

## MINIATURIZED EXTRACORPOREAL CIRCULATION (MECC) VERSUS CONVENTIONAL CARDIOPULMONARY BYPASS (CCPB): CLINICAL OUTCOMES AND COST EFFECTIVENESS ANALYSIS

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### ABSTRACT

The application of cardiopulmonary bypass (CPB) has been the focus of attention in cardiac surgery thereby allowing surgeries to be done on heart reconstructions and heart valve repair, repair of congenital defects and coronary bypass surgery. The classic CPB (CCPB) is reported to possess a number of limitations which comprise: hemodilution, systemic inflammatory responses, initiating of blood coagulation cascades and postoperative crises. These shortcomings prompted the development of Miniaturized Extracorporeal Circulation (MECC), which has fewer tubing and priming, less contact with air and blood and heparin-coated circuits. MECC has been reported to minimize transfusion, inflammatory activation, acute renal failure, atrial fibrillation, and intensive care unit (ICU) stay to improve overall patient recovery and better outcome. There is however no good research done on the economic attitudes of MECC adoption. The initial expenditures on specialized circuits and special infrastructure needs might be translated into downstream savings as saved transfusion, waste of time in the ICU, waste of complications and waste of hospital readmission. These possible advantages explain why costs-effectiveness studies (CEA) and cost-utility studies (CUA) are valuable in informing decision-making in resource rich, resource poor health care systems. Importantly, the review presents MECC and CCPB clinical outcome and economic considerations that need to be integrated with integrative evidence to inform policy, procurement, and clinical practice in value-based cardiac care.

**Keywords:** Cardiopulmonary Bypass (CPB), Conventional CPB (CCPB), Miniaturized Extracorporeal Circulation (MECC), Cardiac surgery, Hemodilution, Postoperative complications, Biocompatible circuits, Clinical outcomes, Cost-effectiveness analysis (CEA), Cost-utility analysis (CUA), Value-based cardiac care.

