The Selective Cytopheretic Device (SCD) in Pediatric AKI Requiring CRRT – Eighteen-Month Post-Approval Clinical Experience From the SAVE Registry

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Introduction

- The Selective Cytopheretic Device for Pediatrics (SCD-PED) is a novel adjunctive extracorporeal therapy integrated with continuous renal replacement therapy (CRRT) that selectively binds and deactivates activated neutrophils and monocytes without inducing systemic immunosuppression, thereby promoting immune homeostasis
- SCD-PED (QUELIMMUNE™) received FDA Humanitarian Device Exemption (HDE) approval in 2024 for use in critically ill children (≥ 10 kg and ≤ 22 years) with acute kidney injury (AKI) due to sepsis requiring CRRT and antibiotic therapy
- As a condition of approval, FDA mandated a post-market surveillance registry (SAVE) to monitor safety and clinical outcomes in all treated patients
- Clinical experience from the 1st 21 patients from SAVE were recently published and revealed no device-related safety events with preliminary non-comparative outcomes of 76% Day 60 and 71% Day 90 survival[1]
- Here we expand on the above data and report preliminary outcomes from an updated cohort of 32 patients from SAVE enrolled over the first 18 months since HDE approval

Methods and Materials

The SAVE Registry[1] (ClinicalTrials.gov ID#: NCT06517810) is a mandatory, prospective, post-approval surveillance registry that will enroll up to 50 patients across approximately 50 participating sites

Primary Safety Outcome:

New (secondary) bloodstream infections (BSIs) in first 28 days after SCD-PED start (or hospital discharge, whichever is sooner) compared to a group of matched non-SCD-treated CRRT patients with sepsis from the WE-ROCK registry[3]

Treatment Period:

SCD-PED initiation through completion of therapy; collecting CRRT parameters, device performance and adverse events (AE) of special interest

Follow-up Period:

Data collected at Day 28 and Day 90 (if available), including: patient status, hospitalization status, renal replacement therapy (RRT) requirement, new BSIs and AEs

Preliminary Non-Comparative Outcomes Analysis:

Preliminary analysis included patients enrolled in SAVE, as well patients treated under Emergency Use post-approval who could not be included into the registry. Survival analyses for the updated cohort were limited to Day 60 because several recently enrolled participants had not yet reached their Day 90 assessment at the time the abstract was drafted.

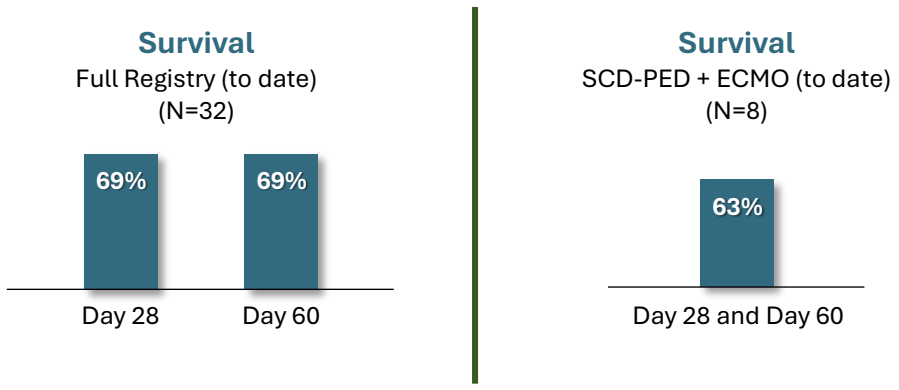
Results

- The SAVE Registry initiated in July 2024; preliminary outcomes available from 32 patients (31 registry patients + 1 additional patient whose case was published as a case report[4])*
- Patient demographics and baseline details are shown in Table 1

Primary Safety Outcome and Other Safety Data:

- Three patients had a positive blood culture during follow-up; none occurring during SCD-PED treatment
- All 3 events were judged unrelated to SCD-PED therapy by the data safety monitoring board (DSMB) and the treating clinicians
- No device-related AEs or evidence of immunosuppression by the device were reported

Preliminary Clinical Outcomes:



(*as of 12/11/2025; FDA has allowed patients treated under Emergency Use to be included in the registry, if consented; 2 Emergency Use patients consented; 1 did not[4]; all 3 are included in this analysis).

Results (continued)

Table 1: Patient Demographics, Baseline Details, and Preliminary Results

Category (# of patients with data reported)	Results
Patients Enrolled (as of 12/11/2025)	32
Median (IQR) Age, years (N=32)	9.58 (5.53, 16.4)
Median (IQR) Weight, kg (N=31)	35.4 (18.3, 63.6)
Median (IQR) Height, cm (N=31)	128 (101.4, 162.3)
Sex (Male / Female) (N=32)	16/16
Race/Ethnicity (White, Black, Hispanic, Other/AAPI, Unknown) %	47, 16, 19, 9, 9
Median (IQR) PRISM III Score at ICU admission (N=27)	15 (8.5, 19.5)
Median (IQR) PELOD-2 Score at SCD-PED initiation (N=29)	8 (6, 10)
Receipt of Vasoactive Medications (%) (N=32)	30 (94)
Intensive Mechanical Ventilation (%) (N=32)	31 (97)
Received extracorporeal membrane oxygenation % (N=32)†	
Concurrently with SCD-PED	8 (25)
Prior to SCD-PED	2 (6)
Median (IQR) Days from CRRT to Treatment Start (N=32)	1.5 (0, 4.3)
Median (IQR) Treatment Days (per cycle) (N=31)	5 (2, 7.5)
Median (IQR) Treatment Cycles (N=32)	1 (1,1)
Clinical Outcomes	
Device-Related Events	0
Positive Blood Cultures:	
During Treatment Period	0
During Follow-up Period (28 days post-initiation)	3
Deemed as related to SCD-PED by DSMB and PI	0
Survival, N (%):	
Survival Day 28 (N=32)	22 (69)
Survival Day 60 (N=32)	22 (69)

Discussion

- Patients treated on-label with SCD-PED were critically ill with AKI requiring CRRT, had sepsis, and a variety of severe underlying illnesses with significant complexities, including malignancies, medical history of ESRD and/or recent kidney transplant, chronic immunosuppression or immunodeficiencies, and open wounds; most of these patients would have been excluded from the SCD-PED registrational studies
- SCD-PED therapy was utilized with no device-related events, and three BSIs occurring within the 28-day period post-SCD-PED initiation, with none attributed to the device
- Survival rates were 69% (Day 28 and Day 60) and demonstrate results consistent with the clinical trial experience of the SCD-PED in this same population[2]

Conclusions

- The clinical experience from this updated cohort enrolled over the first 18 months since HDE approval demonstrated trends consistent with those previously reported from the initial cohort of 21 patients[1], SCD-PED registrational studies[2], and continue to support SCD-PED safety and potential benefit in this critically-ill patient population
- We plan to perform comprehensive comparative outcomes analyses against a matched cohort from WE-ROCK upon completion of the enrollment target of 50 patients in the SAVE registry

References:

1. Goldstein SL, et al. *Pediatr Nephrol*. 2026 Feb 6. doi: 10.1007/s00467-026-07181-1.
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