

TABLES AND FIGURES

TABLES

Table 1: Baseline demographic and procedural characteristics of the overall study population.

Patient Characteristics	Total (n=67)
Demographic	
Age Age groups (n)	Median 0.55 [IQR 0.96] years < 6 months = 32 (47.8%) 6-12 months = 16 (23.9%) > 12 months = 19 (28.4%)
Sex (n)	39 (58.2%) male
Weight	7.1 [5.8] kg
Height	66.0 [24.0] cm
Weight for Height ratio	Median -0.25 [-1.5 – 0.5] Low ($z < -1$) = 25 (37.3%) Mid ($-1 < z < 1$) = 31 (46.2%) High ($z > 1$) = 11 (16.4%)
Ethnicity (n)	Caucasian = 40 (56.7%) MENA = 23 (34.3%) Black African = 4 (6.0%)
Procedural	
Patch application site (n)	Elbow fold = 21 (29.9%) Upper leg = 20 (29.9%) Lower back = 10 (14.9%) Back of the hand = 7 (10.4%) Suprapubic = 6 (9.0%) Foot = 4 (6.0%)
Vascular access type (n)	Central venous catheter = 52 (77.6%) Arterial catheter = 15 (22.4%)

Abbreviations: MENA: Middle East and North African

Table 2. Safety analysis across subgroups. Cmax differences across subgroups were evaluated using the Wilcoxon rank-sum test for two-level variables and the Kruskal–Wallis test for variables with three or more levels. Univariable linear regression models were used to estimate subgroup effects relative to the reference category, and the overall significance of each stratifying variable was determined using Type III sum-of-squares analysis of variance (ANOVA). Multivariable models repeated this analysis with adjustment for the scaled weight-for-height ratio.

	Cmax		Univariable regression		Multivariable regression	
	median [Q1-Q3], mg/L	p	β (95% CI)	p	β (95% CI)	p
Age		0.512		0.344		0.380
< 6 months (n=32)	0.030 [0.017-0.038]		<i>(reference category)</i>		<i>(reference category)</i>	
6 – 12 months (n=16)	0.024 [0.011-0.035]		-0.015 (-0.038 – 0.008)	0.187	-0.016 (-0.039 – 0.008)	0.018
> 12 months (n=19)	0.019 [0.014-0.041]		-0.011 (-0.033 – 0.010)	0.294	-0.012 (-0.035 – 0.011)	0.292
Sex		0.863		0.428		0.444
male (n=39)	0.028 [0.013-0.042]		<i>(reference category)</i>		<i>(reference category)</i>	
female (n=28)	0.024 [0.018-0.034]		-0.007 (-0.026 – 0.011)	0.428	-0.007 (-0.027 – 0.012)	0.444
WFH		0.619		0.938		0.938
Low ($z < -1$) (n = 25)	0.030 [0.014-0.042]		<i>(reference category)</i>		<i>(reference category)</i>	
Mid ($-1 < z < 1$) (n = 31)	0.022 [0.012-0.038]		0.003 (-0.018 – 0.024)	0.804	0.003 (-0.018 – 0.024)	0.804
High ($z > 1$) (n = 11)	0.024 [0.020-0.035]		-0.002 (-0.030 – 0.026)	0.895	-0.002 (-0.030 – 0.026)	0.895
Ethnicity		0.890		0.746		0.687
Caucasian (n=40)	0.024 [0.015-0.036]		<i>(reference category)</i>		<i>(reference category)</i>	
MENA (n=23)	0.025 [0.010-0.040]		0.007 (-0.012 – 0.027)	0.451	0.008 (-0.013 – 0.028)	0.456

