

Major themes for 2013 in cardiothoracic and vascular anaesthesia and intensive care

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ABSTRACT

There has been significant progress throughout 2013 in cardiothoracic and vascular anaesthesia and intensive care. There has been a revolution in the medical and interventional management of atrial fibrillation. The medical advances include robust clinical risk scoring systems, novel oral anticoagulants, and growing clinical experience with a new antiarrhythmic agent. The interventional advances include left atrial appendage occlusion for stroke reduction, generalization of ablation techniques in cardiac surgery, thoracoscopic ablation techniques, and the emergence of the hybrid ablation procedure. Recent European guidelines have defined the organization and practice of two subspecialties, namely general thoracic surgery and grown-up congenital heart disease. The pivotal role of an effective multidisciplinary milieu is a central theme in both these clinical arenas. The anaesthesia team features prominently in each of these recent guidelines aimed at harmonizing delivery of perioperative care for these patient cohorts across Europe. Web-Enabled Democracy-Based Consensus is a system that allows physicians worldwide to agree or disagree with statements and expert consensus meetings and has the potential to increase the understanding of global practice and to help clinicians better define research priorities. This "Democratic based medicine", firstly used to assess the interventions that might reduce perioperative mortality has been applied in 2013 to the setting of critically ill patient with acute kidney injury. These advances in 2013 will likely further improve perioperative outcomes for our patients.

Keywords: atrial fibrillation, clinical risk scoring system, stroke, bleeding, novel oral anticoagulants, dabigatran, rivaroxaban, apixaban, vernakalant, left atrial appendage occlusion, ablation therapy, hybrid procedure, general thoracic surgery, minimally invasive surgery, grown-up congenital heart disease, anaesthesia team, multidisciplinary milieu, guidelines, European Society of Cardiology.

INTRODUCTION

This article is the fifth in an annual series that has reviewed major themes in perioperative cardiothoracic and vascular care

(1). The first major theme for 2013 is the revolution in the clinical approach to atrial fibrillation with a series of major advances in risk stratification, medical management, and interventions. The second major theme for 2013 is the recent focus on the organization of perioperative care in general thoracic surgical procedures across Europe. Other major themes for 2013 is the emerging area of general thoracic surgery and grown-up congenital heart disease that

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has prompted recent guidelines to structure care delivery for this growing patient cohort. The past year has witnessed significant progress in these 3 clinical domains that will gain traction to improve important clinical outcomes in cardiothoracic and vascular anaesthesia and intensive care. Furthermore, a new methodological tool “Web-Enabled Democracy-Based Consensus” has been increasingly used in critically ill settings with the potential of allowing clinicians worldwide to participate in and influence consensus processes.

The Revolution in the Medical Management of Atrial Fibrillation

The incidence of atrial fibrillation (AF) has steadily been increasing worldwide with major morbidity and mortality (2, 3). Furthermore, AF is common and clinically important after cardiothoracic surgery, including transcatheter aortic valve replacement and aortic procedures requiring deep hypothermic circulatory arrest (4-7). There is currently substantial therapeutic interest in optimizing outcomes after AF, including both medical and interventional innovations (8, 9). The imperative to intervene for AF was recently highlighted in a randomized controlled trial (N=2580) in which subclinical AF significantly increased the risk of ischaemic stroke and/or systemic embolism (hazard ratio 2.50; 95% confidence interval 1.28 – 4.89; P = 0.008) (10). Consequently, patients with AF will present to anaesthesia teams for management in diverse clinical environments such as the operating room, the electrophysiologic laboratory and the intensive care unit, depending on the circumstances. The recent guidelines from the European Society of Cardiology (ESC) detail the management options for AF (11). This guideline recommends that anticoagulation be considered in all patients with AF, except those who are truly at low-risk for stroke.

Patients with AF who have one or more stroke risk factors should strongly be considered for effective oral anticoagulation therapy (11). In contemporary practice, well-controlled oral anticoagulation with a vitamin K antagonist such as warfarin is defined as an international normalized ratio in the 2.0–3.0 range with at 70% of the time in this therapeutic range, recognizing the limitations of this classic approach (11, 12). Given the recognized difficulties with chronic anticoagulation utilizing vitamin K antagonists, the guideline also recommends the anticoagulation therapy with novel oral anticoagulant such as an oral direct thrombin inhibitor (dabigatran) or an oral factor Xa inhibitor (rivaroxaban, apixaban) (11, 13, 14). The lack of a reversal agent for these novel oral anticoagulants can have major perioperative implications which have been reviewed in detail elsewhere (13, 14). In selected cases such as patients who refuse oral anticoagulants, dual platelet blockade with aspirin and clopidogrel should be considered for stroke prophylaxis (11). The utility of novel platelet P2Y₁₂ inhibitors such as prasugrel and ticagrelor for stroke prophylaxis in atrial fibrillation has not been explored in the current guidelines (11, 15).

