Original Investigation

Effect of Oximetry on Hospitalization in Bronchiolitis
A Randomized Clinical Trial

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IMPORTANCE Routine use of pulse oximetry has been associated with changes in bronchiolitis management and may have lowered the hospitalization threshold for patients with bronchiolitis.

OBJECTIVE To examine if infants with bronchiolitis whose displayed oximetry measurements have been artificially elevated 3 percentage points above true values experience hospitalization rates at least 15% lower compared with infants with true values displayed.

DESIGN, SETTING, AND PARTICIPANTS Randomized, double-blind, parallel-group trial conducted from 2008 to 2013 in a tertiary-care pediatric emergency department in Toronto, Ontario, Canada. Participants were 213 otherwise healthy infants aged 4 weeks to 12 months with mild to moderate bronchiolitis and true oxygen saturations of 88% or higher.

INTERVENTIONS Pulse oximetry measurements with true saturation values displayed or with altered saturation values displayed that have been increased 3 percentage points above true values.

MAIN OUTCOMES AND MEASURES The primary outcome was hospitalization within 72 hours, defined as inpatient admission within this interval or active hospital care for greater than 6 hours. Secondary outcomes included the use of supplemental oxygen in the emergency department, level of physician agreement with discharge from the emergency department, length of emergency department stay, and unscheduled visits for bronchiolitis within 72 hours.

RESULTS Forty-four of 108 patients (41%) in the true oximetry group and 26 of 105 (25%) in the altered oximetry group were hospitalized within 72 hours (difference, 16% [95% CI for the difference, 3.6% to 28.4%]; $P = .005$). Using the emergency department physician as a random effect, the primary treatment effect remained significant (adjusted odds ratio, 4.0 [95% CI, 1.6 to 10.5]; $P = .009$). None of the secondary outcomes were significantly different between the groups. There were 23 of 108 (21.3%) subsequent unscheduled medical visits for bronchiolitis in the true oximetry group and 15 of 105 (14.3%) in the altered oximetry group (difference, 7% [95% CI, −0.3% to 0.2%]; $P = .18$).

CONCLUSIONS AND RELEVANCE Among infants presenting to an emergency department with mild to moderate bronchiolitis, those with an artificially elevated pulse oximetry reading were less likely to be hospitalized within 72 hours or to receive active hospital care for more than 6 hours than those with unaltered oximetry readings. This suggests that oxygen saturation should not be the only factor in the decision to admit, and its use may need to be reevaluated.

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Bronchiolitis is the leading cause of infant hospitalizations in the United States, with annual costs in excess of $1 billion.[1] Because pharmacotherapeutic interventions have not proven effective, management guidelines and some authors recommend the use of supportive measures and advise against the routine use of pharmacotherapy in the emergency department.[2-7]

Between 1980 and 2000 the rate of hospitalizations for bronchiolitis increased from 12.9 per 1000 to 31.2 per 1000.[8] Pulse oximetry represents a noninvasive method of measuring oxygen saturation, and its routine use has been associated with changes in the management of bronchiolitis,[9,10] possibly because reliance on oximetry may have altered the hospitalization criterion.[8,11,12] The threshold suggestive of the need for supplemental oxygen varies between 90% and 95%.[4,5,13] Although hospitalization is sometimes necessary in children with normal oxygen saturations and not admitting children who require hospitalization can be hazardous, there is no evidence that the aforementioned cutoffs predict progression from relatively mild to severe bronchiolitis.[12] Preliminary work has reported that small differences in oximetry may have a major effect on hospitalizations.[12] Because previous oximetry studies in bronchiolitis have not focused on the emergency department population, experts have called for research evaluating the effect of oximetry on physician behavior and patient disposition.[14] If well-appearing children with mild to moderate bronchiolitis can be sent home, fewer hospitalizations and lower health care costs could result.[15]

To clarify the role of oximetry, we conducted a clinical trial with the primary objective to determine if increasing the displayed oximetry 3 percentage points above the true values in infants with acute bronchiolitis in a pediatric emergency department would decrease the probability of hospitalization within 72 hours compared with those for whom the true oxygen saturation value is displayed. Secondary objectives were to determine if the groups differed in physician level of agreement with discharge, emergency department length of stay, and unscheduled visits.

