Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Tight Glycemic Control versus Standard Care after Pediatric Cardiac Surgery

SUPPLEMENTARY APPENDIX

Contents

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We appreciate the valuable input of our independent Data and Safety Monitoring Board over the course of the study: Daniel Levin, MD (Chair), Yi Li, PhD, Mark Palmert, MD, Darshak Sanghavi, MD, Holly Taylor, MPH, PhD, Stuart Weinzimer, MD (Founding Chair).

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Tables

Table S1. **SPECS Trial Subject Inclusion and Exclusion Criteria**

Inclusion criteria

- Patient ≤ 36 months of age, including neonates and infants, being taken to the operating room for cardiac surgery requiring cardiopulmonary bypass with planned post-operative management in the CICU

Exclusion criteria

- Absence of an indwelling arterial, central venous, or transthoracic catheter that prevents access for blood draws or insulin infusion
- Patient with diabetes mellitus, type I or II
- Patient previously enrolled in SPECS during a separate CICU admission
- Patient who has already consented to participate in a competing clinical trial which the SPECS Data and Safety Monitoring Board has not certified as a SPECS-compatible study

Table S2. **Primary Cardiac Surgical Procedures of Study Subjects, According to Treatment Group.**

	Tight Glycemic Control (N = 490)	**Standard Care (N = 490)**
Ventricular septal defect closure	81	85
Tetralogy of Fallot repair	56	70
Common atrioventricular canal repair	52	47
Atrial septal defect closure	36	46
Arterial switch	39	35
Superior cavopulmonary anastamosis	38	33
Stage 1 palliation for HLHS	28	26
Aortic arch reconstruction/coarctation repair	22	20
Mitral valve surgery	19	15
Fontan	13	13
Left ventricular outflow tract surgery	13	11
Tricuspid valvuloplasty	12	8
Aortopulmonary shunt	6	6
Other	75	75

HLHS denotes hypoplastic left heart syndrome.

Table S3. **Subgroup Analyses of 30-Day Healthcare-Associated Infection Rate, According to Treatment Group.**

Subgroup	**Tight Glycemic Control**		**Standard Care**		**Relative Risk**
	N	**Rate***	**N**	**Rate***	**(95% CI)**
RACHS-1 category ≥ 3 or not assignable	263	10.6	250	8.7	1.22 (0.61-2.46)
CICU length of stay ≥ 3 days**	252	9.3	234	9.6	0.97 (0.51-1.86)

CI denotes confidence interval, RACHS-1 Risk Adjustment for Congenital Heart Surgery-1, and CICU cardiac intensive care unit.

P values for the comparison between treatment groups were calculated by stratified exact tests adjusting for site.

* 30-day healthcare-associated infection rate. Infections include pneumonia, bloodstream and urinary tract infections, which were tracked for up to 30 days in the CICU or until 48 hours after CICU discharge, and surgical site infections, which were tracked for 30 days after the index procedure.

** Subgroup analysis is based on a post-randomization factor.

Figures

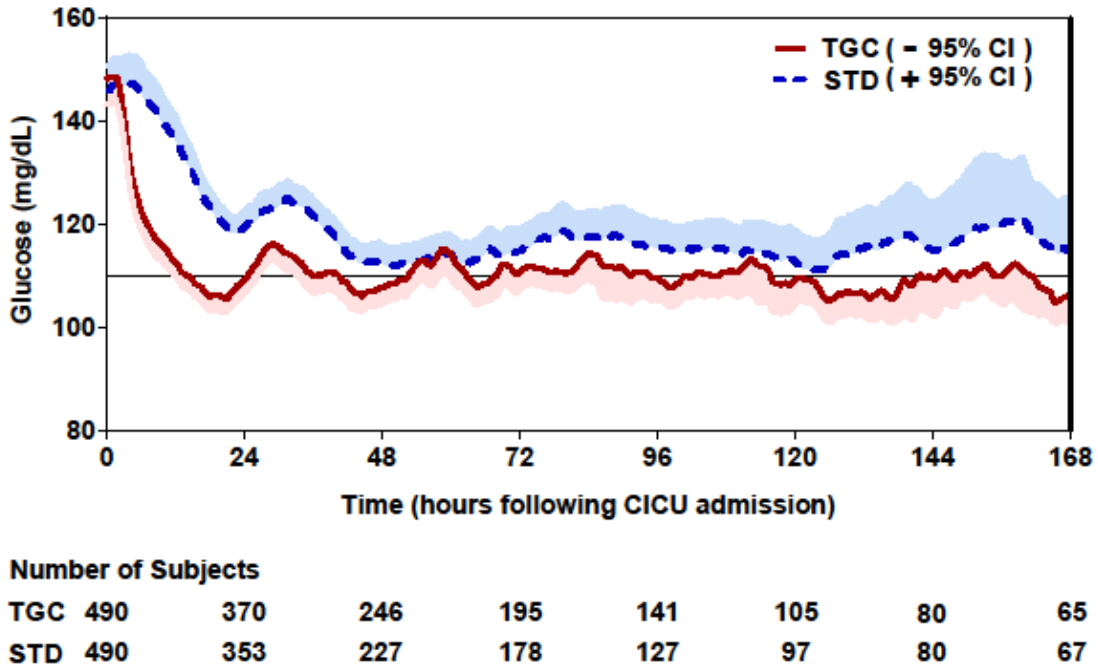

Figure S1. **Glycemic Profile of Study Patients, According to Treatment Group.** Average blood glucose during the first 7 days of CICU admission calculated from measured blood glucose interpolated at ½-hour intervals. Time 0 indicates time of post-operative CICU admission. Glucose concentration may be converted to mmol/L by dividing by 18.