

HOW MUCH CAN COLOMBIAN HOSPITALS EARN FOR EACH THERAPEUTIC PLASMA EXCHANGE (TPE) PROCEDURE? A MULTI-CENTER COST COMPARISON STUDY BETWEEN CENTRIFUGAL AND MEMBRANE SYSTEMS

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INTRODUCTION

Health System in Colombia

- The Ministry of Health and Social Protection (MinSalud), one of the 16 Colombian ministries established 26 years ago, is responsible to control and manage all Colombian healthcare coverage and implement all national policies and social services.¹ It is organized as follows:
 - Health-Promoting Agencies (Entidades promotoras de la Salud – EPS)** are administrative/commercial entities in charge of the Colombian citizens' affiliation to the Colombian healthcare system and of the financial reimbursement to the healthcare centers that provide service and treatments to their affiliates.²
 - IPS (Instituciones Prestadoras de Servicios de salud)** comprise hospitals, clinics, health centers and other actors of the health system that provide healthcare to Colombians.³
 - Sisben (Sistema de Beneficiarios en salud)** is a program destined to provide healthcare to those who cannot pay, and it is handled by the government.⁴
- In Colombia there are several established EPSs, mainly following geographical areas. They have been ranked according to economics, treatment availability and the differences in users' experiences among them.⁵

Therapeutic Plasma Exchange (TPE)

- Therapeutic Plasma Exchange (TPE) is an extracorporeal blood-purification technique that removes large-molecular-weight substances, such as antibodies and cytokines, from the plasma.⁶ The removed plasma volume is exchanged with a replacement fluid such as colloid solution (e.g., albumin and/or plasma) or a combination of crystalloid/colloid solution, tackling the loss of volume and osmotic concentration.^{7,8} Therefore, TPE is used extensively in several medical fields such as neurology, hematology and immunology, among others.^{9,10}
- The American Society of Apheresis (ASFA), an organization of health professionals with worldwide influence, in June 2019 issued the eighth edition of the Journal of Clinical Apheresis. More than 65 diseases were considered appropriate to be treated with TPE and were classified according to their methodological quality of data and clinical evidences, as well as category and grade recommendations. These recommendations range from I-1A, most clinical evidence, e.g., Guillain-Barré Syndrome; to IV-2C, least clinical evidence, e.g., HELLP syndrome – Antepartum.¹¹
- TPE can be performed in two different ways, depending on the medical device used. In centrifugal TPE (cTPE), the medical device has its action based on the centrifugal force that separates particles according to their size, shape, density and viscosity. In membrane TPE (mTPE), the medical device has its action based on the filtration process in which the fluid passes through a membrane that has specific pore sizes and filter thickness. Therefore, both TPE types have different technical, economic, clinical and operational elements.¹²
- Review of the literature shows that, on average, centrifugal devices perform TPE more quickly and have fewer clotting events and fewer adverse events than membrane TPE.^{13,14,15} Severe adverse events might require the use of highly specialized healthcare facilities such as intensive care units (ICUs).
- TPE requires connecting the patient to an apheresis medical device. This can be performed using either central catheter access or peripheral catheter access. All membrane medical devices require central access, as higher flow rates are required for operation. On the other hand, centrifuge devices, as they require lower flow rates, can use either central or peripheral access. Due to the higher clinical complexity of a central catheter, with more adverse events and maintenance compared with peripheral catheter, procedures using centrifugal medical devices should be performed as much as possible through a peripheral catheter.^{9,16}

OBJECTIVES

- Introduce the Colombian health system, the TPE and the two types of medical devices that can perform it.
- Compare the direct and operational cost drivers from both TPE methods and analyze the ones with highest economic impact.
- Examine the total costs of 24-hour hospitalization in the ICU.
- Advise the Colombian population on the costs incurred from both TPE methods.

METHODOLOGY

- Data from several healthcare centers from two Colombian cities have been collected.
- Due to the confidentiality of the data analyzed, only the weighted averages from the targeted centers are included, as well as their relative cost percentage from the total cost amount for cTPE vs. mTPE comparison.
- Focusing on the payer mindset, only direct costs, procedural costs and ICU costs have been assessed. Therefore, although centrifugal medical devices perform TPE more quickly and have fewer clotting events and adverse events, in this study it has been assumed that these technical and clinical parameters are the same in both technologies.
- Consequently, the elements assessed are:
 - Medical device capital cost
 - Maintenance costs
 - TPE exchange set/disposable set
 - Albumin solution
 - Indirect costs for TPE procedures (additional material, bed retention, hospital infrastructures, etc.)
 - Staff cost for TPE procedures
 - TPE access (central vs. peripheral)
 - ICU costs
- The analysis shows two different scenarios for cTPE: 100% access with a peripheral catheter and 100% access with a central catheter.

