COMPARATIVE EFFICACY OF DIMETHYLFUMARATE AND OTHER TREATMENTS FOR MODERATE-TO-SEVERE CHRONIC PLAQUE PSORIASIS

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BACKGROUND

In clinical practice, dimethylfumarate is considered an alternative at the level of conventional systemic drugs in first line (cyclosporine, methotrexate, acitretin).

PURPOSE

To establish whether dimethylfumarate, methotrexate, cyclosporine and acitretin can be considered equivalent therapeutic alternatives (ATE) in efficacy in moderate-to-severe plaque psoriasis (PP).

MATERIALS AND METHODS

We conducted a search of clinical trials of these drugs:

✓Phase III ✓Efficacy evaluated at 12 weeks or next
✓Double-blind
✓uncontrelled disease with topical treatments and/or phototherapy.
✓Controlled with methotrexate or placebo✓ Adults diagnosed with PP

PASI75: The 75% reduction in the Psoriasis Area and Severity index was used as the main variable.

Indirect Comparison (IC)

CYCLOSPORIN — **PASI 75** → FUMARATES

METHOTREXATE — IC The Bucher Method* → DIMETHYLFUMARATE

Δ=15%

Considering that the failure can be recovered with an effective second line, it was taken as delta value, for PASI75 the value in previous published studies of IC of biological in PP, 15%.

*Using the Bucher method, using the Indirect Treatment Comparisons calculator from the Canadian Agency for Health Technology Assessment.

For cyclosporine with more than one published study, a previous meta-analysis was performed (Der Simonian-Laird method), using the Joaquin Primo calculator

The results were analyzed graphically and the relative position of the 95% Confidence Interval (95%CI) and the equivalence margin was observed. To establish the positioning, the ATE Guide was followed.

RESULTS

Included 4 clinical trials, 2 of ciclosporin, one of dimethylfumarate and fumarates

The Acitretin studies were excluded because they did not meet the inclusion criteria.

EFFICACY

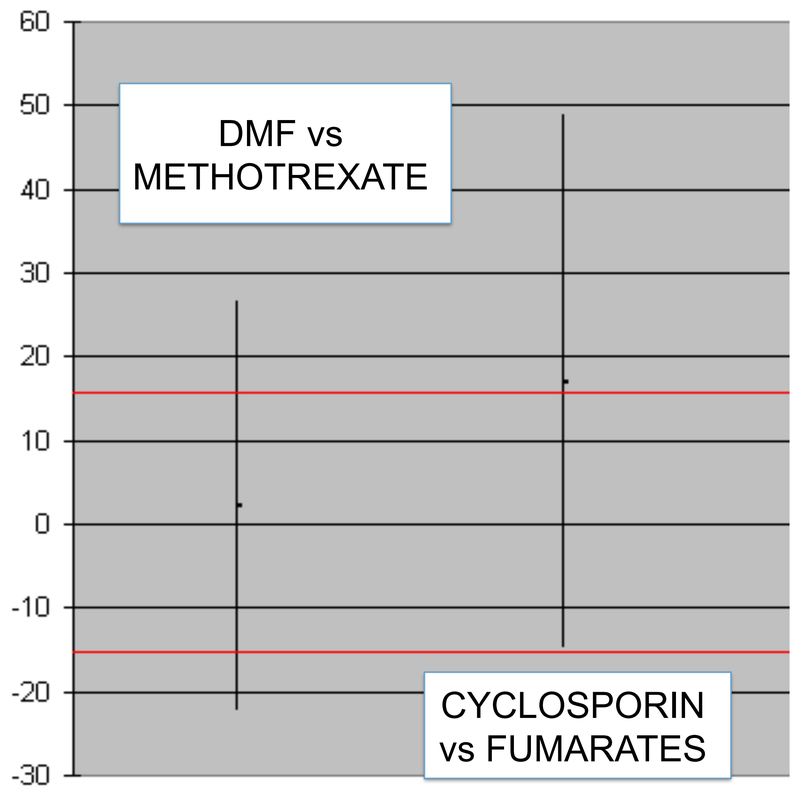
INDIRECT COMPARISON CYCLOSPORIN VERSUS FUMARATES		
Variable (week 12)	Cyclosporin RAR (IC 95%)	
PASI75	17 (-14,83 a 48,83)	

INDIRECT COMPARISON METHOTREXATE VERSUS DIMETHYLFUMARATE		
Variable (week 12)	Methotrexate RAR (IC 95%)	
PASI75	2,2 (-22,2 a 26,6)	

Applying the ATE Guide:

Methotrexate and Dimethylfumarate can be declared ATE, being the probability of clinically relevant difference <50% (most of the 95%CI is in the equivalence range) and the failure does not involve serious/ irreversible damage

Cyclosporine and fumarates **could not be considered ATE** (the RAR exceeded the delta with more than 50% probability that the difference was clinically relevant).



CONCLUSIONS

✓Dimethylfumarate and methotrexate could be considered ATE.
✓Ciclosporin and fumarates could not be considered ATE.

✓For a definitive statement of ATE, criteria of safety and adequacy should be considered.

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