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Solar-Powered Oxygen Delivery in Low-Resource Settings

A Randomized Clinical Noninferiority Trial

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Study concept and design: Hawkes, Conroy, Namasopo, Kain, Opoka.

Acquisition, analysis, or interpretation of data: Hawkes, Namasopo, Bhargava, Kain, Mian, Opoka.

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Critical revision of the manuscript for important intellectual content: Hawkes, Conroy, Bhargava, Kain, Mian, Opoka.

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Study supervision: Hawkes, Namasopo, Kain, Opoka.

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This randomized clinical noninferiority trial compares solar-powered oxygen delivery vs standard oxygen delivery using compressed oxygen cylinders among children younger than 13 years with hypoxemic illness at 2 resource-constrained hospitals in Uganda.

Oxygen is an essential medicine for life-threatening hypoxemic illnesses, including pneumonia, which is currently the leading cause of childhood mortality worldwide.[1,2] However, oxygen is not available in many pediatric wards in low-income countries. In a survey of 12 African countries, only 44% of 231 health centers, district hospitals, and provincial or general hospitals had access to oxygen on a continuous basis.[3] Pragmatic solutions are needed to improve access to oxygen in low-resource settings.

In resource-constrained settings, compressed oxygen cylinders and oxygen concentrators are commonly used. Oxygen cylinders are ready to use and do not require any electricity; however, their availability may be compromised by weak stock management, the need for transportation from supplier to hospital, and leakage from ill-fitting regulators. Oxygen concentrators generate oxygen on site from ambient air through selective adsorption of nitrogen using aluminum silicate sieve beds. Concentrators overcome the logistical supply barriers of cylinder oxygen, require minimal service and maintenance, and are more user-friendly than cylinders. However, oxygen concentrators require a continuous and reliable source of electricity. A systematic review found that only 34% of hospitals in sub-Saharan Africa have reliable access to electricity.[4] Interruptions in oxygen therapy owing to power outages are therefore frequent and potentially fatal in the settings in which most deaths from pneumonia occur.[4]

Methods

We tested a novel strategy, solar-powered oxygen delivery, which concentrates oxygen from ambient air [5]

using solar energy. We conducted a randomized, placebo-controlled clinical trial of solar-powered oxygen delivery vs standard oxygen delivery using compressed oxygen cylinders among children younger than 13 years with hypoxemic illness at 2 resource-constrained hospitals in Uganda. The trial protocol and methods have previously been published[6] (trial protocol in the Supplement) and the trial was registered (clinicaltrials.gov NCT02100865). The trial was designed to demonstrate noninferiority of solar-powered oxygen delivery relative to oxygen cylinders, using a clinically meaningful end point, length of hospital stay, expressed as a continuous variable using the date and hour of admission and discharge, using a noninferiority margin of 1 day. The study was reviewed and approved by the Makerere University School of Biomedical Sciences Research Ethics Committee (REC Protocol SBS 139), the Uganda National Council on Science and Technology (Ref SS 3331), and the University Health Network Research Ethics Committee, Toronto, Canada (UHN REB No. 13-6168-AE). Parents of all patients provided written informed consent for participation in the study.

Results

A total of 130 children (59 girls [45.4%] and 71 boys [54.6%]; mean [SD] age, 16 [22] months) were enrolled between March 29, 2014, and May 13, 2015; of these, 65 (50.0%) were assigned to solar-powered oxygen delivery and 65 to cylinder oxygen. Baseline characteristics were similar between groups (Table). The median length of hospital stay was 4.1 days (interquartile range, 2.9-5.6 days) in the solar-powered oxygen delivery group and 4.5 days (interquartile range, 3.3-6.9 days) in the cylinder oxygen group; the difference of medians was –0.41 days (95% CI, –1.2 to 0.43), meeting the prespecified criterion for noninferiority. In-hospital mortality was similar between groups: 11 patients (17%) in the solar-powered oxygen delivery group vs 8 patients (12%) in the cylinder oxygen group (risk difference, 4.6%; 95% CI, –7.8% to 17%). In a competing risk analysis with in-hospital mortality and hospital discharge as competing events, the time to discharge and mortality were not statistically different between groups (Figure, A). The increase in peripheral blood oxygen saturation (Figure, B), and the time to wean off oxygen were similar (Figure, C). Adverse events were similar in both groups.

Five episodes of battery depletion involving 7 patients required recharging the batteries of the solar-powered oxygen system using the hydroelectric grid or switching patients to the backup oxygen supply. Conversely, 4 patients randomized to receive cylinder oxygen were switched to the backup oxygen supply when cylinders stocks were depleted, despite our best efforts to maintain adequate stocks of cylinders.

