

anticoagulation

news 9

November 2012

International Self-Monitoring Association of oral anticoagulated Patients (ISMAAP)

8th International Patient/Physician Conference on Oral Anticoagulation Therapy, Vienna, Oct 4th-6th, 2012

Anticoagulation and patient cooperation go hand in hand The journey to 70% TTR – How do we get there?

Monitoring new oral anticoagulants, managing thrombosis, or both?

Hugo ten Cate, MD, University Medical Center Maastricht, The Netherlands talked about Monitoring new oral anticoagulants, managing thrombosis, or both?

Dr Cate summarized the current situation with VKAs and NOACs. He discussed first the current practice of INR guided anticoagulation; how good, how bad?



Hugo ten Cate, MD

Dabigatran group in the Netherlands. Once again TTR matters!

What is minimally needed with NOAC's?

On the PRO side NOACs need to be:

- ☐ direct acting,
- ☐ less dependent on food,
- ☐ need to have fewer interactions,
- ☐ with ideally no (frequent) dose adjustment needed and
- ☐ fewer intracranial bleeding.

On the positive side:

- ☐ VKAs are very effective showing 50% risk reduction of Atrial fibrillation;
- ☐ 90% risk reduction of recurrent VTE, and
- ☐ a safety of \pm 2-3 % concerning risk for major hemorrhage.

On the downside:

- ☐ Dosing needs to be INR adjusted;
- ☐ INR has a small therapeutic window and
- ☐ is affected by many factors such as diet, genotype, co-morbidity, and interactions with other medication.

The benefits of NOAC's?

New drugs are developed in the need of practical fixed dose, in the search for a stable INR with no adjustment needed, and should be specific: one target, direct effect. The studies with new drugs were mentioned again (*RE-LY*, *ARISTOTLE*, *Rocket-AF*, *Engage AF*) with the conclusion that the results were not different when TTR is taken into account. Additional note from the Netherlands: the incidence of intracranial bleeding is 0.2%/100 patients' treatment years; as compared to 0.23% in low dose

On the CON side of NOACs there is:

- ☐ Compliance!, short action (forgetting leads to non-anticoagulation),
- ☐ renal impairment may lead to accumulation of drug,
- ☐ some specific side effects (nausea; AMI, with Dabigatran; mechanism unknown),
- ☐ nothing known about long-term (side) effects,
- ☐ lack of validated and available lab tests, no antidote yet,
- ☐ costs (4-8 x as high as VKA all-in!),
- ☐ fixed dose may not be the optimal dose for everyone!

How can thrombosis-care be organized?

Thrombosis is no different from other conditions such as chronic diseases for which most medication used involves some type of monitoring, e.g. glucose, HbA1c in diabetes, blood pressure in hypertension, cholesterol levels. It is also known that about 50% of patients do not take medication in the long run, these highlighted the need for managing thrombosis conditions and involving new anticoagulants monitoring.

Dr Cate gave further update on The Health Council committee decision on NOACs, May 2012, which decided for a stepwise introduction of new anticoagulants.

The Committee has concluded that after more than fifty years of reliance on VKAs, the new medications offer the possibility of significantly simplifying*) anticoagulant treatment for both patients and health care providers. The Committee is therefore of the opinion that these medications should be part of doctors' arsenal of treatments, and should be made available to patients.

***) Actually not all agreed with the wording "simplifying" as no monitoring, not knowing much about side or long-term effect may not really simplify anything.**

The Committee feels however that introduction of the NOACs must be accompanied by more detailed research into their safety, effectiveness and cost-effectiveness, as doubts remain as to the safety of NOACs in everyday practice. It is also uncertain as to whether the health benefits offered by the medications and the cost-effectiveness of the medications in the context of anticoagulant treatment in the Netherlands are sufficient to justify the extra costs.

Where do we stand today?

Dr Cate concluded his presentation by summarizing where do we stand today regarding the NOACs in following points:

- ❑ The goal of the NOACs research should be to remove the remaining uncertainties and definitively establish the added value of the new medications.
- ❑ VKAs are very effective and rather safe, provided good control is maintained.
- ❑ NOACs offer practical advantages to the patient, but "monitoring" needs to be established. Patients cannot just be given new drugs without some kind of management/ monitoring system must be in place.
- ❑ Long-term safety of VKA and NOAC use relies on optimized thrombosis management! This includes patient/ prescriber education,

coaching, monitoring (also by testing) and eventually dose fine-tuning!

- ❑ We do need lab tests! For NOACs in the future also for dose fine tuning.

Reporter: M. Simon ●

Evaluation of quality of oral anti-coagulation in a real-life setting – the multicenter thrombEVAL study program.



Philipp Wild, MD, MSc
Mainz, Germany

The thrombEVAL study program started in January 2011. thrombEVAL is performed as an observational multicenter trial with 21 study centers to investigate the quality of oral anticoagulation therapy with phenprocoumon in German regular medical care and a telemedicine-based coagulation service. Additionally, stakeholder analysis and bio-banking are conducted by the Center for Thrombosis and Hemostasis (CTH) Mainz.

thrombEVAL is supported as leading state project of the initiative health economy by the ministries of health and economy of Rhineland Palatinate, Germany. The first intermediate results rise promising evidence that coagulation service may improve TTR for patients addressing all indications and also stable INR adjustment, although TTR in regular medical care shows surprisingly good quality of care.

Based on the first results CTH scientists are now looking forward to the prospective data which will be available in 2013. The follow-up project will be performed in cooperation with health insurances evaluating both the transition of coagulation services into regular medical care and new oral anticoagulants in daily routine.

Red. ●



**National Day of anticoagulated patients in Spain:
Nov. 18th 2012**

More information: www.anticoagulados.info

*International Self-Monitoring Association of oral Anticoagulated Patients (ISMAAP),
Geneva/Switzerland, www.ismaap.org,
E-Mail: c.schaefer@ismaap.org*