
Minutes EASI Forum

Sorrento, March 13, 2015; 12:00 – 14:00 h

Participants: Yehuda Shoenfeld (IL), Nancy Agmon-Levin (IL), Hristina Andreeva (NO), Maria Orietta Borghi (IT), Ricard Cervera (ES), Valentyna Chopyak (UA), Jan Willem Cohen-Tervaert (NL), Carlos Dias (PT), Marie-Agnes Dragon-Durey (FR), Lucile Musset (FR), Manfred Herold (AT), Pier Luigi Meroni (IT), Aresio Plaza (ES), Antonella Radice (IT), Maria José Sousa (PT), Markku Viander (FI)

Guest: Gustavo Martos (IRMM, BE)

Thermo Fisher Scientific: Nina Olschowka (Global Marketing AI), Christin Anton (Global Marketing AI), Anders Blom (DK), Martin Brandenburg (DE), Thomas Horn (AT), Maryam Poorafshar (Global Marketing AI), Roland Stork (Development), Sune Sved (FI), Sascha Swiniarski (Development)

Protocol: Nina Olschowka

Agenda

1. Introduction round / MAI award
2. New reference material for MPO (and β 2GPI)
3. ANA, CCP and RF questionnaire for clinicians
4. Questionnaire on APS
5. Questionnaire on ANCA for labs
6. Questionnaire on ANCA for clinicians
7. Dutch initiative: national validation of autoantibody assays for certified labs
8. EASI session at the Dresden symposium in September 23-26, 2015
9. Next EASI Forum meeting

1. **Introduction round / May award**

All participants introduced themselves (see list of participants).

Maryam Poorafshar (Thermo Fisher Scientific, Global Marketing in Sweden) introduces the new Thermo Fisher Scientific MAI (Mosaic of Autoimmunity) award, which will be awarded for the first time at the 10th International Congress on Autoimmunity in Leipzig in April 6-10, 2016. The award is for young scientists contributing to the research of autoimmune diseases. The prize will be € 25.000,-. The committee choosing the winner will be totally independent of Thermo Fisher Scientific.

2. **New reference material for MPO (and β 2GPI)**

Gustavo Martos from the Institute for Reference Material and Measurement (IRMM) presents the work of the IRMM / IFCC. A new standard material for MPO antibodies has been developed and will be available soon. It is very well characterized plasmapheresis material which is available in large volumes. Its purpose is

1. calibration or standardization material for commercial assays => units of the assays standardized with this reference material will be μ g/l and
2. quality control for laboratories.

Additionally, IRMM will soon be able to offer a second reference material for β 2GPI antibodies. This material was evaluated by the international work group "APS Action". It will be commercially available during 2015.

The purpose of presenting these standard materials to the EASI forum group is to spread the word that this material exists, and that it should be used as standard / calibration material for as many assays as possible.

Yehuda proposes that the local EASI groups (in cooperation with EULAR and ACR) will test the material and give an official recommendation (“blessing”) for this material. Nina will write a formal letter and send the material, as soon as it is available, to the local EASI groups (via EASI forum members) for distribution. Yehuda and Pier Luigi will involve EULAR and ACR.

3. ANA, CCP and RF questionnaire for clinicians

The questionnaire from EASI Portugal was translated into English.

A major problem is the distribution to clinicians – how to reach as many clinicians as possible? In Portugal, national congresses for internal medicine were used for distribution.

Yehuda proposes to send the questionnaire to the distribution list of the Autoimmunity Community, which is a worldwide organization including a large number of clinicians.

The questionnaire shall be distributed as electronic questionnaire via the Internet. There are several suppliers on the Internet. Nina, Markku and Maria José will take care of the transfer into the Internet. Yehuda will take care of the distribution via the AI community.

4. Questionnaire on APS for clinicians

The questionnaire on APS was sent out by the Israeli EASI team to 44 APS centers worldwide. Nancy Agmon-Levin introduces the results of the questionnaire. See presentation attached to this protocol.

Main open questions were:

- How to handle low level positives? Therapeutic consequences?
- How to handle sudden extreme elevation of titer – what does that mean? (in several cases it was shown that the titer increase was due to the change of the commercial assay => different titers with different assay)
- Can treatment be stopped when ACA are persistently negative?
- What to do with IgA positivity only?

Three major action points for EASI were proposed:

1. Define the 99% percentile in Europe.
(Proposal: 50-100 samples of healthy subjects from each country (both gender, adults, if possible add children) and disease subjects (may be used as a second control cohort))
2. Define differences between platforms - Collect a cohort of APS patients who are very well defined clinically and serologically (i.e. only pregnancy, thrombosis, multiple thromboses – Triple positive, only aCL or a β 2GPI etc...).
3. The role of non-criteria aPL

The EASI forum does not define action points at this meeting but recommends that a small specialists group (Nancy, Ricard and Pier Luigi) discusses further follow-up, and links this also to the group APS Action.

5. Questionnaire on ANCA for labs

The questionnaire for labs was completed or is ongoing in many EASI countries. Unfortunately, Jan Damoiseaux who leads this project could not attend the forum meeting – therefore we could not get an overview of how many countries finalized it and which are close to. In Nice, it was discussed that the aim is to have all results by the end of 2014, so that a publication can be made. The topic will be taken up again at the next EASI forum meeting in Dresden in September 2015.

All countries are asked to go on and finalize the ANCA questionnaire in as many EASI countries as possible and inform Jan Damoiseaux about the time line.

6. Questionnaire on ANCA for clinicians

The questionnaire on ANCA for clinicians is almost finalized, but not yet sent out. Jan Willem Cohen-Tervaert gives an update. Similar to the ANA/CCP/RF questionnaire for clinicians, the ANCA questionnaire shall be sent out as electronic questionnaire via the Autoimmunity Community. Both questionnaires shall be distributed at the same time with the same mail.

7. Dutch initiative: national validation of autoantibody assays for certified labs

Jan Damoiseaux introduced this initiative at the last EASI forum meeting. The forum group showed great interest and wanted to be informed on the follow-up and on experiences of the Dutch group. As Jan Damoiseaux could not attend the EASI forum meeting in Sorrento, the topic will be discussed at the next EASI forum meeting in Dresden.

8. EASI session at the Dresden Meeting on Autoantibodies and EASI session at the 10th International Congress on Autoimmunity in Leipzig

The EASI session at the Dresden Symposium in September 23-26, 2015 will be on Celiac Disease. Xavier Bossuyt will introduce a study on celiac autoantibodies. Further topics will be the big European study PreventCD and the new recommendations for the diagnosis of celiac disease, ProCeDe. Speakers invitations are ongoing.

The EASI session at the Congress on Autoimmunity in Leipzig will be on ANCA and ANCA-associated vasculitis. The former decision to do an APS session was revised as there will be several APS-related meetings and sessions at the same time. To avoid redundancy, the group decided to do an ANCA session instead. Possible content:

1. Huge ANCA study with samples from Belgium, the Netherlands and Denmark,
2. EASI questionnaires on ANCA for clinicians and for labs and, if ready by then, EASI recommendations
3. The new reference material of the IRMM for MPO and PR3 (PR3 is planned to be available by then)

9. Next EASI Forum meeting

The next EASI Forum meeting will be at the 12th Dresden Symposium on Autoantibodies on September 23-26, 2015.