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Methotrexate use in pediatric atopic dermatitis: final results from the STEADY study (Systemic Treatment Efficacy in Atopic Dermatitis in Young Children and Adolescents)

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STEADY

The authors declare no conflict of interest.

OBJECTIVE

- The study was conducted in Department of Dermatology of the Medical University in Lodz within the project STEADY.
- The aim of this trial is to assess efficacy, safety and tolerability of methotrexate in children and adolescents (2-18 y.o.) with moderate-to-severe AD.

RESEARCH PROJECT

- After providing written informed consent, patients were assessed for eligibility at the screening visit. Laboratory tests and medical history must be assessed at this time.
- Methotrexate was given in a dose of 0.3mg/kg, once a week, max. dose 20 mg/week, for 16 weeks.
- Laboratory tests and clinical evaluation were performed in consecutive weeks (2, 4, 8, 12 and 16) during study visits.
- The patients were obliged use emollients twice a day for the whole treatment period, starting on the screening visit.

INCLUSION CRITERIA

- 2-18 yo.;
- Diagnosis of moderate or severe AD established at least 6 months before baseline ;
- EASI>16;
- SCORAD>25;
- BSA>10%;
- Eligible for systemic therapy;
- Within 2 weeks before administration of the first drug dose the patient can use only topical emollients.

EXCLUSION CRITERIA

- Immunosuppressive treatment or use of systemic steroids within 4 weeks before the first dose of IMP;
- Use of phototherapy within 2 weeks prior to baseline visit or PUVA-therapy within 4 weeks prior to baseline visit;
- Use of topical steroids or topical calcineurin inhibitors within two weeks before baseline visit;
- Use of MTX or CsA within 6 months prior to baseline visit;
- Known or suspected hypersensitivity to any component of the IMP.

METHODOLOGY & RESULTS

1. Blood sample collection (laboratory tests)
2. Questionnaire collection: EASI, IGA, SCORAD, DLQI, VAS, NRS.

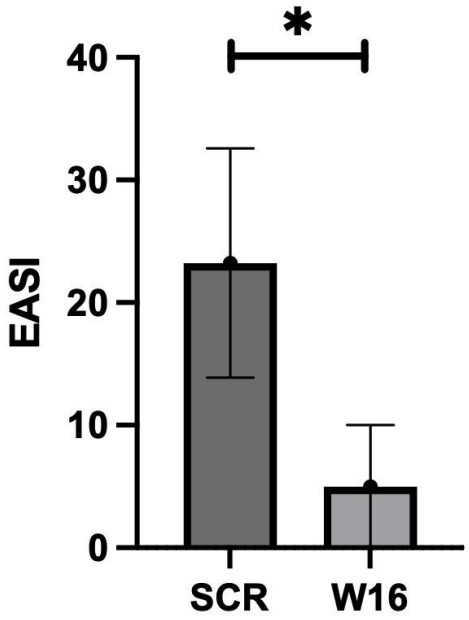
SCR – 2 – 4 – 8 - 16 week

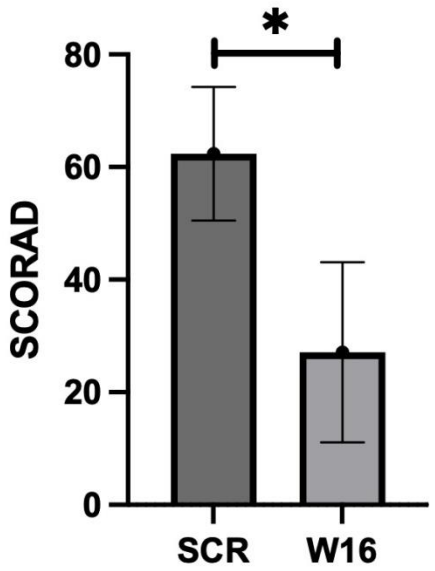
- 65 patients (mean age 8 y.o.; 30 girls, 35 boys) have been recruited of whom 59 have completed the 16th week of observation;
- 6 patients were excluded from the study (adverse events, lack of compliance).

EASI 50	91,53%
EASI 75	69,49%
EASI 90	38,98%

Tab.1. Percentage of patients who achieved EASI50, 75, 90.

RESULTS

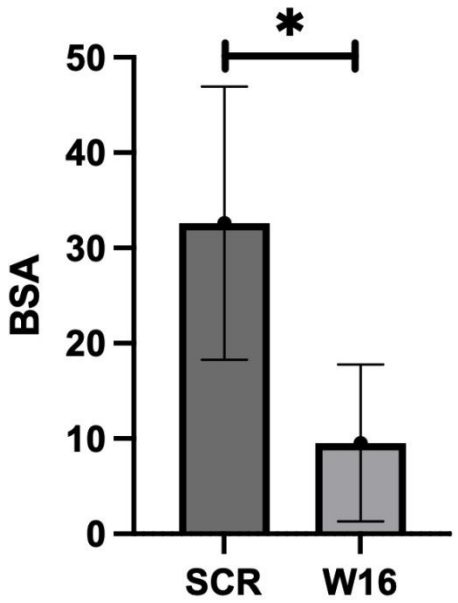


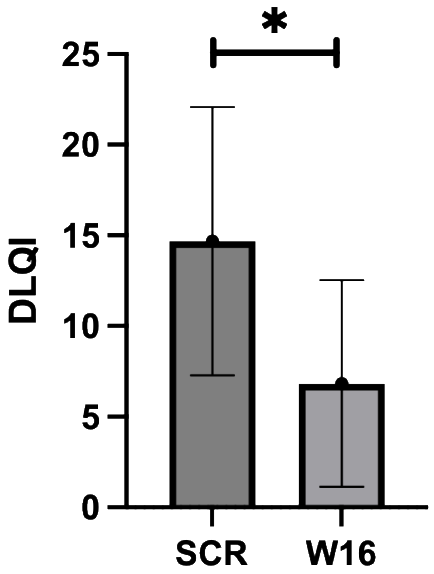


Regarding statistical analysis, EASI improved significantly post-treatment (23.23 ± 9.36 vs. 4.97 ± 5.06; $p < 0.00001$).

