No More Guesswork: The Ideal eGFR Formula for Optimized Healthy Volunteer Study Enrollment

Sabina Paglialunga, PhD
Senior Director, Scientific Affairs
sabina.paglialunga@celerion.com

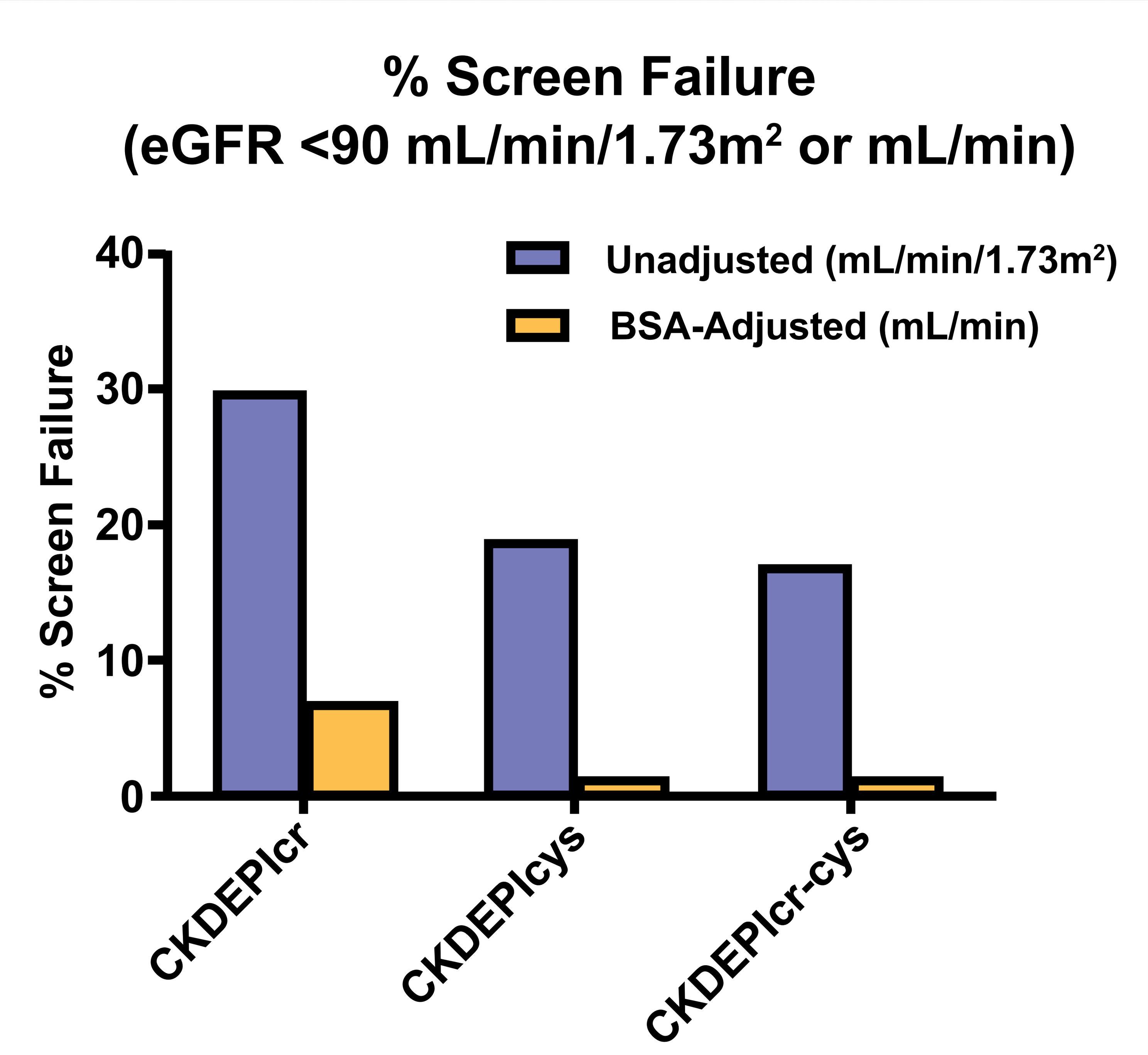
BACKGROUND

- Estimated glomerular filtration rate (eGFR) formulas indirectly measure nephron activity by applying serum creatinine, cystatin C or both parameters
- The 2021 Chronic Kidney Disease Epidemiology Collaboration (CKDEPI) is a popular contemporary equation, used in early phase trials to assess eGFR for study inclusion
- However, the creatinine equation (CKDEPIcr) can yield ***high screen failure*** rates in healthy populations causing exclusion of otherwise healthy participants, study delays and extra costs
- Therefore, we aimed to compare screen failure rates using unadjusted eGFR vs. body surface area (BSA)-adjusted eGFR

METHODS

- Data from a cohort of 163 healthy, adult participants (14F/ 149M) with screening creatinine and cystatin C values were analyzed
- Creatinine (CKDEPIcr), cystatin C (CKDEPIcys) and combined (CKDEPIcr-cys) were calculated to determine BSA-unadjusted eGFR (mL/min/1.73m^2)
- BSA-adjusted eGFR (mL/min) was calculated using the Mosteller formula
- Screen failures were set as eGFR <90 mL/min/1.73m^2 or mL/min

Cystatin C and Body Surface Area (BSA) Adjustment of eGFR Can *Reduce* Phase I Trial *Screening Failures*



Scan here for full abstract and key eGFR equations

RESULTS

Table 1. Participant Characteristics

Parameters	Mean ±SD	Range (Min-Max)
Age (years)	37.1±9.19	19-55
BMI (kg/m^2)	31.6±3.6	22.7-39.1
Mosteller BSA (m^2)	2.18±0.2	1.77-2.77
Creatinine (mg/dL)	0.99±0.15	0.60-1.43
Cystatin C (mg/L)	0.86±0.09	0.66-1.21

Table 2. Mean eGFR

Equations	Unadjusted (ml/min/1.73m^2)	BSA-Adjusted (mL/min)
CKDEPIcr	98.5±15.6	123.9±21.0
CKDEPIcys	103.2±13.3	129.7±18.3
CKDEPIcr-cys	103.0±12.4	129.4±17.1

Data presented as Mean±SD

- Unadjusted values resulting in screen failure rates of 30%, 19% and 17% of participants when applying CKDEPIcr, CKDEPIcys and CKDEPIcr-cys formulas, respectively
- The BSA-adjusted formulas dramatically ***improved the screen failure rate*** to 7%, 1% and 1% respectively

STUDY LIMITATIONS

- Small sample cohort, and limited number of female participants

CONCLUSION

- In a healthy volunteer screening cohort, cystatin C-based formulas resulted in a higer eGFR than CKDEPIcr and led to fewer screen failures
- Overall, BSA correction had the greatest impact on reducing screen failure rates and should be considered when either formula is applied, especially in a study with a wide range of BMIs

Sabina Paglialunga[1] & Staci McDonald[2]
1.Celerion, Tempe, AZ
2.Celerion, Lincoln, NE

celerion
Translating Science to Medicine