ORIGINAL ARTICLE

MEDICAL AND ECONOMIC ANALYSIS OF THE CHOICE OF THERAPEUTIC PLASMAPHERESIS METHOD TO OPTIMIZE THE TRANSFUSION CARE QUALITY

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ABSTRACT

The aim: To analyze the medical and economic aspects of the manual and different types of automatic plasmapheresis (manual, automatic centrifugal, automatic membrane, plasmapheresis with plasma therapy and mixed) used for therapeutic purposes.

Materials and methods: The Baxter Auto-C, Haemonetics PCS2, Haemophenics, Baxter CPDA anticoagulant and saline, Baxter 16GA needles were used. Total protein was examined by the biuret method, hemoglobin by the Sally method, total bilirubin by the colorimetric photometric method, cell fragments by the Goryaev camera microscopy method; patient comfort – with a 10-point scale. Healthy blood donors participated in the study. Manual plasmapheresis was performed in 31 people, automatic plasmapheresis with centrifugal technology – 36 people, with membrane technology – 21 people, mixed technology – 36 people.

Results: An analysis of the different technologies impact on hematological, psychological and medical and economic indicators was performed. Native hemoglobin was absent in the bloodstream and in the final plasma with all technologies. Bilirubin index was within normal limits. There were no cell fragments. It was proved the absence of significant differences in various technologies on hematological parameters. The lower level of patient comfort by manual plasmapheresis was established.

Conclusion: All therapeutic plasmapheresis technologies have the same effect on the patient's blood hematological parameters and did not have a negative impact on the body by the indicators: hemolysis, the presence of cell fragments, patient discomfort and citrate reactions during the standard procedure of sampling 800 ml of plasma. The most effective are plasmapheresis machines with centrifugal technology by medical and economic parametres.

KEY WORDS: automatic plasmapheresis, manual plasmapheresis, membrane plasmapheresis, centrifugal plasmapheresis, economic effect

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INTRODUCTION

Therapeutic plasmapheresis is one of the most modern techniques that can be used by physicians in almost all specialties [1-5]. According to the standards, plasmapheresis is used for pathological conditions resulting from autoimmune pathology, the presence of endo- and exopathology and infectious diseases, especially of viral etiology. According to studies conducted in Ukraine, the most common pathologies for therapeutic plasmapheresis are bronchial asthma, acne, viral hepatitis, psoriasis and alcohol intoxication, which indicates a narrower use of this method [6]. Plasmapheresis is divided into two types: therapeutic and donor [7]. There are five types of plasmapheresis: manual, automatic membrane, automatic centrifugal, plasmapheresis with plasma therapy and with mixed technology.

Manual plasmapheresis is carried aut as discrete collection of whole blood, its further separation and return of cells. Up to 400 ml of blood is taken at a time, in double or triple bags, using stirrer scales. The final blood is separated by centrifugation in special centrifuges. This high-cost and big equipment must be installed in a specially prepared room. In total, it takes about 2-3 hours and at least 4 sets of consumables to obtain 800 ml of plasma [7]. The advantage of this method is the availability of performance in clinics that have such equipment in blood transfusion departments. The disadvantage is not only the high cost of centrifuges, but also significant requirements for the room and the foundation of the building due to the potential danger of long-term vibrations with a large amplitude. Four sets of consumables, and the employment of the production unit with working hours of employees for up to 3 hours, can also be attributed to the disadvantages of significant costs. Also, the human factor is not excluded during this procedure, which, according to the GCP standard, is unacceptable.

Membrane plasmapheresis is a logical development of plasmapheresis. This procedure uses a filter that passes only blood plasma, trapping cells. Such filters are produced in the city of Dubno (Russia) using an elementary particle accelerator, that punches holes in the membrane of the appropriate size. Thanks to the static or pressurized pump, a transmembrane pressure is created, it pushes plasma through the filter element. The advantages of this method are the low volume of blood taken outside the body (this allows you to perform low-volume plasmapheresis without additional

effort) and the mobility of the device. The disadvantages are the need to create transmembrane pressure, which could theoretically lead to cell destruction, as well as the relatively high cost of the membranes and filters in general. It should also be kept in mind that some of these machines do not automatically control dilution with anticoagulant.

Centrifugal machines have a slightly larger volume of blood to be processed. Due to the fundamental difference in technology and the lack of high-cost materials in cost systems, the cost of one procedure is much lower. According to some authors, the use of a centrifuge can also lead to cell destruction, but we have not found confirmed data on this. In addition, from our personal experience, this was not observed. Among the advantages of this method, the high speed of the procedure, low cost, and the ability to use on the road are significant. These devices were primarily designed for donor plasmapheresis, so safety and reliability are at extremely high level; the normal load of these machines is up to 6 procedures per day [6]. The basis of this technique is the use of a centrifugal bell, which in a completely closed system, with single-needle access, that is periodically filled with whole blood, with roller pumps that have no contact with the blood itself. The rate of collection and return, as in membrane plasmapheresis is clearly controlled, a separate pump is used for dosing anticoagulant. Air sensors, are responsible for safety. Reliability, simplicity and mobility of a design made these automatic machines one of the market leaders.

