PEDIATRIC RHEUMATOLOGY

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Dosing patterns of canakinumab in patients with Cryopyrin-Associated Periodic Syndromes (CAPS): A comparative analysis of a study in Western versus Japanese patients

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Background

CAPS is an orphan auto-inflammatory disease, generally diagnosed in childhood that requires life-long treatment. Canakinumab, a fully human anti-IL-1b antibody, has previously demonstrated rapid, complete and sustained response in CAPS patients.

Aim

To compare dosing patterns of canakinumab in pediatric and adult CAPS patients of a predominantly Western population (WP) vs Japanese patients (JP).

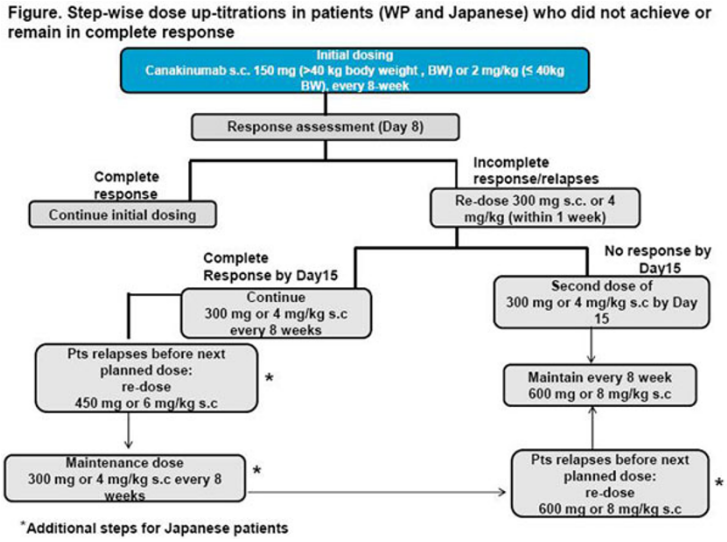

Figure 1 Step-wise up-titrations in patients (WP and Japanese) who did not achieve or remain in complete response

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Table 1 Canakinumab doses by phenotypes

Phenotype (n=WP/JP)	Wester population		Japanese population	
	Adult[1] Mean/median (mg) (N=136)	Pediatrics[2] Mean/mdeian (mg/kg) (N=29)	Adult[1] Mean/median (mg) (N=8)	Pediatrics[2] Mean/mdeian (mg/kg) (N=11)
MWS (103/7)	200/150	5.5/4.0	225/150	6.0/6.0
NOMID (32/11)	299/150	5.8/4.0	300/225	5.5/6.0
FCAS (30/0)	189/150	2.7/2.0	-	-

Methods

Canakinumab s.c. 150 mg (if >40 kg) or 2 mg/kg (if ≤40 kg) was dosed every 8 weeks. Step-wise up-titrations in dose were allowed in patients who did not achieve/remain in complete response (CR, Figure 1).

Results

Median duration of treatment was 414 (29-687) days in WP and 337 days (59-373 days) in JP. In the WP, CR was achieved in 85/109 (78%) canakinumab-naive patients. 127/141 (90%) evaluable patients remained in CR throughout the study. 47/166 patients in WP and 11/19 patients in the Japanese study were pediatrics. 36.2% vs 81.8% (WP vs JP) of children received up-titrated and/or more frequent doses. Higher median doses were required in pediatric patients in the JP compared with WP to control MWS and NOMID (Table 1). 13% vs 45% (WP vs JP) of the children received the maximum permitted dose. None of those children showed an unusual type or frequency of adverse events.

Conclusions

Increased doses of canakinumab were equally efficacious in patients of a WP and Japanese population comprising different CAPS phenotypes without evidence of a change in AE profile. These data suggest that children and patients with more severe CAPS phenotypes, irrespective of ethnicity, require differential dosing.

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