Methods

Study Design and Population

This was a randomized, double-blind, parallel-group trial comparing outcomes of infants presenting with bronchiolitis to a tertiary-care pediatric emergency department between March 2008 and May 2013, who had either true or altered oximetry values displayed. We included previously healthy infants aged 4 weeks to 12 months diagnosed with bronchiolitis, defined as the first episode of respiratory distress with coryza, cough, wheezing/crackles, and tachypnea or chest retractions.[4,16] Children with cardiopulmonary, neuromuscular, hematologic, or congenital airway anomalies were excluded, as were those with true triage saturations below 88%, those transferred from outside institutions, and those with severe respiratory distress defined by an initial retraction component of the Respiratory Disease Assessment Instrument (RDAI)[17] score of 8 or 9 points. They were also excluded if there was concern about impending respiratory failure. The RDAI (range of possible scores, 0 [normal] to 17 [most severe]) is an instrument used in bronchiolitis studies to quantify the degree of respiratory abnormality by using severity of chest retractions (0-9 points) and wheezing (0-8 points).[17] The oxygen saturation threshold of 88% includes stable infants with saturations slightly below the 90% cutoff (while eating or sleeping) recommended by the American Academy of Pediatrics.[4,18] This difference is within the measurement error of the saturation monitors.[19]

Written informed consent was obtained from all participating families, and the institutional research ethics board approved the study.

Study Procedure and Treatment Allocation

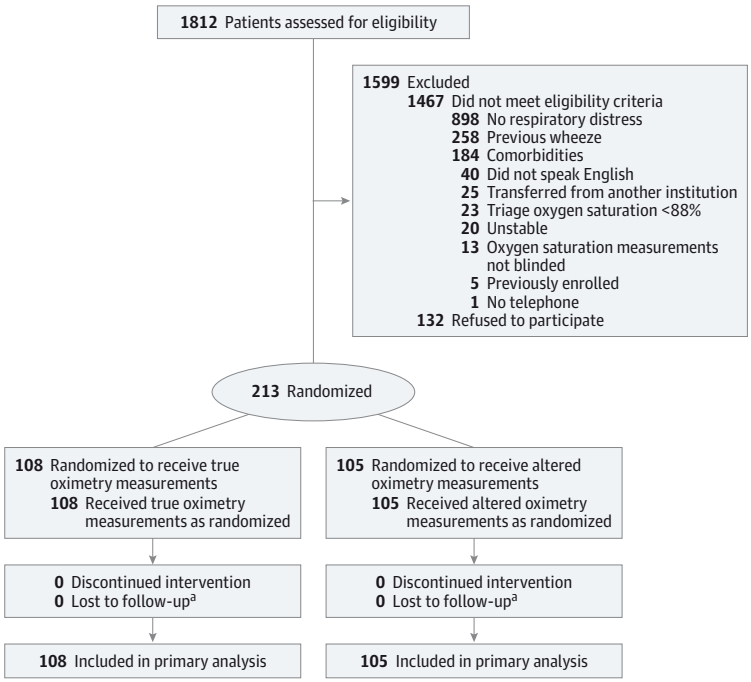
All infants had their true oxygen saturation measured by the triage nurse who notified a research nurse of patients with saturation 88% or higher. Although the families were allowed to see the saturation values, these results are not routinely explained to families. Potential study candidates were screened for eligibility and approached for enrollment by 2 trained research nurses on duty between noon and midnight 6 days a week. They maintained a log of all potentially eligible children. A structured data collection form was used to document baseline features that may confound the comparison.

Participating infants were randomly allocated to either true saturation (ie, true saturation values displayed) or altered saturation (ie, saturation measurements displayed were 3 points higher, to a maximum of 100%). The magnitude of alteration was selected based on prior work demonstrating that this difference may have a major effect on disposition in bronchiolitis.[12] The emergency department physicians were not told the primary hypothesis of the study. They were informed that participants had a 50% probability of having their displayed saturations altered by a physiologically small amount and that the true triage saturation was 88% or higher. They were not informed of the magnitude or the direction of oximeter manipulation and were encouraged to continue their usual practice regarding management and disposition. Prior to study commencement, 3 of the 6 study oximeters were altered by the manufacturer (Masimo Corporation) so that the saturation display was increased by 3 percentage points.

