

Letters

RESEARCH LETTER

Effect of Neonatal Outcome Estimates on Decision-Making Preferences of Mothers Facing Preterm Birth: A Randomized Clinical Trial

Extremely preterm infants born before a gestational age (GA) of 25 weeks are in a prognostic gray zone,¹ which means that outcomes are poor but not hopeless and that life-sustaining treatments are not obligatory. Treatment decisions are value-laden and challenging² and ought to be shared between parents and physicians while imperatively aligned with parental preferences.^{3,4} When counseling parents, physicians commonly present numerical outcome estimates⁵ and may assume that parents derive their preferences from them. However, it is unknown whether probabilistic data affect parents' choices in prognostic gray zones.⁶ Here, we hypothesized that better or worse neonatal outcome estimates do not affect expectant mothers' preferences for life-sustaining treatments.

Methods | This single-center, double-blinded, randomized clinical trial was performed from December 2017 to January 2019 (Trial Protocol in the Supplement). Expectant mothers between a GA of 28^{0/7} weeks and 36^{6/7} weeks hospitalized because of impending premature birth were eligible for the study. Patients were randomly allocated to respond to either a case vignette of 60% or 30% survival rate. Written case vignettes included a detailed description of an impending preterm birth at 23^{6/7} weeks (60% survival) or 22^{6/7} weeks GA (30% survival) and were identical except from numerical data. Pa-

tients were asked to indicate a preference for life-sustaining treatments, palliative care, or no preference and to complete a short questionnaire. The study was approved by the local ethics committee of the Rhineland-Palatinate Medical Association. Participants provided written informed consent before inclusion in the study. The study was registered at the German clinical trial database (identifier: DRKS00013034). A multinomial logistic regression was performed to determine the association between the case vignettes and mothers' preferences. A multivariate version was performed, including 6 variables in addition to the case vignettes (education, religiousness, marital status, previous children, fertility treatment, and age), with the stepwise backward selection method to identify the most influential variables on the mothers' preferences. Categorical variables were compared using a χ^2 test and continuous variables were compared using a *t* test; *P* < .05 indicated statistical significance. For the primary outcome, a sample size of 64 patients was calculated to show with a power of 90% that the difference in the preference rates of life-sustaining treatment decisions was less than 30%.

Results | A total of 64 patients were included in the analysis (Figure and Table). The 60% or 30% survival group was simi-

Figure. Consolidated Standards of Reporting Trials Flow Diagram

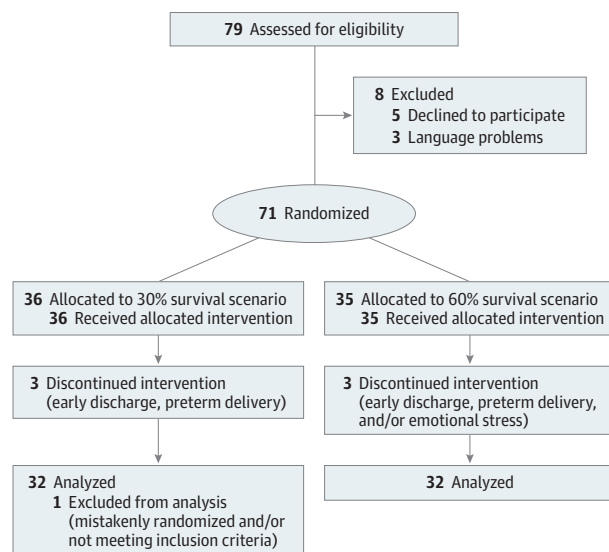


Table. Demographic Characteristics

Characteristic	Survival group, No. (%)		P value
	60%	30%	
No. (%)	32 (50)	32 (50)	NA
GA, mean (SD), wk	31.5 (2.6)	31.2 (2.4)	.57
Age, mean (SD), y	32.1 (4.3)	32.8 (4.5)	.68
Previous children			
No	26 (81.3)	22 (68.8)	
1	6 (18.8)	8 (25.0)	.27
2	0 (0.0)	2 (6.3)	
Marital status			
Single	1 (3.1)	0 (0.0)	
With partner	31 (96.6)	32 (100.0)	.31
Religiousness			
1 (Not)	6 (18.8)	7 (21.9)	
2	7 (21.9)	8 (25.0)	
3	14 (43.8)	13 (40.6)	.99
4	4 (12.5)	3 (9.4)	
5 (Strong)	1 (3.1)	1 (3.1)	
Education			
Regular school	3 (9.4)	7 (21.9)	
High school	6 (18.8)	5 (15.6)	.39
University	23 (71.9)	20 (62.5)	
Social experiences with prematurity	15 (46.9)	26 (81.3)	.004
History of miscarriage	9 (28.1)	13 (40.6)	.29
Fertility treatment (current pregnancy)	7 (21.9)	9 (28.1)	.56

Abbreviations: GA, gestational age; NA, not applicable.

lar with respect to the preference rates for life-sustaining treatments compared with palliative care (46.9% vs 34.4% in the 60% survival group and 50.0% vs 40.6% in the 30% survival group; odds ratio [OR], 0.90; 95% CI, 0.31-2.63). A few patients were not able to formulate a preference (6 patients (18.8%) in the 60% survival group and 3 patients (9.4%) in the 30% survival group; OR, 0.423; 95% CI, 0.08-2.10). An analysis of the patients who formulated a preference showed that an attitude that mere survival is at least as important as quality of life was associated with a preference for life-sustaining treatments (OR, 10.28; 95% CI, 2.94-35.90). Increasing maternal age (OR, 0.77; 95% CI, 0.61-0.98) and childlessness (OR, 0.12; 95% CI 0.01-0.98) were associated with a preference for palliative care. Most patients would decide together with their partners (63 of 64 [98.4%]) and preferred to be empowered by their physicians in the decision-making process (48 of 64 [75%]).

Discussion | In this study, it appeared that treatment preferences originated from individual characteristics and values rather than from reasoning about numerical outcome estimates. However, generalizability is limited and the results should be interpreted in light of the methods used. Patients made a one-time decision without personal feedback and patients actually affected might indicate different preferences. More studies are needed to help to improve our understanding of the information that parents facing extremely preterm birth want and need.

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