Renal Replacement Therapy

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Efficacy of selective plasma exchange as pre-transplant apheresis in ABO-incompatible kidney transplantation

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Abstract

Background: Selective plasma exchange (SePE) is a new simple plasma exchange (PE) modality that enables removal of small and medium-sized molecules without removing larger substances such as coagulation factors. In this study, we examined the efficacy of SePE for removal of isoagglutinins in pre-transplant desensitization for ABO-incompatible (ABOi) kidney transplantation.

Materials and methods: A case series study was performed in 15 ABOi kidney transplant recipients (KTRs) who underwent SePE alone (7 cases) and SePE in combination with double-filtration plasmapheresis or simple plasma exchange (8 cases). The target processed plasma volume (PV) was set at 2 PV, and 5% albumin solution was used as the substitution fluid in all SePE sessions. Changes in isoagglutinin titers (IgG and IgM) and serum IgG, IgM, and fibrinogen levels were examined. We also compared the decrease in isoagglutinin titers between SePE and conventional methods (PE and double-filtration plasmapheresis).

Results: A total of 29 sessions of SePE were performed in the 15 KTRs. Isoagglutinin titers were controlled to ≤ 1:16 in all patients except for 2 with high isoagglutinin titers, and there were no cases of antibody-mediated rejection. SePE led to a median twofold decrease in isoagglutinin titers (IgG and IgM), with median IgG, IgM, and fibrinogen removal rates of 64.2, 11.7, and 25.5%, respectively. Side effects occurred in only 4 of the 29 sessions. Neither titer decreased after SePE in 30% of the sessions. However, the reductions in isoagglutinin titers in patients undergoing SePE were significantly less than those in patients treated with conventional methods.

Conclusion: Because SePE is less efficient in removing isoagglutinins compared to conventional methods, the use of SePE alone should be limited to patients with low isoagglutinin titers, and SePE in combination with conventional methods should be used for patients with high isoagglutinin titers. SePE may be a useful treatment option, if applied in appropriate cases, due to its lower cost (about half the price of PE using fresh frozen plasma in Japan) and fewer side effects. However, care is required because about 25% of fibrinogen is removed during SePE.

Keywords: Kidney transplantation, Selective plasma exchange, Apheresis, ABO-incompatible

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Introduction

Recently, pre-transplant apheresis is less frequently being performed in ABO-incompatible (ABOi) kidney transplantation for patients with already low isoagglutinin titers or those successfully desensitized by immunosuppressants such as rituximab [1–6]. However, multiple sessions of apheresis are still performed at many institutions for isoagglutinin removal in pre-transplant desensitization for ABOi kidney transplantation [7–11]. Double-filtration plasmapheresis (DFPP), simple plasma exchange (PE), and antigen-specific immunoadsorption (IA) are also often performed as methods of apheresis in ABOi kidney transplantation [12–14].

Repeated DFPP or PE (using albumin solution as substitution fluid) can cause a marked loss in coagulation factors [15, 16], which can then cause perioperative bleeding, especially if the last session was performed on the day before the transplant [17]. With PE, there have been reports of treatment being suspended due to side effects such as allergic reactions to fresh frozen plasma (FFP) [18, 19]. This is particularly disadvantageous for hemodialysis (HD) and apheresis combination therapy because both apheresis and HD may have to be discontinued due to allergic reactions. Antigen-specific IA using Glycosorb®-ABO columns is a useful method that causes fewer side effects without removing coagulation factors, but the columns cost about 3000 euro each [13]. Moreover, the use of this column has not been approved in Japan.

Selective plasma exchange (SePE) is a new simple PE modality that uses a membrane plasma separator with a smaller pore size compared to conventional plasma separators and enables removal of small and medium-sized molecules without removing larger substances such as coagulation factors [20]. SePE has increasingly been reported as an effective method in cases where the etiologic agent can be removed [21–24], since it exhibits fewer side effects through the use of albumin as the substitution fluid, in contrast to the use of FFP in PE. SePE also has a cost benefit because albumin is cheaper than FFP. SePE is about half the price of PE using FFP in Japan. However, a disadvantage of SePE is that it is less effective in removing relatively larger molecules, and SePE requires a greater volume of substitution fluid compared with regular PE [20]. In this study, we examined the efficacy of SePE for removal if isoagglutinins in pre-transplant desensitization for ABOi kidney transplantation.

