

HYPOFIBRINOGENEMIA IN BLEEDING CARDIAC SURGERY: A PROBLEM IN DISGUISE

Dr. Worasak Keeyapaj, Stanford University

Excessive post-operative hemorrhage in cardiac surgery is known to result in substantial increases in post operative complications such as need for re-exploration, prolonged ICU stay, ventilation for >24 hours, need for any kind of blood products and associated risks, and increased mortality.¹ Several

professional societies have published protocols for assessing coagulopathy and optimizing blood component replacement aiming to stop bleeding as quickly as possible. A 1:1:1 transfusion ratio of red cells to platelets to plasma shows a benefit for massive hemorrhage treatment in cardiovascular surgery.²

A targeted (goal directed) transfusion algorithm promotes individual component therapy with concentrated clotting factors instead of a fixed ratio transfusion in cardiac surgery. Fibrinogen, the precursor for fibrin, a key protein in clot formation, is the first clotting factor to reach critically low levels during hemorrhage.³

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WINNING WITH A NOVEL STATISTICAL ANALYSIS IN CT TRIALS: USE OF THE WIN RATIO

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RBT-1 is a novel preconditioning drug being developed to prevent postoperative complications in patients undergoing cardiothoracic surgery. It activates various antioxidant, anti-inflammatory, and iron-scavenging pathways and, when administered

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POST-OPERATIVE ATRIAL FIBRILLATION: CLINICAL IMPLICATIONS, GUIDELINES, AND EMERGING EVIDENCE

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Loyola University Medical Center, Chicago, IL

New-onset post-operative atrial fibrillation (POAF) occurs in 20-50% of patients after cardiac surgery. POAF usually develops within the index hospital stay and often extends it. Post-discharge POAF may be underdiagnosed. POAF is not a benign condition: it confers a 5- to 8-fold risk of AF recurrence^{1,2} and has been associated with increased risks of stroke and mortality, as demonstrated by large meta-analyses.^{3,4} POAF reveals atrial myopathy and atrial myocardial substrate vulnerable to fibrillation. The substrate for AF exists before the episode of POAF and of course,

persists as a durable risk. Thus, lessening the likelihood of POAF with temporary drug therapy or inflammation reduction may not confer substantial long-term protection.

The ESC/EACTS gave a 2020 Class I (Level of Evidence [LOE] A) recommendation for peri-operative amiodarone or beta-blockers for POAF prevention, whereas a 2a recommendation (LOE B) was given by ACC in 2023. However, these drugs may be underutilized in part due to side effects, including bradycardia, or real-world use compliance. Long-term

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MORE INSIDE:

- **Introducing:**
The Virtual Training Center (VTC)
- **Announcing:**
The 2024 ERAS® Cardiac Fellowship Awardee
- **Upcoming Meetings**
- **ERAS Members & Sponsors**
- **Our Mission**

ERAS PROGRAM IN THE SPOTLIGHT

THE I HATE INFECTIONS TEAM (#IHIT)

Mike Modrow PA-C

WakeMed Health, Raleigh NC

Enhanced recovery after heart surgery (ERAS®) must include infection prevention strategies.¹ WakeMed's cardiac surgery service line developed a robust, multidisciplinary infection prevention team to evaluate and act in all phases of perioperative care to achieve a cardiac surgery DSWI rate of zero. We call this team the **I Hate Infections Team**²

Patient-related interventions consisted of pre-operative methicillin-resistant Staphylococcus

aureus identification, individualized perioperative antibiotics, antimicrobial dosing strategies, and maintenance of normothermia.

Operative-related interventions involved glycemic control, sternal adhesives, medications and hemostasis, rigid sternal fixation for high-risk patients, chlorhexidine gluconate dressings over invasive lines, and use of disposable health care equipment, where able, to prevent cross contamination.

