

Complications in patients treated with plasmapheresis in the intensive care unit

Wojciech Szczeklik^{1,2}, Katarzyna Wawrzycka¹, Anna Włodarczyk¹, Aurelia Segal², Ilona Nowak²,
Bożena Seczyńska², Izabela Fajfer², Krzysztof Zając¹, Wiesław Królikowski^{1,2}, Maria Kózka³

¹*II Department of Internal Diseases, Jagiellonian University Medical College, Cracow, Poland*

²*IX Department of Anaesthesiology and Intensive Therapy, University Hospital in Cracow, Poland*

³*Faculty of Health Sciences, Jagiellonian University Medical College, Cracow, Poland*

Abstract

Introduction. Plasmapheresis is one of the methods of extracorporeal blood purification involving the removal of inflammatory mediators and antibodies. The procedure is used in a variety of conditions, including autoimmune diseases. The aim of the present study was to analyse the incidence of plasmapheresis-related complications in patients treated in the intensive care unit (ICU).

Methods. The analysis involved 370 plasmapheresis procedures in 54 patients. The data were collected from patients' medical records, including procedure protocols.

Results. The most common diseases treated with plasmapheresis included: myasthenia gravis (33.3%), Guillain-Barré syndrome (14%), Lyell's syndrome (9.3%), systemic lupus erythematosus (7.4%), and thrombotic thrombocytopenic purpura (7.4%). The adverse side effects observed most frequently during plasma filtration were: fall in arterial blood pressure (8.4% of all procedures), arrhythmias (3.5%), sensations of cold with temporarily elevated temperature and paresthesias (1.1%, each). In most cases the symptoms were mild and transient. Severe and life-threatening episodes, i.e. shock, fall in arterial blood pressure requiring pressor amines, persistent arrhythmias and haemolysis, developed in 2.16% of procedures.

Conclusions. Plasmapheresis can be considered a relatively safe method of treatment of ICU patients. Continuous observation and proper monitoring of patients provided by highly trained medical personnel are essential for its safety.

Key words: plasmapheresis, complications, intensive care

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Plasmapheresis is a method of extracorporeal plasma filtration designed to remove immunoglobulins (mainly autoantibodies) and pro-inflammatory factors (cryoglobulins, lipoproteins, immune complexes, immunoglobulin light chains), which are crucial for the pathogenesis of numerous diseases. The procedure is to separate plasma, hence eliminate the substances of high molecular weight, to return the blood morphotic elements and to supplement the fluid volumes lost [1]. The indications for plasmapheresis are based on recommendations of the working groups consisting of specialists in various fields and dealing with techniques of extracorporeal blood purification. The first consensus guidelines were presented by the American Medical Asso-

ciation in 1985 [2]; the recent ones were published by the American Society for Apheresis in June 2010 [3].

According to the categories of indications, plasmapheresis is a preferable, standard therapeutic method (IA category) for Guillain-Barré syndrome, Goodpasture's syndrome, familial hypercholesterolaemia, myasthenia gravis and thrombotic thrombocytopenic purpura. Moreover, plasmapheresis may be useful for the treatment of various neurologic, hematologic or nephrologic diseases (IB category), such as chronic inflammatory demyelinating polyradiculoneuropathy, cryoglobulinemia, hyperviscosity syndrome, paediatric autoimmune neuropsychiatric disorders (PANDAS), renal transplant rejection, Rh incompatibility-associated serolo-

gical conflict [3, 4, 5, 6]. Various ongoing studies focus on the usefulness of therapeutic plasma exchange in many other diseases.

As an invasive method, plasmapheresis is not complication-free. The incidence of severe, life-threatening complications is estimated at 0.025–4.75% of procedures [7, 8]. The adverse-side effects are associated with large vessel catheterisation, clotting disorders, septic complications resulting from impaired immunity caused by the removal of antibodies during the procedure, catheter-associated infections, and those related to transfusion of blood products. Moreover, life-threatening fall in arterial blood pressure, cardiac arrhythmias and water-electrolyte imbalance are likely to develop. Less severe reactions and symptoms are more common, e.g. urticaria, pruritus, limb paresthesias and pains, muscle contractions, dizziness, nausea, vomiting, transiently elevated temperature, shivers, seizures, head and chest pains. Taking into consideration all possible adverse events, together with isolated deviations from reference values in laboratory tests, which predominantly include: reduced levels of haemoglobin, thrombocytopenia, hypokalaemia, and reduced concentrations of fibrinogen [9], the total incidence of complications is estimated at 25–40% [10, 11]. The safety of procedures markedly depends on experiences of the therapeutic team and disease severity (stage).

