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Renal oxygen extraction trajectories in functionally univentricular patients during the interstage period: insights from outpatient near infrared spectroscopy monitoring

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Abstract

Background

Serial renal near-infrared spectroscopy may extend physiologic assessment in high-risk outpatient settings. This study evaluated feasibility and renal oxygen extraction trajectories during interstage follow-up.

Methods

This prospective investigational pilot obtained serial clinic measurements with the clinical team blinded. Visit values represented medians after a five-minute calibration period. Oxygen extraction was calculated from paired arterial and renal oxygen saturations. Infant-level comparisons and spline mixed-effects models evaluated clinical associations. Models accounted for days after discharge and repeated observations within infants. A false discovery rate adjusted exploratory significance threshold of $p < 0.100$ was selected.

Results

Twenty infants contributed 115 paired measurements across 123 visits spanning 3 to 212 days after hospital discharge. Oxygen extraction declined at a median rate of 7.24 percentage points per 30 days ($p < 0.001$). Moderate or severe tricuspid regurgitation was associated with higher median oxygen extraction (34.3% versus 29.1%; $p = 0.024$) and different overall trajectories ($p = 0.025$). A history of small for gestational age was associated with higher minimum extraction (25.8% versus 17.3%; $p = 0.032$) and less first-to-last decline ($p = 0.007$). A history of prematurity was associated with less decline ($p = 0.049$), although findings were sensitive to classification. Infants who ultimately underwent a functionally univentricular repair strategy had steeper declines than those with a biventricular strategy ($p = 0.093$). Initial palliation, ventricular function, and interventions showed no significant associations.

Conclusions

Serial renal near-infrared spectroscopy monitoring was feasible in the interstage clinic, with developmental and circulatory characteristics associated with variation in oxygen extraction. These exploratory findings support larger multicenter studies in high-risk outpatient populations.

Introduction

Infants in the interstage period have a functionally univentricular multidistributive circulation in which cardiac output is distributed between the pulmonary and systemic circulations. Systemic oxygen delivery is influenced by ventricular and valvar function, pulmonary and systemic vascular resistance,

hemoglobin concentration, and arterial oxygen saturation, making this a tenuous circulation in which altered blood flow or oxygen content may compromise tissue oxygen availability. Although structured home monitoring has improved outcomes through surveillance of oxygen saturation, weight, feeding, and symptoms, ongoing morbidity supports further refinement of outpatient assessment (1).

Near-infrared spectroscopy provides a noninvasive estimate of regional venous saturation and when combined with arterial oxygen saturation, facilitates assessment of regional oxygen extraction. Renal near infrared spectroscopy correlates moderately with inferior caval vein oxygen saturation with a stronger correlation with the underlying trend in cardiac output (2, 3, 4). Serial measurements may help characterize changes in regional oxygen balance, while noninvasive models incorporating renal oxygenation offer another approach to estimating venous saturation (5, 6).

In hospitalized children, venous oxygen saturation and regional oxygenation have been associated with morbidity and mortality after cardiac surgery, with higher renal oxygen extraction associated with adverse events after systemic-to-pulmonary arterial shunt placement and acute kidney injury after the Norwood operation (7, 8, 9, 10). These observations support investigation in outpatient care where the balance between oxygen delivery and consumption remains relevant after discharge, although the expected outpatient trajectories and clinical factors associated with their variation require characterization.

Interstage clinic visits provide an opportunity to obtain serial outpatient measurements using trained personnel and a consistent protocol, complementing established home surveillance. The primary aim of this prospective, investigational, blinded pilot study was to evaluate the feasibility of serial renal near-infrared spectroscopy monitoring during outpatient interstage follow-up, characterize renal oxygen extraction trajectories after discharge, and identify associations with developmental characteristics, initial palliation, ultimate repair strategy, echocardiographic findings, and recorded interventions.

Methods

Study design

This was a prospective investigational blinded trial evaluating renal regional oxygen saturation during interstage outpatient follow-up. The study protocol was approved by the institutional review board, and the study was conducted in accordance with the Declaration of Helsinki. A member of the study team obtained informed consent from the parents before enrollment. Measurements were obtained using near-infrared spectroscopy, and the treating clinical team was blinded to the measurements. The primary aim was to evaluate the trajectory of estimated renal oxygen extraction after discharge and its associations with patient characteristics, initial palliation, echocardiographic findings, and recorded interventions.