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HYPOFIBRINOGENEMIA IN BLEEDING CARDIAC SURGERY: A PROBLEM IN DISGUISE

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Pre-operative fibrinogen levels in cardiac surgery are independently associated with post-operative blood loss and re-exploration.⁴ Similarly, post-operative fibrinogen levels below 200 mg/dL are an independent risk factor for severe hemorrhage.⁵

Early identification and prompt treatment of hypofibrinogenemia by viscoelastic

whereas fibrinogen concentrate contains only fibrinogen.^{9,10} Risk of infection transmission delaying treatment due to thawing time and high wastage due to its short shelf-life (4-6 hours) are limitations of cryoprecipitated AHF. The high cost and lack of other clotting factors are the drawbacks of fibrinogen concentrate. Factor XIII promotes the cross-linkage of fibrin monomer into fibrin polymer and strengthens the blood

reduced cryoprecipitated fibrinogen complex (Cerus®, Concord, CA) has been introduced as an alternative treatment option for hypofibrinogenemia. It can be stored in thawed-form, ready-to-transfuse, for up to 5 days and in addition to fibrinogen, contains other clotting factors such as vWF and factor XIII.¹³ Early detection and prompt treatment of acquired hypofibrinogenemia in bleeding cardiac surgical patients with a concentrated source of fibrinogen may reduce adverse outcomes associated with hemorrhage.

EARLY IDENTIFICATION AND PROMPT TREATMENT OF HYPOFIBRINOGENEMIA BY VISCOELASTIC TESTING OR LABORATORY TESTING IS ASSOCIATED WITH REDUCED BLOOD COMPONENT UTILIZATION AND IMPROVED MORTALITY RATES IN CARDIOVASCULAR SURGERY.

testing or laboratory testing is associated with reduced blood component utilization and improved mortality rates in cardiovascular surgery.^{6,7} The common treatments for acquired hypofibrinogenemia are cryoprecipitated AHF and fibrinogen concentrate. Cryoprecipitated AHF⁸ replenishes fibrinogen as well as von Willebrand factor (vWF), factor VIII and factor XIII,

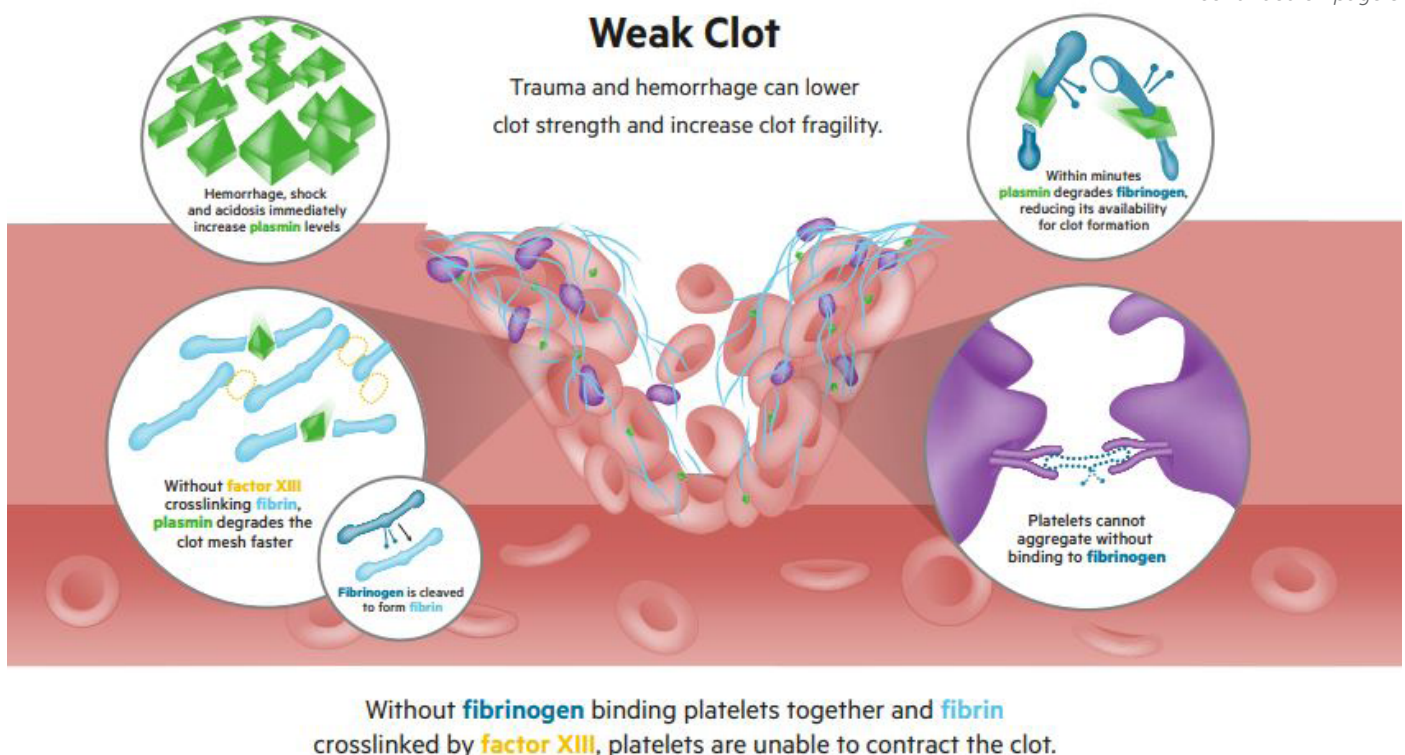
clot. The result of FIBRES trial showed the efficacy of fibrinogen concentrate was non-inferior to cryoprecipitated AHF in bleeding cardiac surgical patients with hypofibrinogenemia.¹¹ However, the REPLACE trial showed fibrinogen concentrate administration in bleeding cardiac surgical patients was associated with increased allogenic blood transfusion.¹² Recently, pathogen