Patients and methods

Study design and participants

A retrospective, case series study was conducted in patients with end-stage renal disease who underwent ABOi kidney transplantation with apheresis therapy from January 2015 to December 2017 at Osaka City University Hospital. The inclusion criteria were kidney transplant recipients (KTRs) who had undergone at least one session of SePE. Patients with donor-specific antibodies were excluded. A total of 15 KTRs were enrolled in the study.

This study protocol was conducted in accordance with the Principles of the Declaration of Helsinki and the Declaration of Istanbul and was approved by the ethics committee of the Osaka City University Graduate School of Medicine (No. 4009). Opt-out consent was obtained instead of written informed consent; i.e., we provided the patients with information explaining the proposed research project (the purpose, required individual data, and duration of the study) by means of an information sheet or hospital website and gave them the opportunity to opt out. The demographic and baseline clinical data are presented in Table 1.

Desensitization protocols

Desensitization was conducted by immunosuppressive therapy, centering on rituximab, and apheresis to reduce the pre-transplant isoagglutinin titers (immunoglobulin G (IgG) and IgM) to ≤ 1:16 [8, 25–27].

1. Immunosuppression protocols [4, 28]: The pre-transplant desensitization regimen included 4 weeks of mycophenolate mofetil (MMF; 1 g/day). Patients aged ≥ 65 years old underwent treatment with 0.5 g/day MMF for 4 weeks. Almost all patients with titers < 1:512 underwent treatment with a single dose of rituximab (150 mg/m^2) 2 weeks before transplantation. Patients with titers > 1:512, rebound of antibody titers, or donor-specific antibodies underwent both splenectomy at transplantation and treatment with two doses of rituximab (150 mg/m^2) 2 weeks before and on the day of transplantation. Post-transplant immunosuppression consisted of a calcineurin inhibitor (tacrolimus or cyclosporine, initiated 3 days prior to transplantation), MMF or everolimus, steroids, and two doses of basiliximab.
2. Apheresis protocols: For removal of isoagglutinins, patients underwent 1 to 13 sessions (at least 1 session) of apheresis (PE, DFPP, SePE) before transplantation until isoagglutinin titers decreased to < 1:16. In earlier cases (cases 1 and 2), SePE was performed in patients with high titers. However, after we learned that this procedure was not as effective as DFPP and PE in reducing isoagglutinin titers, SePE was performed after the isoagglutinin titers were reduced to some extent by DFPP or PE in patients with high titers (> 1:64). Currently, SePE alone is performed once or twice in patients with isoagglutinin titers < 1:32.

Table 1 Characteristics and results of the study subjects

Case	Order and frequency of apheresis including SePE	SePE +HD	Sex/ age	Donor (sex/ age)	Relationship	Blood type	Isoagglutinin titers (IgG)			Isoagglutinin titers (IgM)		
							Base	At Tx	Max	Base	At Tx	Max
1	DFPPx1 → SePEx6	No	M/ 67	F/66	Spouse	AB+ → O+	256/ 256	32/ 128	256/ 256	16/ 16	8/8	16/ 16
2	SePEx2 → PE(f)x1 → PE(a)×1 → PE(f)×1 → DFPP×1 → PE(a)×7	Yes	F/60	M/58	Spouse	B+ → O+	1024	64	1024	512	1	1024
3	DFPPx1 → PE(f)×1 → SePE×1	Yes	F/64	M/59	Spouse	A+ → B+	16	8	32	16	2	16
4	DFPPx2 → SePEx1	Yes	F/32	M/55	Parent	AB+ → B+	8	1	16	8	1	16
5	DFPPx1 → PE(a)×1 → DFPP×1 → SePE×1	Yes	F/39	M/61	Parent	B+ → O+	256	4	256	32	2	32
6	DFPPx2 → SePEx1	No	M/ 44	F/67	Parent	B+ → O+	64	8	64	32	2	32
7	DFPPx2 → SePEx1	No	F/69	M/69	Spouse	AB+ → B+	16	< 1	16	16	1	16
8	SePEx2	Yes	F/44	F/48	Sibling	B+ → A+	1	< 1	1	2	1	2
9	SePEx2	Yes	M/ 52	F/50	Spouse	B+ → A+	4	1	4	4	1	4
10	SePEx2	Yes	M/ 53	F/49	Parent	B+ → A+	8	2	16	4	2	8
11	SePEx2	Yes	M/ 53	F/50	Spouse	B+ → A+	8	2	8	4	4	4
12	SePEx2	Yes	M/ 53	F/55	Spouse	B+ → A+	2	1	1	2	1	2
13	PE(f)x1 → SePEx3	No	M/ 51	F/50	Spouse	A+ → B+	32	1	32	32	1	32
14	SePEx2	No	M/ 37	M/39	Spouse	A+ → B+	16	8	32	8	4	32
15	SePEx1	No	M/ 53	M/55	Sibling	B+ → A+	16	8	16	16	8	16