A small sample size was anticipated during study planning, as children with functionally univentricular multidistributive circulation represent a subset of children with congenital malformations of the heart,

and the population available for outpatient interstage follow-up is further restricted by infants who remain hospitalized throughout the interstage period or die before hospital discharge.

Patients were recruited from August 1, 2024 to August 6, 2026.

This study was supported by an investigator-sponsored research program grant by Medtronic (Minneapolis, Minnesota, US). This provided a near infrared spectroscopy monitor (INVOS™ 7100 Regional Oximeter) as well as infant-neonatal sensors for the study.

Patient inclusion

The present analysis included enrolled infants with interstage clinic measurements from which renal oxygen extraction could be calculated and the interval from initial hospital discharge could be determined. Available paired measurements of peripheral arterial oxygen saturation and renal near infrared spectroscopy were included, with repeated observations retained for longitudinal analysis. Visits without a calculable extraction value were excluded from the physiologic analyses, while available echocardiographic assessments at those visits could contribute to subgroup classification.

Variables of interest

Renal oxygen extraction was calculated as 100 multiplied by the difference between peripheral arterial oxygen saturation and renal regional oxygen saturation, divided by peripheral arterial oxygen saturation. This saturation-derived measure was expressed as a percentage, with absolute changes expressed in percentage points. Time was measured in days after initial hospital discharge.

Patient characteristics included birth weight, gestational age, history of prematurity, history of small for gestational age, and ultimate repair strategy. The recorded ultimate repair strategy was classified as functionally univentricular or biventricular. Initial palliation was classified as Norwood operation, shunt only, pulmonary arterial banding, or hybrid palliation.

Additional comparisons considered any recorded unplanned intervention, unplanned cardiac intervention, tricuspid regurgitation, and ventricular function. Tricuspid regurgitation and ventricular dysfunction were classified according to whether moderate or severe degrees were documented at any interstage assessment.

Study protocol

Patients were screened for study eligibility by the interstage clinical team during the inpatient admission. As hospital discharge approached, the study team informed the parents of eligible patients about the study and obtained informed consent before enrollment. Assent was not possible as all eligible patients were infants.

At each study visit, a member of the study team placed a near-infrared spectroscopy sensor on the right or left flank, below the costal margin and above the iliac crest, at the level of the tenth through twelfth thoracic vertebrae. The sensor remained in place for at least 10 minutes, with the first 5 minutes treated as a calibration period and excluded from analysis. The median of the remaining renal regional oxygen saturation measurements was recorded as the value for that clinic visit.

The measurement was recorded by a study team member who was not part of the clinical team caring for the patient during that visit, and the interstage clinical team remained blinded to the recorded value. Measurements were obtained at serial clinic visits using the same protocol, and additional clinical data were obtained through medical record review.

Statistical analyses

Continuous variables were summarized using medians and interquartile ranges, and categorical variables using counts and percentages. For each infant, renal oxygen extraction was summarized by its median, mean, standard deviation, maximum, minimum, and change from the first to the last available measurement. The individual temporal slope was estimated using the Theil–Sen method and expressed in percentage points per 30 days. Each infant contributed one value to each summary comparison, preventing infants with more frequent visits from contributing multiple independent observations to these tests.

Infant-level summaries were compared using two-sided exact rank permutation tests for binary comparisons and omnibus rank permutation tests for the primary palliation comparison. The overall temporal slope and first-to-last change were evaluated against zero using exact Wilcoxon signed-rank tests.

Longitudinal trajectories were evaluated using Gaussian mixed-effects models with an infant-specific random intercept and linear time slope. Fixed effects included group, a natural cubic spline for days after discharge with three degrees of freedom, and interactions between group and the time-spline terms. Boundary knots were placed at days 3 and 212, with internal knots at days 30 and 65. Each clinical grouping was analyzed separately. Overall trajectory differences were assessed by comparing the group-specific model with a shared-trajectory model using a joint likelihood-ratio test, with p-values calculated from 1,999 parametric bootstrap samples under the null model. This joint test assessed differences in extraction level, temporal pattern, or both. No additional clinical covariates were included, and peripheral arterial oxygen saturation was not entered separately because it was already incorporated in the extraction calculation.