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WINNING WITH A NOVEL STATISTICAL ANALYSIS IN CT TRIALS: USE OF THE WIN RATIO

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1-2 days prior to surgery, could potentially improve clinical outcomes across various organ systems, including the heart, lung, kidneys, liver, and brain, based on preclinical data. A recently completed Phase 2 study met the primary endpoint of a cytoprotective preconditioning biomarker response¹. Additional predefined endpoints included clinical outcomes, such as ventilator, ICU, and hospital days; 30-day readmission rates; AKI incidence; and MAKE- (major adverse kidney events) assessment. Analysis of these outcomes suggested statistically significant or numerical improvement across most domains.

Multi-organ benefits, even if small, could add to meaningful improvement in overall outcomes (akin to the concept of “the aggregation of marginal gains” by Dave Brailsford)². Quantification of such outcomes requires using a relevant composite endpoint. As such, a post-hoc analysis was performed in the Phase 2 study of RBT-1 using the Finkelstein-Schoenfeld method (win ratio)², wherein clinical outcomes were assessed in a

severity-based hierarchy (death > AKI requiring dialysis > ICU days > 30-day cardiopulmonary readmission). This analysis showed that patients treated with RBT-1 had improved outcomes compared to placebo and formed the basis of RBT-1 receiving a Breakthrough Therapy designation by the US FDA, as well as the agency's agreement on a hierarchical composite endpoint for the upcoming Phase 3 RBT-1 clinical trial.

The win ratio's hierarchical structure, flexibility and statistical power (every placebo patient is compared to every treatment patient) make it an attractive approach for determining efficacy of randomized treatments. Lack of familiarity of the win ratio among clinicians and regulatory entities may have slowed its initial utilization and broad adoption in clinical trial design, however change is afoot.³ This novel endpoint approach, which allows multi-organ benefits to be examined across continuous and binary variables based upon severity, could form the basis of future clinical trial designs in cardiac surgery.

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oral anticoagulation (OAC) has an ESC/EACTS Class IIb recommendation (LOE B) for POAF patients at risk of stroke after cardiac surgery, noting net clinical benefit and patient preference should be considered. This may reflect the mixed published outcomes on the role of OAC in POAF patients regarding stroke prevention versus bleeding risk.

There is emerging evidence on strategies to prophylactically reduce POAF incidence

In summary, the increased morbidity and mortality associated with POAF are well-documented. Research on various prophylactic interventions to prevent POAF continues but underscores the importance of peri-operative rhythm/rate control combined with long-term rhythm monitoring for at-risk patients.

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at index procedure. Prophylactic radiofrequency ablation of the left atrium has recently been published with evidence of decreased POAF.^{5,6} Because substrate is modified, it has the potential to translate into longer term AF reduction. Myocardial inflammation reduction has been explored with colchicine⁷ or posterior pericardiotomy⁸, which recently received a 2a (LOE B) ACC recommendation for POAF reduction. Prophylactic exclusion of the left atrial appendage (LAA), the predominant site of thrombus in AF, has been evaluated in feasibility and retrospective studies.⁹⁻¹¹ LeAAPS (NCT05478304) is an ongoing prospective, multi-center, randomized, superiority trial to evaluate the effectiveness of LAEE for the prevention of ischemic stroke or systemic arterial embolism in non-AF cardiac surgery patients who have risk factors for AF and ischemic stroke.