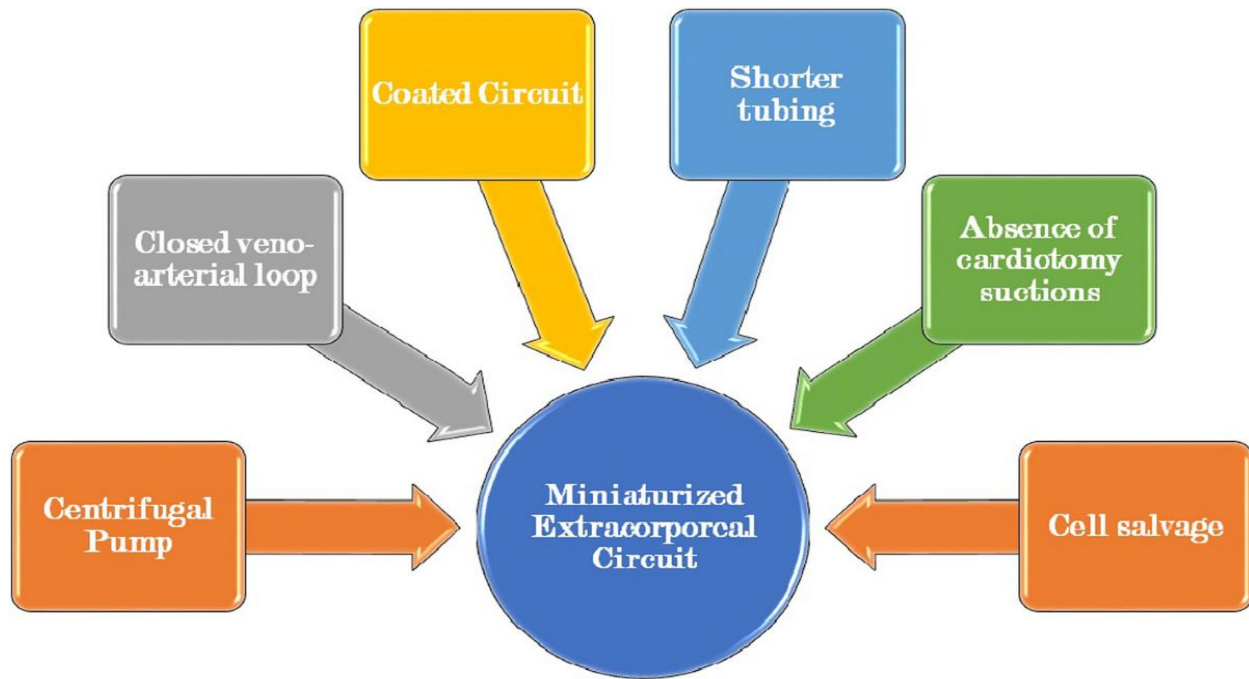
## 1. INTRODUCTION

Cardiopulmonary bypass (CPB) is a non-dialytic extracorporeal circulation system that replaces the functions of the heart and lungs temporarily (venous blood is diverted to a heart-lung machine to receive oxygen and blood pressure regulation, e.g., temperature/filtration) and is pumped back into the arterial system, to allow cardiac surgery on a still, bloodless heart [1]. Since the initial successful cardiac surgeries which were done with the help of extracorporeal support, cardiac surgery underwent several changes [2]. Cardiopulmonary bypass (CPB) is one of the technologies which made modern open-heart surgery possible. CPB gives surgeons the capability of temporarily operating the heart and lung processes of the patient during operations including coronary artery bypass grafts (CABG), valve repair, and complex congenital repairs [3]. This works by diverting the blood of the patient to an external circuit with the help of which the patient is taken into a position, whereby the heart is arrested and made to undergo surgery, in a blood-free and motionless field [4]. The commonly used Conventional Cardiopulmonary Bypass (CCPB) system is normally constituted of a venous reservoir, oxygenator, heat exchanger, arterial filter, and roller or centrifugal pump. Blood is collected in the venous system and pumped back into the reservoir

where it is directed to the oxygenator where it is exposed to oxygen and a replenishment of its gasses and finally passed back into the arterial system. But in this circuit the blood is subject to big total surface areas of foreign substances and there is frequently an open circuit with contact with the air. The interactions that occur result in the hemodilution, systemic inflammatory responses, the activation of coagulation and complement pathways, which can facilitate several postoperative complications such as renal dysfunction, coagulopathy, cognitive impairment and the need of increased use of transfusions [5].

### 1.1 MECC as a Modern Alternative To CCPB

Minimized extracorporeal circulation MECC is a modulation of cardiopulmonary bypass that has been developed over the recent years to support extracorporeal circulation in a more natural way and in a less invasive manner. MECC, structurally, is a closed-loop system, which in comparison to conventional bypass circuits is compact. Its key features are length reduction of tubing to minimize blood contact with surfaces, use of biocompatible surface coating to enhance hemocompatibility, centrifugal pump for stable blood flow, a membrane oxygenation that is effective in hemoglobin oxygenation, and a minimized priming volume minimizing hemodilution [6].



**FIG.1.1: VARIOUS COMPONENT OF MECC WITH DIFFERENCE FROM CECC [7]**

MECC enhances clinical advantages which became evident in the past five years. The smaller priming volume will help preserve hematocrit and minimize the requirement of allogeneic transfusion, whereas the coatings with biocompatibility and closed structure will reduce the activation of inflammatory and coagulation pathways. MECC makes the hemodynamics more stable, the postoperative events less, and the recovery faster than in conventional cardiopulmonary bypass with the focus on coronary artery bypass grafting and valve surgeries. MECC decreases in postoperative atrial fibrillation, a decreased possibility of developing acute kidney injury, and ICU and hospital length of stay [8] These results confirm MECC is not just a refinement technologically but also a clinically important advancement in a contemporary cardiac surgery.