Smoothed population mean trajectories were displayed with pointwise 95% confidence intervals obtained from parametric bootstrap refitting. The models accounted for the timing and clustering of repeated measurements while assuming a common random-effect covariance and residual variance across groups. Visit frequency and dropout were not modeled as informative processes.

Sensitivity analyses repeated infant-level comparisons using observations obtained within the first 90 days after discharge, defined a history of prematurity using gestational age below 37 weeks, examined alternative cardiac intervention definitions, and included other or unclassified initial palliation. Observation counts and follow-up duration were also compared between groups.

For this exploratory analysis, false discovery rate adjusted p-values below 0.100 were designated statistically significant. This threshold was selected to increase sensitivity to associations that might warrant evaluation in a larger study, accepting a higher nominal false-positive rate than the conventional threshold of 0.050.

Power was evaluated through simulation-based design-sensitivity analyses for an absolute difference of 10 percentage points in renal oxygen extraction at significance thresholds of both 0.050 and 0.100. Two subgroup scenarios were examined: a persistent difference throughout follow-up and a difference increasing linearly from zero at discharge to 10 percentage points at day 90, continuing linearly thereafter. Simulations preserved the observed group allocations, visit schedules, spline specification, and infant-level correlation structure, with variance parameters estimated from the overall model using restricted maximum likelihood. For the palliation comparison, all three non-Norwood categories were assumed to share the specified difference from the Norwood category.

For each subgroup comparison, 1,999 null simulations calibrated the likelihood-ratio critical values and 999 alternative simulations estimated power, with full and reduced models refitted by maximum likelihood. The same simulated datasets were evaluated at both significance thresholds. Power for an overall decline of 10 percentage points over 90 days was evaluated separately using 20,000 simulated datasets and the exact signed-rank test of individual Theil–Sen slopes. These calculations used specified hypothetical effects rather than observed group differences, were performed after study completion, and did not constitute the original enrollment calculation. The 10-point effect was an illustrative planning value rather than an established minimum clinically important difference.

Results

Cohort characteristics

The cohort included 20 infants with 123 recorded clinic visits, of which 115 provided paired measurements suitable for calculating renal oxygen extraction. Median gestational age was 38.1 weeks, with an interquartile range of 36.9 to 39.2 weeks, and median birth weight was 3,265 grams, with an interquartile range of 2,806 to 3,498 grams. Five (25%) infants had a history of prematurity with a gestational age below 37 weeks; three (15%) had a history of small for gestational age. The ultimate repair strategy was functionally univentricular in 17 (85%) infants and biventricular in three (15%).

Initial palliation comprised a Norwood operation in 12 (60%) infants, shunt only in two (10%), pulmonary arterial banding in one (5%), and hybrid palliation in one (5%), with four (20%) having other or no palliation. Seven (35%) infants had a recorded unplanned intervention or admission with four (20%)

having had an unplanned cardiac intervention. Moderate or severe tricuspid regurgitation was documented during follow-up in 10 (50%) infants and moderate or severe ventricular dysfunction in two (10%).

The median number of usable measurements per infant was 5.5, with an interquartile range of 4 to 7. Measurements were obtained between 3 and 212 days after discharge, and the median interval between an infant's first and last usable measurements was 77 days, with an interquartile range of 47 to 105 days.

Table 1 summarizes the cohort characteristics.

All patient trajectory

Renal oxygen extraction decreased over time after discharge. The median individual slope was − 7.24 percentage points per 30 days, with an interquartile range of − 11.21 to − 1.60, and differed significantly from zero ($p < 0.001$). The median change from the first to the last measurement was − 17.21 percentage points, with an interquartile range of − 24.54 to − 6.07 ($p < 0.001$).

The median of the individual median extraction values was 32.8%, with an interquartile range of 28.6%–34.8%. The median within-infant standard deviation was 9.0 percentage points, while the median individual maximum and minimum were 45.0% and 18.5%, respectively. Smoothed trajectories illustrated the overall decline, although estimates later in follow-up were supported by fewer observations.