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To learn more about our organization, including our board members and upcoming meetings:
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COACHES CORNER

ERAS PROGRAM IN THE SPOTLIGHT

THE I HATE INFECTIONS TEAM (#IHIT)

Mike Modrow PA-C
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Patient-related interventions	• Preoperative MRSA identification • Individualized perioperative antibiotics • Antimicrobial dosing strategies • Normothermia maintenance
Environment-related interventions	• Proper OR ventilation • OR professional cleaning • Reducing airborne particle counts • Decreasing OR foot traffic
Operative-related interventions	• Glycemic control • Sternal adhesives and medications • Rigid sternal plating for high risk patients • Use of disposable healthcare equipment • Use of CHG dressings over invasive lines

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Environment-related interventions included optimizing operating room ventilation and terminal cleaning, reducing airborne particle counts, and decreasing OR foot traffic.

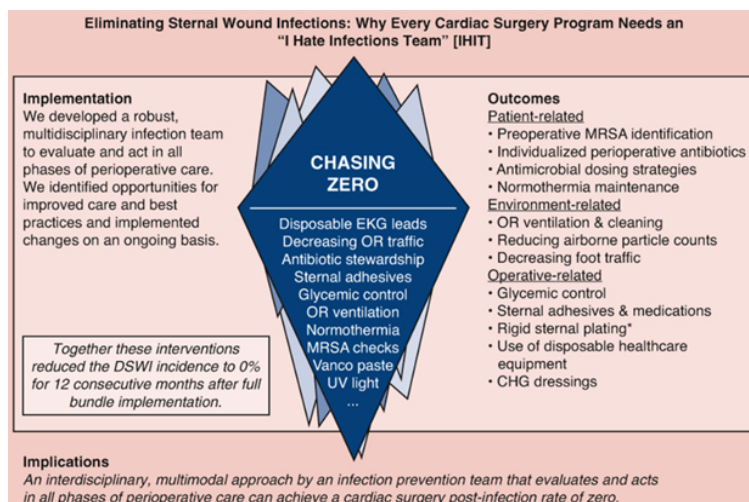
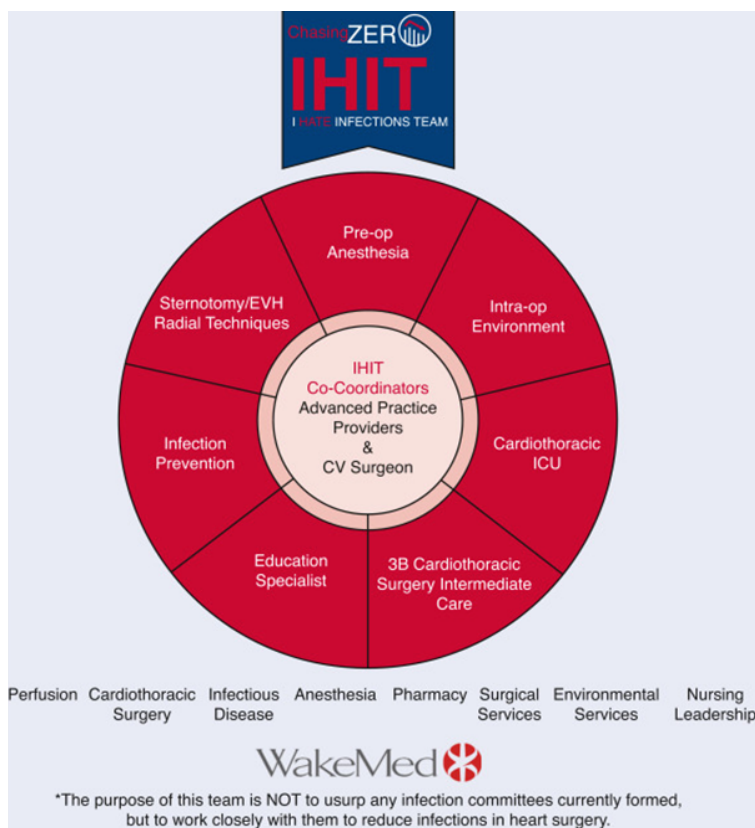
We even now have an after-discharge care plan in place called Tele Heart Care. This program affords for a minimum of two additional APP touch points, prior to the patient's follow up visit with their surgeon. This allows for real time wound evaluations, to get in front of any developing wound issues, as well as address other post discharge opportunities to adjust medications and evaluate overall post-op well-being etc.