CONCLUSION

- This study has concluded that disposable sets and the type of access are the key differentiators of cost and that peripheral access is more cost-effective than central access.
- Centrifugal TPE uses lower-cost disposable sets and can often provide TPE using peripheral access, which is less expensive than central access, including both catheter and procedure costs.
- Membrane TPE uses more expensive disposable sets and can perform TPE only via central access.
- Centrifugal TPE has clear cost savings compared with membrane TPE, up to USD \$814 for full TPE treatment.
- From a payer perspective, it is highly recommended to perform all TPE procedures with centrifugal medical devices. Due to the high costs of the albumin solution, it would be advisable to analyze which would be the best health supplier.

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RESULTS

- The data collected supported the importance of TPE devices that are placed throughout the Colombian healthcare system at no cost to the hospitals for maintenance or repair. This is usually performed through a contract between the medical technology company and the hospital management, which agrees to perform annually a minimum established quantity of TPE procedures, based on disposables bought from the same company.
- One of the highest cost drivers is the albumin solution, used equally in both procedures and with a cost of USD \$441 per procedure. The indirect costs for TPE procedure, including additional materials and usage of hospital infrastructures, are being reimbursed equally for both systems by the EPS: USD \$346. The professional fees for a TPE procedure, including mainly nurse and physician salaries, are also reimbursed by the EPS: USD \$46. [Table 1]
- The cost of the disposable set is the key cost driver for both TPE systems. On average, the cTPE kit costs USD \$275 and the mTPE kit USD \$410. For a complete treatment series of 5 TPE sessions, cTPE would save USD \$675 compared with mTPE. Furthermore, the mTPE devices sometimes require additional materials that would further increase the cost difference. [Figure 1]
- The cost of the vascular access is a key driver as well. Central access has higher costs than peripheral access. The central catheter costs on average USD \$79 and the peripheral catheter only USD \$3. The placement of the central catheter, including direct and indirect costs related to the material and infrastructures used and for the clinical procedure, is reimbursed by the EPS: USD \$75. The hospital's costs are assumed to be equal to the amount reimbursed.
- Considering that the central access will use only one catheter throughout the 5 TPE procedures for the full treatment, and the peripheral access will use one new catheter per each TPE procedure, full treatment with central access costs USD \$79 + USD \$75 = USD \$154, while with peripheral access it costs USD \$3 × 5 catheters = USD \$15. [Table 1]
- On average, 24 hours of hospitalization in an ICU is reimbursed by the EPS: USD \$781.

