Wait-and-See Prescription for the Treatment of Acute Otitis Media

A Randomized Controlled Trial

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Context Acute otitis media (AOM) is the most common diagnosis for which antibiotics are prescribed for children. Previous trials that have evaluated a "wait-and-see prescription" (WASP) for antibiotics, with which parents are asked not to fill the prescription unless the child either is not better or is worse in 48 hours, have excluded children with severe AOM. None of these trials were conducted in an emergency department.

Objectives To determine whether treatment of AOM using a WASP significantly reduces use of antibiotics compared with a "standard prescription" (SP) and to evaluate the effects of this intervention on clinical symptoms and adverse outcomes related to antibiotic use.

Design, Setting, and Patients A randomized controlled trial conducted between July 12, 2004, and July 11, 2005. Children with AOM aged 6 months to 12 years seen in an emergency department were randomly assigned to receive either a WASP or an SP. All patients received ibuprofen and otic analgesic drops for use at home. A research assistant, blinded to group assignment, conducted structured phone interviews 4 to 6, 11 to 14, and 30 to 40 days after enrollment to determine outcomes.

Main Outcome Measures Filling of the antibiotic prescription and clinical course.

Results Overall, 283 patients were randomized either to the WASP group (n=138) or the SP group (n=145). Substantially more parents in the WASP group did not fill the antibiotic prescription (62% vs 13%; $P<.001$). There was no statistically significant difference between the groups in the frequency of subsequent fever, otalgia, or unscheduled visits for medical care. Within the WASP group, both fever (relative risk [RR], 2.95; 95% confidence interval [CI], 1.75 - 4.99; $P<.001$) and otalgia (RR, 1.62; 95% CI, 1.26 - 2.03; $P<.001$) were associated with filling the prescription.

Conclusion The WASP approach substantially reduced unnecessary use of antibiotics in children with AOM seen in an emergency department and may be an alternative to routine use of antimicrobials for treatment of such children.

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ACUTE OTITIS MEDIA (AOM) IS the most common reason for which an antibiotic is prescribed to children.[1,2] Treatment of AOM accounts for an estimated 15 million antibiotic prescriptions written per year in the United States.[3] Untreated AOM has a high rate of spontaneous resolution, with similar rates of complications whether antibiotics are prescribed or withheld.[4-7] Resistance to antibiotics is a major public health concern worldwide and is associated with the widespread use of antibiotics.[8-10]

Two randomized trials have evaluated a management approach for AOM in which use of antibiotics is optional.[11,12] One of these trials specifically evaluated children with nonsevere AOM,[11] while the other excluded children with high fever and prescribed suboptimal doses of antibiotics compared with current standards in the United States.[12] Both of these studies used convenience samples and were performed in office practices in which the parents had a prior relationship with the clinicians, and neither prescribed topical analgesia to treat otalgia.

We conducted a randomized controlled trial with a consecutive series of children diagnosed with AOM during a 1-year period in a pediatric emergency department using diagnostic recommendations from evidence-based guidelines.[13] The objectives of

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the study were to determine whether treatment of AOM using a "wait-and-see prescription" (WASP) significantly reduced use of antibiotics compared with a "standard prescription" (SP) in this setting and to evaluate the effects of this intervention on clinical symptoms and adverse outcomes related to antibiotic use.

METHODS

Patients

Participants were enrolled from July 12, 2004, to July 11, 2005, from a consecutive sample of children diagnosed as having AOM in the pediatric emergency department of Yale-New Haven Hospital in New Haven, Conn. All attending clinicians in the pediatric emergency department agreed to recruit patients for the study.

Children between the ages of 6 months and 12 years who were diagnosed as having AOM were eligible for inclusion in the study. To replicate routine clinical practice, the diagnosis of AOM was made at the discretion of the clinician. The most current evidence-based guidelines for diagnosing AOM were reviewed individually with all clinicians, and these diagnostic criteria were posted in the pediatric emergency department throughout the study.[13] Children were excluded if any of the following criteria were present: (1) an additional intercurrent bacterial infection such as pneumonia was either diagnosed or suspected; (2) the patient appeared "toxic" as determined by the clinician; (3) the patient was hospitalized; (4) the patient was immunocompromised; (5) the patient was treated with antibiotics in the preceding 7 days; (6) the patient had either myringotomy tubes or a perforated tympanic membrane; (7) there was uncertain access to medical care, including no telephone access; (8) the primary language of the parent or guardian was neither English nor Spanish; or (9) the patient had already enrolled in the study. The study was approved by the Yale University Human Investigations Committee.