The issue of plasmapheresis-related complications was comprehensively analysed and presented in studies involving several thousand patients [10, 12]; however, to date the problem has not been meticulously discussed in the intensive care unit (ICU) patients. Given severe general conditions of patients and specificity of ICU treatment, the number of complications in those patients can be higher. The aim of the present study was to assess their incidence.

METHODS

The study encompassed patients treated in ICU of the II Department of Internal Diseases, Jagiellonian University Medical College, Cracow, who underwent therapeutic plasma exchange procedures in the years 2006–2011. The study was observational, retrospective in nature without the control group.

Plasmapheresis procedures were performed using the filtration method and Hospal BSM devices. The vascular access was provided by placing a central venous catheter according to the Seldinger technique. In all cases, the double-lumen 12 Fr/16 or 12 Fr/20 cm cannulae were inserted. The extracorporeal circulation circuits consisted of a set of drains (Achim Schulz-Lauterbach VMP GmbH; Iserlohn, Austria) and capillary plasma filters Hemaplex BT 900 (Dideco; Mirandola, Italy). Prior to the procedure, the system was filled with 0.9% NaCl solution. The plasma filter was deaerated according to the manufacturer's instructions. The procedures of plasma-

pheresis were performed daily or every second day and the duration of one procedure did not exceed 4 h. The mode of plasmapheresis depended on the patient's clinical condition and the underlying disease.

The type and amount of supplementary fluids depended on the patient's clinical condition and were based on monitoring of cardiovascular functions, water-electrolyte and acid-base balance. Patients received on average 1000–1500 mL of crystalloids, 500–1000 mL of colloids and 3–4 units of fresh frozen plasma (FFP), i.e. about 930 mL. In each case, 400 mL of 20% albumin solution together with antihistamine drug (before the administration of FFP) and 5 mL of 10% calcium gluconate for each unit of transfused plasma were administered. The procedures were planned in such a manner as to transfuse the amount of fluid equal to the volume of plasma removed. The substitutive fluids were mainly colloids (including gelatin preparations and 20% albumin solution) and crystalloids (0.9% NaCl, multi-electrolyte and Ringer's solutions). Additionally, patients received FFP by the end of procedure to prevent the filtration of the proteins transfused. The proportions of fluids infused were tailored individually for each patient depending on his/her clinical condition.

Non-fractionated heparin, with the initial dosage 3000 units, was administered with the initial dosage for necessary anticoagulation; its supply was continued in the intravenous infusion in a dose of 1000–1500 U/h⁻¹ under the control of activated clotting time (ACT). If required, patients received additional doses of heparin.

The rate of blood flow depended on the circulatory efficiency and was maintained within the limits of 50–60 mL min⁻¹. Transmembrane pressure (TMP) was within 20–70 mm Hg. During one procedure, 1.4 of estimated plasma volume (EPV) was exchanged. EPV was calculated according to the Kaplan formula based on body weight and haematocrit (Ht): $EPV = [0.065 \times \text{body weight (kg)}] \times (1 - Ht)$. On average, the exchanged plasma volume was 40–50 mL kg⁻¹ body weight, which constitutes 2800–3500 mL for a patient weighing 70 kg. Sixty-three percent of procedures were completed with the zero fluid balance. In the remaining cases, the difference between the amounts of transfused fluids and separated plasma ranged from –200 to +500 mL.

The patient's clinical status was strictly monitored to detect pre-, intra- and post-procedure adverse side effects. The following vital parameters were assessed: heart rate, arterial blood pressure, central venous pressure, arterial haemoglobin oxygen saturation, frequency and nature of respirations, body temperature, diuresis, and awareness; skin was observed searching for possible rash or erythema. Moreover, technical parameters of procedures were regularly controlled, i.e. TMP, blood pressure (BP), ultrafiltration, flow and temperature of substitutive fluids. ACT was measured at least three times during the procedure.

