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Study Title
Enhanced Recovery After Surgery (ERAS) guidelines in Mitral valve surgeries , Questionnaire

Research Protocol Template

Anesthesia Research Scientific Committee

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Introduction:

Enhanced recovery after surgery (ERAS) is a term that include a series of evidence-based perioperative care pathways designed to reduce physiological and psychological stress in surgical patients and to achieve rapid recovery.

In 2016, the first pilot study was published, which analyzed enhanced recovery after cardiac surgery (ERACS). Weaning from mechanical ventilation is considered one of the items that forms the concept of enhanced recovery in cardiac surgery.

Pain is an undesirable consequence of surgery especially cardiac surgery as pain during and following cardiac surgery has been shown to be a risk factor for increased morbidity. Systemic opioids have been the main stay for the management of perioperative pain in cardiac surgery. Lower doses of opioids has been related to early extubation and minimizing opioid-related side effects, such as prolonged ventilation, tolerance, nausea, vomiting, gut dysfunction, and immunosuppression.

On the other hand we find cases of morbidity and mortality not related to the surgical procedure. ERAS protocol discuss the optimum condition that can we use to avoid the morbidity and mortality complications.

We aim to know how well ERAS protocol is known and applied

Aim of the work

Our aim is to know how well cardiac anesthesiologists, cardiac intensivists and cardiothoracic surgeons know and apply ERAS protocol in mitral valve surgery.

Objectives:

We will use the questionnaire about ERAS guidlines to assess the knowledge of doctor about the guidelines.

Hypothesis:

Our hypothesis is that ERAS guidelines are not well known among doctors.

Ethical Considerations

The study will be conducted after taking approval of the research and ethical committees.

Informed consent will be obtained from study participants or their legally authorized representative.

Methodology

I. Study design

Cross section study to assess of knowledge about Enhance Recovery After Surgery (ERAS) guidelines between cardiac anesthesiologists, cardiac intensivists and cardiothoracic surgeons.

II. Study setting and location

- Anesthesia department, Cairo university hospitals, kasr al-ainy.
- Cardiothoracic thoracic surgery department, Cairo university hospitals, kasr al-ainy.
- Anesthesia department, National Heart Institute.
- Cardiothoracic surgery department, National Heart Institute.

III. Study population

- Cardiac anesthesiologists
- Cardiac intensivists
- Cardiothoracic surgeons

IV. Eligibility Criteria

1. Inclusion criteria

- Cardiac anesthesiologists.
- Cardiac intensivists.
- Cardiothoracic surgeons.
- All stuff members from resident to consultant are included inside this study

V. Study Procedures

1. Randomization (in RCT only)

A questionnaire will be sent online to a random sample of anesthesiologists and intensive care physicians.

The random sample will be taken by use of random list.

2. Study Protocol:

The questionnaire consists of number of questions that the doctor has to answer in a set format. It will be a closed-ended questions:-

- Dichotomous
- Nominal-polytomous
- Ordinal-polytomous

Grading system will be described as:-

- Grade A (knows well (: more than 60 % correct answer
- Grade B (fair): 35 :60 % correct answer
- Grade C (knows nothing) :- less than 35 % correct answer

2. Measurement tools

1. Questions about ERAS society
2. Questions about premedications
3. Questions about opioids
4. Questions about ERAS guidelines :-
    - Preoperative Hb A_{1c} measurement
    - Preoperative measurement of Albumin
    - Preoperative correction of nutritional deficiency
    - Consumption of clear liquid before GA
    - Preoperative carbohydrates loading
    - Prehabilitation

VI. Study outcomes

1. Primary outcome

Assessement of the knowledge of doctors to ERAS guidelines in cardiac surgery by using the grading system.

2. Secondary outcome(s)

Statistical Analysis

I. Sample size

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The sample size had determined using epi-infoVersion 7 based on the following prerequisites:

- Confidence level = 95%

- Expected frequency of knowledge about Enhance Recovery After Surgery (ERAS) guidelines between cardiac anesthesiologists, cardiac intensivists and cardiothoracic surgeons = 50%.

- Confidence limit =5%

- Population size = 1000 (cardiac anesthesiologists, cardiac intensivists and cardiothoracic surgeons in Cairo University hospitals (Kasr Al Ainy) and National Heart Institute).

This gave a minimum sample size two hundred and seventy eight physicians had selected to be included in the study.

II. Statistical analysis

The collected data will be revised, coded and analyzed using SPSS version 21 software for tabulation and analysis.

The following statistical measures will be calculated:

A. Descriptive statistics:

1- Count and percentage.

2- For quantitative variables, arithmetic mean and standard deviation will be calculated.

B. Analytical statistics:

The data will be analyzed and when $p<0.05$ will be considered statistically significant.