Mixed type devices have a rotating membrane. In general, this system corresponds to the principle of operation of centrifugal devices, but is more expensive and immobile (can be moved only within the room).

Plasma therapy devices for plasmapheresis in Ukraine are beyong compare for the above methods, due to the complex use and incomparably higher price.

Nowadays in Ukraine the following plasmapheresis machines are used:

1. Scinomed
2. Nigale
3. Haemonetic
4. Fenwall (Baxter)
5. Haemophenix
6. AmPlTT (as Haemophenix)
7. AC-B-02
8. Phemos-PF [6].

There are plasma therapy machines and centrifuges presentsd on the market. However, the cost of the procedure with using these systems is much higher.

According to the research, the procedure of plasmapheresis is performed according to conventional methods, but the method of the course is very different, which allows to obtain different results for the same pathology on the same equipment.

Plasmapheresis is a modern technique in donation and therapy [8]. More and more blood centers in the world use the automatic method instead of the manual one [6]. And this despite the fact that the method is used for almost 100 years [7].

The procedure according to the analysis of many sources, does not differ depending on the type of equipment used. Any single-needle plasmapheresis is performed intermittently. Plasma is removed and the cells are returned to the patient. This method works on all methods of plasmapheresis, including manual, using the centrifuge (collecting whole blood in a plastic container, followed by centrifugation at a speed sufficient to separate the blood into components and separation on the device for squeezing). Plasma is moved to an additional package that is removed at manual plasmapheresis whole blood sampling of some volume (from 30 to 400 ml) then its separation on plasma on cells is carried out repeatedly.

Plasmapheresis is a complex procedure that requires highly qualified doctors. Thus, despite the fact that the history of the blood service of Ukraine dates back to 1918-1919 [9-10], the first plasmapheresis was performed only in the 1970s. It should be noted that in some clinical cases, plasmapheresis in combination therapy gives much better effect than conventional therapy [11]. Also, therapeutic plasmapheresis is often used to promote donor plasmapheresis as a useful procedure [12-20].

THE AIM

The aim of the work is to analyze the medical and economic aspects of the manual and different types of automatic plasmapheresis (manual, automatic centrifugal, automatic membrane, plasmapheresis with plasma therapy and mixed) used for therapeutic purposes.

To achieve this goal it is necessary to perform the following tasks:

1. To establish the difference between the influence of different plasmapheresis technologies on hematological blood parameters.
2. To highlight the negative impact of the studied technologies on the following indicators: hemolysis, the presence of cell fragments, discomfort and citrate reactions during the collection of 800 ml of plasma.
3. To establish the most effective technology for therapeutic plasmapheresis among the studied ones.

MATERIALS AND METHODS

The Baxter Auto-C machines with mixed technology (it includes rotating membrane technology), Haemonetics PCS2 machines (using centrifugal technology, blood separates in the bell during its rotation), Haemophenics machines (using filters «Rosa», separation occurs in them) for the study) were used. The Baxter CPDA anticoagulant and saline to compensate for hypovolemia were used. Vascular access was performed with 16GA needles.

Total protein was examined by the biuret method, hemoglobin by the Sali method, total bilirubin by the colorimetric photometric method, and cell fragments by the Goryaev camera microscopy method. The patient's comfort was assessed with a 10-point scale, where 10 is a state of complete comfort, 1 – a state of complete discomfort.

Table I. Comparison of methods

Type of technology	Mixed		Centrifugal		Membrane		Manual plasmapheresis	
	before	after	before	after	before	after	before	after
Access	1 needle 16GA		1 needle 16GA		1 needle 16GA		1 needle 16GA	
Procedure time	58±5		58±4		62±10		120±30	
Plasma volume, ml	800		800		800		800	
Total protein, g/l	75±4	73±5	79±6	74±2	70±3	68±8	72±1	70±6
Haemoglobin	145±7	146±6	140±10	142±6	135±7	136±8	148±9	145±4
Native haemoglobin in plasma	Missing		Missing		Missing		Missing	
Native haemoglobin in the channel	Missing		Missing		Missing		Missing	
Bilirubin	Norm		Norm		Norm		Norm	
Cell fragments	Missing		Missing		Missing		Missing	
Hematocrit	Norm	±5%	Norm	±5%	Norm	±5%	Norm	±5%
Patient comfort	9,2±0,8		9,6±0,4		8,9±1,1		7±2	
Used ml of anticoagulant	255ml±30		250 ml ±25		355 ml ±80		290 ml ±60	
Set cost, $ *	38		20		60		20	
Other expenses**	10		10		10		30	
The cost of the procedure	48		30		70		50	

* According to data obtained from open sources.
** According to the assessment of the blood center.

Blood donors admitted to the donation as healthy (participated) in this study. This eliminated the effects of pathological conditions in the result.

In total, manual plasmapheresis was performed in 31 persons, including 15 women and 16 men. Automatic plasmapheresis with centrifugal technology was performed in 36 persons, including 16 women and 20 men. Automatic plasmapheresis with membrane technology was performed in 21 persons, including 11 women and 10 men. Automatic plasmapheresis by mixed technology was performed in 36 person, including 18 women and 18 men.