The standard monitoring involved blood tests, in particular, concentrations of haemoglobin, haematocrit, RBC, WBC and PTC. During the coagulation tests, the prothrombin time (PT), expressed as the international normalized ratio (INR), activated partial thromboplastin time (APTT) and fibrinogen levels were controlled. Furthermore, the concentrations of electrolytes — potassium, sodium, calcium and bilirubin were measured. The tests were performed before and after the procedure. The course of plasmapheresis, supply of drugs and fluids supply and test findings were noted in the medical records. The procedure protocol contained a record of orders and a plasmapheresis course monitoring record, including vital signs (arterial blood pressure, heart rate, SpO₂, central venous pressure) and technical parameters (TMB, BP, ultrafiltration volume). Additionally, laboratory results, vascular access type, fluid balance, type of a filter were written down and the final report prepared.

The procedures were analysed as for complaints reported by patients, clinical symptoms observed, procedure-related problems and deviations from reference values in laboratory tests. The changes in general patients conditions during procedure were compared with information obtained from medical records, the therapy instituted, plasmapheresis protocols, laboratory results, observation charts, and ICU epicrisis.

Prior to assessment of the course of plasmapheresis in individual patients, possible adverse events were defined. A fall in arterial blood pressure was defined as a drop in baseline value by over 20%. Abnormal heart rate was determined according to the WHO definitions. Fever was

defined as an increase in body temperature above 38° C, at normal baseline value.

The abnormalities in laboratory tests included: anaemia (haemoglobin concentration < 14 g dL⁻¹ for male and < 12 g dL⁻¹ for female patients), leukocytopenia (WBC < 4 G L⁻¹), thrombocytopenia (PTC < 150 G L⁻¹), hypokalaemia (serum potassium level < 3.5 mmol L⁻¹), hyponatraemia (serum sodium level < 135 mmol L⁻¹), and hypercalcaemia (serum calcium level < 2.1 mmol L⁻¹).

RESULTS

The study included 54 patients aged 19–85 years, 27 women and 27 men. In total, 370 plasmapheresis procedures were carried out. The mean number of procedures per one patient was 7 per one patient (95% CI: 6–8); one female patient with therapy-resistant thrombotic thrombocytopenic purpura underwent 27 procedures. Twenty-six patients were undergoing procedures on a daily basis, whereas 28 every other day. In 13 patients plasmapheresis was the only therapeutic method administered and in 41 was combined with steroid therapy and immunosuppression; 21 (39%) patients required mechanical lung ventilation on admittance for plasmapheresis. Clinically significant improvement was observed in 91% of patients. The types of diseases necessitating the institution of plasmapheresis and therapy outcomes were presented in Table 1.

THERAPY OUTCOMES

In patients requiring mechanical ventilation on initiation of plasmapheresis, the improvement was defined as the

Table 1. Diseases diagnosed in ICU patients treated with plasmapheresis and therapy outcomes

Disease	Number of patients (%) (n = 54)	Clinically significant improvement* Number of patients with improvement/all patients with a given disease
Myasthenia gravis	18 (33.3%)	16/18 (89%)
Guillain-Barré syndrome	14 (25.9%)	13/14 (93%)
Lyell's syndrome	5 (9.7%)	5/5 (100%)
Systemic lupus erythematosus (with rapidly progressing renal failure)	4 (7.4%)	4/4 (100%)
Thrombotic thrombocytopenic purpura	4 (7.4%)	3/4 (75%)
Granulomatosis with vasculitis (Wegener's granulomatosis)	2 (3.7%)	2/2 (100%)
Schonlein-Henoch purpura	1 (1.85%)	1/1 (100%)
Microscopic vasculitis	1 (1.85%)	1/1 (100%)
Other, undetermined vasculitis	1 (1.85%)	1/1 (100%)
Idiopathic thrombocytopenic purpura	1 (1.85%)	1/1 (100%)
Mixed connective tissue disease	1 (1.85%)	1/1 (100%)
Brainstem demyelination	1 (1.85%)	0/1 (0%)
Non-demyelinating myopathy	1 (1.85%)	1/1 (100%)

*criteria of "clinically significant improvement" accepted by authors for individual diseases are described in the text