Subgroup comparisons

Moderate or severe tricuspid regurgitation was associated with higher median renal oxygen extraction than none or mild regurgitation, with group medians of the individual median values of 34.3% and 29.1%, respectively ($p = 0.024$). Overall trajectories also differed ($p = 0.025$), and the individual mean extraction values differed at the exploratory threshold ($p = 0.063$). Standard deviation, maximum, minimum, and individual slope did not differ significantly.

A history of small for gestational age was associated with a higher minimum extraction value, with medians of 25.8% and 17.3% in infants with and without this history, respectively ($p = 0.032$). The first-to-last change also differed, with medians of + 4.79 and − 18.25 percentage points ($p = 0.007$). The decline was less pronounced among infants with a history of small for gestational age, with median slopes of − 0.22 and − 8.07 percentage points per 30 days ($p = 0.054$), and overall trajectories differed at the exploratory threshold ($p = 0.082$). Median, mean, maximum, and standard deviation did not differ significantly.

A history of prematurity was associated with a smaller first-to-last decline, with median changes of − 0.15 and − 19.24 percentage points in infants with and without a history of prematurity, respectively ($p = 0.049$). Infants with a history of prematurity also had a lower within-infant standard deviation, with

medians of 7.44 and 9.74 percentage points (p = 0.080), and a less negative slope, with medians of − 0.66 and − 7.73 percentage points per 30 days (p = 0.080). Median, mean, maximum, and minimum extraction did not differ significantly.

Infants who underwent a functionally univentricular ultimate repair strategy had a more negative slope than those with a biventricular ultimate repair strategy, with median slopes of − 8.07 and − 1.74 percentage points per 30 days (p = 0.093). The first-to-last change also differed at the exploratory threshold, with medians of − 18.25 and − 3.77 percentage points (p = 0.093). Other infant-level extraction summaries did not differ significantly.

No significant differences in infant-level extraction summaries were identified by initial palliation, any unplanned intervention, unplanned cardiac intervention, or ventricular function. The corresponding overall trajectory p-values for these were 0.566, 0.823, 0.999, and 0.359, respectively.

Figure 1 demonstrates the temporal change in oxygen extraction as a function of post-discharge days.

Sensitivity analyses

When analysis was restricted to the first 90 days after discharge, the association between moderate or severe tricuspid regurgitation and higher extraction persisted. Group medians of the individual median values were 36.3% and 28.3% for moderate or severe versus none or mild regurgitation (p = 0.002), and individual mean values also differed (p = 0.005). Minimum extraction was higher in the moderate or severe group, with medians of 27.3% and 17.9% (p = 0.054).

The difference in slope by history of prematurity persisted within the first 90 days, with median slopes of − 0.66 and − 8.82 percentage points per 30 days for infants with and without a history of prematurity, respectively (p = 0.029). First-to-last changes also differed at the exploratory threshold (p = 0.080). The full follow-up period was shorter among infants with a history of prematurity, with median observation spans of 49 and 84 days (p = 0.086), which was relevant to interpretation of the full-period variability and change comparisons.

Within the first 90 days, history of small for gestational age remained associated with a smaller first-to-last decline, with median changes of − 2.88 and − 12.84 percentage points (p = 0.040), and a less negative slope, with medians of − 2.51 and − 8.63 percentage points per 30 days (p = 0.054). The difference in minimum extraction did not persist in this restricted interval (p = 0.183). The slope difference between ultimate repair strategies also persisted, with medians of − 8.63 and − 1.47 percentage points per 30 days for the functionally univentricular and biventricular pathways, respectively (p = 0.019).

Power analyses

For a persistent 10-percentage-point difference in renal oxygen extraction, estimated power across subgroup comparisons ranged from 43.0% to 92.7% at $p < 0.050$ and from 57.5% to 96.6% at $p < 0.100$. Power was lower when the difference developed progressively over time, ranging from 16.9% to 51.3% at

p < 0.050 and from 27.4% to 65.6% at a p-value of less than 0.100 for a difference reaching 10 percentage points at day 90.