Baseline Assessment

Parents of children diagnosed as having AOM were invited to enroll in the study. Once written informed consent was obtained, the parent (or guardian) was asked to complete a questionnaire about associated symptoms and to identify the adult who would be "most likely to decide whether or not to fill the prescription." Clinicians classified the race/ethnicity of participants as either black, white, Hispanic, or other. Race and ethnicity were assessed to describe the population, which was more heterogeneous than in previous studies.

Randomization

Numbered folders containing enrollment forms, a unique prescription form, and discharge instructions were used sequentially for patients enrolled in the study. Whether a patient would be given a WASP or an SP was determined by computer-assisted randomization (True Epistat, Version 5.3; Epistat Services, Richardson, Tex). Either WASP or SP discharge instructions were sealed in opaque envelopes and then placed in randomly assigned, numbered folders. Group designation was revealed to the clinician and to the parent only after enrollment by opening the envelope in the next folder in sequence.

Intervention

All participants were given a written prescription for an antibiotic, chosen and dosed by the clinician. The prescription itself would expire (ie, could not be filled) 3 days after the child's visit to the emergency department. Participants randomized to the WASP group were given written and verbal instructions "not to fill the antibiotic prescription unless your child either is not better or is worse 48 hours (2 days) after today's visit." Parents of children randomized to the SP group were given written and verbal instructions by the clinician to "fill the antibiotic prescription and give the antibiotic to your child after today's visit." All participants received complimentary bottles of ibuprofen suspension (100 mg/5 mL) and otic analgesic drops (each milliliter contains antipyrene, 54 mg/benzocaine, 14 mg). Treating pain associated with AOM has been recommended by current guidelines,[13] and use of otic drops has been the standard of care in this emergency department. Instructions for the use of the ibuprofen (10 mg/kg per dose every 4-6 hours as needed for pain or fever) and use of otic drops (4 drops in affected ears every 2 hours as needed for pain) were written on discharge forms and were reviewed orally with each parent. Primary care physicians received a summary of the visit by fax, and all participants were instructed to contact their primary care physician if symptoms persisted or worsened. Demographic information about children who were excluded, who were eligible but whose parent refused to participate, or who were not enrolled by discretion of the clinician was tabulated without individual identifiers.

Outcomes

Two trained research assistants blinded to group assignment conducted standardized, structured telephone interviews with the parent or guardian at 4 to 6, 11 to 14, and 30 to 40 days after enrollment. Parents who were unavailable within the specified time window were interviewed at the next follow-up period.

The primary outcome was the proportion of each group that filled the prescription for an antibiotic. This was defined by whether the parent filled the prescription within 3 days of enrollment and was determined by the response to this question at the 4- to 6-day interview. Secondary outcomes included clinical course of the illness, adverse effects of medications, days of school or of work missed, unscheduled medical visits, and comfort of parents with management of AOM without antibiotics for future episodes. For the 30- to 40-day follow-up, only the latter 2 outcomes were assessed. After March 1, 2005, at the time of enrollment, all parents were asked to supply the name and location of the pharmacy at which they would fill the pre-

scription. The research assistant called these pharmacies a minimum of 4 days after enrollment to confirm whether the prescription was filled or not filled.