Randomization and Masking

A random permuted block randomization scheme with a block size of 6 was prepared by an independent Internet randomization service (http://www.randomize.net), which randomly allocated enrolled infants to 1 of the 2 study groups (**Figure**). The randomization code, provided through email confirmation, directed the nurse to use an oximeter with a code number corresponding to either an unaltered or altered device. Prior to the study, the study nurses were unable to distinguish which oximeter belonged to each study group; the oximeters appeared identical. Only the director of the respiratory therapy division had the key to which monitors had been altered. Code numbers were securely stored until enrollment and all decisions regarding analyses had been finalized. The treat-

Figure. Enrollment, Randomization, and Follow-up of Pulse Oximetry in Infant Bronchiolitis Trial



[a] The follow-up at 72 hours was carried out in patients discharged at the index visit (82 in true oximetry group, 89 in altered oximetry group). A total of 26 and 16 patients were remaining in hospital at the time of follow-up in the true and altered oximetry groups, respectively.

ing emergency department physicians, nurses, families, and research nurses were blinded to group assignment.

To maintain blinding, the triage nurse kept the triage saturation data separate from the clinical chart and did not document this information in the patients' clinical charts until after the disposition had been determined. Supplemental oxygen and pharmacotherapy were provided at the discretion of the treating physician.

Follow-up

Using standardized interviewing techniques, the study nurses conducted telephone follow-up of all participants discharged home at the index visit 72 hours following enrollment to identify unscheduled visits for bronchiolitis and delayed hospitalizations.

Outcome Measures

After group assignment, the infants had their initial (ie, experimental) oxygen saturation, heart rate, respiratory rate, and RDAI score assessed by the trained research nurse.[17] Saturations were measured in room air and displayed for approximately 5 minutes during the initial physician evaluation. The primary outcome was hospitalization for bronchiolitis within 72 hours of enrollment, defined as admission to an inpatient ward or a decision by the emergency department physician to provide active hospital care for more than 6 hours because of concerns about respiratory distress. The latter definition captured information for children ultimately sent home who received treatment in the emergency department for prolonged periods owing to the unavailability of an inpatient bed. Active care was defined by the use of bronchodilators, intravenous fluids, or oxygen. The 72-hour interval accounted for children initially sent home who returned and were hospitalized. Accepted standards for discharge from the emergency department include ability to self-hydrate; appropriate state of wakefulness, eye contact, and play; absence of severe respiratory distress; parental comfort with discharge; and availability of close follow-up. In keeping with our pragmatic study design, our institution and the study protocol did not specify a saturation cutoff dictating a need for hospitalization, although many emergency department physicians favor hospitalization in infants with saturation values in the low 90s.[15]

Secondary outcomes included supplemental oxygen administration in the emergency department, hourly physician level of agreement with discharge home, length of stay in the emergency department, and unscheduled visits for bronchiolitis within 72 hours. The level of agreement with discharge was based on the proportion of emergency department physicians indicating "agree/strongly agree" with discharge on a 5-point Likert scale based on the following question: "Based on this infant's clinical appearance, respiratory distress, hydration, vital signs and saturation, he/she is ready for discharge."

Exploratory outcomes included hospitalization at the index visit, active treatment in the hospital beyond 6 hours after randomization with inhaled bronchodilators, oxygen, or intravenous fluids, and delayed hospitalizations at any medical facility for bronchiolitis within 72 hours.

Safety of Participants

We excluded infants with conditions necessitating normal oxygen saturations. Although we normally limit continuous oximetry to children with severe respiratory distress, all infants

underwent concealed continuous oximetry for safety reasons, with monitors programmed to alarm when the saturation dropped below 92%, which prompted a clinical reassessment and evaluation of the probe placement to ensure that desaturation reflected clinical changes. The data and safety monitoring committee met every bronchiolitis season to review participants admitted to the intensive care unit.