For persistent differences, changing the significance threshold from 0.05 to 0.10 increased power from 92.7% to 96.6% for tricuspid regurgitation and from 70.6% to 82.7% for history of prematurity. The corresponding increases were from 71.6% to 82.2% for history of small for gestational age and from 86.4% to 92.9% for any recorded intervention. Power increased from 73.5% to 82.9% for cardiac intervention including Glenn and from 51.6% to 66.9% for ventricular function, while the increases for ultimate repair strategy and initial palliation were from 67.2% to 80.8% and from 43.0% to 57.5%, respectively.

For progressive differences reaching 10 percentage points at day 90, changing the significance threshold from 0.050 to 0.100 increased power from 51.3% to 65.6% for tricuspid regurgitation and from 19.3% to 30.8% for history of prematurity. The corresponding increases were from 32.5% to 44.5% for history of small for gestational age and from 47.4% to 60.9% for any recorded intervention. Power increased from 30.7% to 41.5% for cardiac intervention including Glenn and from 16.9% to 27.4% for ventricular function, while the increases for ultimate repair strategy and initial palliation were from 33.0% to 44.9% and from 19.0% to 28.1%, respectively.

For an overall decline of 10 percentage points over 90 days, estimated power was 58.1% at p < 0.050 and 71.0% at p < 0.100. The higher threshold increased sensitivity under the specified scenarios, although power remained limited for differences that emerged gradually and for some subgroup comparisons.

Despite these limitations, several observed findings were statistically significant even at p < 0.050, including the overall decline in extraction, the association of tricuspid regurgitation with median extraction and overall trajectory, and the associations of history of small for gestational age with minimum extraction and first-to-last change. Additional associations met the exploratory threshold of p < 0.100. The simulated power estimates describe sensitivity to the specified hypothetical effects and do not independently validate the observed associations or establish equivalence for comparisons without statistically significant differences.

Discussion

This exploratory pilot study demonstrated the feasibility of serial renal near-infrared spectroscopy monitoring during outpatient interstage visits while maintaining clinical team blinding. Renal oxygen extraction declined after discharge, with moderate or severe tricuspid regurgitation associated with higher extraction and a different overall trajectory. History of small for gestational age, history of prematurity, and ultimate repair strategy were associated with measures of temporal change, although consistency varied across analyses. These findings identify clinical characteristics relevant to interpreting outpatient trajectories without establishing predictive or therapeutic value.

Infants remain vulnerable during the interstage period despite improvements from structured home monitoring, and better outcomes should encourage continued refinement of outpatient surveillance (1). Clinic measurements assessing the adequacy of oxygen delivery could complement existing monitoring. Reproducible sensor placement, movement-related signal disturbance, equipment access, and interpretation complicate routine home use at the moment but evaluation during clinic encounters with trained personnel is feasible.

Renal near infrared spectroscopy correlates moderately with inferior caval vein saturation (2, 3, 4). Serial changes may provide information beyond isolated values, although tissue and invasive venous measurements remain distinct (2, 5). Monitoring venous oxygenation, or estimating it noninvasively, permits more complete circulatory assessment by adding information about oxygen delivery relative to consumption. Models incorporating renal near infrared spectroscopy have also been developed to estimate inferior caval vein saturation (6).

In hospitalized children, venous saturation and near infrared spectroscopy have been associated with postoperative morbidity and mortality, including adverse events after systemic-to-pulmonary arterial shunt placement and kidney injury after Norwood palliation or heart transplantation (7, 8, 9, 10, 11). Associations with extubation outcomes and changes preceding death or medication interruption further support evaluating longitudinal measurements (12, 13, 14). These physiologic relationships remain relevant after discharge, providing a rationale for outpatient investigation, although inpatient findings cannot establish outpatient thresholds or predictive performance. A mortality study lacked comparable near-infrared spectroscopy data in survivors, so the observed deterioration could not establish discrimination between survivors and nonsurvivors (13).

The overall decline in extraction noted in the current study could reflect improved adequacy of oxygen delivery during recovery and growth. It cannot be identified whether this is due to increased systemic oxygen delivery, decreased oxygen consumption, or a combination of both. The extraction index combines arterial and regional saturations and does not directly measure renal venous saturation or identify the mechanism of an observed change.

