Patient experiences with prednisone and methotrexate: results of the PREDMETH trial

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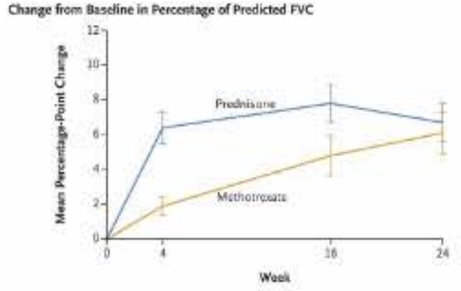
Background

- Patient perspectives are essential in shared decision making
- The PREDMETH study showed that methotrexate is non-inferior to prednisone for pulmonary sarcoidosis



Aim

- To evaluate patient perspectives using the patient experiences and satisfaction with medication (PESAM) questionnaire

Study sites

Methods

- Patients with pulmonary sarcoidosis, about to start prednisone or methotrexate, completed the PESAM at baseline and 24w.
- We used independent and paired student T-tests

PESAM

- Expectation module before treatment (baseline)
- Experience module after treatment (24 weeks)
- Validated in patients with idiopathic pulmonary fibrosis; minimal clinical importance difference is unknown.
- Expectation and experience module consist of 11 questions
  - **Effectiveness** (4 items), **Side effects** (4 items), and **Ease of use** (3 items), rated on a 0–4 Likert scale (higher scores more positive experiences) or I do not know
- Additional items in the experience module:
  - Satisfaction with medication (4-items, -5 (very dissatisfied) to 5 (very satisfied)
  - Importance of effectiveness, side effect and ease of use (0 = not important at all, 4 = very important)

Baseline

- 137 patients participated
- Expectations before start of treatment were positive and comparable for prednisone and methotrexate

Expectations before treatment	Prednisone (n=69)	Methotrexate (n=68)
Effectiveness	2.6 (0.7); n=62	2.7 (0.7); n=60
Side effects	2.6 (0.7); n=54	2.8 (0.6); n=53
Ease of use	3.4 (0.6); n=65	3.7 (0.5); n=65

* Data depicted as mean (SD). Higher scores signify more positive experiences.

Differences in expectations and experiences

Figure 1: Effectiveness (mean scores)

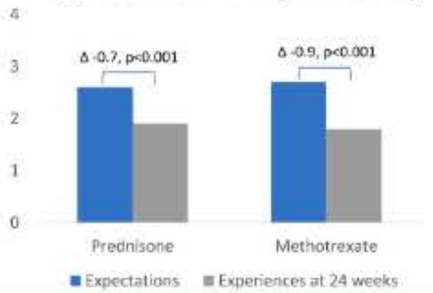
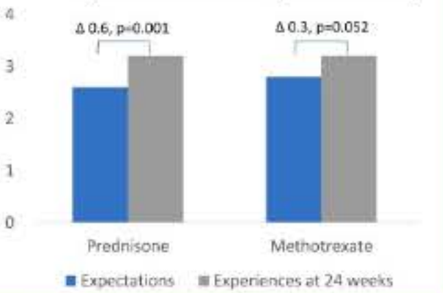


Figure 2: Side effects (mean scores)



Satisfaction and importance at 24 weeks

Figure 3: Satisfaction (mean scores)

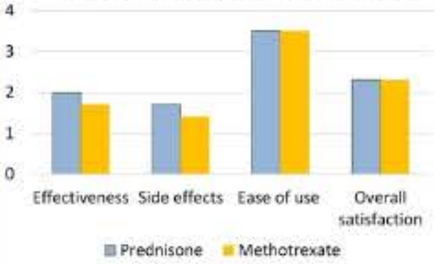
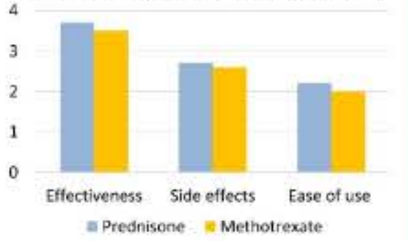