USE OF THIS BUNDLED INFECTION PREVENTION APPROACH REDUCED THE INCIDENCE TO ZERO FOR THE FIRST 14 MONTHS AFTER IMPLEMENTATION AT OUR INSTITUTION.

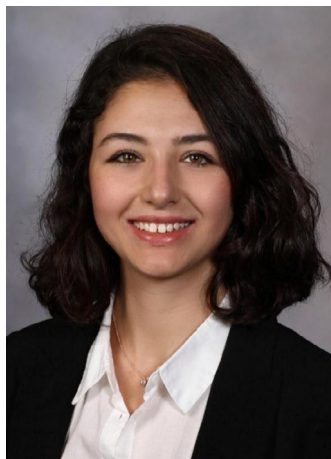
Together, these interventions reduced the DSWI incidence from 1.6% pre-intervention to 0% for 14 consecutive months after full bundle implementation. Although the influence of each individual intervention on our DSWI remains unknown, use of this bundled infection prevention approach reduced the incidence to zero for the first 14 months after implementation at our institution. As our executive medical director, Dr. Judson Williams often states- "it is through these marginal gains that our patients benefit the most." The ongoing challenges are continuing educational opportunities, for ever changing staffing, to minimize drift from in place practices. We are doing this through IHIT educational videos, like our ERAS® Virtual Training Center video, and continuing educational in-service opportunities. Of course the above interventions clearly are not all inclusive but rather representative of an organized, multimodal, multidisciplinary approach to achieving ZERO deep sternal wounds. The effort, we believe, MATTERS to achieving optimal enhanced recovery after surgery(ERAS)! Good luck on your journey to ZERO!

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IN THE NEWS:



Busra Cangut, MD is the 2024 recipient of the Richard Engelman Cardiac Enhanced Recovery Fellowship Award.

Announcing the 2024 ERAS® Cardiac Fellowship Awardee:

We are proud to announce that Busra Cangut, MD is the 2024 recipient of the Richard Engelman Cardiac Enhanced Recovery Fellowship Award. This award affords the recipient the opportunity to join the ERAS® Cardiac Executive Board in focused research, collaboration, and presentations at academic meetings. The intent is to provide an enriched experience for the awardee to gain advanced training in perioperative care of cardiac surgical patients. Awardees may also travel to expert institutions for advanced training.

Dr. Busra Cangut completed her medical school at Istanbul-Marmara University School of Medicine and pursued her basic science research year, postdoctoral fellowship, master's degree and general surgery intern year at Mayo Clinic.

She is currently working on the development of novel cardiac imaging technologies for specific valve pathologies as well as clinical outcome research at Mount Sinai Hospital/New York. Her multifaceted approach to cardiothoracic surgery, encompassing basic science, clinical, and imaging aspects, reflects her unique and holistic understanding of the field.



Dr. Richard Engelman

Beyond her outstanding research and clinical accomplishments, Dr. Cangut has demonstrated exemplary commitment, dedication, and leadership in her role as the committee chair for Women in Thoracic Surgery (WTS). Her exceptional contributions to the field have been recognized with the prestigious 2023 STSA Carpenter Scholarship, a testament to her unwavering dedication to advancing medical knowledge.



ERAS® Cardiac Society Executive Board in Lisbon

The ERAS® Cardiac Society Executive Board met in Lisbon this June at the ERAS® World Congress, where they were invited to present a specialty session on innovations in cardiac surgery.

Introducing the Virtual Training Center

Amanda Rea, DNP, CRNP, University of Maryland St. Joseph Medical Center, Towson, MD
Alex Gregory, MD, Cumming School of Medicine & Libin Cardiovascular Institute, University of Calgary, Alberta, CA

The Enhanced Recovery After Surgery (ERAS®) Cardiac Society strives to promote the engagement and adoption of ERAS® protocols for the cardiac surgery patients around the world. Traditionally, this has been accomplished through publications, work groups, and presentations on national and international platform from meetings and conferences hosted by the expert organizations that support the cardiac surgery perioperative continuum.