SCORAD improved significantly po st-treatment (62.36 ± 11.84 vs. 27.10 ± 15.97; $p < 0.00001$).

RESULTS



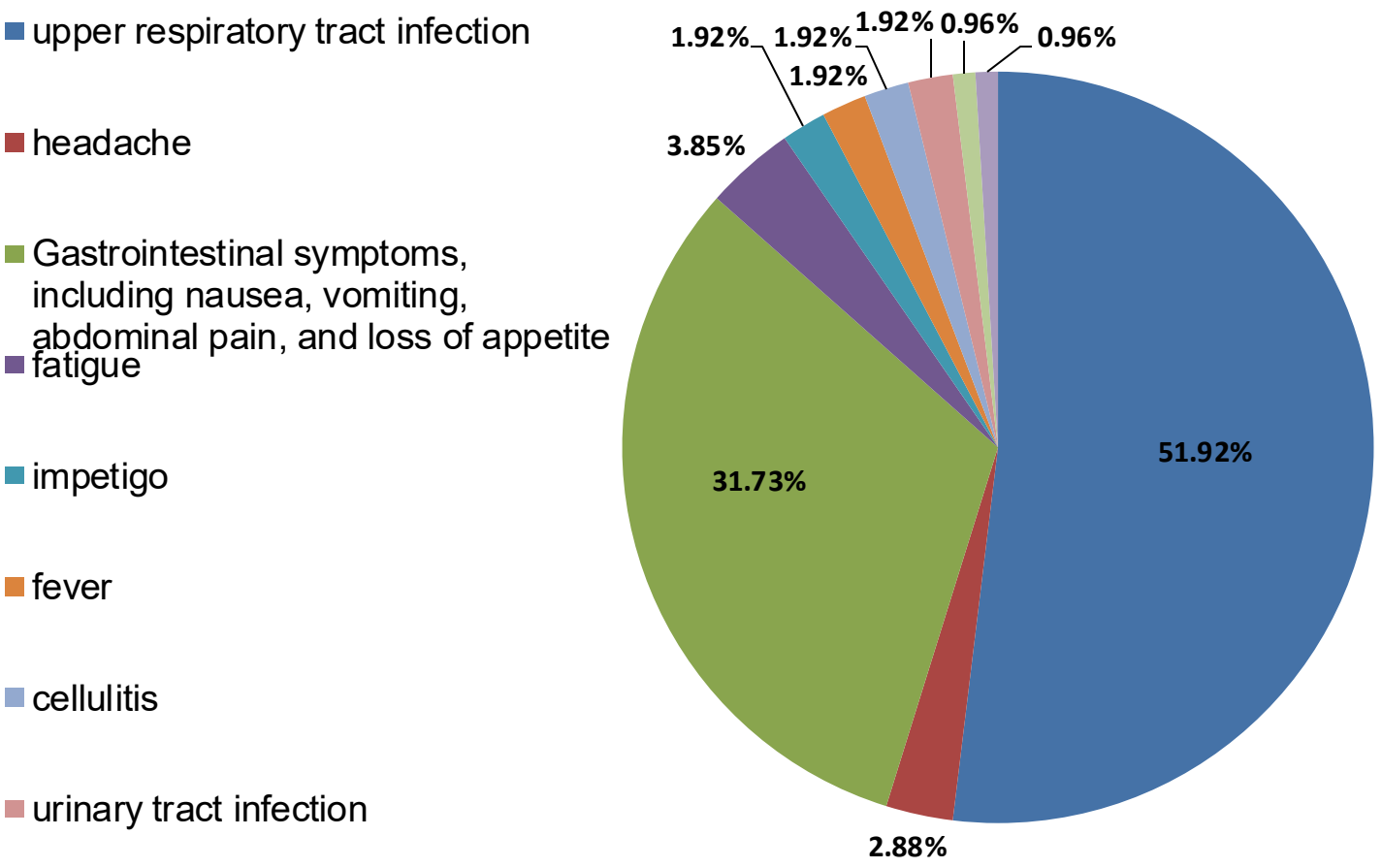


BSA improved significantly post-treatment (32.60 ± 14.33 vs. 9.53 ± 8.23; $p < 0.00001$).

DLQI improved significantly post-treatment (14.68 ± 7.40 vs. 6.83 ± 5.70; $p < 0.00001$).

Statistical analysis:
For quantitative variables, data were analyzed using Student's t-test.
Differences were considered statistically significant for $p < 0.05$.
Statistical analysis was performed using SPSS v20 (StatCorp, College Station, TX, USA).

ADVERSE EVENTS reported at 25% of control visits



SUMMARY

- The results of the clinical trial show good clinical effectiveness and safety profile of methotrexate and we do hope that in future they will enable to create treatment algorithms for children with moderate-to-severe AD.
- The study is sponsored by Medical Research Agency (ABM) grant No 519/5-064-01/519-01-002-08.

THANK YOU FOR YOUR ATTENTION