SePE selective plasma exchange, *DFPP* double-filtration plasmapheresis, *PE (f)* simple plasma exchange using fresh frozen plasma as the substitution fluid, *PE (a)* simple plasma exchange using 5% albumin solution as the substitution fluid, *HD* hemodialysis, *M* male, *F* female, *IgG* immunoglobulin G, *IgM* immunoglobulin M, *Tx* kidney transplantation

Conditions for performing SePE (Fig. 1)

Plasmapheresis therapies were performed using a KM-9000 (Sanyo Electronic Industries Co., Ltd. Okayama, Japan) or TR55X (Toray Medical Co., Ltd. Tokyo, Japan) blood purification system. SePE was performed using an Evacure Plus EC-4A10 (Evaclio, EC-4C in overseas model) (Kawasumi Laboratories, Inc., Tokyo, Japan) selective plasma separator [29]. The volumes used for priming the circuit were about 370 mL in SePE (about 320 mL in PE). Albumin solution (5%) was used as the substitution fluid in all SePE sessions. During SePE, blood flow was maintained at 100 ml/min with a plasma separation rate of 30 ml/min, and unfractionated heparin or nafamostat mesilate was used as the anticoagulant. Plasma volume (PV) was calculated using the following equation [30]: $PV = (BW/13) \times (100\text{-}Ht)/100$, where BW and Ht indicate body weight (kg) and hematocrit (%), respectively. The target processed PV was set at 2 PV. In tandem HD and SePE, SePE was performed in parallel with the HD circuit, with a blood flow rate of 100 mL/min into the SePE circuit (Fig. 1). The cost of SePE using 2 PV 5% albumin solution is about half the price of PE using 1.5 PV FFP.

Measurement of clinical data

Isoagglutinin titers were measured by the tube centrifugation test, anti-A/B IgM titers were determined using the saline agglutination technique, and IgG titers were evaluated using the indirect Coombs test. Changes in isoagglutinin titers and serum IgG, IgM, and fibrinogen levels were studied, in addition to any adverse effects. The removal rates (RR) of IgG, IgM, and fibrinogen were corrected for the change in hematocrit (Ht) with the change in colloid osmotic pressure, using the following equation [30]: $RR = [1\text{-pre Ht } (1\text{-post Ht}/100) \text{ post-conc}/\text{post Ht } (1\text{-pre Ht}/100) \text{ pre-conc}] \times 100$, where pre Ht and post Ht indicate hematocrit (%) before and immediately after apheresis, respectively.

