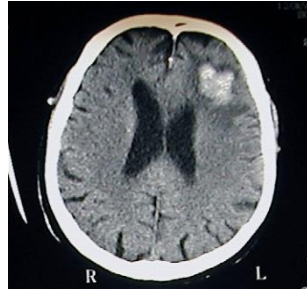


# Actualités biblio intérêt de la dexaméthasone en 1<sup>ère</sup> ligne dans le PTI de l'adulte ?

M Michel

# 1st -line treatment for newly-diagnosed ITP in adults (plt ct < 30 x 10<sup>9</sup>/L):

Life-threatening  
hemorrhage

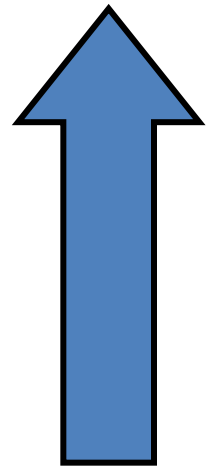


IVIg (2g/kg) + HDMP + platelet transfusions ± anti-D (if available) ± vinca alkaloids\* = « total therapy »

IVIg (1 to 2 g/kg) +  
 iv. HDMP or prdn or  
 Dexamethasone

Si Score ≥8

oral PRDN 1mg/kg/d x 3 weeks or **DXM** 40 mg x 4 days



Minor or no  
bleeding  
symptoms



PRDN = prednisone, DXM = dexamethasone,  
IVIg = intravenous immunoglobulin,  
HDMP = high dose of methylprednisolone

\*off label use

Rodeghiero F *et al.* Blood 2008  
Provan D *et al.* Blood 2010;115:168–186  
Neunert *et al.* ASH guidelines Blood 2011

## High-dose dexamethasone versus prednisone for treatment of adult immune thrombocytopenia: a prospective multicenter randomized trial

Yu Wei, Xue-bin Ji, Ya-wen Wang, Jing-xia Wang, En-qin Yang, Zheng-cheng Wang, Yu-qi Sang, Zuo-mu Bi, Cui-ai Ren, Fang Zhou, Guo-qiang Liu, Jun Peng and Ming Hou

**Table 1. Patient demographics and baseline characteristics**

|  | HD-DXM<br>(n = 95) | PDN<br>(n = 97) | <i>P</i> |
|--|--------------------|-----------------|----------|
| Median age, years (range)                      | 43 (18 – 73)       | 44 (18 – 75)    | 0.473    |
| Gender, n (%)                                  | 64 (67.4)          | 72 (74.2)       | 0.342    |
| Median platelet count, $\times 10^9/L$ (range) | 7 (0 – 29)         | 8 (0 – 36)      | 0.292    |
| Median bleeding score*, score (range)          | 4 (0 – 13)         | 4 (0 – 12)      | 0.836    |
| Antiplatelet autoantibodies, n (%)             |                    |                 |          |
| Anti-GPIIb/IIIa positive only                  | 22 (23.2)          | 19 (19.6)       | 0.599    |
| Anti-GPIb/IX positive only                     | 12 (12.6)          | 11 (11.3)       | 0.827    |
| Double positive                                | 18 (18.9)          | 20 (20.6)       | 0.857    |
| Double negative                                | 43 (45.3)          | 47 (48.5)       | 0.667    |

HD-DXM indicates high-dose dexamethasone; PDN, prednisone; n, number;

\* Bleeding score was graded by an ITP specific bleeding scale by Khellaf et al.<sup>10</sup>

Randomized  
controlled  
open-label trial in  
treatment naive  
newly-diagnosed ITP  
1/1 randomization:

**DXM: 40mg D1-D4**  
(repeated by D10 if  
plt ct  $<30 \times 10^6/L$ )

**vs PRDN 1 mg/kg/day**  
X 4 weeks (then tapered  
over 4 to 6 weeks)

## High-dose dexamethasone versus prednisone for treatment of adult immune thrombocytopenia: a prospective multicenter randomized trial

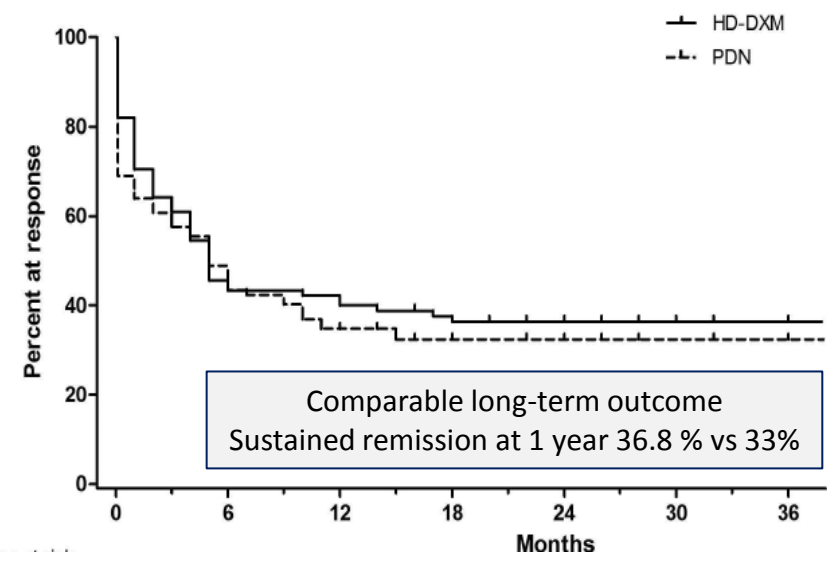
Yu Wei, Xue-bin Ji, Ya-wen Wang, Jing-xia Wang, En-qin Yang, Zheng-cheng Wang, Yu-qi Sang, Zuo-mu Bi, Cui-ai Ren, Fang Zhou, Guo-qiang Liu, Jun Peng and Ming Hou