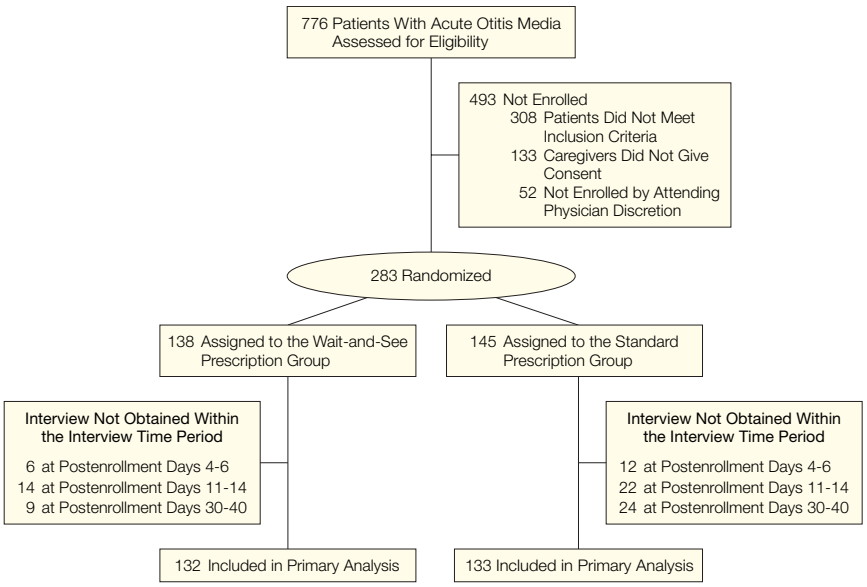
Sample Size and Statistical Analysis

To detect at least a 15% difference in the absence of otalgia at the 4- to 6-day follow up (SP=85%; WASP=70%), with a 2-tailed α error of .05 and statistical power of 90%, each group required a minimum of 120 patients based on the results of 2 previous trials (Power and Precision, Version 2.0.37, Biostat Inc, Englewood, NJ).[12,14] We selected this variable because the sample size needed for our primary outcome would leave the study underpowered for secondary outcomes such as otalgia. The calculated sample size provided more than adequate power (>90%) to detect as small as a 10% difference in proportions of prescriptions filled between the groups.

The χ^2 and Student *t* tests were used for simple comparisons of differences between groups in categorical and continuous variables, respectively. Differences in means and risk ratios are presented with 95% confidence intervals (CIs) to summarize group comparisons. Logistic regression was used to assess dichotomous outcomes while adjusting for race/ethnicity, insurance status, and baseline symptoms and to identify variables associated with filling the prescription in the WASP group. Adjusted risk ratios were obtained from logistic regression using the method described by Zhang and Yu.[15] For all statistical tests, a 2-tailed *P* value of <.05 was considered statistically significant. Analyses were conducted using SAS, Version 9.1 (SAS Institute Inc, Cary, NC).

The primary intention-to-treat analysis included all patients who were enrolled. To assess the implicit missing-at-random assumption, we performed a worst-case sensitivity analysis in which we assumed that parents of all of the children in the WASP group for whom outcome data were missing filled the prescription, and the parents of those children whose outcome data were missing in the SP group did not fill their prescriptions.

Figure. Enrollment, Randomization, Follow-up, and Data Analysis for Study Participants



RESULTS

Participants

During the enrollment period, 776 patients were diagnosed as having AOM (FIGURE); 283 were randomized, 138 to the WASP group and 145 to the SP group. Of the 308 patients who did not meet the inclusion criteria, 27% had been treated with antibiotics in the previous 7 days, 16% had a perforated tympanic membrane, 19% were suspected to have an intercurrent bacterial illness, 7% either were toxic in appearance or were hospitalized, 4% had myringotomy tubes, and 27% were excluded for one of the other reasons for exclusion. Those who did not meet inclusion criteria compared with all those enrolled were younger (median age=2.3 years vs 3.2 years) with a higher percentage of white patients (26% vs 11%) but were similar in regard to sex and insurance status. There were 185 patients who either refused to participate or were not enrolled by discretion of the attending physician. Their age, sex, race/ethnicity, and insurance status were similar to those who were enrolled.

For a small number of enrolled patients, ranging from 6 to 24 per follow-up period, the interview was not obtained because the research assistant could not contact the parent within the interview time period. However, the great majority of patients completed at least 1 follow-up interview (WASP=98%; SP=94%). More parents assigned to the WASP group completed the interviews at each follow-up period. However, this difference was only statistically significant at the 30- to 40-day follow-up (*P*=.009).

Demographic variables and baseline symptoms of the 2 groups were similar (TABLE 1). There were no statistically significant differences in type of primary care, number of children living in the home, or mean ages of the parent who completed the interviews between the groups.