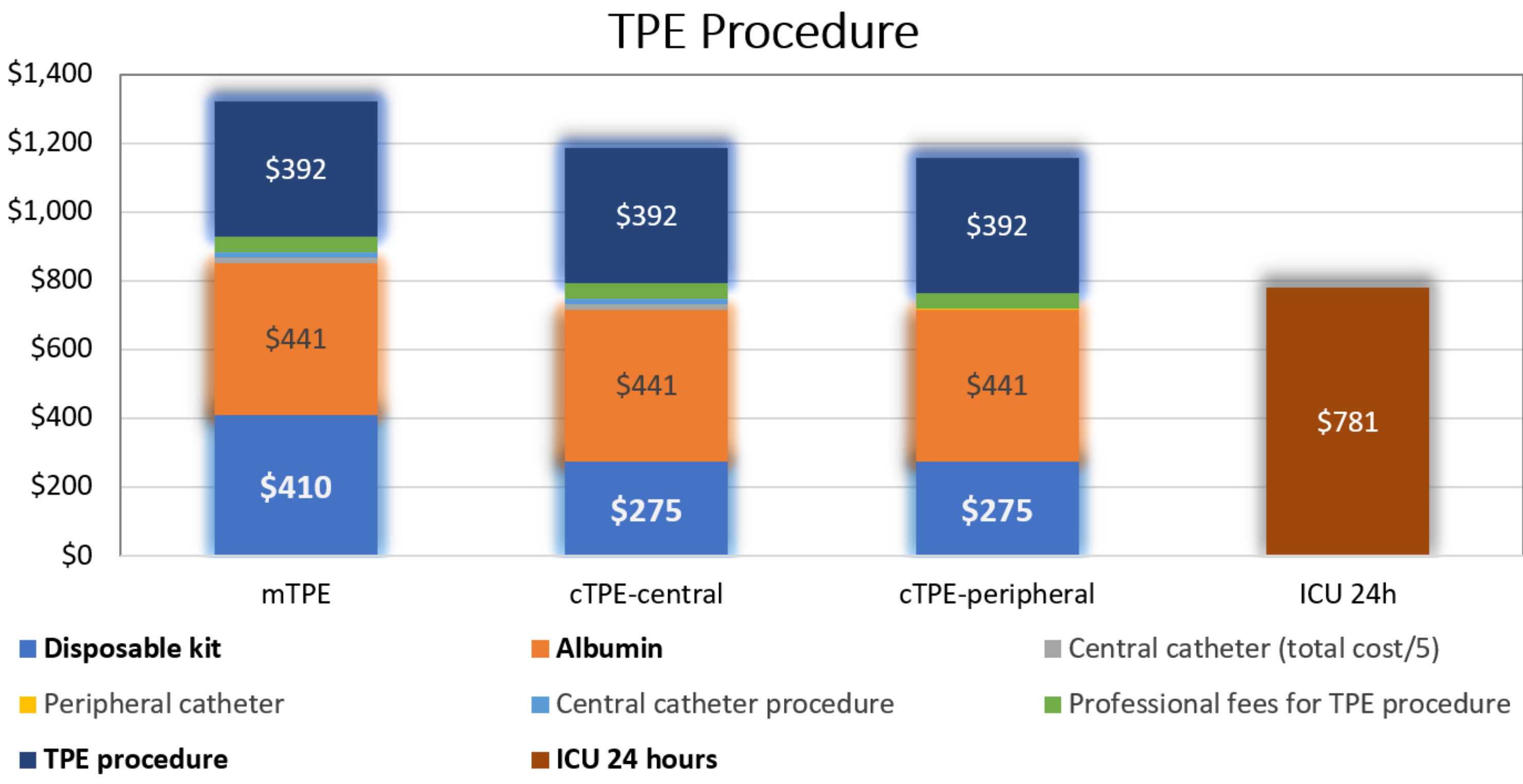


Figure 1. Analyzed costs for a TPE procedure using mTPE, cTPE with central access and cTPE with peripheral access; and the cost of 24-hour hospitalization in the ICU.

Parameters	TPE Procedure (USD)			Full Treatment (5 × TPE) (USD)		
TPE system	mTPE	cTPE-c	cTPE-p	mTPE	cTPE-c	cTPE-p
Disposable set	410	275	275	2,050	1,375	1,375
Albumin	441	441	441	2,205	2,205	2,205
Central catheter	16	16	-	79	79	-
Peripheral catheter	-	-	3	-	-	15
Central catheter procedure	15	15	-	75	75	-
TPE procedure	392	392	392	1,960	1,960	1,960
Professional fees TPE procedure	46	46	46	230	230	230
TOTAL COST (USD)	1,320	1,185	1,157	6,599	5,924	5,785

Table 1. Costs incurred for a TPE procedure and for a full treatment for mTPE, cTPE-c (central access) and cTPE-p (peripheral access).

DISCUSSION

- This study has assumed that both technologies have the same clinical and technical parameters to simplify the comparison between both technologies. However, in most of the peer-reviewed publications, cTPE outperforms mTPE with a faster TPE procedure and fewer adverse and clotting events. Therefore, it would be relevant to incorporate these parameters and perform a cost-simulation model with different data ranges to analyze all the possible scenarios and quantify in how many cases cost savings can be found in a healthcare center when a centrifuge medical device is used for TPE.
- It is of utmost importance to monitor the usage of the ICU because, if one TPE system would have higher severe adverse events than the other one, each episode would require at least 24 hours in the ICU. In addition, due to the complexity of the surgical procedure and its related events, the use of central access is associated with more ICU hospitalizations than the use of peripheral access. This would greatly increase the total cost of TPE, as 24 hours in the ICU costs USD \$781, and would decrease the operational efficiency of the healthcare system, overcrowding the required facilities.
- From the EPS perspective, it would be advisable to position and promote centrifugal TPE as the gold standard for all TPE procedures; from the hospital management perspective, it would be useful to determine which EPS can best provide centrifugal TPE to patients.

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