

Improved Outcomes in Pediatric Sepsis-Associated (SA) AKI: Comparison of the Selective Cytopheretic Device for Pediatrics (SCD-PED) Surveillance Registry (SAVE) with a Historical Cohort

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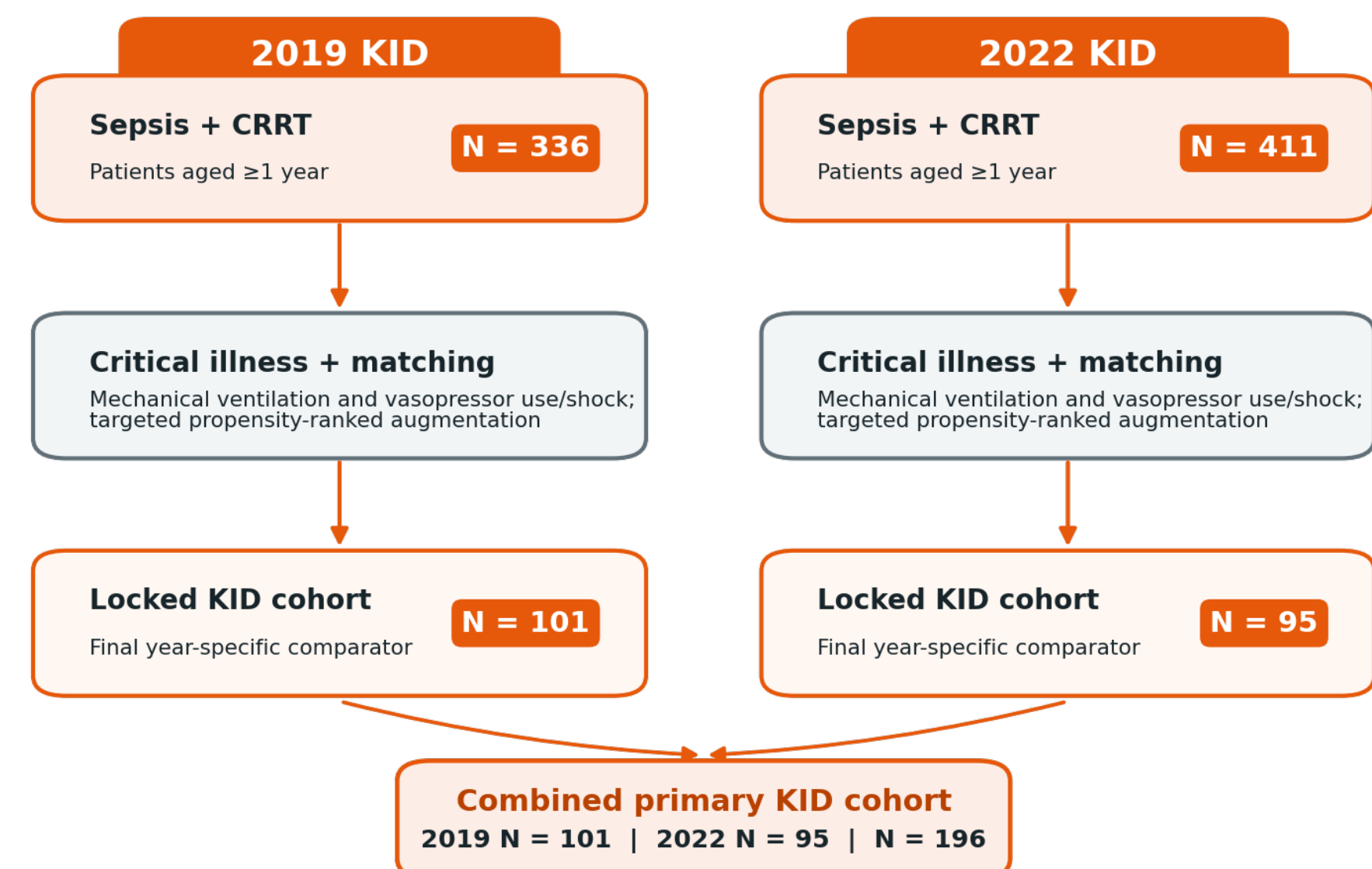
Background

- SCD-PED is approved under an FDA humanitarian device exemption (HDE) for patients ≥ 10 kg and ≤ 22 years with sepsis-associated acute kidney injury (AKI) requiring renal replacement therapy (RRT)
- The FDA mandated SCD-PED post-approval registry (SAVE) enrolled 50 clinically complex patients, including substantial extracorporeal membrane oxygenation (ECMO) use¹
- We compared survival in SCD-PED-treated patients with two clinically aligned, covariate balanced external cohorts from KID, a large US pediatric inpatient database representing broad clinical complexity, including ECMO²

