



## Do Goal Directed Therapies Improve Postoperative Outcome in Children? (Perioperative Goal Directed Fluid and Hemodynamic Therapy; Transfusion goal directed therapy using viscoelastic methods and enhanced recovery after surgery and Postoperative outcome): A Study Research Protocol

**Claudine Kumba\***

*Department of Pediatric Anesthesia and Critical Care, Necker –Enfants Malades University Hospital, Paris France*

**\*Corresponding Author:** Claudine Kumba, Department of Pediatric Anesthesia and Critical Care, Necker –Enfants Malades University Hospital, Paris France. **E-mail:** claudine.kumba@gmail.com; **Contact Number:** +33 144494000

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**\*ORCID:** <https://orcid.org/0000-0002-9748-5141>

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### Abstract

**Background:** In adults, studies have shown that perioperative goal directed fluid and hemodynamic therapy, goal directed transfusion using viscoelastic methods and enhanced recovery after surgery improved postoperative outcome. In children evidence is not clear in these fields.

**Objective:** This is a Thesis Project which was developed to demonstrate whether the above mentioned goal directed therapies applied perioperatively in children improve postoperative outcome.

**Methods:** A prior analysis was realized in 5 retrospective pediatric studies in orthopedics, abdominal surgery and neurosurgery to determine predictors of postoperative adverse outcome. Several independent risk factors of postoperative outcome were identified. In order to apply corrective measures on these predictors, three meta-analyses of randomized and non randomized studies were realized in children.

The second stage of the project is to develop prospective and randomized studies based on the results of the retrospective studies and the meta-analyses to determine the impact of the corrective measures on postoperative outcome in children.

**Results:** Studies realized in the second stage of the project will determine whether perioperative goal directed therapies in children impact on postoperative outcome.

**Conclusion:** This Thesis project was developed to determine the impact of goal directed therapies on postoperative outcome in children.

**Keywords:** Goal Directed Therapies; Children; Outcome; Pediatric Anesthesia; Pediatric Critical Care; Echocardiography; Viscoelastic Methods; ERAS

### Introduction

Several studies have evidenced that perioperative goal directed fluid and hemodynamic therapy, goal directed transfusion protocols using viscoelastic methods and enhanced recovery after surgery improve postoperative outcome [1-3].

In children evidence concerning these subjects is not clear. To determine the impact of the above mentioned goal directed therapies in children a prior analysis of the existing medical practices was conducted [4]. Since what is validated in adults cannot be al-

ways extrapolated to children, specific pediatric studies need to be developed for clarification in this population.

### Methods

The first phase of this Thesis Project consisted in conducting 5 retrospective pediatric studies in three different pediatric surgical population [5-9] to determine predictors of postoperative outcome. Several risk factors were identified. To apply corrective measures three meta-analyses of randomized and non randomized studies were realized.

The second phase of this Thesis Project is to develop prospective and randomized studies based on the results of the meta-analyses to determine the impact of the corrective measures on postoperative outcome in children.

## Results

Four retrospective studies concerning more than 500 children less than 18 years in orthopedics, in abdominal surgery and neurosurgery evidenced that transfusion, emergency surgery, age and ASA (American Society of Anesthesiologists) score status were predictors of adverse postoperative outcome (complications, length of hospital stay, repeated surgery) [5-8]. These studies showed that ASA score status was the predictor of mortality. The fifth study concerning 41 children in scoliosis surgery [9] revealed that length of hospital stay was predictive of postoperative complications in this population.

In order to define corrective measures to be applied on the predictors of adverse postoperative outcome identified in the five studies, three systematic reviews and meta-analyses were conducted [10-14].

The first systematic review and meta-analysis of 23 randomized and non randomized studies in 3389 children less than 18 years [10] concerned perioperative goal directed fluid and hemodynamic therapy (GDFHT) in children and postoperative outcome. This study evidenced that compared to adults, GDFHT was not developed in children however some biomarkers of adverse postoperative outcome were identified in the pediatric cardiac surgical population namely cerebral and renal regional oxygenation, lactate levels for instance. The results of this meta-analysis suggest developing prospective randomized trials where these biomarkers are integrated in GDFHT protocols to determine their impact on postoperative outcome.

The second meta-analysis of 9 randomized and non randomized trials in 1365 children less than 18 years [11,12] concerned transfusion goal directed therapy with viscoelastic methods. This meta-analysis revealed that mortality was not reduced nevertheless fresh frozen plasma administration and length of hospital stay related to transfusion were reduced. The results of this trial suggest to develop goal directed transfusion protocols with viscoelastic methods in pediatric hemorrhagic surgery in order to diminish fresh frozen plasma administration and length of hospital stay related to transfusion.

The third meta-analysis of 6 non randomized trials in 1620 children under 18 years old in hypospadias, appendicectomy and scoliosis surgery concerned enhanced recovery after surgery in

children and postoperative outcome [13,14]. This study evidenced that when enhanced recovery protocols after surgery were applied postoperative complications and length of hospital stay were reduced. These results suggest to develop randomized controlled trials with enhanced recovery protocols to confirm these findings.

The second stage of this Thesis Project will be to develop prospective and randomized trials based on the results of the retrospective studies and meta-analyses described above.

## Conclusion

The results of the second phase of this Thesis Project will determine the impact on outcome of the above mentioned goal directed therapies in Pediatric Anesthesia and Critical Care.

This second phase will be separated in three periods.

In the first period, a prospective randomized controlled trial in pediatric cardiac patients will be realized. The objective or endpoint of this trial will be to determine the impact on goal directed fluid and hemodynamic therapy on postoperative outcome in these patients. We will use echocardiography in the perioperative and postoperative periods as a therapeutic tool to optimize fluid and hemodynamic therapy. The primary outcome will be postoperative morbi-mortality. The secondary outcomes will be length of hospital stay in the intensive care unit, length of mechanical ventilation and length of hospital stay. This study will be the leading trial of the second phase after which two other studies will be realized.

During the second period, a prospective randomized controlled trial in pediatric cardiac surgery or in hemorrhagic pediatric surgery will be realized. The objective or endpoint of this trial will be to determine the impact of transfusion directed therapy with viscoelastic methods on postoperative outcome. Transfusion goal directed therapy with viscoelastic methods will be employed as a therapeutic mean to guide the optimization of blood product administration namely fresh frozen plasma, fibrinogen, cryoprecipitate or other coagulation factors. The primary outcome will be postoperative morbi-mortality. The secondary outcomes will be length of hospital stay and the quantity of blood products administered.

The last period will include the realization of a prospective randomized controlled trial. The objective of this study will be to determine the impact of enhanced recovery pathways after pediatric surgery (ERAS) on postoperative outcome. ERAS will be used as a therapeutic mean or tool to improve postoperative outcome. The primary outcome will be postoperative morbidity. The secondary outcome will be length of hospital stay.

## Conflict of Interest

None

## Ethic Approval

Since this is a Thesis Project in development, no ethic approval was necessary at this stage.

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