Acute otitis media was unilateral in 83% of children in the WASP group and in 85% of the children in the SP group (*P*=.68). Overall, 54% of all patients and 51% of patients older than 2 years received a prescription for a 10-day course of antibiotics. The mean length of antibiotic therapy prescribed for each group was not significantly different between the 2 groups. Amoxicillin

was prescribed for most patients (WASP=91% vs SP=93%; $P=.91$). The majority of children younger than 2 years in both groups received a prescription for amoxicillin (80-90 mg/kg per day), consistent with current guidelines.[13]

Primary Outcome

Prescriptions were not filled for 62% and 13% of patients in the WASP and SP groups, respectively ($P<.001$; TABLE 2). Adjustment for race, insurance status, and baseline symptoms did not substantially change the results. For the worst-case sensitivity analysis, 59% and 20% of parents in the WASP and SP groups did not fill the prescriptions, respectively ($P<.001$). For children younger than 2 years, 47% of parents did not fill the prescription in the WASP group compared with 5% in the SP group ($P<.001$). Verification of whether the prescription was filled was assessed for 28% of the study population. Of those reports that were assessed, pharmacies of record at enrollment confirmed all instances in which parents reported they did not fill the prescription, and 90% were confirmed when parents reported they did fill the prescription.

The patients in the WASP group whose parents filled the prescription reported they did so because of fever (60%), otalgia (34%), or fussy behavior (6%). Patients in the WASP group whose parents filled the prescription were significantly more likely to report ear pain, fever, or diarrhea than were those whose parents did not fill the prescription (TABLE 3). In the WASP group at the 4- to 6-day follow-up, both fever (relative risk [RR], 2.95; 95% CI, 1.75 - 4.99; $P<.001$) and otalgia (RR, 1.62; 95% CI, 1.26-2.03; $P<.001$) were associated with filling the prescription, but insurance status and race/ethnicity were not.

Table 1. Baseline Characteristics of the Participants

Characteristic	WASP Group (n = 138)	SP Group (n = 145)	*P* Value
Male sex, No. (%)	79 (57)	76 (52)	.41
Age			
Median, y	3.6	3.2	.15
Age <2 y, No. (%)	39 (28.3)	40 (27.6)	.90
Race/ethnic group, No. (%)			
Black	49 (36)	62 (43)	.21
Hispanic	65 (47)	61 (42)	
White	13 (9)	18 (12)	
Other	11 (8)	4 (3)	
Temperature at triage, mean (SD), °C	37.1 (1.0)	36.9 (1.0)	.12
Temperature >38.0°C, No. (%)	26 (19)	18 (12)	.14
Symptoms within 5 d of enrollment, No. (%)			
Otalgia	113 (82)	127 (88)	.10
Fever	59 (43)	77 (53)	.17
Cough or rhinorrhea	110 (80)	128 (88)	.08
Diarrhea	10 (7)	22 (15)	.07
Vomiting	30 (22)	41 (28)	.28
No. of previous ear infections in past year, No. (%)*			
1	77 (57)	77 (57)	.31
2	25 (19)	36 (26)	
≥3	28 (21)	18 (13)	
Unsure	5 (4)	5 (4)	
Decision maker, highest level of education, No. (%)*			
<High school	25 (19)	33 (24)	.56
High school degree	66 (49)	55 (40)	
Some college	26 (19)	34 (25)	
College degree	18 (13)	14 (10)	
Medicaid insurance, No. (%)*	113 (84)	102 (75)	.13
Passive exposure to smoke, No. (%)*	44 (33)	51 (38)	.40
Attends day care or school, No. (%)†	71 (54)	74 (56)	.76
Parent employed part- or full-time, No. (%)†	85 (64)	78 (59)	.34

Abbreviations: SP, standard prescription; WASP, wait-and-see prescription.
*Values were obtained during follow-ups and are different from those at enrollment (WASP group, n=135; SP group, n=136).
†Values were obtained during follow-ups and are different from those at enrollment (WASP group, n=132; SP group, n=133).

Secondary Outcomes

No serious adverse events were reported for patients in the study. Of those parents who reported otalgia in their children, there were statistically significant but minor differences between the WASP and SP groups in total days of otalgia only at the 4- to 6-day interview (2.4 vs 2.0; $P=.02$) (Table 2). Diarrhea was more frequently reported in the SP group, and this difference was statistically significant (8% vs 23%; $P<.001$). There were no statistically significant differences in the frequencies of rash, otorrhea, or unscheduled medical visits between enrollment at either the 4- to 6-day or 11- to 14-day follow-up periods. At the 30- to 40-day follow-up, the rates of unscheduled medical visits were similar between the WASP and SP groups (22% vs 21%; $P=.85$). For all unscheduled medical visits, the most common diagnosis was otitis media (WASP=61%, SP=60%; $P=.85$).