Table 2. Complications during plasmapheresis

	Compilation	Incidence (all procedures n = 370)
Life-threatening	Fall in the arterial blood pressure requiring pressor amines/shock	4 (1.08%)
	Arrhythmias requiring pharmacological treatment	3 (0.81%)
	Haemolysis	1 (0.27%)
Non-life-threatening	Arterial blood pressure fall not requiring pressor amines	27 (7.30%)
	Arrhythmias requiring fluid supply or subsiding spontaneously	10 (2.7%)
	Anxiety/agitation requiring sedation	5 (1.35%)
	Sensation of cold/paresthesias	4 (1.08%)
	Allergic reactions	3 (0.81%)
	Lower limb pain	3 (0.81%)
	Fever	2 (0.54%)
	Abdominal pain	2 (0.54%)
	Eyelid tremor	1 (0.27%)

possibility of the endotracheal tube removal and the ability to maintain normal gas exchange parameters at passive oxygen therapy. In patients with myasthenia gravis, significant improvement, considered as a reduction in disease severity by two grades according to the Osserman classification compared to the admission values, was achieved in 89% of patients. In patients with Guillain-Barré syndrome, clinical improvement was defined as restored respiratory efficiency and increased muscle strength in the limbs by 2 points according to the Lovett scale. In the group treated for immune thrombocytopenic purpura, the marker of primary disease improvement was assumed as the absence of fresh bleeding features such as skin and mucous lesions (petechiae and internal bleeding) and improved parameters of peripheral blood morphology. In Lyell's syndrome patients, clinical improvement was considered to be reduced skin lesions allowing to discharge patients from ICU, without infection symptoms and opioid analgesics required.

In some patients whose underlying disease was accompanied by kidney damage, the concentration of creatinine after the plasmapheresis cycle decreased by 41% (on average). Five patients (9%) showed no anticipated plasmapheresis-related positive effects. These patients were admitted due to idiopathic thrombocytopenic purpura, Guillain-Barré syndrome, myasthenic gravis and brainstem demyelination and died relatively long after the completion of plasmapheresis.

COMPLICATIONS

88.9% of procedures were carried out without complications. During the plasmapheresis therapy, 65 adverse effects were observed associated with the deterioration of clinical condition. In 10 cases, interventions were required due to procedure-related technical problems. During some procedures, more than one complication developed. Pla-

smapheresis was discontinued five times (1.35% of procedures) — 3 times (0.81% of procedures) because of increased symptoms of shock, bleeding due to mechanical damage to a vascular cannula and haemolysis; twice (0.54% of procedures) due to too high TMP and filter clotting.

Complications of procedures were presented in Table 2.

The most common adverse effect was fall in the arterial blood pressure. Eleven episodes of hypotension were accompanied by significant changes in the heart rate. Tachycardia was observed in 70% of cases and bradycardia requiring the administration of atropine in 30% of cases. Isolated abnormal heart rate without reduced arterial blood pressure was noted twice (0.54%). During 19 procedures, interventions were decided due to prolonged hypotension or abnormal heart action. In the vast majority of such cases (12 procedures, 7 patients), infusions of additional amounts of fluids (gelatine solution) were sufficient to stabilise the cardiovascular parameters. In 4 patients (1.08% of procedures), the institution of pressor amines (dopamine) or their increased doses were needed; in 3 of them plasmapheresis was discontinued due to persistent hypotension despite the treatment provided. After discontinuation, the cardiovascular system stabilised.

Allergic reactions were observed during three procedures (0.81%), i.e. micromacular rash accompanied by moderate pruritus. One patient received hydrocortisone in a single bolus. During two procedures, body temperature increased, yet spontaneously normalised.

Episodes of bleeding from the areas of vascular accesses developed in two cases (0.54%). One resulted from mechanical damage to the vascular cannula and the other one accompanied severe disseminated intravascular coagulation unrelated to plasmapheresis. The pathological bleeding from mucous membranes and organ haemorrhages were not observed in any procedure.