Sample Size

A sample size of 108 patients per group was estimated to provide 80% power to detect an absolute 15% difference in the primary outcome between the groups, assuming a hospitalization rate of 30% in the true oximetry group,[20] allowing for a 1-sided α=.05.[21]

Statistical Analysis

A statistician not otherwise involved in the study carried out the analysis using SAS version 9.3 (SAS Institute Inc). Since the primary objective was 1-sided (ie, does elevating the saturation by 3 percentage points decrease the probability of hospitalization), the difference in the primary outcome was compared using the 1-sided unadjusted Fisher exact test. All other comparisons were 2-sided. The relevant 95% CIs were determined. The primary analysis was performed using the intention-to-treat principle. For the primary analysis, a 1-sided α=.05 was used for significance.

As a sensitivity analysis, logistic regression analysis was used to examine the association between the primary outcome (ie, hospitalization within 72 hours) as the dependent variable and study group, age, triage saturation, duration of distress, and initial RDAI score as independent variables. The selected variables were assessed as to whether a significant effect existed. A multivariable model was then refined using backward stepwise elimination. Variables in the initial model with $P > .20$ were removed from the multivariable regression model.

To control for clustering of hospitalizations at the physician level, we conducted a regression analysis with the emergency department physician as a random effect. To test if oxygen saturation was the main factor associated with hospitalizations, we performed a sensitivity analysis in which the saturation presented to the treating emergency department physician was added to a logistic regression model as a covariate. We used a 2-sided Fisher exact test to examine the differences in the proportions of patients receiving supplemental oxygen in the emergency department and to examine hourly differences in the proportions of physicians agreeing/strongly agreeing with discharge home and a *t* test to calculate the difference in the length of emergency department stay between the groups. For the secondary and exploratory analyses, a 2-sided α=.05 was used for significance.

Results

During the study period, 1812 patients were screened, 345 met enrollment criteria, and 213 were randomized (Figure). A total of 995 patients presented outside of study hours, and 52 were missed. From the 132 families who refused to participate, 10 children (8%) were hospitalized at the index visit, vs 42 children (20%) from the 213 participating families. Most refusals occurred because of lack of interest in research.

One hundred eight patients were randomized to the true oximetry group and 105 to the altered oximetry group. One infant with a saturation of 86% was mistakenly enrolled in the true saturation group (protocol violation). Infants in the 2 groups had comparable disease severity, with a total of 13% of the participants presenting with triage saturations of less than 94% (**Table 1**). The difference in mean oxygen saturations between the 2 groups was 1.6%, less than the 3 percentage points expected, because the displayed oximetry reading of patients in the altered oximetry group with saturations of 98% or above could not exceed 100%. Thirteen physicians cared for study participants, treating a median of 8 patients.

Primary Outcome

Forty-one percent (44/108) of children in the true oximetry group were hospitalized within 72 hours, compared with 25% (26/105) in the altered oximetry group (difference, 16% [95% CI for the difference, 3.6% to 28.4%]; $P = .005$; odds ratio [OR], 2.1 [95% CI, 1.2 to 3.8]). Hospitalizations by group (ie, true vs elevated) controlling for experimental saturation level revealed no significant difference ($P = .16$; see eTable 1 and eTable 2 in the Supplement). Controlling for age, duration of respiratory distress, triage saturation, and initial RDAI score yielded an OR of 4.0 (95% CI, 1.8 to 9.6; $P = .001$).

Sensitivity Analyses

The regression analysis with the treating emergency department physician as a random effect showed persistence of the treatment effect (unadjusted OR, 2.1 [95% CI, 1.1 to 4.0]; $P = .03$; adjusted OR, 4.0 [95% CI, 1.6 to 10.5]; $P = .009$). Adjusting for the experimental oxygen saturation presented to the emergency department physician revealed lack of association between hospitalization within 72 hours and the study group (OR, 1.4 [95% CI, 0.9 to 2.3]; $P = .12$).

Secondary Outcomes

There were no significant differences in the length of emergency department stay, hourly physician level of agreement with discharge, or supplemental oxygen use (**Table 2**). The rates of unscheduled visits were also comparable between the groups (Table 2).

Exploratory Outcomes

These differences are summarized in Table 2. With the exception of the proportion of children receiving treatment beyond 6 hours, no differences reached statistical significance. The proportions of delayed hospitalizations within 72 hours were comparable (Table 2). No participant was admitted to the intensive care unit.

A total of 6 of 11 and 11 of 17 infants with triage saturations less than 94% in the true and altered oximetry groups, respectively, were discharged home at the index emergency department visit; none were hospitalized within 72 hours.