Figure 4: Importance (mean scores)



*No significance differences were found for satisfaction and importance between the two groups

Conclusion

- Patient experiences were comparable between prednisone and methotrexate
- Effectiveness: lower than expected for both groups
- Side effects: better than expected for both groups
- Patients prioritized effectiveness over side effects and ease of use
- Results highlight importance of patient education and expectation management

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ERS CONGRESS | 2025
27 September – 1 October | Amsterdam, Netherlands

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Introduction

Patient perspectives are essential in shared decision making and choosing the optimal treatment. The PREDMETH study, a RCT, showed that methotrexate is non-inferior to prednisone as first-line treatment for pulmonary sarcoidosis (NCT04314193). Here, we evaluate patient perspectives using the patient experiences and satisfaction with medication (PESAM) questionnaire, which was an exploratory endpoint of the PREDMETH study.

Methods

Patients with pulmonary sarcoidosis, about to start prednisone or methotrexate, completed the PESAM at baseline and 24 weeks. Expectations, experiences and importance were rated on 0-4 Likert Scale (negative to positive); satisfaction from -5 to 5. We used independent and paired student T-tests.

Results

137 patients participated; expectations of prednisone and methotrexate were positive and comparable. At 24 weeks, experiences with effectiveness were fairly positive, but lower than expected (prednisone Δ-0.7, $p<0.001$; methotrexate Δ-0.9, $p<0.001$); side effects were better than expected (prednisone Δ0.6, $p=0.001$; methotrexate Δ0.3,$p=0.05$). Effectiveness was prioritized over side effects

Table 1: Expectations and experiences with prednisone and methotrexate*						
	Expectations module baseline		Experiences module 24 weeks		Difference between expectations and experiences (95%CI)	
	Prednisone (n=69)	Methotrexate (n=68)	Prednisone (n=69)	Methotrexate (n=68)	Prednisone (n=69)	Methotrexate (n=68)
Expectations/ experiences						
- Effectiveness	2.6 (0.7) n=62	2.7 (0.7) n=60	1.9 (1.0) n=48	1.8(1.1) n=48	-0.7 (-1.1;-0.3) **p<0.001**	-0.9 (-1.2;-0.5) **p<0.001**
- Side effects	2.6 (0.7) n=54	2.8 (0.6) n=53	3.2 (0.9) n=55	3.2 (0.8 n=46	0.6 (0.2;0.9) **p=0.001**	0.3 (0;0.6) p=0.052
- Ease of use	3.4 (0.6) n=65	3.7 (0.5) n=65	3.8 (0.4) n=55	3.8 (0.4) n=50	0.4 (0.3-0.6) **P<0.001**	0.1 (-0;0.3) p=0.142
Satisfaction						
- Effectiveness	Not applicable	Not applicable	2.0 (2.0) n=55	1.7 (2.0) n=50	Not applicable	Not applicable
- Side effects			1.7 (2.0) n=43	1.4 (2.0) n=34		
- Ease of use			3.5 (1.2) n=55	3.5 (1.3) n=50		
- Overall satisfaction			2.3 (1.9) n=55	2.3 (2.0) n=50		
Importance						
- Effectiveness	Not applicable	Not applicable	3.7 (0.7)	3.5 (0.9)	Not applicable	Not applicable
- Side effects			2.7 (1.0)	2.6 (1.0)		
- Ease of use			2.2 (1.3) n=55	2.0 (1.0) n=50		

*Data are presented as mean (SD). *Number of patients is variable as patients had the option to fill out "don't know".*
The expectations module includes 11 items rated on 0-4 Likert Scale (negative to positive).
The experiences module includes 18 items; experiences and importance were rated on 0-4 Likert scale; satisfaction from -5 to 5.

Conclusion

Patient experiences were comparable for prednisone and methotrexate, and generally positive. In both groups, effectiveness was lower than expected upfront, while side effects were better than expected. These results provide valuable information to enhance patient education and expectation management.