Methods

- Design:** Exploratory observational external-control cohort study comparing 50 SAVE + 1 non-registry case* vs. KID 2019 and 2022 (**see below**)
- Cohorts:** Eligible KID cases: age ≥ 1 y with sepsis, continuous RRT (CRRT), invasive mechanical ventilation (IMV), and vasopressor (VP) use or shock; Two SCD-PED analytic cohorts: Primary (>1 day of SCD-PED therapy to allow for sufficient treatment exposure) and Landmark sensitivity (survival beyond 1 day post-initiation); the KID landmark was approximated by survival beyond the calendar day of CRRT initiation
- Survival endpoints:** Day-90 (**Primary**); Days 28, 60, and hospital discharge (Supportive); Day-90 time-to-death
- Analysis:** Frequentist methods reported odds ratios (OR) with 95% CIs. Bayesian: estimated risk differences and the probability of higher SCD-PED survival, with $>95\%$ representing complementary evidence
- SAVE only outcomes:** New bloodstream infections ≤ 28 d of SCD-PED initiation, device-related adverse events (AEs), and Day-90 RRT-free status among survivors not RRT-dependent at baseline descriptively reported

Results – KID Cohort Derivation

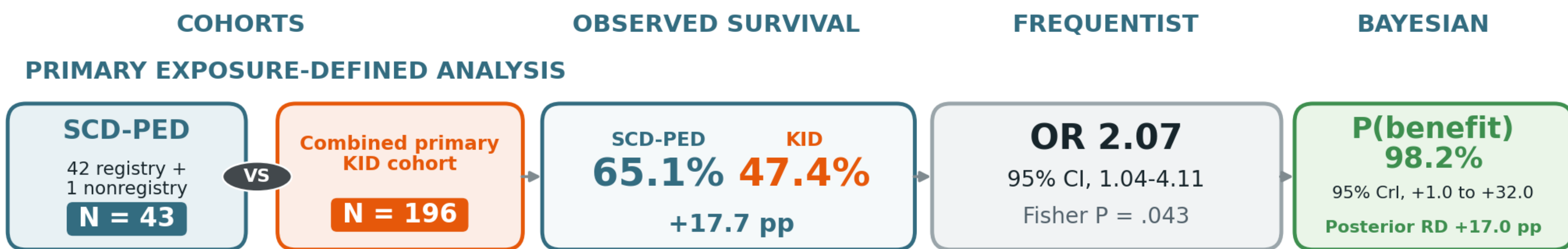


Highly clinically complex, critically ill patients across all analytic cohorts

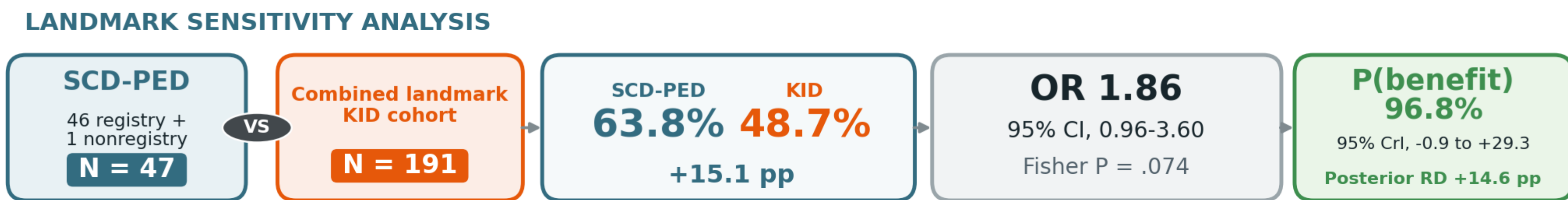
- 100% CRRT in both cohorts; $>95\%$ IMV and VP use/shock in both cohorts
- ECMO: 33% to 34% in SAVE and 28% to 29% in KID
- Substantial malignancy, immunocompromised, hemophagocytic lymphohistiocytosis (HLH), and transplant-related complexity
- Other characteristics were similar except for age (KID patients had a higher mean age)

*One previously reported non-registry SCD-PED patient was included for consistency with prior analyses; treatment details were obtained from the published case report³

Results – Day-90 Survival Higher With SCD-PED in Primary and Landmark Analyses



For the primary SAVE cohort, 8 patients were excluded because they received ≤ 1 day of SCD-PED therapy.

