

Executive Summary

Prevention of Thromboembolic Events: The Role of Point of Care Management

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The Infection, Thrombosis, Embolism and Bleeding Working Group of the Society for Heart Valve Disease (SHVD) held an International Symposium and Workshop, in Berlin, from 28th to 30th September 2006. A total of 80 participants was involved, with attendees from around Europe, Israel and the United States. A range of topics were discussed, from the organization of oral anticoagulation clinics in different countries to data on how best to detect and manage early signs of prosthesis malfunction.

Session I provided an insight into how point of care (POC) management has improved the management of arterial hypertension. In this respect, S. Eckert (Bad Oeynhausen, Germany) presented data from the OLMETAL study, which combined self-monitoring of blood pressure with a tele-medicine approach to management with up to an 8 mmHg reduction in diastolic blood pressure possible with twice-daily home monitoring. Tele-medicine and the handling of data and data transfer were further explored by H. Korb (Düsseldorf, Germany) and S. Sack (Essen, Germany). Later, G. Corbucci (Medtronic Inc., Arnheim, Holland) demonstrated the potential for improved diagnostic accuracy for patients with suspected atrial fibrillation through the use of implantable devices which can capture periods of arrhythmia more successfully than conventional recording techniques. In addition, J. M. Hasenkam (Aarhus, Denmark) outlined the experience of the International Self-Management Association for Anticoagulation (ISMAA). This organization has been in existence for approximately six years, and has been successful in producing international guidelines for the self-management of oral anticoagulation; the organization has also led several meetings focusing on self-management. A website (www.ismaa-int.org) is available (this is currently being upgraded) to provide information for both healthcare professionals and patients. There is also a sister organization for patients (ISMAA-P), and this has been successful in lobbying for patient-centered issues, such as re-imburement, in several countries.

Sessions II and III were interactive workshops on the development of registries for valvar patients receiving oral anticoagulation and patient training for self-management of oral anticoagulation. Data were presented from the UK training model, with points of contention discussed between the participants. There was much agreement regarding the content of training courses, with most countries adopting the model originally developed through the Association of Self-Management of Anticoagulation (ASA) in Germany. The intensity of training differs across countries. For example, in the UK training is generally delivered in two sessions, each lasting for up to 2 hours, and approximately one week apart. Most countries, including France and Austria, provide extended training with patients generally learning first to self-test before being allowed also to self-dose. The German model of training is apparently very didactic, with patients given detailed information, for example concerning the vitamin K content of food, and extensive lists of interacting drugs. The feeling of the majority of participants was that patients should be taught general principles and learn to be consistent in their life-style rather than worrying about specific foodstuffs. There was also disagreement of the frequency of testing that patients should be asked to perform, and also arrangements for follow up. The UK model asks for routine tests to be conducted every two weeks, whereas most other countries would test routinely more often. Similarly, while the UK model requires medical follow up at least every six months, other countries do not have any formal requirement for follow up. On this point, J. M. Hasenkam suggested that ISMAA and ISMAAP would be suitable organizations to explore the setting of international standards in these contentious areas.

Session IV concentrated on training for healthcare professionals in delivering self-management for orally anticoagulated patients in different countries. Here, M. M. Levi (Amsterdam, Holland) provided an historical perspective of developments in Holland, while J. Ansell (Boston, USA) described the development of training tools in North America. This included the first

use of a 'traffic light' system to enable patients to undertake dosing, and this has subsequently been adopted in several countries including the UK, as described by D. Fitzmaurice. This system essentially defines the International Normalized Ratio (INR) parameters within which patients can adjust doses themselves, and when they should contact a healthcare professional. Whilst the duration and intensity of training differs across countries, the basic components remain very similar, covering mechanisms of action, intensity of therapy, and interacting agents. Most training programs have been derived from the German ASA model.

In Session V, the evidence was reviewed for antithrombotic therapy in both valvar heart disease (C. Piper, Bad Oeynhausen, Germany) and cardiac arrhythmias, particularly atrial fibrillation (W. Schoels, Duisburg, Germany) with data presented on new antithrombotic agents including oral direct thrombin inhibitors and parenteral factor Xa inhibitors. Whilst some of these new data appear promising, the Ximelagatran story reminds us that coumarin-based anticoagulants will likely be the mainstay of antithrombotic therapy for years to come.

Sessions *VI and VII* covered the international experience of both developing and delivering oral anticoagulation management across Germany (J. Ennker, Lahr, H. Voeller, Berlin), Holland (M. M. Levi, Amsterdam), Switzerland (A. Bernardo), France (A. Kasra, Clermont Ferrand), Denmark (J. M. Hasenkam, Aarhus), and the USA (J. Ansell, Boston). The striking feature was the similarity of developments across these countries, with patients self-testing or monitoring for oral anticoagulation providing benefits in terms of reductions in adverse events compared to the rather haphazard care provided routinely. In many countries, cardiac surgeons have pioneered the development of self-testing schemes in order to ensure maximum benefit for patients receiving new mechanical valves. This pioneering work has subsequently led to patients with other thromboembolic risks - particularly atrial fibrillation - also to be considered for home testing. One of the strengths of the model utilized for heart valve patients is in the training which can be undertaken prior to discharge. In this way, self-testing becomes part of the total patient care package.

Session VIII provided data on both bioprosthetic and mechanical heart valve failure, with new data on a novel approach to detecting early, subclinical valve dysfunction. M. Lengyel (Budapest, Hungary), and A. Sagie (Tel Aviv, Israel) both outlined the extent of the

problem, while D. Horstkotte and D. Fritzsche (Bad Oeynhausen, Germany) provided data on the use of a new POC device (Thrombochek), which may detect the first signs of valve dysfunction. The device was developed following research demonstrating that every prosthetic heart valve emits distinctive 'clicks' which are individual to that valve. The Thrombochek is a sound recorder which is placed on the individual's chest, and in most patients will detect the distinctive clicks. In a few patients the unit was unable to detect any click, and this was deemed machine failure. However, for the majority of patients in whom a click is detectable, any change in the distinctive pattern is detected by the machine. Data obtained from 71 patients in Israel found eight with no detectable click, 10 who had a change in signals requiring intervention, and 53 with no problems. Of the 10 patients with a change in signals, six were re-tested with the device following antithrombotic or thrombolytic therapy. Of these six patients, four had returned to normal, one patient gave no detectable click, and another gave a 'warning' signal. None of these patients had lesions detectable by any imaging technique. This gave a sensitivity of 90% and a specificity of 98% in terms of detecting abnormal valve function. The consequent possibility of intervention in terms of either thrombolytic therapy or intensified antithrombotic therapy provides a real opportunity to avoid reoperating on patients, with huge potential gains in terms of both mortality and morbidity. A panel discussion explored the introduction of these devices for patients at high risk of valve failure, for example, in the first few months following surgery, or in pregnant women.

Sessions IX and X focused on the developments of new POC devices for oral anticoagulation management, including the INRatio (S. Testa, Cremona, Italy), PROTImE (U. Taborski, Ludwigshafen, Germany), SmartCheck (H. Kamlah, Dannenfels, Germany), and the CoaguChek XS (B. Piso, Vienna, Austria). Two reports were made from Oxford, UK, providing data on a meta-analysis of published data for self-testing and management of oral anticoagulation (C. Heneghan), with a call for trialists to collaborate in an individual patient-level meta-analysis (R. Perera).

Overall this was a very useful meeting, with reviews of existing data and presentation of new data particularly around new POC devices. The possibility of patients monitoring both their own anticoagulation and their own valve function would enable vast numbers to take control of their care back from the physicians and surgeons.

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