Table 1. Demographic and Clinical Characteristics of the Participating Infants

Characteristic	Oximetry	
	True (n = 108)	Altered (n = 105)
Age, mean (SD), mo	4.8 (3.0)	5.4 (3.0)
Male sex, No. (%)	63 (58)	62 (62)
Fever ≥38°C within 48 h, No. (%)	53 (49)	57 (54)
History of atopy, No. (%)	31 (29)	20 (19)
Family history of atopy, No. (%)	46 (43)	48 (47)
Duration of respiratory distress, median (range), h	48 (7-672)	48 (7-360)
Therapy within 48 h of arrival, No. (%)		
Inhaled albuterol	20 (19)	31 (30)
Oral corticosteroids	16 (15)	11 (10)
Inhaled corticosteroids	8 (8)	2 (2)
Triage oxygen saturation, mean (SD), %[a]	97.3 (2.1)	96.8 (2.2)
Triage saturation <94%, No. (%)	11 (10)	17 (16)
Experimental oxygen saturation, %		
Mean (SD)[a,b]	96.0 (2.8)	97.6 (2.4)
Median (IQR) [total range]	96 (95-98) [86-100]	98 (96-100) [90-100]
Initial respiratory rate per min, mean (SD)	53.0 (11.6)	50.0 (15.0)
Initial heart rate per min, mean (SD)	152 (18)	151 (22)
Initial RDAI, mean (SD)[c]	8.0 (2.9)	8.3 (2.9)
Participating emergency department physicians, No.	13	12
No. of patients per same physician, median (IQR)	8 (6-10)	8 (7-9)

Abbreviations: IQR, interquartile range; RDAI, Respiratory Disease Assessment Instrument.

[a] Saturation values provided to emergency department physician.

[b] One hundred percent had displayed oximetry values of 100%.

[c] Possible range, 0-17; higher scores indicate greater respiratory distress.

Table 2. Outcomes of Patients in the True vs Altered Oximetry Groups

Outcome	Oximetry		Difference, % (95% CI)	*P* Value
	True (n = 108)	Altered (n = 105)		
Primary				
Hospitalized within 72 h, No. (%)	44 (41)	26 (25)	16 (0.04 to 0.28)	.005
Secondary				
Length of emergency department stay, h				
Mean (SD)	5.2 (5.6)	5.0 (2.4)	0.2 (-0.13 to 0.12)	.82
Median (IQR)	4.0 (3.0-5.6)	4.1 (2.9-5.5)		.76
Supplemental oxygen in emergency department, No. (%)	4 (3.7)	4 (3.8)	-0.1 (-0.05 to 0.05)	.97
Agree/strongly agree with discharge home, No. (%)				
At initial assessment	29 (27)	28 (27)	0 (-0.16 to 0.15)	.94
At 60 min	46 (43)	58 (55)	8 (-0.25 to 0.02)	.08
At 120 min	39/71 (55)	29/64 (45)	10 (-0.26 to 0.07)	.26
Unscheduled visits within 72 h, No. (%)	23 (21)	15 (14)	7 (-0.3 to 0.17)	.18
Exploratory, No. (%)				
Delayed hospitalizations within 72 h	8 (7)	7 (7)	0 (-0.06 to 0.08)	.99
Treatment in hospital >6 h	37 (34)	20 (19)	15 (0.04 to 0.27)	.01
Hospitalization at index visit	26 (24)	16 (15)	9 (-0.01 to 0.2)	.10

Discussion

Artificially increasing the oximetry display in emergency department patients with mild to moderate bronchiolitis by a physiologically small amount significantly reduced hospitalizations within 72 hours or active hospital care for more than 6 hours compared with infants with unaltered oximetry readings. This conclusion also held true after adjustment for other variables significantly associated with this outcome. Because the groups had similar severity and the adjustment for the experimental saturation resulted in lack of primary treatment effect, the difference in displayed saturations was likely the primary reason for the observed reduction in hospitalizations.