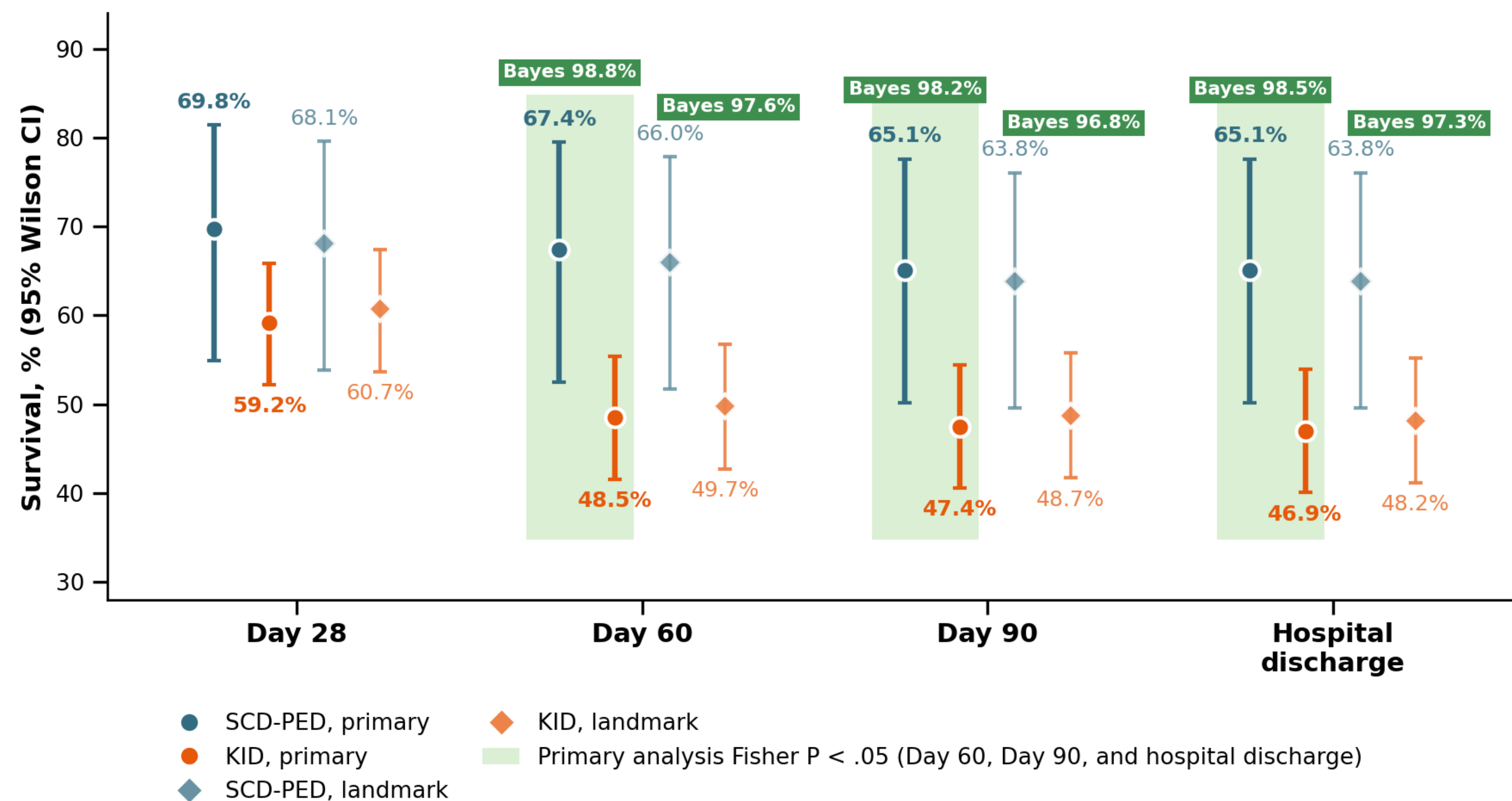


For the landmark SAVE cohort, 4 patients were excluded because they died <1 day of SCD-PED initiation.