Higher extraction with tricuspid regurgitation is physiologically plausible because regurgitant flow can reduce effective forward flow while elevated venous pressure may impair renal venous drainage. Postoperative Norwood data similarly associate higher extraction with greater central venous pressure and systemic vascular resistance and lower systemic blood flow (15). It is more likely, however, that tricuspid regurgitation mediates increased oxygen extraction due to decreased cardiac output and subsequently decreased systemic oxygen delivery. Persistence within 90 days strengthens consistency.

The absence of a ventricular function association does not exclude circulatory limitation despite preserved qualitative systolic function. Stroke volume, and subsequently cardiac output, can still be maintained even in the setting of decreased ventricular function. Additionally, decreased oxygen extraction may also help offset the effects of ventricular dysfunction, with extraction relating to systemic flow, hemoglobin concentration, and vascular resistance in catheterization data, although shared

calculation terms contribute to these associations (16). Uneven function groups may have also limited detection of differences.

A history of small for gestational age was associated with higher minimum extraction and less decline, potentially reflecting differences in oxygen delivery, renal development, or metabolic requirements. However, this history does not establish pathological fetal growth restriction. Higher renal oxygenation and lower extraction reported in growth-restricted premature neonates illustrate that developmental associations can differ by clinical setting (18). Loss of the minimum-value difference within 90 days suggests observation duration contributed.

A history of prematurity was associated with flatter trajectories and lower variability, potentially reflecting developmental changes in renal blood flow and oxygen requirements (19). Shorter follow-up could narrow the observed range.

Initial palliation showed no association despite previously reported early postoperative extraction differences between arterial ductal stenting and surgical shunt placement (20). Sparse procedural groups and evolving physiology may explain this discrepancy. Likewise, combining measurements before and after heterogeneous interventions could obscure event-related changes.

Growth, neurodevelopmental outcomes, and subsequent surgical length of stay were also collected, with exploratory associations identified. These findings will be reported separately to provide appropriate methodological and physiologic detail.

Strengths include prospective acquisition, consistent serial sampling, and clinical blinding. Infant-level comparisons and longitudinal models addressed complementary questions, while exact tests, bootstrap inference, and sensitivity analyses reduced reliance on large-sample assumptions. The novelty lies in extending regional oxygen balance assessment across outpatient interstage encounters.

Limitations of this study include the small, uneven cohort, potentially informative visit timing, and unmeasured confounding. The post hoc significance threshold of 0.100 was done intentionally, and it should be noted that a p-value of 0.050 is an arbitrary selection. Sensor position, tissue depth, and laterality may influence measurements, with bilateral differences demonstrated in preterm infants (21). Intermittent sampling cannot characterize physiology between visits, and reproducibility, workload, and cost were not quantified.

Larger multicenter studies should standardize acquisition, establish expected trajectories, and test incremental prognostic value using prespecified outcomes and thresholds. Pilot power estimates can inform planning, recognizing lower sensitivity to progressively emerging differences. Planning estimates remain conditional on this cohort’s variance and visit schedules rather than confirming observed associations. Documentation should include hemoglobin concentration, feeding, behavioral state, medications, growth, and contemporaneous echocardiographic findings. Other high-risk outpatient settings, including heart failure clinics, warrant consideration; prior thenar oxygenation findings support

regional monitoring research without validating renal measurements or treatment targets (22). Future work should establish added clinical information before testing whether measurement-guided management improves outcomes.

Conclusion

This exploratory pilot study extends near-infrared spectroscopy monitoring into the outpatient interstage setting and demonstrates the feasibility of obtaining serial measurements while maintaining blinding of the clinical team. Clinical factors associated with differences in renal oxygen extraction and its trajectory were identified, highlighting the importance of interpreting these measurements within each patient's developmental and circulatory context. This approach offers an opportunity to incorporate longitudinal assessment of regional oxygen balance into high-risk outpatient care alongside established surveillance. These findings provide a starting point for larger multicenter studies to establish expected trajectories, determine their prognostic value, and evaluate whether incorporating these measurements into clinical decision-making improves outcomes.

Declarations

Competing Interests

This study was sponsored by Medtronic. Medtronic was involved as they provided a NIRS monitor and NIRS sensors for the study. They did not have access to the data nor were they involved in data analysis or mansucript preparation.

Author Contribution

Study design- RL, JW, GG, HWStudy execution- RL, JW, GG, HWDAta colection- JW, GG, HWData analysis- RL, JWManuscript preparation- RL, JW, GG, MM, HW

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Table 1 summarizes the cohort characteristics.