The manipulation performed for study purposes was deemed to be physiologically safe yet anticipated to have substantial clinical effect based on prior work.[12] The oxygen dis-

sociation curve has an upper inflection point at an arterial pressure of 60 mm Hg, which corresponds to a saturation of 90%.[22] Above and to the right of this point, the curve is flat and large changes in saturation correspond to small changes in arterial oxygen pressures. At sea level, the estimated difference in arterial pressure corresponding to a 3% difference in saturations in the 90% to 95% range is approximately 9 mm Hg.[12] Since the accuracy of most saturation monitors is of the order of ±2%[19] and oximetry readings are subject to multiple sources of error,[23] the actual physiological difference between the true and altered oximetry measurements in our study was of minor importance. Yet this difference had significant implications on hospitalizations.

Two key studies have shown that oxygen saturation thresholds may play a major role in influencing patient outcomes. The first study used hypothetical vignettes describing children with varying respiratory rates and saturations.[12] Although the varying respiratory rates had little effect on the response regarding the need for admission, the 2% difference in saturations doubled the hospitalization rate.[12] In a retrospective inpatient study, 26% of children hospitalized for bronchiolitis remained in hospital an extra 1.6 days owing to low saturation alone.[15] In addition, previously expressed expert opinion cautions against overreliance on oximetry and argues for the use of clinical judgment when making disposition determinations.[24]

A multicenter study showed that an oxygen saturation value of less than 94% is the best predictor of hospitalization.[14] However, the authors noted that the decision to admit children with bronchiolitis is multifactorial and that the proposed cutoff may not be optimal.[14] Our results suggest that an even lower cutoff might be appropriate and that among children with saturation levels of 88% and higher, disposition determination should be based primarily on the degree of respiratory distress and hydration status, rather than on a particular saturation value. Indeed, some participating infants were hospitalized despite normal saturations, reflecting other reasons for hospital admission.

Although the high number of refusals in this study is comparable with those in previous bronchiolitis studies,[2,7] the possibility of selection bias is an important consideration. However, our nonparticipating population did not have a higher admission rate and therefore was probably not sicker than the participants. Also, a change in physician behavior attributable to their knowledge that the saturation would be altered cannot be excluded.

The limited number of infants with low oxygen saturation levels represents a significant limitation of this study and did not permit us to determine a specific threshold for safe discharge. In keeping with other reports,[14] the majority of infants admitted to hospital in our study had near-normal saturation levels or modest hypoxia. Rather than assessing the effect of hypoxemia on decision making, this study may have assessed the effect of artificially elevating oxygen saturations in infants with near-normal saturations. A future multisite study of infants with low saturation levels may help clarify the optimal threshold. Although the American Academy of Pediatrics recommends that infants with bronchiolitis with saturation levels of 90% or higher do not require supplemental oxygen,[4] other factors must be affecting admissions in infants without hypoxemia.

We also did not assess family-centered outcomes such as satisfaction with care, and the study was not powered for rare but serious complications. Although controversial and of unclear relevance to acute bronchiolitis, the relationship between hypoxemia and long-term effect on the developing brain is beyond the scope of this study.[25] Future studies may shed light on this issue. Because this was a single-center study, the decision making of a single small set of physicians may not be fully generalizable to other settings. These finding are only relevant to infants with bronchiolitis and not to those with hypoxia attributable to other etiologies. Select infants with bronchiolitis, particularly those residing at a high altitude, may also benefit from home supplemental oxygen.[14,26]

Conclusions

Among infants presenting to a pediatric emergency department with mild to moderate bronchiolitis, those with an artificially elevated pulse oximetry reading were less likely to be hospitalized within 72 hours or receive active hospital care for more than 6 hours than those with unaltered oximetry readings. This suggests that oxygen saturation should not be the only factor in the decision to admit or discharge and may need to be reevaluated.

ARTICLE INFORMATION

Author Contributions: Dr Schuh had full access to all of 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: Schuh, Freedman, Coates, Allen, Parkin, DaSilva.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Schuh, Coates, Willan.
Critical revision of the manuscript for important intellectual content: Schuh, Freedman, Coates, Allen, Parkin, Stephens, Ungar, DaSilva.
Statistical analysis: Stephens, Ungar, Willan.
Obtained funding: Schuh, Freedman, Allen.
Administrative, technical, or material support: Coates, DaSilva.
Study supervision: Schuh, Freedman.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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Role of the Sponsors: This was an investigator-initiated study. The Thrasher Research Fund, Physicians' Services Incorporated Foundation, and Masimo had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; the preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

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