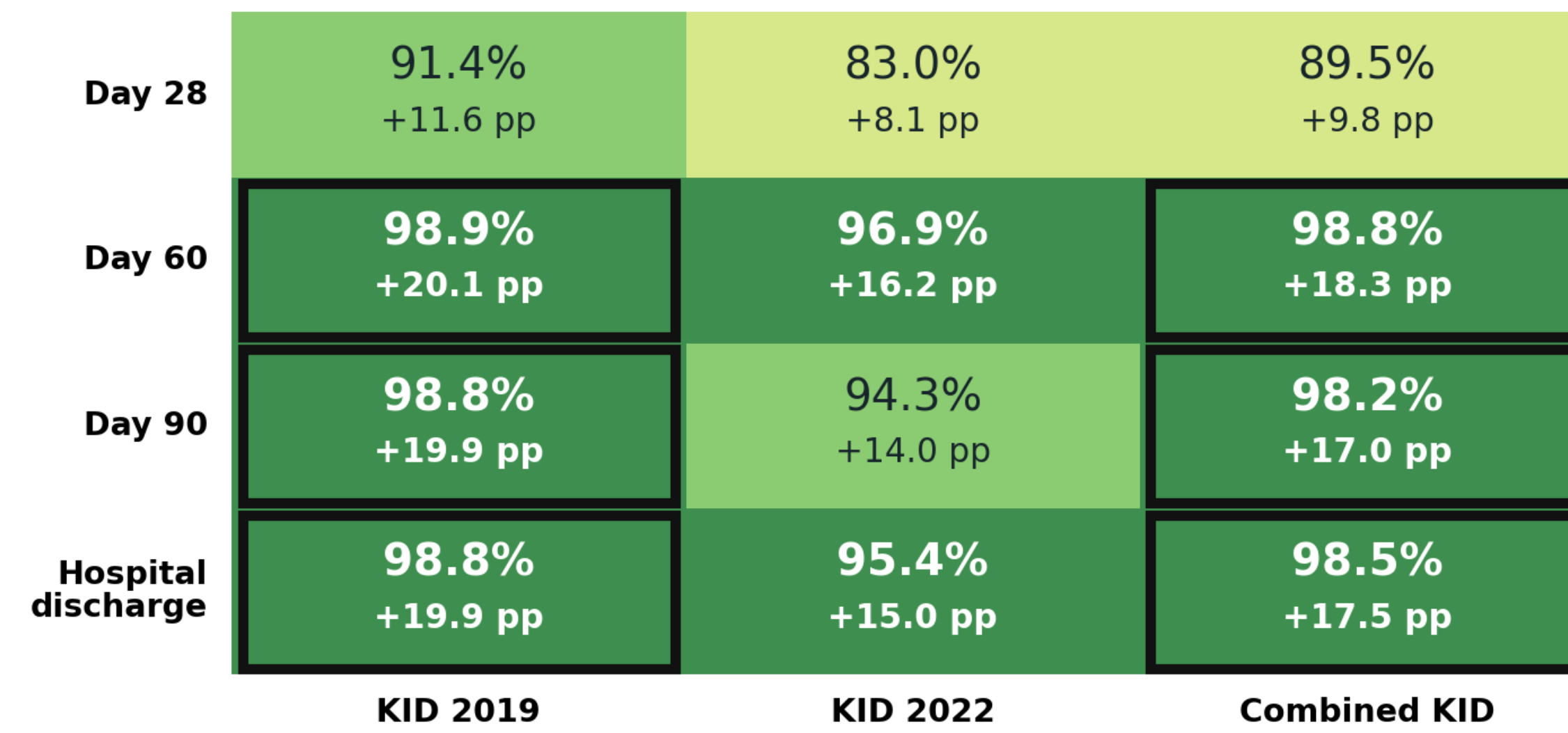
For the landmark KID cohort, hospitalizations ending in death on the calendar day of CRRT initiation were excluded.

SAVE was associated with a higher Day-90 survival versus combined KID in the primary analysis, with directionally higher survival in the landmark cohort analysis.

Results – Survival Favored SCD-PED at Every Time Point in Both Analyses



Results – Year-Specific Comparisons and Day-90 Mortality Models Consistently Favored SCD-PED