Up to this time most comparisons between MECC and CCPB in a clinical setting have been directed at physiological and surgical indices. The literature has been however lacking in the economic

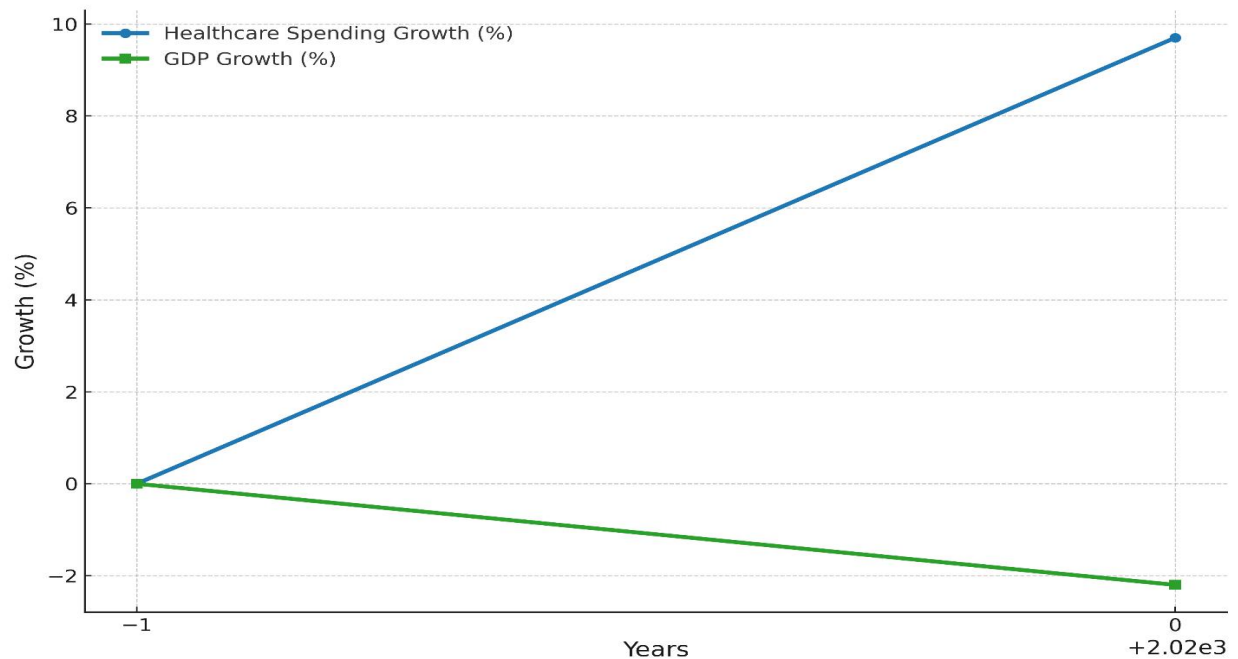
assessments like direct costs to hospital, use of resources and quality adjusted life years (QALYs). The concept of economic sustainability cannot be underestimated compared to the concepts of clinical safety and efficacy as the healthcare system throughout the entire world is heading towards value-based care [9]. This is what policymakers, surgeons, and healthcare institutions should be aware of in deciding whether they need to implement new technologies or not, and the trade off between these cost and clinical benefit. The contemporary healthcare context is undergoing a reformation as the cost levels are on the rise, the population is growing old, and the demands to achieve high-quality outcomes are growing significantly. Innovation of clinical devices and surgical technologies goes much beyond the extent of its therapeutic impact and is converted into complex economic impacts [10]. The differences of the initial costs, the downstream costs and total costs are presented in the type of graph. Although MECC miniaturizes slightly higher initials

(Heparin-coated circuit, Integrated pumps, Specialized consumables), it is much less downstream costs (e.g., a short stay in the ICU, fewer transfusions, fewer complications), and in total cost turns out cheaper than CCPB.

### 1.2. Economic Burden and CEA

Thus, CEA has established itself as necessary field in the decision-making in healthcare. It offers an organizing system of determining the worth of a medical intervention by counterbalancing its spending plans against the health it would bring. Applying the principles of cost-effectiveness is not only important but essential in any modern system that is more cost-effective and results-based [11]. Figure; shows the growth of the GDP reduced -2.2% dramatically in the year 2020 in accordance

with the global spread of the COVID-19 pandemic, the increase of the level of healthcare expenditures increased by 10% as a result of the expansion of consumption of medical care, intensive treatment, and resources to cope with the crisis [12]. This disparity highlights the increasing economic burden on healthcare systems across the world and the significance of cost-effectiveness analyses that should be conducted when integrating novel surgical technologies including Miniaturized Extracorporeal Circulation (MECC) which not only must have clinical advantages but should also be financially sustainable in terms of care health budgets already put to the test by financial constraints [13].



