

Supplementary material

Supplementary Table 1 Distribution of Wong-Baker FACES Pain Rating Scale scores by category at each assessment time point (intention-to-treat population, n = 150)

Pain score	Group A, n (%)	Group B, n (%)	Difference (B – A), percentage points
<i>Before injection</i>			
0 (no hurt)	49 (66.2)	62 (81.6)	+15.4
2 (hurts little bit)	17 (23.0)	1 (1.3)	–21.7
4 (hurts little more)	8 (10.8)	4 (5.3)	–5.5
6 (hurts even more)	0 (0.0)	9 (11.8)	+11.8
8 (hurts whole lot)	0 (0.0)	0 (0.0)	0.0
10 (hurts worst)	0 (0.0)	0 (0.0)	0.0
<i>Immediately after injection (primary endpoint)</i>			
0 (no hurt)	34 (45.9)	46 (60.5)	+14.6
2 (hurts little bit)	1 (1.4)	0 (0.0)	–1.4
4 (hurts little more)	17 (23.0)	0 (0.0)	–23.0
6 (hurts even more)	22 (29.7)	28 (36.8)	+7.1
8 (hurts whole lot)	0 (0.0)	2 (2.6)	+2.6
10 (hurts worst)	0 (0.0)	0 (0.0)	0.0
<i>5 minutes after injection</i>			
0 (no hurt)	39 (52.7)	46 (60.5)	+7.8
2 (hurts little bit)	1 (1.4)	1 (1.3)	–0.0
4 (hurts little more)	29 (39.2)	21 (27.6)	–11.6

more)			
6 (hurts even	5 (6.8)	8 (10.5)	+3.8
more)			
8 (hurts whole lot)	0 (0.0)	0 (0.0)	0.0
10 (hurts worst)	0 (0.0)	0 (0.0)	0.0

Data are presented as n (%); percentages are calculated within each group at each time point and may not sum to exactly 100% due to rounding. The Wong-Baker FACES Pain Rating Scale uses six scores in two-point increments (0, 2, 4, 6, 8, 10), with higher scores indicating greater pain. Differences are presented as Group B minus Group A in percentage points. For lower pain categories, positive differences indicate a distribution favourable to Group B; for higher pain categories, negative differences indicate a distribution favourable to Group B. This category-level distribution is descriptive only and is not used to support the primary non-inferiority claim, which was based on the linear mixed-effects model of mean Wong-Baker FACES scores (see Table 2 of the main text).

Reference: Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs* 1988; 14: 9-17 [PMID: 3344163].