was Hispanic.

Table 2.

Outcomes for Participants Randomized to Antibiotics^a

Characteristic	No. (%)		
	Overall (n = 776)	English (n = 538)	Spanish (n = 238)
Appendectomy within 48 h			
Yes	89 (11)	61 (11)	28 (12)
No	682 (88)	473 (88)	209 (88)
Lost to follow-up	5 (1)	4 (1)	1 (0)
Appendectomy within 30 d			
Yes	155 (20)	104 (19)	51 (21)
No	601 (77)	422 (78)	179 (75)
Lost to follow-up	20 (3)	12 (2)	8 (3)
Appendectomy within 1 y			
Yes	299 (39)	202 (38)	97 (41)
No	398 (51)	279 (52)	119 (50)
Lost to follow-up	79 (10)	57 (11)	22 (9)
Symptom resolution at 7 d			
No	364 (51)	259 (52)	105 (48)
Yes	350 (49)	235 (48)	115 (52)
Symptom resolution at 14 d			
No	239 (35)	156 (33)	83 (40)
Yes	446 (65)	319 (67)	127 (60)
Symptom resolution at 30 d			
No	214 (32)	148 (31)	66 (32)
Yes	462 (68)	324 (69)	138 (68)
EQ-5D at 30 d, mean (SD)	0.92 (0.13)	0.92 (0.14)	0.93 (0.12)
Any emergency department/urgent care visits within 30 d			
Yes	38 (6)	31 (7)	7 (4)
No	625 (94)	432 (93)	193 (97)
Any hospital overnights within 30 d			

Abbreviation: EQ-5D, European Quality of Life–5 Dimensions.

^a See eAppendix 1 in Supplement 1 for information about missing data.

^b For work missed, the median (IQR) for the Spanish and English groups are 4 (9.75) and 2 (5).