**FIGURE 1.2: THE TRENDS IN THE GLOBAL HEALTH EXPENDITURE IN COMPARISON TO THE GLOBAL GDP GROWTH (2019-2020)**

Cost-effectiveness, in this regard, emerges a determination factor to the systems of healthcare that wish to deliver quality, equitable and fair-minded care without the burdens that will be unaffordable to the systems [14]. Health economic assessments, in particular CEAs and cost-utility

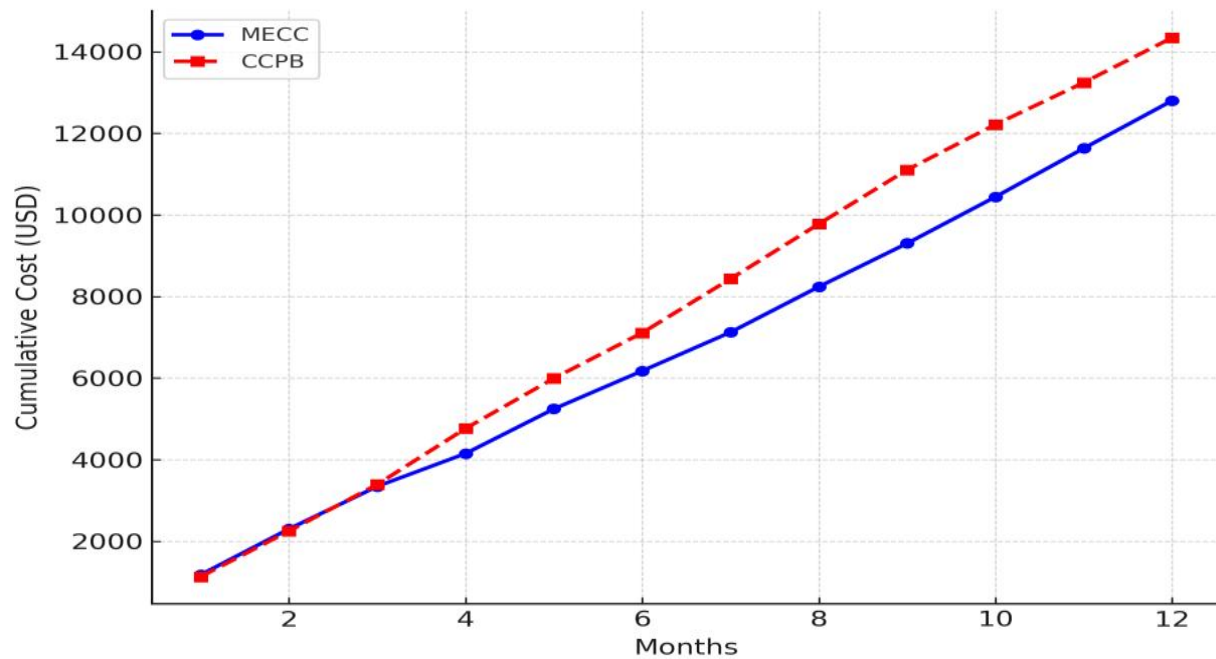
analyses (CUAs) are increasingly being used by both national health services and private healthcare payers (insurance providers and hospital administrators) in determining whether an organization should go ahead and adopt a new intervention, cover the specific treatment, or

expand It [15]. Surgical and intensives workflows using extracorporeal circulation are associated with adverse events, including acute kidney injury, bleeding and infections, which entail longer time in the ICU and the hospital outcome, and thus increase the overall cost [16]. Regarding MECC, it has been shown time and again that clinical parameters are always improved (less transfusion, less inflammation, and shorter ICU time) but few have performed a detailed economic analysis [17]. Nevertheless, such small changes in complication rates, or length of hospital stay, can achieve significant cost savings when applied in hundreds or thousands of episodes. Therefore, the localization of MECC using the cost-effectiveness parameter can facilitate the rational decision of expanding its full implementation. In countries with less resource, finding cost effectiveness healthcare solution matter even more because clinics simply don't have budget to spend freely [18]. With these environments, investments in more recent technology should be validated by the ability to show a payoff both in the results and effectively of treating the patient. This analysis is required because otherwise there is the possibility that these high-cost innovations are very restricted in their adoption as MECC in spite of being clinically sound. As per this structure, hospitals and other providers would be motivated to reduce the costs and enhance the quality of care. Changes fulfilling these goals therefore by reducing the expenditure incurred in complications or enabling timely recovery can have a revolutionary impact in performance based models of payment. To sum up, the issue of cost-effectiveness is not optional any more but the bedrock on which contemporary healthcare systems make decisions in regard to introduction, adoption, and continuing of innovations [19]. In the case of technologies like