References

[1] Scott MJ, Baldini G, Fearon KC, Feldheiser A, Feldman LS, Gan TJ, Ljungqvist O, Lobo DN, Rockall TA, Schricker T, Carli F. Enhanced Recovery After Surgery (ERAS) for gastrointestinal

surgery, part 1: pathophysiological considerations. Acta Anaesthesiol Scand. 2015 Nov;59(10):1212-31. doi: 10.1111/aas.12601. Epub 2015 Sep 8. PMID: 26346577; PMCID: PMC5049676.

[2] Kehlet H. Multimodal approach to control postoperative pathophysiology and rehabilitation. Br J Anaesth. 1997 May;78(5):606-17. doi: 10.1093/bja/78.5.606. PMID: 9175983.

[3] Fleming IO, Garratt C, Guha R, Desai J, Chaubey S, Wang Y, Leonard S, Kunst G. Aggregation of Marginal Gains in Cardiac Surgery: Feasibility of a Perioperative Care Bundle for Enhanced Recovery in Cardiac Surgical Patients. J Cardiothorac Vasc Anesth. 2016 Jun;30(3):665-70. doi: 10.1053/j.jvca.2016.01.017. Epub 2016 Jan 16. PMID: 27321791.

[4] Engelman DT, Ben Ali W, Williams JB, Perrault LP, Reddy VS, Arora RC, Roselli EE, Khoynezhad A, Gerdisch M, Levy JH, Lobdell K, Fletcher N, Kirsch M, Nelson G, Engelman RM, Gregory AJ, Boyle EM. Guidelines for Perioperative Care in Cardiac Surgery: Enhanced Recovery After Surgery Society Recommendations. JAMA Surg. 2019 Aug 1;154(8):755-766. doi: 10.1001/jamasurg.2019.1153. PMID: 31054241.

[5] Kaushal B, Chauhan S, Magoon R, Krishna NS, Saini K, Bhoi D, Bisoi AK. Efficacy of Bilateral Erector Spinae Plane Block in Management of Acute Postoperative Surgical Pain After Pediatric Cardiac Surgeries Through a Midline Sternotomy. J Cardiothorac Vasc Anesth. 2020 Apr;34(4):981-986. doi: 10.1053/j.jvca.2019.08.009. Epub 2019 Aug 12. PMID: 31515190.

[6] Gürkan Y, Aksu C, Kuş A, Yörükoğlu UH, Kılıç CT. Ultrasound guided erector spinae plane block reduces postoperative opioid consumption following breast surgery: A randomized controlled study. J Clin Anesth. 2018 Nov;50:65-68. doi: 10.1016/j.jclinane.2018.06.033. Epub 2018 Jul 2. PMID: 29980005.

[7] Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The Erector Spinae Plane Block: A Novel Analgesic Technique in Thoracic Neuropathic Pain. Reg Anesth Pain Med. 2016 Sep-Oct;41(5):621-7. doi: 10.1097/AAP.0000000000000451. PMID: 27501016.

[8] Nagaraja PS, Ragavendran S, Singh NG, Asai O, Bhavya G, Manjunath N, Rajesh K. Comparison of continuous thoracic epidural analgesia with bilateral erector spinae plane block for perioperative pain management in cardiac surgery. Ann Card Anaesth. 2018 Jul-Sep;21(3):323-327. doi: 10.4103/aca.ACA_16_18. PMID: 30052229

[9] Krishna SN, Chauhan S, Bhoi D, Kaushal B, Hasija S, Sangdup T, Bisoi AK. Bilateral Erector Spinae Plane Block for Acute Post-Surgical Pain in Adult Cardiac Surgical Patients: A Randomized Controlled Trial. J Cardiothorac Vasc Anesth. 2019 Feb;33(2):368-375. doi: 10.1053/j.jvca.2018.05.050. Epub 2018 Jun 4. PMID: 30055991.

[10] Macaire P, Ho N, Nguyen T, Nguyen B, Vu V, Quach C, Roques V, Capdevila X. Ultrasound-Guided Continuous Thoracic Erector Spinae Plane Block Within an Enhanced Recovery Program Is Associated with Decreased Opioid Consumption and Improved Patient Postoperative Rehabilitation After Open Cardiac Surgery-A Patient-Matched, Controlled Before-and-After Study. J Cardiothorac Vasc Anesth. 2019 Jun;33(6):1659-1667. doi: 10.1053/j.jvca.2018.11.021. Epub 2018 Nov 19. PMID: 30665850.

[11] Moitra VK, Guerra C, Linde-Zwirble WT, Wunsch H. Relationship Between ICU Length of Stay and Long-Term Mortality for Elderly ICU Survivors. Crit Care Med. 2016 Apr;44(4):655-62. doi: 10.1097/CCM.0000000000001480. PMID: 26571190; PMCID: PMC4792682.

[12] Song K, Xu Q, Knott VH, Zhao CB, Clifford SP, Kong M, Slaughter MS, Huang Y, Huang J. Liposomal Bupivacaine-Based Erector Spinae Block for Cardiac Surgery. J Cardiothorac Vasc Anesth. 2021 May;35(5):1555-1559. doi: 10.1053/j.jvca.2020.09.115. Epub 2020 Sep 20. PMID: 33046362.