THE MULTI-BIOMARKER DISEASE ACTIVITY SCORE IN METHOTREXATE INCOMPLETE RESPONDERS PREDICTS CLINICAL RESPONSES TO NON-BIOLOGICAL VERSUS BIOLOGICAL THERAPY IN EARLY RA

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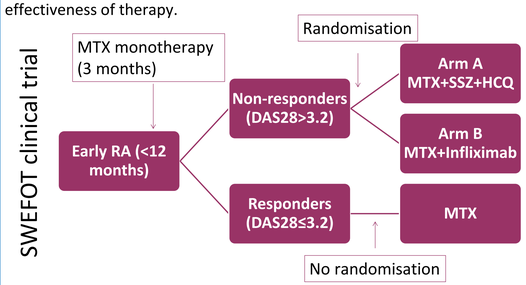
Background

For patients with early RA, methotrexate (MTX) is recommended as first-line treatment and in non-responders both the addition of conventional non-biological disease modifying anti-rheumatic drug therapy (triple DMARD therapy) and of biological (anti-TNF) therapy are supported by data. Identification of patients with a higher likelihood of responding to one or the other of these options would lead to more personalised medicine and an increased effectiveness of therapy.



Objectives:

To evaluate the multi-biomarker disease activity (MBDA) score after MTX monotherapy, in MTX-incomplete responders, as a predictor of response to subsequent triple versus biological therapies.

Methods

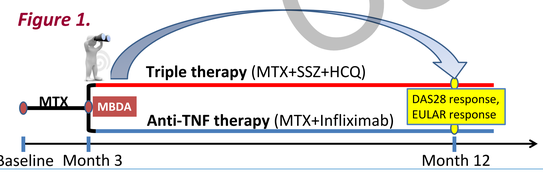
1) Non-responders at month 3 (DAS28>3.2) N=157
2) Categories of MBDA score at Month 3 based on ROC curve analysis:
   - Lower (MBDA≤38)
   - Higher (MBDA>38)

3) Categories for CRP at Month 3 based on ROC curve analysis:
   - Low (CRP≤32)
   - High (CRP>32)

4) Categories of ESR score at Month 3 based on ROC curve analysis:
   - Low (ESR≤25.5 mm/h))
   - High (ESR>25.5mm/h)

5) Response of patients at 12 months by DAS28 (≤3.2) and EULAR criteria was assessed for triple and biological arms.
6) Homogeneity of the odds ratios (TT *vs.* anti-TNF) between the two MBDA categories was assessed by Breslow-Day.

Figure 1.



Results

Figure 2. Relationship between disease activity measures at Month 3 and clinical response to triple or anti-TNF therapy at year 1.

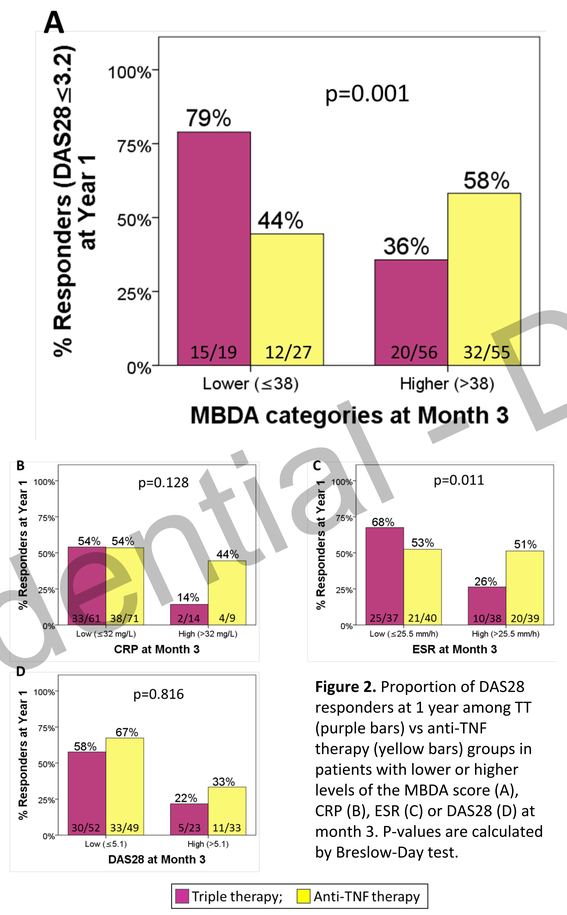


Figure 2. Proportion of DAS28 responders at 1 year among TT (purple bars) vs anti-TNF therapy (yellow bars) groups in patients with lower or higher levels of the MBDA score (A), CRP (B), ESR (C) or DAS28 (D) at month 3. P-values are calculated by Breslow-Day test.

Figure 3. Relationship between disease activity measures at Month 3 and Good EULAR response to triple or anti-TNF therapy at year 1.

Figure 3. Proportion of Good EULAR responders at 1 year among TT (purple bars) vs anti-TNF therapy (yellow bars) groups in patients with lower or higher levels of the MBDA score (A), CRP (B), ESR (C) or DAS28 (D) at month 3. P-values are calculated by Breslow-Day test.

Figure 4. Proportion of DAS28 responders at year 1 in patients stratified by validated categories of the MBDA score at Month 3.

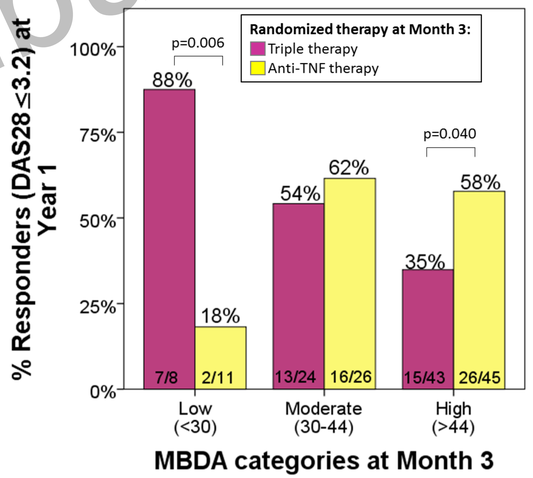


Figure 4. Proportion DAS28 responders at 1 year among TT (purple bars) vs anti-TNF therapy (yellow bars) groups in patients with low (<30) moderate (30-44) or high levels (>44) of MBDA score at 3 months. P-values are calculated by Fisher's Exact test.

Conclusions

- ❑ Patients with lower MDBA score were more likely to respond to triple therapy (achieve low DAS28 or good EULAR response) whereas patients with higher MBDA score were more likely to respond to anti-TNF therapy.
- ❑ The MBDA score at 3 months compared with CRP, ESR and DAS28 showed better prediction of response at year 1 (either according to DAS28 or EULAR response criteria) to both conventional triple and anti-TNF therapies.
- ❑ **Among patients with early RA who do not achieve low disease activity on 3 months MTX monotherapy, the MBDA score at 3 months may have potential to help guide subsequent therapy.**

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