There were no statistically significant differences between groups in willingness of parents to withhold antibiotics for future occurrences of AOM. Within the WASP group at all 3 interviews, parents who did not fill the prescription were substantially more likely to indicate they would be willing to withhold antibiotics for future episodes of AOM compared with those who did fill the prescription: 4- to 6-day follow-up, 63% vs 28% ($P<.001$); 11- to 14-day follow-up, 65% vs 31% ($P<.001$); 30- to 40-day follow-up, 66% vs 26% ($P<.001$).

Table 2. Clinical Outcomes According to Group Designation*

Outcome	WASP Group (n = 132)	SP Group (n = 133)	Unadjusted Difference (95% CI)	Adjusted Difference (95% CI)†	*P* Value‡
4- to 6-Day Follow-up					
Parent did not fill the antibiotic prescription, No. (%)	82 (62)	17 (13)	4.86 (3.06 to 7.73)‡	4.80 (3.57 to 5.85)‡	<.001
Days postenrollment prescription was filled, mean (SD)	2.0 (0.8)	1.2 (0.7)	0.77 (0.53 to 1.06)	0.75 (0.53 to 1.03)	<.001
Otalgia, No. (%)	85 (64)	89 (67)	0.96 (0.81 to 1.15)‡	1.01 (0.83 to 1.17)‡	.96
Total days of otalgia, mean (SD)	2.4 (1.2)	2.0 (1.2)	0.42 (0.07 to 0.78)	0.43 (0.07 to 0.80)	.02
Use of otic analgesia, No. (%)	123 (93)	120 (90)	1.03 (0.96 to 1.11)‡	1.04 (0.94 to 1.08)‡	.34
Total days of otic analgesia use, mean (SD)	2.9 (1.3)	2.8 (1.5)	0.11 (–0.24 to 0.46)	0.11 (–0.25 to 0.46)	.56
Fever, No. (%)	42 (32)	46 (35)	0.92 (0.65 to 1.30)‡	1.04 (0.70 to 1.44)‡	.85
Total days of fever, mean (SD)	2.0 (1.1)	1.7 (1.0)	0.24 (–0.22 to 0.63)	0.33 (–0.13 to 0.73)	.20
Use of ibuprofen or acetaminophen, No. (%)	118 (89)	110 (83)	1.08 (0.98 to 1.19)‡	1.09 (0.98 to 1.14)‡	.11
Total days of ibuprofen or acetaminophen, mean (SD)	2.6 (1.3)	2.4 (1.3)	0.18 (–0.16 to 0.52)	0.22 (–0.13 to 0.58)	.22
Diarrhea, No. (%)	10 (8)	31 (23)	0.33 (0.17 to 0.64)‡	0.30 (0.14 to 0.64)‡	<.001
Total days of diarrhea, mean (SD)	2.3 (1.4)	2.0 (1.3)	0.33 (–0.60 to 1.19)	0.20 (–0.80 to 1.15)	.76
Vomiting, No. (%)	15 (11)	15 (11)	1.01 (0.51 to 1.98)‡	1.24 (0.59 to 2.41)‡	.56
Total days of vomiting, mean (SD)	1.5 (0.9)	1.2 (0.6)	0.33 (–0.20 to 0.80)	0.60 (0.06 to 1.15)	.02
Unscheduled visit(s) to a clinician, No. (%)	13 (10)	11 (8)	1.19 (0.55 to 2.56)‡	1.17 (0.51 to 2.51)‡	.70
11- to 14-Day Follow-up					
	WASP Group (n = 124)	**SP Group (n = 123)**			
Otalgia, No. (%)	83 (67)	75 (61)	1.10 (0.91 to 1.32)‡	1.19 (0.98 to 1.34)‡	.07
Total days of otalgia, mean (SD)	3.0 (2.1)	2.7 (2.1)	0.31 (0.35 to 0.96)	0.33 (0.36 to 1.02)	.35
Use of otic analgesia, No. (%)	118 (95)	110 (89)	1.06 (0.99 to 1.14)‡	1.07 (0.99 to 1.10)‡	.08
Total days of otic analgesia use, mean (SD)	3.2 (2.0)	3.7 (2.7)	–0.45 (–1.07 to 0.16)	–0.40 (–1.03 to 0.24)	.22
Fever, No. (%)	40 (32)	38 (31)	1.04 (0.72 to 1.51)‡	1.20 (0.79 to 1.68)‡	.37
Total days of fever, mean (SD)	2.3 (1.2)	1.7 (0.8)	0.54 (0.08 to 1.02)	0.55 (0.08 to 1.10)	.03
Use of ibuprofen or acetaminophen, No. (%)	105 (85)	105 (85)	0.99 (0.89 to 1.10)‡	1.01 (0.88 to 1.09)‡	.83
Total days of ibuprofen or acetaminophen, mean (SD)	3.2 (2.3)	2.9 (2.3)	0.27 (–0.35 to 0.88)	0.37 (–0.28 to 1.02)	.26
Diarrhea, No. (%)	15 (12)	29 (24)	0.51 (0.29 to 0.91)‡	0.44 (0.21 to 0.83)‡	.01
Total days of diarrhea, mean (SD)	2.6 (1.8)	2.2 (2.4)	0.36 (–0.82 to 1.54)	0.68 (–0.30 to 1.99)	.15
Vomiting, No. (%)	11 (9)	12 (10)	0.91 (0.42 to 1.98)‡	1.13 (0.48 to 2.47)‡	.79
Total days of vomiting, mean (SD)	2.1 (1.3)	2.1 (2.9)	0.01 (–2.15 to 1.64)	0.56 (–2.31 to 2.90)	.54
Unscheduled visit(s) to a clinician, No. (%)	18 (15)	14 (11)	1.28 (0.67 to 2.45)‡	1.27 (0.62 to 2.39)‡	.51