Discussion

Solar-powered oxygen delivery is noninferior to standard oxygen delivery using cylinders among African children hospitalized with hypoxemic illness. This technological innovation may be suitable for low-resource hospitals with pediatric inpatient services where the supply chain of cylinders and electrical power are not reliable. Solar-powered oxygen delivery addresses a critical gap in access to oxygen and has the potential for global consequences, given the magnitude of childhood pneumonia deaths, currently estimated at 900 000 per year.[1]

Notes

Supplement.

Trial Protocol

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Figures and Tables

Table.

Baseline Characteristics of the 2 Treatment Groups

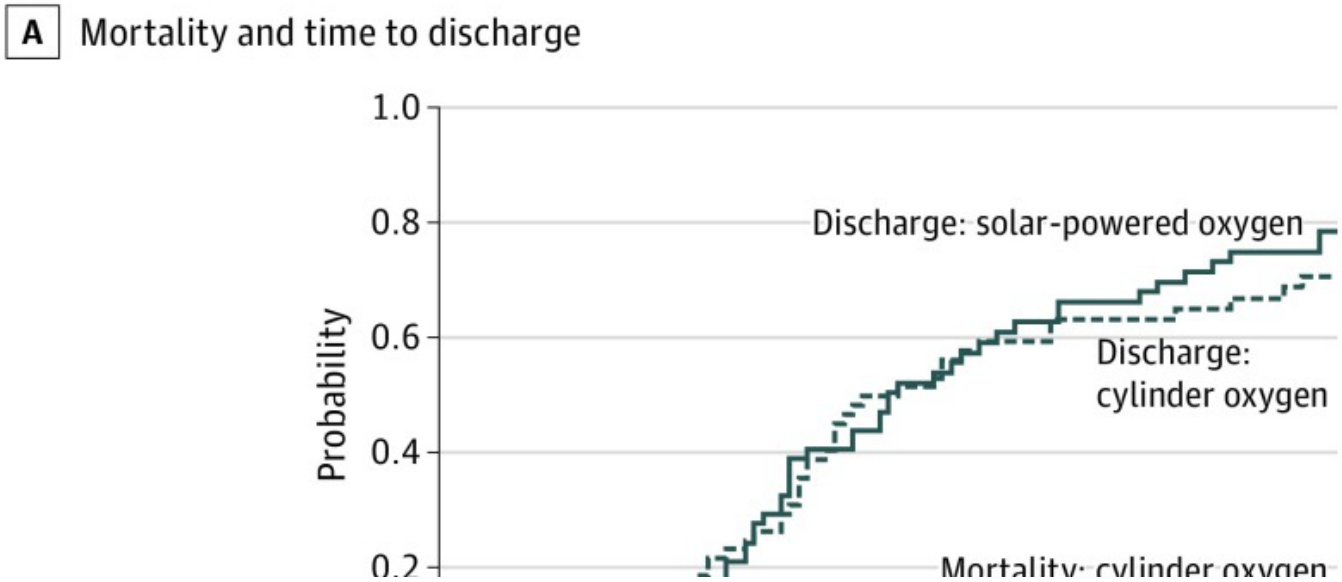
Characteristic	Children, No. (%)	
	Solar-Powered Oxygen (n = 65)	Cylinder Oxygen (N = 65)
Female sex	27 (42)	32 (49)
Age, median (IQR), mo	10 (3-19)	10 (1-22)
Clinical features at enrollment		
Cough	53 (82)	51 (78)
Difficulty breathing	58 (89)	56 (86)
Unable to drink or feed	25 (38)	28 (43)
Results of clinical examination at enrollment		
Weight, median (IQR), kg	8.0 (5.0-10)	7.0 (4.3-10)
Underweight[a]	9 (14)	9 (14)
Oxygen saturation, median (IQR), %	83 (72-87)	84 (76-87)
Respiratory rate, median (IQR), min^{-1}	68 (54-78)	66 (48-80)

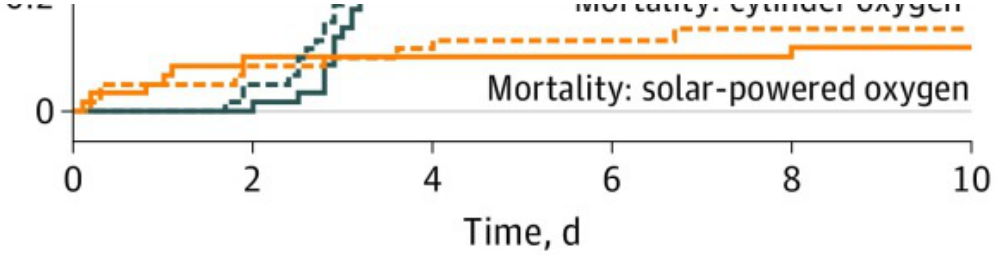
Tachypnea[b]	48 (74)	47 (72)
Pulse rate, median (IQR), min^{-1}	160 (145-176)	158 (146-178)
Tachycardia[c]	33 (51)	34 (52)
Temperature, median (IQR), °C	37.6 (36.6-38.5)	37.3 (36.9-38.3)
Fever[d]	26 (40)	34 (52)
Intercostal retractions	44 (68)	47 (72)
Subcostal retractions	52 (80)	41 (63)
Diagnoses at admission		
Severe pneumonia or very severe disease	65 (100)	65 (100)
HIV	1/59 (2)	2/55 (4)
Malaria[e]	5 (8)	4 (6)
Radiographic findings		
Alveolar consolidation	12/54 (22)	12/55 (22)
Other infiltrate	25/54 (46)	26/55 (47)
No consolidation, infiltrate or effusion	16/54 (30)	18/55 (33)