Black African (n=4)	0.035 [0.021-0.046]	0.001 (-0.039 – 0.040)	0.984	0.001 (-0.040 – 0.041)	0.990
Vascular access type		0.874	0.556		0.539
Arterial catheter (n=15)	0.028 [0.014-0.037]	<i>(reference category)</i>		<i>(reference category)</i>	
Central venous catheter (n=52)	0.023 [0.014-0.038]	0.006 (-0.015 – 0.028)	0.556	0.007 (-0.16 – 0.030)	0.539
Patch application site		0.069	0.443		0.982
Elbow fold (n=21)	0.030 [0.025-0.044]	<i>(reference category)</i>		<i>(reference category)</i>	
Back of the hand (n=7)	0.013 [0.009-0.017]	-0.030 (-0.062 – 0.003)	0.073	-0.031 (-0.065 – 0.003)	0.071
Upper leg (n=20)	0.022 [0.014-0.046]	-0.011 (-0.034 – 0.013)	0.368	-0.010 (-0.035-0.014)	0.408
Lower back (n=10)	0.022 [0.016-0.035]	-0.016 (0.045 – 0.012)	0.256	-0.017 (-0.047 – 0.013)	0.255
Suprapubic (n=5)	0.032 [0.014-0.036]	-0.016 (-0.053 – 0.021)	0.383	-0.017 (-0.055 – 0.021)	0.373
Foot (n=4)	0.012 [0.005-0.022]	-0.029 (-0.070 – 0.011)	0.154	-0.031 (-0.072 – 0.011)	0.149

Abbreviations: MENA: Middle East and North African

Table 3: Local adverse events, exclusively manifesting as local erythema, across subgroups. Differences are tested using Fishers' exact test

	Adverse events, n (%)	p
Age		0.544
< 6 months (n=32)	22 (69%)	
6 – 12 months (n=16)	12 (75%)	
> 12 months (n=19)	16 (84%)	
Sex		1.000
male (n=39)	29 (74%)	
female (n=28)	21 (75%)	
WFH		0.608
Low ($z < -1$) (n = 25)	17 (68%)	
Mid ($-1 < z < 1$) (n = 31)	23 (79%)	
High ($z > 1$) (n = 11)	8 (73%)	
Ethnicity		0.003
Caucasian (n=40)	33 (83%)	
MENA (n=23)	17 (74%)	
Black African (n=4)	0 (0%)	
Vascular access type		0.743
Arterial catheter (n=15)	12 (80%)	
Central venous catheter (n=52)	38 (73%)	
Patch application site		1.000
Elbow fold (n=21)	16 (76%)	
Back of the hand (n=7)	5 (71%)	
Upper leg (n=20)	15 (75%)	
Lower back (n=10)	7 (70%)	
Suprapubic (n=5)	4 (80%)	
Foot (n=4)	3 (75%)	

Table 4: Feasibility study across subgroups. Caregiver satisfaction at patch application and removal was rated using a 5-point Likert scale (1 = lowest, 5 = highest). Differences in scores between subgroups were assessed using one-way ANOVA.

	Patch application		Patch removal	
	Likert score, mean (SD)	p	Likert score, mean (SD)	p
Overall	4.48 ± 0.84	/	4.37 ± 0.92	/
Age		0.097		0.210
< 6 months (n=32)	4.25 ± 0.95		4.22 ± 1.01	
6 – 12 months (n=16)	4.62 ± 0.81		4.31 ± 1.01	
> 12 months (n=19)	4.74 ± 0.56		4.68 ± 0.58	
Sex		0.636		0.679
male (n=39)	4.44 ± 0.82		4.33 ± 0.90	
female (n=28)	4.54 ± 0.88		4.43 ± 0.96	
WFH		0.214		0.798
Low ($z < -1$) (n = 25)	4.24 ± 0.93		4.40 ± 0.82	
Mid ($-1 < z < 1$) (n = 31)	4.55 ± 0.83		4.38 ± 0.90	
High ($z > 1$) (n = 11)	4.73 ± 0.65		4.18 ± 1.25	
Ethnicity		0.197		0.272
Caucasian (n=40)	4.50 ± 0.82		4.28 ± 1.04	
MENA (n=23)	4.57 ± 0.79		4.61 ± 0.66	
Black African (n=4)	3.75 ± 1.26		4.00 ± 0.82	
Vascular access type		0.955		0.411
Arterial catheter (n=15)	4.47 ± 0.74		4.20 ± 1.01	
Central venous catheter (n=52)	4.48 ± 0.87		4.42 ± 0.89	
Patch application site		0.688		0.974
Elbow fold (n=21)	4.43 ± 0.81		4.24 ± 1.14	
Back of the hand (n=7)	4.29 ± 0.95		4.43 ± 1.13	
Upper leg (n=20)	4.50 ± 0.89		4.45 ± 0.69	
Lower back (n=10)	4.70 ± 0.68		4.50 ± 0.85	
Suprapubic (n=5)	4.80 ± 0.45		4.40 ± 0.89	
Foot (n=4)	4.00 ± 1.41		4.52 ± 0.96	

