Clinical study: Intratect® (50 g/l) for primary immune thrombocytopenia

Typical for primary immune thrombocytopenia (ITP) is a significantly reduced thrombocyte lifecycle. The resulting thrombocyte loss can give rise to complications in connection with bleeding; this condition requires treatment.

The only patients treated are those with acute haemorrhages and thrombocyte levels below 50/nl, and patients with chronic ITP and an increased risk of haemorrhage prior to an operation or before giving birth.

The success parameter for treatment is a doubling of the initial thrombocyte level or a thrombocyte increase of more than 50/nl within a few days.[2]

In a prospective clinical study, 24 adults with chronic ITP and thrombocyte levels ranging from 3/nl to 27/nl received Intratect® therapy.[1]

Fifteen patients were each given 1.0 g/kg BW Intratect® on two days; nine patients were each given 0.4 g/kg on five days. Test criteria were a thrombocyte increase to ≥ 50/nl and a drop in the number of haemorrhages within 28 days.

Table: Changes in the thrombocyte counts with Intratect®

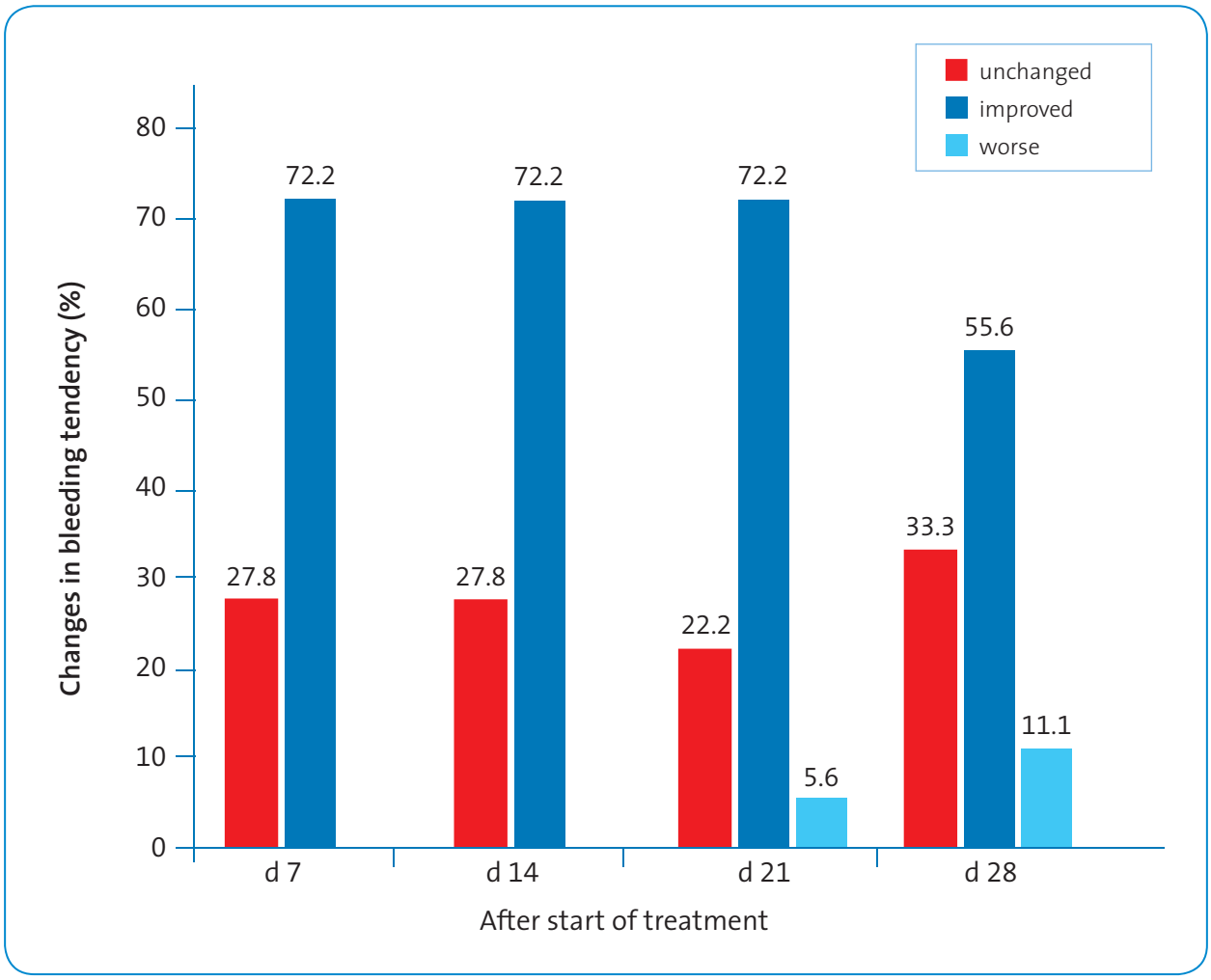
Parameter	Number of days	
	Mean	Median
Time to rise to ≥ 50/nl		
total (n=24)	3.9 ± 2.4	3.0
at 1.0 g/kg/d for 2 days (n=15)	4.4 ± 2.8	2.5
at 0.4 g/kg/d for 5 days (n=9)	2.9 ± 0.6	3.0
Duration of response ≥ 50/nl		
total (n=24)	19.8 ± 7.8	22.5
at 1.0 g/kg/d for 2 days (n=15)	17.6 ± 8.0	18.0
at 0.4 g/kg/d for 5 days (n=9)	23.6 ± 6.3	22.5
Duration of response over starting count		
total (n=24)	24.4 ± 3.6	25.5
at 1.0 g/kg/d for 2 days (n=15)	23.0 ± 3.7	22.5
at 0.4 g/kg/d for 5 days (n=9)	26.8 ± 1.7	27.0

Results

22 of the 24 (91.7 %) patients responded to Intratect® treatment. Significant thrombocyte increases were found after an average of 3 days. On average, the maximum increase of 224 ± 144/nl thrombocytes was reached after 7.5 days. Average response time to treatment was 25.5 days.

Bleeding tendency decreased significantly just a few days after administering Intratect®. After 7 days, 72.2 % of patients experienced less haemorrhaging. Not until three weeks later did some patients find they tended to bleed again.

Fig.: Changed bleeding symptoms compared to the initial situation



SUMMARY

Intratect® is able to reduce the bleeding tendency in ITP patients within just a few days and to induce an increase in thrombocytes of over 50/nl that then lasts for several weeks. It therefore meets the criteria of the European Guideline for the use of IVIG.[2]

References: (1) Colovic M et al.: Hematol. (2003) 4: 358–362, (2) EMA Guideline: EMA/CHMP/BPWP/94033/2007 rev. 2 (Feb. 2011)