Abbreviations: CI, confidence interval; SP, standard prescription; WASP, wait-and-see prescription.
*Total days during which participants had symptoms or whose parents filled their prescription.
†Adjusted for race/ethnicity, insurance status, and baseline symptoms.
‡Data are relative risk.

Table 3. Clinical Outcomes in the Wait-and-See Prescription Group 4 to 6 Days After Enrollment

Outcome	Parent Filled Prescription (n = 50)	Parent Did Not Fill Prescription (n = 82)	Difference (95% CI)	*P* Value
Otalgia, No. (%)	42 (84)	43 (52)	1.62 (1.26 to 2.03)*	<.001
Total days of otalgia, mean (SD)	2.8 (1.1)	2.1 (1.3)	0.69 (0.18 to 1.20)	.002
Use of otic analgesia, No. (%)	48 (96)	75 (91)	1.05 (0.96 to 1.15)*	.32
Total days of otic analgesia use, mean (SD)	3.0 (1.2)	2.9 (1.3)	0.13 (–0.34 to 0.60)	.60
Fever, No. (%)	27 (54)	15 (18)	2.95 (1.75 to 4.99)*	<.001
Total days of fever, mean (SD)	2.3 (1.2)	1.5 (0.5)	0.79 (0.12 to 1.47)	.03
Use of ibuprofen or acetaminophen, No. (%)	48 (96)	70 (85)	1.12 (1.01 to 1.25)*	.05
Total days of ibuprofen or acetaminophen, mean (SD)	2.8 (1.3)	2.4 (1.3)	0.39 (–0.09 to 0.88)	.05
Diarrhea, No. (%)	6 (12)	4 (5)	2.46 (0.73 to 8.29)*	.13
Total days of diarrhea, mean (SD)	2.5 (1.6)	2.0 (1.1)	0.50 (–1.70 to 2.70)	.71
Vomiting, No. (%)	10 (20)	5 (6)	3.28 (1.19 to 9.04)*	.01
Total days of vomiting, mean (SD)	1.8 (1.0)	1.0 (0)	0.80 (–0.22 to 1.82)	.10

Abbreviation: CI, confidence interval.
*Data are relative risk.

COMMENT

The WASP reduced the use of antibiotics by 56% in children between 6 months and 12 years of age diagnosed as having AOM. We demonstrated that the WASP is a successful treatment strategy for AOM when patients may not have an established relationship with the clinician. In studies that have evaluated a delayed prescription approach, parents have had a previous relationship with a clinician who recommended a delayed prescription as an alternative to immediate use of antibiotics.[12,16,17] Ours is the first trial to enroll patients in the setting of an emergency department.

