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The Australian and New Zealand Intensive Care Society Clinical Trials Group

Authors

John A Myburgh *PhD, FANZCA, FJFICM*

Chairman

Simon R Finfer *FRCP, FRCA, FJFICM*

Immediate Past Chairman

Rinaldo Bellomo *MD, FRACP, FJFICM*

Inaugural Chairman, ANZICS Clinical Trials Group

Carlton, Australia

Introduction

The specialty of intensive care medicine in Australia and New Zealand (ANZ) is regarded as one of the most advanced in the world. This reputation has developed over the last 25 years, based on established high-quality training and certification programs currently administered through the Joint Faculty of Intensive Care Medicine (JFICM) of the Australian and New Zealand College of Anaesthetists and Royal Australasian College of Physicians. In addition, the Australian and New Zealand Intensive Care Society (ANZICS) has functioned as a cohesive bi-national society to further advance professional development and research. Whilst the focus of these bodies has been directed at ensuring best outcomes for patients managed in ANZ intensive care units (ICUs) through education, training, certification and quality assurance, research activities were, until recently, limited to unit-based, usually commercially-sponsored, initiatives and a small number of clinicians who completed higher degrees through ANZ universities. In order to increase research opportunities for the broader intensive care community and to capitalize on the collegiate and homogenous nature of intensive care practice in ANZ, a research initiative – the ANZICS Clinical Trials Group (ANZICS-CTG) – was established in 1994. The principal aims of the ANZICS-CTG were to:

1. Conduct high-quality, collaborative clinical trials directed at improving patient-centered outcomes.

2. Provide a forum for members to present research ideas and obtain feedback and advice from experienced researchers and colleagues.

3. Encourage smaller ICUs to join in research initiatives.

Early Development and Progress

In many ways, the environment to establish a collaborative research group in ANZ in 1994 was ideal. There was an abundance of energy and enthusiasm, a relatively unencumbered governance structure to conduct clinical research in public hospitals and a rich supply of patients from a wide range of ICUs. Furthermore, clinicians who voluntarily participated in the early ANZICS-CTG activities did so primarily for intellectual and altruistic reasons. At the time, almost all intensive care physicians were full-time, salaried and tenured clinicians, and therefore, the imperative to conduct research was not influenced by the need to “publish or perish” that exists in some countries. Nevertheless, there were many challenges in the early years, including a paucity of experienced researchers, and limited personnel, funding and equipment available for clinical research.

The focus of the ANZICS-CTG was to conduct investigator-initiated studies, independent of commercial influence, primarily to address clinically relevant questions. The first project conducted by the ANZICS-CTG was a point-prevalence study of the use of antimicrobials in ICUs in ANZ (Bellomo et al. 1998). This was followed by a randomized placebocontrolled trial of the use of “low dose” dopamine for the prevention of acute renal failure (Bellomo et al. 2000). Apart from the high-quality scientific results, the major benefit from these studies was the experience obtained by the fledgling ANZICSCTG. The group was able to develop rigorous, effective protocols by dialogue and consensus, garner participation from more than 20 ICUs (some with no prior experience in multi-centered trials) and complete the studies in an acceptable timeframe with excellent protocol adherence, data quality and completion rates. The dopamine study, published in the Lancet in 2000, has become a landmark intensive care medicine manuscript, providing the ideal platform for the emerging ANZICSCTG to conduct future large-scale trials.

Governance and Consolidation

During the course of the dopamine study, a more formal administrative structure, policies and procedures were developed to assist the ANZICS-CTG in furthering its goals and to ensure good communication and collegiality within the group. The ANZICS- CTG Executive was constituted as a subcommittee of the ANZICS Board. The Executive is comprised of representatives from all Australian states and New Zealand, in addition to representatives from the ANZICS Adult Patient Database, Paediatric Study Group and the intensive care research co-ordinators group. The ANZICS-CTG also employs a full-time executive officer to coordinate its activities. The Executive meetings four times per year, two of which are held in conjunction with the three-day, annual ANZICS-CTG Meeting in Noosa, Queensland, and the ANZICS Annual Scientific Meeting. The ANZICS-CTG Noosa Meeting commenced in 1998 and has become a key part of the Australasian intensive care calendar. The format is very informal and designed to encourage discussion and free flow of ideas.