Abbreviation: IQR, interquartile range.

[a]Weight for age less than first percentile on World Health Organization growth charts.
[b]Respiratory rate greater than 99th percentile for age.
[c]Pulse rate greater than 99th percentile for age.
[d]Axillary temperature greater than 37.5°C.
[e]All children were tested for malaria using rapid diagnostic test (histidine-rich protein–2 antigen) and/or light microscopy of Field-stained peripheral blood film.

Figure.

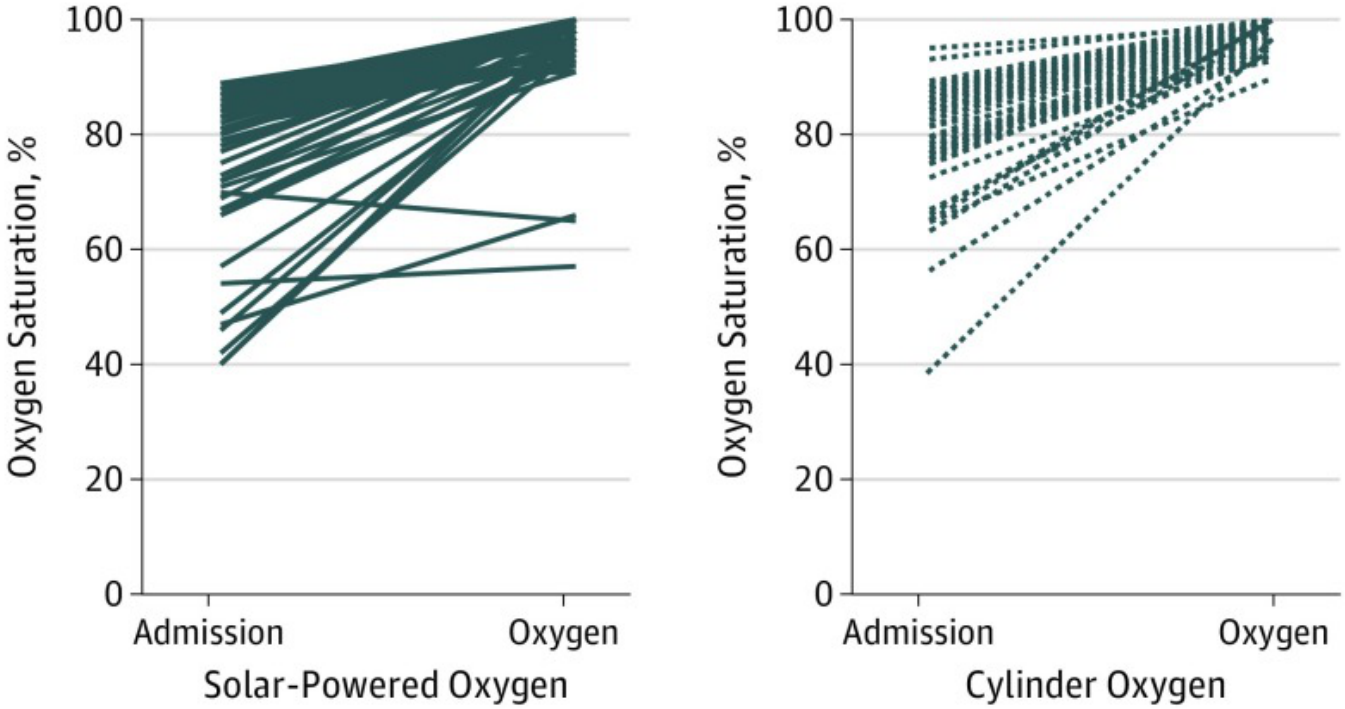




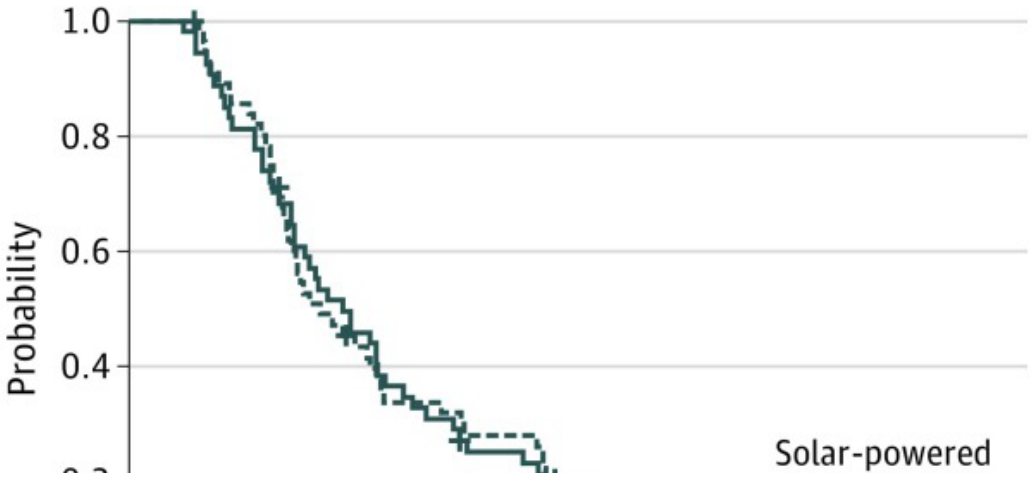
No. at risk

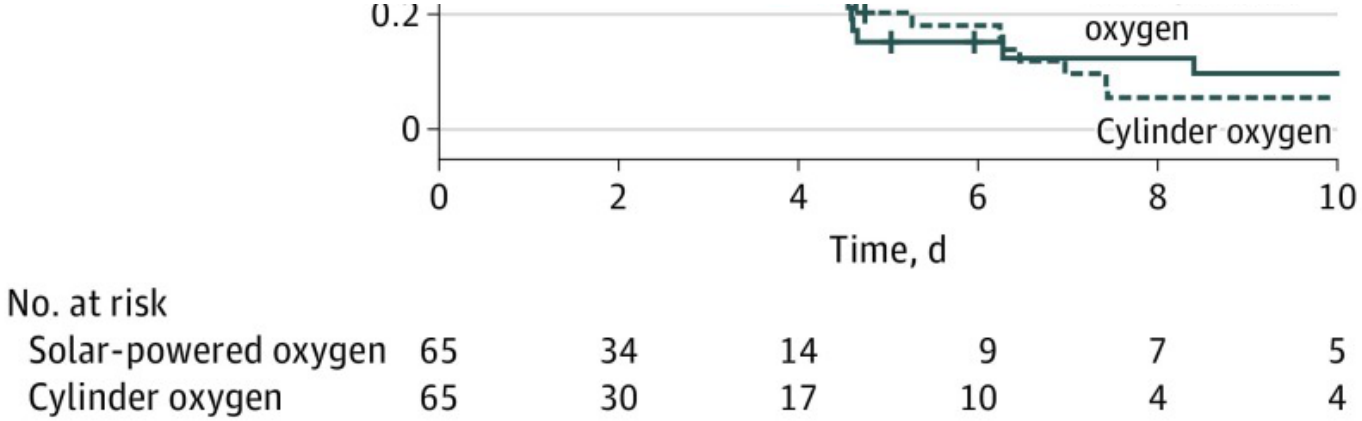
Solar-powered oxygen	65	57	32	18	11	6
Cylinder oxygen	65	57	33	18	12	8

B Rapid resolution of hypoxemia



C Time to wean off oxygen





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Mortality, Time to Hospital Discharge, Rapid Resolution of Hypoxemia, and Time to Wean Off Oxygen Among Trial Participants

A, Mortality and time to hospital discharge among trial participants. Mortality (orange lines) and hospital discharge (blue lines) in the solar-powered oxygen delivery group (solid lines) and cylinder oxygen comparator group (dashed lines) are modeled as competing risks. Differences between treatment arms were not statistically significantly different for mortality or time to hospital discharge. B, Rapid resolution of hypoxemia among trial participants. Immediate improvements in oxygen saturation were observed in both trial arms after administration of oxygen therapy, with no difference between patients receiving solar-powered oxygen (median change, 15% [interquartile range, 12%-21%]) and cylinder oxygen (median change, 15% [interquartile range, 11%-23%]). C, Time to wean off oxygen among trial participants. The median duration of oxygen therapy was similar in patients receiving solar-powered oxygen (2.6 days [interquartile range, 1.6-4.0 days]) and cylinder oxygen (2.1 days [interquartile range, 1.7-4.9 days]). A standardized protocol for stopping oxygen therapy was observed.