Table 3. Abnormalities in laboratory test results

Abnormality	Number of patients with abnormal results (n = 54) (% of all patients)
Anaemia	40 (74.07%)
Leukocytopenia	7 (12.96%)
Thrombocytopenia	32 (59.26%)
Hypokalaemia	19 (35.19%)
Hyponatraemia	12 (22.22%)
Hypocalcaemia	19 (35.19%)

Patients reported symptoms like: cold/transiently elevated body temperature, anxiety, lower limbs and abdominal pain, eyelid tremor. The complaints were of mild or moderate severity and subsided; therefore, discontinuation of procedures was not necessary. Analgesics (pethidine, fentanyl in continuous infusion) were required in 2 cases and additional sedatives in 4 cases.

Technical plasmapheresis-related problems (observed in 2.16% of patients) resulted from complete or partial occlusion of catheters; in 4 patients (1.08%) of procedures, cannulae had to be replaced. When problems with proper inflow to the filtration circuit occurred, first the catheter position was changed, which in most cases was sufficient. In five cases, plasmapheresis catheters were replaced due to suspected sepsis of unknown origin with positive blood cultures or accompanying local inflammatory reactions around the insertion site.

Abnormal laboratory results were presented in Table 3.

DISCUSSION

Analyzing the incidence of adverse events in presented study, one should consider, that it was overtaken in the population of the ICU patients. Other studies describing complications of plasmapheresis, emphasize the fact, that in patients with severe comorbidities, especially those requiring mechanical ventilation and on aminopressors, the prevalence of adverse events during plasmapheresis is significantly higher [11, 13, 14]. In our study all patients undergoing plasmapheresis were in severe clinical condition and required ICU hospitalisation; nonetheless, the method was effective in 91% of patients and contributed to the subsidence of symptoms of the underlying disease. Similarly to reports from other centres, the best therapeutic effects were obtained in immunological and acute processes, i.e. Guillain-Barré syndrome, myasthenic crisis, acute renal injury in the course of vasculitis or acute thrombocytopenic purpura and Lyell's syndrome [15, 16, 17, 18, 19].

As an invasive method, plasmapheresis is not complication-free. The incidence of complications was estimated at 11.1%; however, the majority of them were mild. The life-threatening complications include fall in arterial pressure

in arterial blood pressure, shock, arrhythmias and haemolysis. Such incidents in our populations were observed only in 8 procedures (2.16%). The remaining adverse events were not severe and transient as they subsided spontaneously or required minor interventions.

In the analysed group, the most common complications were fall in arterial blood pressure, and accompanying arrhythmias. Their causes include disproportion between the volume of transfused fluids and of removed plasma, anaphylactic or vasovagal reactions, fluctuations in serum ion concentrations and bleedings. Hypotension generally subsided after fluid supply and pressor amines were rarely necessary. Strict monitoring of patient's hydration status and basic vital parameters, elimination of complication-contributing factors, including the use of vasodilating drugs, are essential for prevention of serious episodes of hypotension. The procedures should be particularly meticulously planned in patients with the history of hypotension during earlier plasmapheresis procedures and with arrhythmias before the institution of therapy.

The side effects most frequently described in literature result from the supply of citrate, which can be used as an anticoagulant within the circuit and filter, being also the constituent of the plasma transfused. Citrate binding of calcium ions leads to a reduction in its serum concentration. Hypocalcaemia decreases the cell irritability threshold and is likely to induce a wide spectrum of tetany or paresthesia symptoms. In most cases, the symptoms are slight, however, it is worth remembering that they can cause discomfort or anxiety and hinder the completion of plasmapheresis. The above symptoms were rare in our population, which can result from the fact that 10% calcium solution was routinely administered during each procedure.

Allergic reactions are rare yet in patients with the history of atopy, they are a risk factor of anaphylactic shock. To prevent them, antihistamine drugs are recommended, which were also used in our ICU before the administration of FFP during plasmapheresis. Huge impact of proper hydration of patients should be strongly re-emphasised.

If we would consider abnormalities in laboratory test values as complications of the plasmapheresis, than they would be present even in 89% of procedures. In the context of the results of additional tests, the main attention should be paid to patient's condition and ICU settings, in which the majority of patients have abnormal morphological and biochemical results. In our patients, periodically occurring anaemia did not translate into the development of clinical symptoms.