MECC, stringent economic analysis of such an implementation is necessary to determine whether such technology is opportune to adopt as well as to provide high-value care to patients and systems.

### 1.3 Balancing Clinical and Economic Endpoints

Other cost factors endpoints are present at least in part in several recent clinical trials e.g. cost of staying in the ICU, or transfusion needs, as proxy measures of economic costs. Full cost-benefit analyses (CEA) involving direct and indirect costs long term costs and quality-adjusted life years (QALYs) are seldom done in this regard [20]. In addition, even the most studies that report cost outcomes report on either secondary analyses or narrow subgroups in such a way that the effect of cost on the health care system has not been well-explored methodologically. Although moderately cheaper on a per-use basis, because of economies of scale as well as an existing infrastructure, CCPB is known to provide higher postoperative complications and extended time to recovery, which is an indicator of higher downstream healthcare expenditure. Conversely, MECC systems are more expensive to purchase initially but can cut down on the requirement of blood products, and decrease the duration of stay in the ICU and hospital, and reduce the readmission rates as well [21]. The figure shows a cumulative comparison of MECC and CCPB in 12 months. These two methods demonstrate gradual increase in the expenses, however, CCPB is always high compared to MECC during the year. At the 12th month, CCPB surpasses the figure of over 14,000USD whereas MECC is nearer to 13,000USD which is a definite economic benefit of MECC in the long term. This tendency indicates that despite the fact that upfront costs can be comparable, MECC turns out to be more cost-effective than it is in the short-term.



**FIGURE 1.3:** Long-term cumulative cost meta-analysis of Miniaturized Extracorporeal Circulation (MECC) versus Conventional Cardiopulmonary Bypass (CCPB) in elective cardiac surgery and treatment, which show the economic advantage of MECC over the long term.

This lack of concordance of clinical and economic data is representative of a larger problem in the field of surgical innovation research where putting clinical endpoints first has outweighed economic endpoint data [22]. In order to better determine the worth of MECC, future investigations need to consider integrated designs consisting of both clinical outcomes and explicated information of costs. They must be multi-centered and involve long term follow-up as well as they should utilize standardized economic evaluation frameworks (e.g., cost-minimization, cost-effectiveness or cost-utility analyses). Summing it up, albeit the clinical advantages of MECC in the chosen cardiac interventions are gaining more and more evidence-based grounds, the absence of comprehensive economic analysis makes it difficult to implement into practice and consider it by authorities [23].

#### FUTURE DIRECTIONS

Further research needs to combine clinical and economic outcomes using extensive, cross center,

and rigorously designed studies. It should also contain cost-effectiveness and cost-utility analyses, including direct hospital expenses, long-term expenses, readmissions, and QALYs. Comparability between healthcare systems requires standardized evaluation structures. The economic viability of MECC in low- and middle-income countries should be given special attention. Its cost-saving and clinical advantages can be highlighted through further development of health-economic modeling to be used in policy decision-making. MECC has the potential to become a disruptive technology in cardiac surgery because of its potential to achieve the clinical utility and economic viability.

#### CONCLUSION

Although MECC has increasingly seen clinical evidence to support the idea that it is safer and more effective than CCPB across a range of outcomes, in the absence of accurate and uniform economic analyses, its adoption has remained stagnant. The change to MECC is accompanied by

uncertainty whether it makes sense to implement, as without in-depth cost-effectiveness analyses, policymakers and providers simply cannot demonstrate that such a move will lead to better outcomes and resource savings

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