We found that rates of otalgia were not significantly different between groups at either the 4- to 6-day or 11- to 14-day follow-up periods. However, mean days with otalgia were found to be slightly greater (0.4 days) in the WASP group at the 4- to 6-day follow-up, a finding consistent with previous reports that immediate use of an antibiotic shortens the duration of otalgia.[6,12,17] This difference may have been minimized by the use of otic analgesia and ibuprofen. These medications are beneficial for symptomatic relief of pain and fever[18,19] and are strongly recommended in recent guidelines.[13] Meta-analyses have reported a number needed to treat of 15 to 17 children with AOM to eliminate otalgia in 1 child 2 to 7 days after initial presentation.[5,20] This is a high number needed to treat considering the potential adverse effects associated with use of antibiotics. Additionally, we found that immediate treatment of AOM with an antibiotic resulted in rates of diarrhea that were 2- to 3-fold higher than those in the WASP group, consistent with previous studies.[7,21]

Patients in the WASP group whose parents filled the prescription were more likely to report ear pain and fever than those whose parents did not fill their prescription. In previous studies, fever and otalgia have been reported as the predominant factors that influenced the decision of parents to fill the prescription for an antibiotic.[12,16,17] It was our intention to empower the parents to fill the prescription based on either severity of illness or duration of symptoms beyond 48 hours after the initial evaluation. Although our methods were unable specifically to evaluate rates of relapse or reinfection, the most common reason for subsequent unscheduled medical visits was AOM, but the frequency of these unscheduled visits at the 30- to 40-day follow-up was similar in the 2 groups.

The study has several limitations. Parents were not blinded to group designation since the primary outcome was based on the treatment choice of the parent. Physician recruiters were blinded to group designation until after the patient was enrolled, and the interviewers were blinded to group designation until the interview period was completed. Nonresponse bias is negligible as very few parents failed to complete the interviews, and small differences in attrition rates between groups were not significant at each of the first 2 interview periods at which the majority of outcomes were determined. Most parents were truthful in reporting whether they did or did not fill the prescription based on confirmation of the reports with pharmacies. Our results may not be generalizable to all acute-care settings as this was a single-center study performed in an urban emergency department. While we did not independently confirm that each participant met the diagnostic criteria for AOM, it is unlikely that this led to bias since participants were randomly allocated to the treatment groups. We did not grade the severity of AOM as this is not part of routine clinical practice. We also did not quantify the use of otic analgesic drops, which may have underestimated their use in the WASP group. Although a previously published guideline and a meta-analysis both recommended short-course (5-7 days) antibiotics for AOM for children older than 2 years,[22,23] half of our clinicians prescribed long-course (10 days) therapy for this particular age group. Finally, the study was not powered to detect rare outcomes. Larger studies may demonstrate differences in rates of mastoiditis or other serious complications of AOM between patients treated with the WASP or the SP. However, the frequency of mastoiditis in the United States is similar to that in other countries where clinicians do not routinely prescribe antibiotics for AOM.[24]

This randomized controlled trial has provided evidence that the WASP strategy significantly reduces the use of antibiotics in an urban population presenting to an emergency department and may be an alternative to routine treatment of AOM with antibiotics. Wait-and-see prescriptions remain controversial as most pediatricians in the United States have been trained to routinely prescribe antibiotics for AOM and believe that many parents expect a prescription; a small minority of practitioners who care for children routinely use watchful waiting.[25] The WASP approach may interrupt the cycle of antibiotic prescription, the expectation of parents to immediately treat AOM with an antibiotic, and subsequent medical visits for this illness.[26,27] The risks of antibiotics, including gastrointestinal symptoms, allergic reactions, and accelerated resistance to bacterial pathogens[28,29] must be weighed against their benefits for an illness that, for the most part, is self-limited.[4] The routine use of WASP for AOM will reduce both the costs and adverse effects associated with antibiotic treatment and should reduce selective pressure for organisms resistant to commonly used antimicrobials.

Author Contributions: As principal investigator of the study, Dr Spiro had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Spiro, Arnold, Baker, Shapiro.
Acquisition of data: Tay.
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