RESULTS AND DISCUSSION

According to a survey in patients with plasmapheresis on a Baxter device, the level of comfort during the procedure according to a 10-point scale was 9.2 ± 0.8. We used anticoagulant CPD in an amount of 255 ml ± 30 ml ($p < 0,05$). At the same time the possibility of carrying out procedure without use of citrates at their replacement by heparin, in the corresponding dose for ensuring decrease in level of blood coagulation within to 1 hour remains. The cost of consumables was $ 38, and other costs were $ 10.

When performing the procedure on a Haemonetic device, according to a survey of patients, the level of comfort during the procedure according to a 10-point scale was 9.6 ± 0.4. We used anticoagulant CPD in an amount of 250 ml ± 25 ml ($p < 0,05$). At the same time, it is possible to perform the procedure without the use of citrates and replace them with heparin in the appropriate dose to reduce blood clotting for up to 1 hour. The cost of consumables was $ 20, and other costs were $ 10.

During using the Heamophenix device, the level of comfort during the procedure according to a 10-point scale was 8.9 ± 1.1. We used anticoagulant SPD in the amount of 285 ml ± 80 ml ($p < 0,05$). At the same time, it is possible to perform the procedure without the use of citrates and replace them with heparin in the appropriate dose to reduce the level of blood clotting for up to 1 hour. The cost of consumables was $ 60, and other costs were $ 10.

During manual plasmapheresis the level of comfort at procedure on a 10-point scale made 7 ± 2. We used anticoagulant GPD in the amount of 290 ml ± 60 ml ($p < 0,05$). At the same time, it is possible to perform the procedure without the use of citrates and replace them with heparin in the appropriate dose to reduce the level of blood clotting for up to 1 hour. The cost of consumables was $ 20, and other costs were $ 30.

As a result of comparing the effect of plasmapheresis on hematological parameters, no significant changes were shown, that indicates the same impact of this procedure on the body, regardless of the method by which it was performed (Table I).

Thus, the reduction of total protein occurs in all types of procedures without significant difference. In the analysis of the possible negative impact of different types of plasmapheresis, no significant differences were found. Thus, in no case did plasmapheresis lead to hemolysis, the presence of cell fragments that could be found in the methods we used.

Patient comfort is slightly reduced in manual plasmapheresis due to increased procedure time and accentuation of the patient, long cycles of collection and return, as well as significantly longer procedure time, according to the method associated with multiple blood sampling of 400-450 ml. To obtain plasma, this method requires from 4 to 6 cycles, which also include the preparation of containers with blood and its centrifugation. The use of high-cost centrifuges leads to increasing of depreciation costs and a significant increase in time of the procedure leads to a significant levels of cost of this procedure. In addition, this is indicated by the need for each cycle to use a new cost set and the involvement at this time of both nurses and doctors. Thus, the considerable time of the procedure with manual method, which also leads to an increase in its cost, the need to use special centrifuges that have special requirements for installation, make this method not competitive with automatic plasmapheresis. However, the greatest value in this case is the cost of the procedure, as shown by its effectiveness, there are no significant differences depending on the type of technique.

It should be noted that the procedure on a plasma therapy machine is very expensive due to the price, consumables, that are designed for more complex and technological procedures: hemofiltration, immunosorption, hemodialysis and others.

The cost of sets for machines such as Haemophenix is quite high due to the use of filtration technology, which according to some data is less traumatic to blood cells, but we did not find this effect in the study. Such filters are manufactured, using particle accelerators and other state-of-the-art technologies, but this makes them high-value.

Haemonetic machines (Scinomed iPCM, etc.) are designed primarily for donor plasmapheresis. That is why, in addition to high technology and quality, the manufacturer has another priority – the price, which is the lowest among the technologies we study. These machines are not inferior in quality and efficiency of the procedure for therapeutic purposes to other technologies. They also have European certification according to the standard of medical equipment. In the process of plasmapheresis, the patient, donating plasma, feels just as comfortable as when using other technologies. It should be noted that modern plasmapheresis machines are available in a large number of plasma centers, and can be used by doctors of medical institutions. This allows one to use these machines in a flexible mode and achieve high results in the treatment of most diseases.

Unfortunately, during the study it was not possible to compare the effect on the patient of plasma therapy machines on the studied technologies. This needs further study.

CONCLUSIONS

Based on the study, it was found that all 4 studied therapeutic plasmapheresis technologies have the same effect on the hematological parameters of the patients' blood in this study.

It was found that the study did not have a negative impact on the body by the following indicators: hemolysis, the presence of cell fragments, patient discomfort and citrate reactions during the standard procedure of sampling 800 ml of plasma in patients without predisposition to reactions.

It was found that the most perfect are plasmapheresis machines with centrifugal technology according to the result of medical and economic justification. They lead to increased efficiency by reducing the price with the same quality of procedures. It helps to improved quality of medical care. This is because efficiency is an inherent part of quality.

The results of this study can be used in clinical work when choosing a method of plasmapheresis, if the procedure on plasma therapy machines is impractical or unavailable.

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