The establishment of the ANZICS-CTG Executive allowed the promulgation of a number of key policy documents, which have been integral in main 44 taining the cohesion of the group. These policies, available online, include a mission, vision and values statement to which all ANZICS-CTG initiatives accord, publication and authorship policies for ANZICS- CTG studies, a policy on conflict of interest, site selection criteria for participation in ANZICS-CTG studies, conditions for researchers to conduct higher degrees through ANZICS-CTG initiatives and criteria for ANZICS-CTG endorsement of publications and grant submissions (www.anzics.com.au).

In 1996, ANZICS and the Intensive Care Foundation launched a bi-national strategy to reduce mortality in ANZ intensive care patients. Part of this strategy was to develop research initiatives in four key areas: acute lung injury/acute respiratory distress syndrome (ALI/ARDS), traumatic brain injury (TBI), sepsis and critical illness prevention. In response, the ANZICS-CTG developed a two-stage process to address this initiative. Based on our experience with the antibiotic point-prevalence study (Bellomo 1998), we conducted large-scale prospective epidemiological studies examining current practices and outcomes in sepsis (Finfer et al. 2004), TBI (Myburgh et al. 2006) and ALI/ARDS (Bersten et al. 2002). These studies have provided vital information that defines our patient populations and outcomes, and the data have facilitated the planning of future interventional trials in these areas – the second stage of the ANZICS-CTG strategy.

Collaboration and Expansion

Since 1998, the ANZICS-CTG conducted a number of major interventional trials in the areas mentioned above. Foremost of these was the Saline vs. Albumin Fluid Evaluation (SAFE) study that was completed in 2004 (SAFE 2004). This study was conducted following a systematic review that suggested that administration of human albumin resulted in increased mortality in critically ill patients (Cochrane Injuries Group Albumin Reviewers 1998). Apart from providing a definitive result addressing the question posed by the systematic review, the SAFE study had a major impact on the research culture and experience within the ANZICS-CTG. Most importantly, the SAFE study was a collaboration between the ANZICS-CTG (including 16 ICUs in ANZ), the George Institute for International Health and the Australian Red Cross Blood Transfusion Service. This collaboration was integral in the success of the study, which enrolled 6,997 patients and was concluded ahead of schedule and within budget. Using web-based data acquisition hosted by the George Institute, the study was published one year following completion of enrolment and was described “not only as a landmark trial, but a milestone in the discipline of Critical Care Medicine” (Cook 2004). Another major collaborative study conducted by the ANZICS- CTG was the MERIT study – a cluster-randomized controlled trial analyzing the effect of the introduction of a medical emergency team on aggregate outcomes (MERIT 2005). This is the largest study of system change in intensive care published to date. The success and experience of SAFE and MERIT also facilitated the development and consolidation of other major interventional trials that are underway by the ANZICS-CTG. They did so by consolidating a track record for funding, protocol development, research coordinator experience and international collaboration.

Current initiatives underway by the ANZICS-CTG include a 6,000-patient study of 2 target ranges for blood glucose, conducted in collaboration with the Canadian Critical Care Trials Group (the NICESUGAR study); a 1,500-patient study comparing standard vs. augmented level renal replacement therapy (the RENAL study); a comparison of decompressive craniectomy standard therapy for intracranial hypertension in TBI (the DECRA study); and a study addressing compliance with evidenced- based feeding guidelines. A number of other initiatives in nutrition, adjunctive therapies for sepsis and outcome evaluations are underway or in advanced stages of development.

As a result of many of the successes outlined above, the ANZICS-CTG was awarded a federal grant in 2006 to establish a research methods center (the ANZIC Research Centre), based at the Monash University Department of Epidemiology and Preventive Medicine. This center will be an integral component of research outputs of the ANZICS-CTG for the next five years.

Conclusion

The ANZICS-CTG has had a major impact in critical care research in ANZ, with study results now published in major international journals. Much of the ANZICS-CTG’s success is attributed to the collegiate and enthusiastic research culture that has been fostered within the ANZ intensive care community, the establishment of sound governance processes within CTG administration and consolidation of vital collaborations with other centers of research excellence.

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