Table is available in the Supplementary Files section.

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Figures

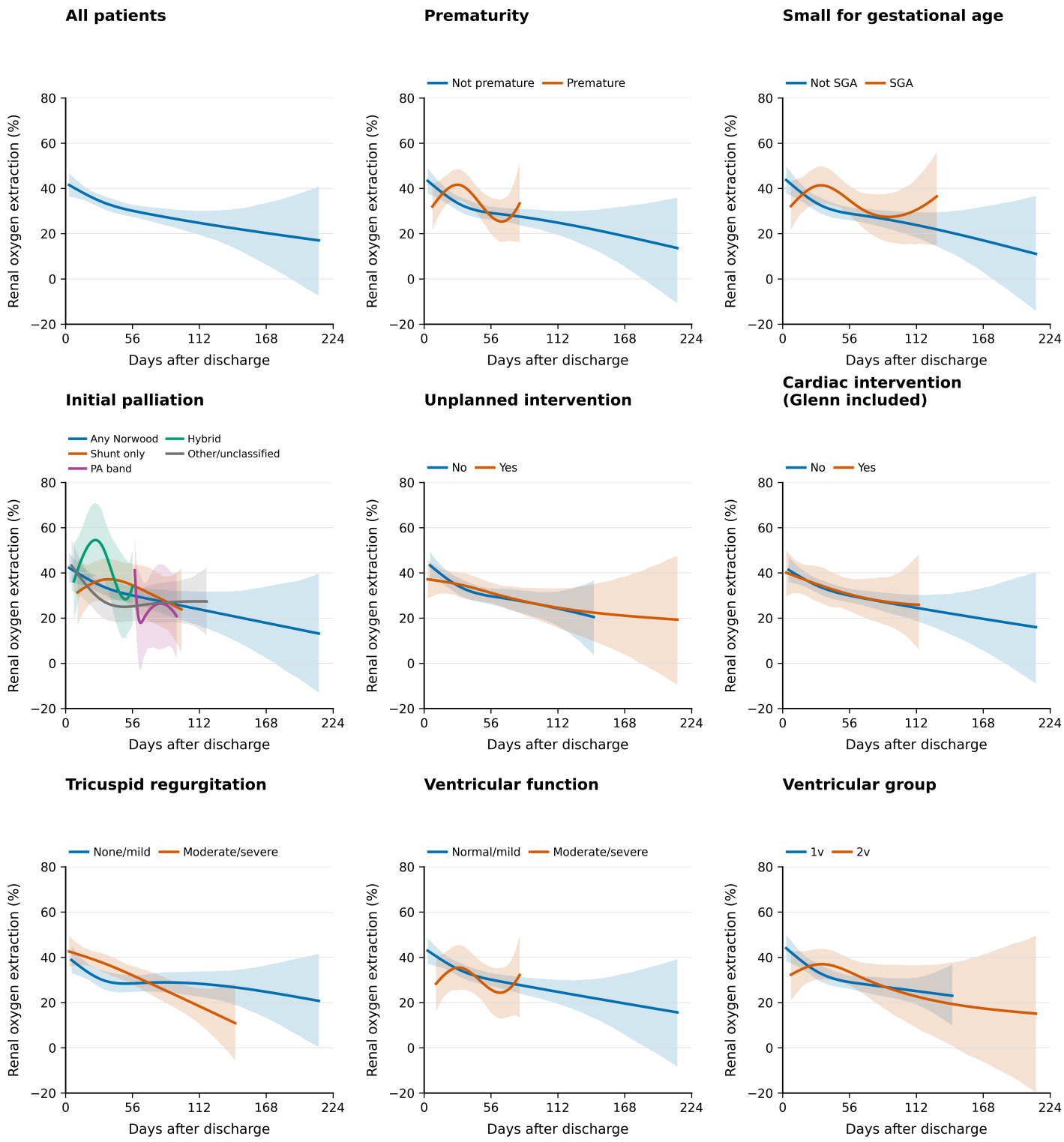

Figure 1

Demonstrates the temporal change in oxygen extraction as a function of post-discharge days.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- table1cohortcharacteristics.docx