The identification of patients with AF who have reasonable stroke risk has been standardized by a clinical scoring system summarized in the acronym CHA₂DS₂ – VASc (Congestive Heart failure/left ventricular dysfunction; Age ≥ 75 years [doubled]; Diabetes; Stroke [doubled] – Vascular disease; Age 65-74 years; Sex category [female]) (16, 17). Each risk factor in this scheme is given at least a score of 1: the additive total represent the total score. The CHA₂DS₂ – VASc score has been validated for stroke risk assessment in adult AF by multiple studies and had consequently been adopted as the standard risk score tool in this setting (11, 18-20). The profile for the low-risk patient

would be patients below 65 years old with lone AF. The ESC AF guideline provides not only a detailed discussion of this risk score but also recommends anticoagulation for patients with a CHA₂DS₂ – VASc score ≥ 1 or in the setting of AF associated with mitral stenosis or prosthetic heart valves (11).

Thromboprophylaxis in AF must also balance the bleeding risks of this intervention, especially intracranial hemorrhage. This is a major consideration, given that a serious bleeding complication has significant mortality and morbidity (11). The ESC guidelines has recommended the HAS-BLED (Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol concomitantly) score for assessment of bleeding risk in AF, as it has been validated in multiple trials (11, 21, 22). Each risk factor in this scheme is given at least a score of 1: the additive total represent the total score. The ECS guideline has recommended that patients with AF who have a HAS-BLED score ≥ 3 should have a careful risk-benefit assessment of chronic oral anticoagulation since they are at higher risk for bleeding complications (11). Furthermore, in this high-risk group, clinical attention should also be focused on correctable risk factors for bleeding such as uncontrolled hypertension, labile levels of anticoagulation, and concomitant antiplatelet drugs (11). The utilization of scoring systems such as the CHA₂DS₂ – VASc score and the HAS-BLED score could further optimize the risk/benefit ratio for oral anticoagulation in adult AF. In 2010, the intravenous antiarrhythmic, vernakalant, was approved in Europe for pharmacological cardioversion of AF of less than 7 days duration or within 3 days after cardiac surgery (11). Vernakalant preferentially prolongs atrial refractoriness through ion channel blockade – it has a rapid onset of action with a mean elimination half-time in the range of (3-5) hours

(23). A recent meta-analysis (N=1099: 5 randomized trials) demonstrated that vernakalant significantly increased cardioversion of AF within 90 minutes of administration (relative risk 8.4; 95% confidence interval 4.4 – 16.0; P<0.00001) without any difference in adverse events (relative risk 0.90; 95% confidence interval 0.6-1.4; P=0.64) (24).

The contraindications to vernakalant therapy include hypotension (defined as systolic blood pressure below 100 mmHg), an acute coronary syndrome within the last 30 days, New York Heart Association class III/ IV heart failure, severe aortic stenosis, and prolongation of the QT interval (defined as an uncorrected QT interval >440 ms) (11). Furthermore, it should be applied cautiously in patients with hemodynamically stable New York Heart Association class I/ II heart failure due to the risks of hypotension and ventricular arrhythmia (11). The integration of this novel pharmacologic intervention for AF into perioperative cardiovascular practice requires further clinical experience and additional focused clinical trials. Vernakalant is currently not approved commercially in the United States of America.

The revolution in the medical management of AF includes mature clinical outcome scoring systems and new drugs for oral anticoagulation and cardioversion. Although these advances will likely further improve overall health for patients with AF, they may also complicate perioperative management, especially in the setting of novel oral anticoagulants that are not readily reversible.

The Revolution in the Interventional Management of Atrial Fibrillation

As implied in the aforementioned discussion, the clinical scoring systems for AF predict for patient cohorts with a high stroke and bleeding risk. These patients

may not be ideal candidates for chronic oral anticoagulation due to their high bleeding risk. Mechanical approaches to reduce stroke risk in AF are thus very relevant. Since left atrial appendage (LAA) thrombus is a common thromboembolic source in AF, catheter-based and surgical approaches to LAA occlusion have recently attracted considerable interest (25). A recent multicenter cross-sectional clinical trial (N=1889) demonstrated that LAA occlusion can be safely performed at the time of cardiac surgery with no increase in adverse events (relative risk 0.71; 95% confidence interval 0.19-2.66; P=0.61) (26). These pilot data have provided the basis for a large randomized multicenter trial (N=4700) in patients with AF undergoing on-pump surgical procedures who will be randomized to LAA occlusion or no LAA occlusion (27).

The primary outcome has been defined as a first occurrence of stroke or systemic arterial embolism over a mean follow-up period of 4 years. Secondary outcomes include total mortality, perioperative bleeding, heart failure, and myocardial infarction (27). As of September 9 2013, study enrollment was 162 patients (27).