Primary endpoint:  
Rate of initial and sustained response\* in both arms

Table 2. Comparison of outcomes between the two arms

|                         | HD-DXM<br>(n = 95) | PDN<br>(n = 97) | P       | OR    | 95% CI        |
|-------------------------|--------------------|-----------------|---------|-------|---------------|
| Overall response, n (%) | 78 (82.1)          | 67 (69.1)       | 0.044   | 2.054 | 1.042 – 4.050 |
| CR, n (%)               | 48 (50.5)          | 26 (26.8)       | 0.001   | 2.789 | 1.526 – 5.097 |
| Median TTR, d (range)   | 3 (1 – 9)          | 6 (2 – 24)      | < 0.001 |       |               |
| SR, n (%)               | 38 (40.0)          | 40 (41.2)       | 0.884   | 0.950 | 0.534 – 1.690 |
| Sustained CR, n (%)     | 26 (27.4)          | 17 (17.5)       | 0.120   | 1.773 | 0.889 – 3.539 |
| Additional therapy*, n  |                    |                 |         |       |               |
| HD-MP                   | 2                  | 3               |         |       |               |
| IVIg                    | 15                 | 14              |         |       |               |
| Splenectomy             | 5                  | 8               |         |       |               |
| Rituximab               | 12                 | 11              |         |       |               |
| Rh-TPO                  | 9                  | 8               |         |       |               |
| Vincristine             | 5                  | 4               |         |       |               |
| Ciclosporin             | 4                  | 4               |         |       |               |
| Azathioprine            | 5                  | 3               |         |       |               |
| Herbs                   | 0                  | 2               |         |       |               |

the difference is non significant if evaluated by PP population (84.8% vs 74.4%, p = 0.099)



\* Rodeghiero R. et al. Blood 2009



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No deaths (patients with life-threatening bleeding were excluded), occurrence of some adverse events were more frequent in the prednisone arm (NS) leading to treatment discontinuation in 2 patients in the prdn arm  
One case of pneumonia in a 74-year old woman

DXM versus PRDN  
*Point à discuter dans nouveau PNDS...*

Table 4. Adverse events during treatment

| Adverse events, n (%) | HD-DXM         |                     | PDN            |                     |
|-----------------------|----------------|---------------------|----------------|---------------------|
|                       | Total (n = 95) | ≥ 60 years (n = 18) | Total (n = 97) | ≥ 60 years (n = 20) |
| ALT                   | 1 (1.1)        | 0 (0)               | 0 (0)          | 0 (0)               |
| Arthralgia            | 0 (0)          | 0 (0)               | 2 (2.1)        | 1 (5.0)             |
| Cushingoid appearance | 0 (0)          | 0 (0)               | 13 (13.4)      | 2 (10.0)            |
| Diarrhea              | 0 (0)          | 0 (0)               | 1 (1.0)        | 0 (0)               |
| Dizziness             | 2 (2.1)        | 1 (5.6)             | 5 (5.2)        | 2 (10.0)            |
| Edema                 | 0 (0)          | 0 (0)               | 4 (4.1)        | 2 (10.0)            |
| Fatigue               | 1 (1.1)        | 0 (0)               | 4 (4.1)        | 1 (5.0)             |
| Fever                 | 1 (1.1)        | 0 (0)               | 0 (0)          | 0 (0)               |
| Hyperglycemia         | 4 (4.2)        | 1 (5.6)             | 6 (6.2)        | 3 (15.0)            |
| Hypertension          | 4 (4.2)        | 2 (11.1)            | 8 (8.2)        | 3 (15.0)            |
| Infection             | 0 (0)          | 0 (0)               | 3 (3.1)        | 1 (5.0)             |
| Insomnia              | 8 (8.4)        | 3 (16.7)            | 5 (5.2)        | 2 (10.0)            |
| Mood disorders        | 7 (7.4)        | 2 (11.1)            | 4 (4.1)        | 1 (5.0)             |
| Nausea                | 2 (2.1)        | 1 (5.6)             | 3 (3.1)        | 1 (5.0)             |
| Palpitation           | 2 (2.1)        | 1 (5.6)             | 1 (1.0)        | 0 (0)               |
| Peptic ulcer          | 2 (2.1)        | 0 (0)               | 5 (5.2)        | 1 (5.0)             |
| Weight gain           | 0 (0)          | 0 (0)               | 10 (10.3)      | 3 (15.0)            |

HD-DXM indicates high-dose dexamethasone; PDN, prednisone; ALT, alanine aminotransferase.