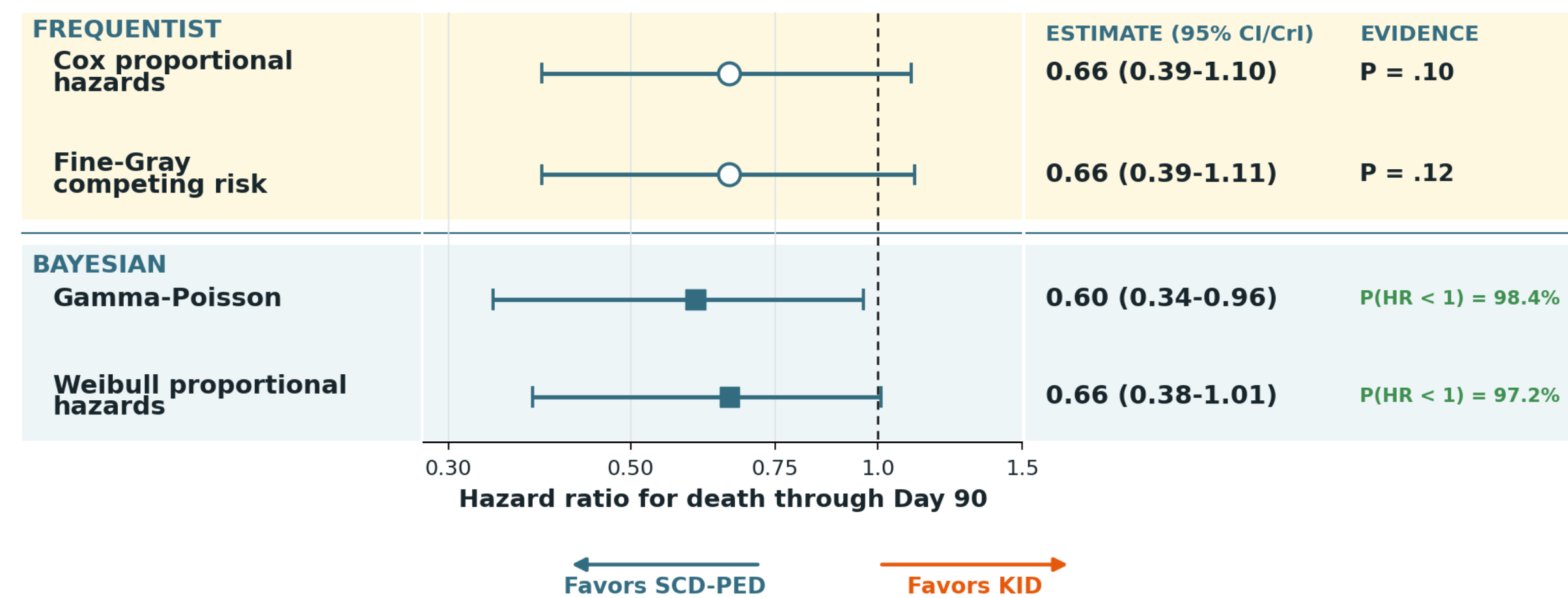


70% to $<80\%$ 80% to $<90\%$ 90% to 95% $>95\%$ Bayesian threshold Fisher P < .05

Cells show posterior probability and posterior mean absolute survival difference (SCD-PED - KID).

Day-90 Mortality: Concordance Across Models

SCD-PED (N = 47) vs combined landmark KID (analytic N = 190)



All 4 Day-90 mortality models favored SCD-PED (HR range, 0.60-0.66); both Bayesian models exceeded 95%.

Results (SAVE Registry Only) – No Device-Related Infections or AEs

- No device-related adverse events (AEs) occurred
- Secondary BSIs occurred in 12% of patients within 28 days of SCD-PED initiation, including 6% during treatment; all were adjudicated by an independent data and safety monitoring board (DSMB) to be unrelated to device
- Twenty (83%) of the 24 survivors who were not RRT-dependent at baseline were independent of RRT at Day 90

Conclusions

- Survival consistently favored SCD-PED across all endpoints, analytic cohorts, and complementary analytic approaches
- In the primary exposure-defined analysis, Day-90 survival was significantly higher with SCD-PED (P = 0.043) while the landmark sensitivity analysis was directionally consistent. Bayesian probability of Day-90 survival benefit exceeded the predefined 95% threshold in both analyses (98.2% and 96.8%)
- These findings provide supportive post-approval evidence of favorable safety and survival associated with real-world SCD-PED HDE use; interpretation is limited by the small sample, nonrandomized external controls, residual confounding, and differing mortality ascertainment

References:

1. Goldstein SL, et al. *Pediatric Nephrology*. 2026. <https://doi.org/10.1007/s00467-026-07181-1>. 2. HCUP Kids' Inpatient Database (KID). Healthcare Cost and Utilization Project (HCUP). 2019 and 2022. Accessed July 16, 2026. <https://hcup-us.ahrq.gov/kidoverview.jsp>. 3. Humes HD, et al. *Pediatric Nephrology*. 2025. <https://doi.org/10.1007/s00467-025-06798-y>.

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