This high-quality clinical trial should significantly advance our understanding and evidence base of the role LAA occlusion as an intervention for stroke reduction in AF. Currently, the ESC guidelines for AF recommend this intervention as a reasonable option in selected patients undergoing open heart surgery (Class IIb Recommendation; Level of Evidence C) (11).

Catheter-based interventions for LAA occlusion have recently been evaluated. There are currently 2 self-expanding devices currently available clinically in Europe, although their complete evaluation is still in progress with randomized clinical trials (11). Both these percutaneous devices reach the LAA by crossing the interatri-

al septum in a catheter-based fashion. The first platform is the Watchman LAA system (Boston Scientific, Natick, MA, USA) (28). A recent non-inferiority randomized trial (N=707) demonstrated that LAA closure with this percutaneous system, as compared to oral anticoagulation, did not significantly increase the primary efficacy event rate, defined as a composite endpoint of stroke, cardiovascular death, and systemic embolism) (28). The results from the Watchman continued access registry demonstrate a significant learning curve that is typically a feature of a novel clinical intervention (29). A larger multicenter randomized trial is currently in progress to explore the efficacy of the Watchman LAA system (11).

The second percutaneous system for LAA occlusion is the Amplatzer Cardiac Plug (St Jude Medical, St Paul, MN, USA) (30). The feasibility and safety study (N=143) demonstrated a technical success rate of 96% with a serious complication rate of 7.0% (30). This device is currently being evaluated in a randomized prospective clinical trial (11). The current ESC AF guideline has recommended percutaneous LAA occlusion as a reasonable option in patients with AF who both have a high stroke risk and contraindications to chronic oral anticoagulation (Class IIb Recommendation; Level of Evidence B) (11).

The surgical management of atrial fibrillation has also experienced major innovations (31). The Cox-Maze procedure was first performed in 1987 and demonstrated the feasibility of this strategy for AF (31). The clinical advent of linear ablation lines generalized this technically challenging procedure throughout cardiac surgery with preserved clinical efficacy (32, 33). A recent meta-analysis (N=4647: 10 randomized trials; 23 non-randomized control studies) demonstrated that AF ablation during concomitant cardiac surgery signifi-

cantly increased the likelihood of durable sinus rhythm (odds ratio 10.1; 95% confidence interval 4.5-22.5 for randomized studies) (34).

There remains significant variation across studies with respect to ablation technique that hinders detailed outcome comparisons. A second consequence of effective linear ablation therapy for AF has been the advent of minimally invasive surgery for the management of AF, including thoracoscopic approaches (35).

The hybrid approach to AF ablation has also recently emerged due to these recent advances in AF technology (31). This approach in selected patients aims for transmural ablation by combining minimally invasive surgical epicardial lesions with percutaneous catheter-based endocardial lesions (36, 37). The hybrid procedure is typically performed in a stepwise fashion. The surgical procedure is performed first via a thoracoscopic approach without cardiopulmonary bypass.

The electrophysiologist then completes the procedure in a catheter-based fashion: detailed electrical mapping facilitates the identification of lesion gaps, the connection of lesions that are not transmural, and the induction of additional lesions (31, 36, 37). The recent results of this hybrid approach to AF ablation are favorable.

Further trials are currently in progress to define its overall niche in the management of AF. These procedures could be performed in hybrid operating rooms where the heart rhythm team consisting of surgeons, electrophysiologists and anaesthesiologists would work together in close cooperation.

The Specialty of General Thoracic Surgery in Europe

General thoracic surgery may be defined as the surgical specialty pertaining to the diagnosis and management of both congeni-

tal and acquired chest diseases, including conditions of the chest wall, pleura, lungs, airways, mediastinum, diaphragm and esophagus (38-41). Clinical studies have consistently demonstrated that specialized general thoracic teams achieve superior outcomes in the management of chest diseases as compared to generalists (38, 39). The organization and practice of this specialty across Europe was accordingly reviewed in a 2001 guideline (40). As part of a quality initiative, this guideline set was very recently updated with the goal to outline a set of recommendations for the harmonization of general thoracic perioperative practice across Europe (41). The following review of this updated guideline will focus on aspects that particularly concern the anaesthesia team in this specialty. In the section concerning the scope of general thoracic surgery, the procedures are defined at 3 levels: minor (e.g. diagnostic biopsy), major (e.g. lung lobectomy), and specialist (e.g. esophagectomy; lung transplantation). The multidisciplinary nature of the general thoracic team is highlighted, especially in the perioperative conduct of advanced procedures (41). The second section outlines the recommendations for the organization of the general thoracic surgical unit, defined a two types: a standard unit, and a high-specialization unit (41). This third section then explores the structural requirements for the conduct of advanced procedures such as lung transplantation, esophageal surgery, and minimally invasive procedures.