In October, the ERAS® Cardiac Society launched a new membership for the global enhanced recovery community. One of the benefits of membership is access to educational resources, materials and presentations that have been collated into a platform titled The Virtual Training Center (VTC). The VTC includes experts from all across the world providing recorded presentations on topics of ERAS®. In addition to the presentations, the society developed implementation materials for team members to utilize when developing or expanding an ERAS® program. These items are all customizable for individual institutions and have been developed by leaders whom have implemented and sustained successful ERAS® programs. Examples of the items included are an implementation checklist, a standardized patient education booklet, visual pathways for patients and healthcare teams, a PowerPoint for team education, an ERAS® coordinator job description, and a data tracking spreadsheet. The VTC will continue to evolve by adding content on a regular basis to provide the most up to date information and resources. This entire platform was designed to provide teams and individuals with the tools we wish we had when embarking on this ERAS® adventure. Our goal is to continue perfecting the surgical journey by spreading the word, supporting each other, researching, and providing evidenced based care to improve our patients' outcomes.

Scan the QR code to sign up for the ERAS® Cardiac membership.



RECENT ERAS® CARDIAC PUBLICATIONS:

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24. [An enhanced recovery programme significantly improves postoperative outcomes after surgical aortic valve replacement.](#)

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UPCOMING MEETINGS:

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Society of Critical Care Medicine
Critical Care Congress
San Francisco, CA
January 21-24, 2024



Society of Cardiovascular
Anesthesiologists 46th Annual
Meeting
Toronto, Canada
April 27-30, 2024



European Association for
Cardio-Thoracic Surgery 38th
Annual Meeting
Lisbon, Portugal
October 9-12, 2024



Society of Thoracic Surgeons 60th
Annual Meeting
San Antonio, TX
January 27-29, 2024



Evidence Based Perioperative
Medicine World congress 2024
London, England
July 2-4, 2024



Society of Thoracic Surgeons
Perioperative Medicine and
Critical Care Meeting
Philadelphia, PA
October 24-30, 2024



American Association for Thoracic
Surgery 104th Annual Meeting
Toronto, Canada,
April 27-30, 2024



10th ERAS World Congress
Malaga, Spain
September 18-20, 2024

ERAS® Cardiac Society MISSION

The mission of the ERAS® Cardiac Society is to optimize perioperative care of cardiac surgical patients through collaborative discovery, analysis, expert consensus, and dissemination of best practices worldwide.

Who We Are

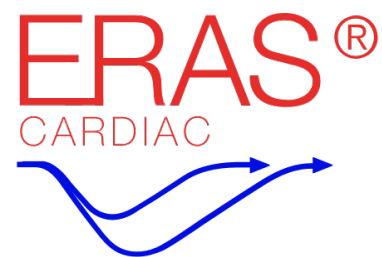
The ERAS® Cardiac Society is an international non-profit organization comprised of experts from around the world, including participation from all members of the healthcare team. Led by an executive board, an advisory board, and a pool of subject matter experts, our members strive to implement enhanced recovery principles at their local institutions while advancing improved patient care internationally through collaboration, education, and dissemination of up-to-date knowledge regarding optimal perioperative care.

ERAS® Society

The ERAS® Society is an international organization with enhanced recovery guidelines for several surgical sub-specialties. Beginning as the ERAS® Study Group in 2001, team leaders Professor Ken Fearon (University of Edinburgh) and Professor Olle Ljungqvist (Karolinska Institutet) spearheaded the developments made in multimodal surgical care. The ERAS® Study Group soon discovered that there were a variety of local traditions in practice, as well as an inconsistent application of evidence-based best practices. This prompted the group to examine the process of change from tradition to best-practice. Since its inception, the ERAS® Society has expanded to include several subspecialties, emphasized the benefits of standardized best-practices across the continuum of the perioperative period, highlighted the importance of data-driven self-evaluation, and promoted the improvement of patient care.

Our Organizational Structure

Our ERAS® Cardiac Society is made up of experts from around the world, including participation from all members of the healthcare team. Our members strive to implement enhanced recovery principles at their local institutions while advancing improved patient care internationally through collaboration, education, and dissemination of up-to-date knowledge regarding optimal perioperative care. Our organization is divided into an Executive Board, Advisory Board, and a pool of Subject Matter Experts.



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