Lower WBC counts could have affected increased susceptibility to infections; however, the pathomechanism of infections in the group described is complex and it is difficult to attribute them exclusively to plasma exchange

procedures. The immune disorders accompanying the underlying diseases, numerous comorbidities or specificity of the diagnostic-therapeutic process in ICU are involved. Patients treated in ICUs undergo many invasive procedures associated with a significant risk of hospital-acquired infections. Finally, the methods of treatment in the studied group should be taken into consideration. Immunosuppressive drugs were administered to 76% of patients. The key role in reduced immunity of individuals treated with plasmapheresis is played by depletion of immunoglobulins and complement component 3 and 4 (C3, C4). All the factors mentioned above explain relatively high incidence rates of septic complications in patients undergoing plasmapheresis and, together with laboratory findings, should be the signal for enhanced observation of patients to detect possible fever and other features of infections.

Abnormalities in coagulation tests can be expected due to continuous supply of heparin. They may also be associated with the removal of the majority of plasma clotting factors during plasmapheresis. Although quite frequently detected, they are not usually accompanied by clinical symptoms. However, increased bleeding can develop during the procedures, which was observed twice in our study. To prevent bleedings, clinical observation in search of possible internal haemorrhage and ACT control during the procedure are crucial. Moreover, determinations of fibrinogen concentrations may be valuable. Reduced levels are characteristic of patients whose procedures are complicated by haemorrhages. A small proportion of patients may require additional supply of fresh frozen plasma or transfusion of platelet concentrates. Moreover, it is noteworthy that the removal of a substantial amount of antithrombin and other antithrombotic factors increases the risk of thromboembolic diseases [21].

In the pathogenesis of adverse events, lower efficacy of pharmacologic therapy in individuals undergoing plasmapheresis should be considered. This phenomenon is caused by the removal of drugs from blood during filtration; the amount of the drug removed depends on its ability to bind proteins. Blood concentrations significantly decrease in following therapeutics: acetylsalicylic acid, cefazolin, ceftriaxone, chlorpropamide, diclofenac, heparin, ibuprofen, valproic acid, warfarin, thyroxine, phenytoin and others [15]; however, this problem has not been fully elucidated and requires further studies.

The complications related to technical aspects of plasmapheresis largely depend on the experience of the personnel performing procedures. In many cases, early detection of increased TMP, shortened ACT and clotting on the filter during the procedure can prevent severe complications.

While analysing the effectiveness of plasmapheresis, special attention should be paid to cases in which the expected clinical improvement was not observed. During the the-

rapy, the condition of four patients deteriorated; however, the relation between this deterioration and plasmapheresis chosen as a therapeutic method is difficult to prove. The markedly advanced stage of the underlying disease led to death of one patient during plasmapheresis therapy. The affection of vital organs by the disease indicated poor prognosis already on admission to the Unit, irrespective of the therapy instituted. In one case, the cause of death was bacterial infection. Two patients who died several days after the completion of plasmapheresis had numerous comorbidities before the exacerbation of the underlying disease — arterial hypertension, diabetes mellitus type 2, chronic renal disease and respiratory failure.

Assessing the results of the present study, its limitations should be taken into account. Due to the retrospective nature of our study and a variety of the underlying diseases, detailed intragroup statistical analysis was impossible. Moreover, it was not possible to compare the incidences of complications in mechanically ventilated and spontaneously breathing patients undergoing passive oxygen therapy because of small sizes of groups.

Nonetheless, the above limitations do not challenge the importance of the study, which demonstrates that plasmapheresis procedures in patients treated in the intensive care unit were highly effective and life-threatening complications were rare (2.16% of procedures). The incidence rates observed in our study are comparable to the data from various centres in the USA, Sweden, and Italy [10, 15, 22]. Thus, the procedure is relatively safe and its benefits in selected diseases outnumber the risks of complications, particularly when administered by the experienced therapeutic team.

CONCLUSIONS

1. Plasmapheresis can be considered as a relatively safe therapeutic method for patients hospitalised in intensive care units.
2. Continuous observation and proper monitoring of patients provided by highly trained personnel are essential for procedure-related safety.

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Corresponding author:

Wojciech Szczeklik MD, PhD

II Department of Internal Diseases,
Jagiellonian University Medical College, Cracow
ul. Skawińska 8, 31–066 Kraków, Poland
tel.: +48 12 430 53 14, fax: +48 12 430 50 68
e-mail: wszczeklik@gmail.com

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