The importance of experienced anaesthesia teams is specifically highlighted in this section dedicated to the optimal practice of advanced procedures (41). This recent guidelines stresses the outcome importance of case volume in advanced procedures such as a minimum of 15 esophageal resections for cancer per year and (25-30) lung transplants per year (42, 43). The

guideline also highlights the cumulative evidence that minimally invasive lung resection further improves major outcomes both at the level of single-center studies and meta-analysis (44-46). These advantages have resulted in recommendations for minimally invasive approaches for lung resection to be a standard surgical therapy in appropriate patients (41, 47). As a result, the European guideline has listed these surgical techniques as a core skill for general thoracic surgical teams. At the surgical level, the guideline recommends a minimum of 20 minimally invasive lobectomies per year to maintain essential skills (41, 48). The advent of minimally invasive esophageal resection for cancer has already begun to challenge the supremacy of the current open surgical approaches such as the transhiatal, Ivor-Lewis, and McKeown techniques (49, 50). Further trials are still required to decide the final clinical niche of minimally invasive approaches for esophageal resection. The guidelines then concludes with a set of recommendations for training, education, research and quality assurance in general thoracic surgery across Europe, primarily focused on the surgical members of the team at all levels (41). The conclusion of the guideline outlines that the likely future of this surgical specialty across Europe will involve multidisciplinary harmonization to optimize patient outcomes (41, 51).

The Specialty of 'Grown-Up Congenital Heart Disease' in Europe

The remarkable advances in the multidisciplinary management of patients with congenital heart disease has resulted in an increasing number of adults with grown-up congenital heart disease, currently estimated at over 2 million in Europe (51, 53). The recognition that these adults require special expertise prompted the dedicated ESC 2010 practice guidelines for their care

(53). Despite intervention, the majority of these patients cannot be considered cured, but rather are palliated and therefore require long-term surveillance in the setting of multiple advances in medical, interventional and surgical therapies. The organization of this specialized care delivery for patients with grown-up congenital heart disease prompted the recent publication of dedicated ESC guidelines with the realization that expert consensus is the current basis for the majority of recommendations in this area (54).

The model proposed by these guidelines is based on the concept of a specialist-based supra-regional grown-up congenital heart disease centre that could serve a population of about (5-10) million people with excellence in clinical care, education and training (54, 55). The recommended staffing requirements for such a specialist centre of excellence are multidisciplinary, including cardiologists, cardiac surgeons, anaesthesiologists, imaging specialists, invasive electrophysiologists, pathologists, psychologists, and social workers.

The expert panel has recommended that each center should have at least 2 anaesthesiologists with experience and expertise in congenital heart disease (54). In a similar fashion, the remaining team members should all have the appropriate clinical expertise and credentialing where possible (54). The ESC guidelines then review the requirements for equipment of a referral-based grown-up congenital heart disease center, including outpatient and inpatient services. These focused guidelines then conclude with a detailed assessment of training requirements for certification in the cardiology subspecialty of grown-up congenital heart disease (54). The implementation of pan-European certification process for echocardiography of congenital heart disease has proven feasible and durable (56). This skill set is considered a core

function of a specialist center, as defined earlier (54). The planning of anaesthetic care for these patients presenting for non-cardiac surgery requires the identification of high-risk patients, multidisciplinary planning and decision-making, and careful anaesthetic planning (57).

Further studies are required to assess the organization and delivery of anaesthetic care for patients with grown-up congenital heart disease. These studies could provide a basis for decision-making in this area of anaesthesiology beyond expert opinion.

Although congenital cardiac anaesthesiology is a young subspecialty, it is rapidly growing and demands a current appreciation of the relevant multidisciplinary milieu, including the expanding clinical needs of adults with grown-up congenital heart disease (58).

Democratic Base Medicine

Recent consensus conferences used transparent and reproducible processes to identify interventions with published evidence of reduction in mortality in the perioperative period (59) and in critically ill patients with acute kidney injury (60).

The authors added something different from the usual consensus approach of grading and ranking such evidence and proposing recommendations.

They placed a brief description of each study on the Web and asked people to “vote” in the first Web-enabled democracy-based consensus effort. Irrespective of its future evolution, this methodology has the potential to increase the understanding of global practice and help clinicians better define research priorities (61).

CONCLUSION

The past year has seen significant strides forward in cardiothoracic and vascular anaesthesia and intensive care. The medical

and interventional management of atrial fibrillation has been revolutionized. The subspecialties of general thoracic surgery and grown-up congenital heart disease have been the focus of recent European guidelines aimed at setting standards for the delivery of care to these patient cohorts. Web-based consensus processes are giving voice to physicians beliefs and practices. As a result of these strides forward, patient outcomes should be enhanced.

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