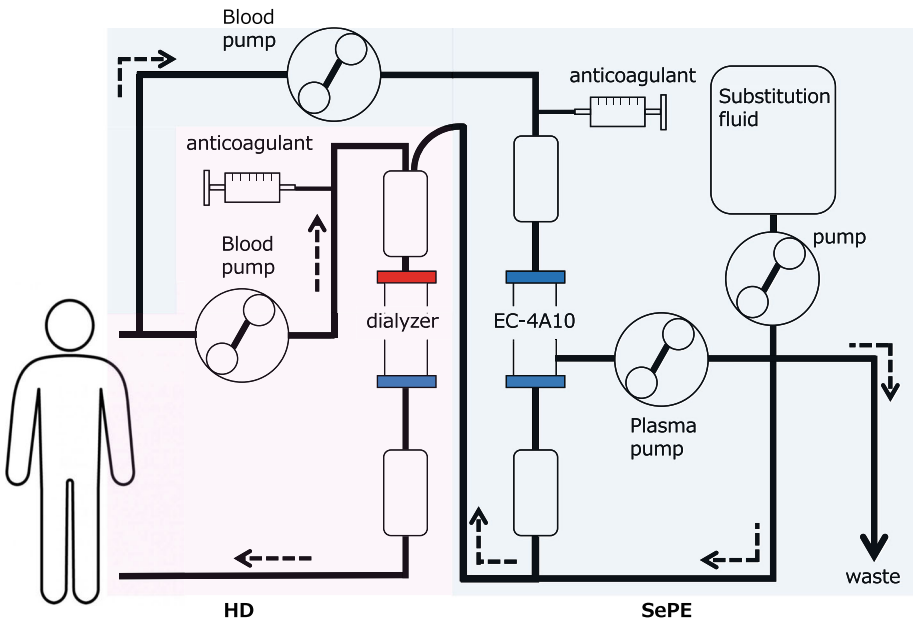

Fig. 1 Selective plasma exchange circuit with hemodialysis

Statistical analysis

Baseline demographic and clinical characteristics are summarized as the median and interquartile range for continuous variables and counts and percentage for categorical variables. In order to examine the effect of SePE on the isoagglutinin titers change rates, multivariable proportional odds ordinal logistic regression models were used with IgG and IgM as independent variables, separately. In these models, baseline values of isoagglutinin titers were adjusted. In the analysis, changes in isoagglutinin titers were counted individually for anti-A and anti-B in case 1 because the kidney was transplanted from AB + → O+. All statistical analyses were two-sided with a 5% significance level and were performed using R version 3.3.2 (https://www.r-project.org/foundation/) with the "rms" and "RcmdrPlugin.EZR" packages.

Results

Characteristics of subjects (Table 1)

A total of 29 sessions of SePE were performed in 15 KTRs, including SePE alone (7 KTRs) and SePE in combination with DFPP or PE (8 KTRs). HD and SePE combination therapy was performed in 9 KTRs and SePE monotherapy was performed in 6 KTRs (3 peritoneal dialysis and 3 preemptive kidney transplantation). Isoagglutinin titers were controlled to ≤ 1:16 in all except 2 KTRs with high titers (cases 1 and 2, who also underwent splenectomy) before transplantation, and there were no cases of antibody-mediated rejection. There were two cases of acute rejection (case 6 and case 9, 13.3%). Side effects occurred in 4 of the 29 sessions, including general ill feeling and hot flashes in case 1, nausea and hypotension in case 4, epigastric distress in case 8, and leg cramps in case 15. No circuit coagulation occurred in all sessions. All were considered to be minor side effects and were improved by symptomatic treatment.

Median decrease and removal rate by SePE (Table 2)

There was a median twofold decrease in isoagglutinin titers (IgG and IgM) by SePE. The median removal rates (%) of IgG, IgM, and fibrinogen were 64.2 [60.1–68.1], 11.7 [8.3–18.3], and 25.5 [18.0–32.2] %, respectively.

Comparison of the reduction volumes distribution in isoagglutinin titers between SePE and conventional methods (PE, DFPP) (Figs. 2 and 3)

The reduction in isoagglutinin titers was compared between SePE (29 sessions) and conventional methods (4 sessions of PE using FFP, 9 sessions of PE using 5% albumin solution, and 11 sessions of DFPP). The distribution of reductions in isoagglutinin titers (IgG and IgM) with each modality are shown in Figs. 2 and 3, respectively.

Table 2 Median decrease and removal rate of clinical data by SePE

Isoagglutinin titers (IgG)	Isoagglutinin titers (IgM)	IgG	IgM	Fibrinogen
× 2	× 2	64.2%	11.7%	25.5%

SePE selective plasma exchange, *IgG* immunoglobulin G, *IgM* immunoglobulin M

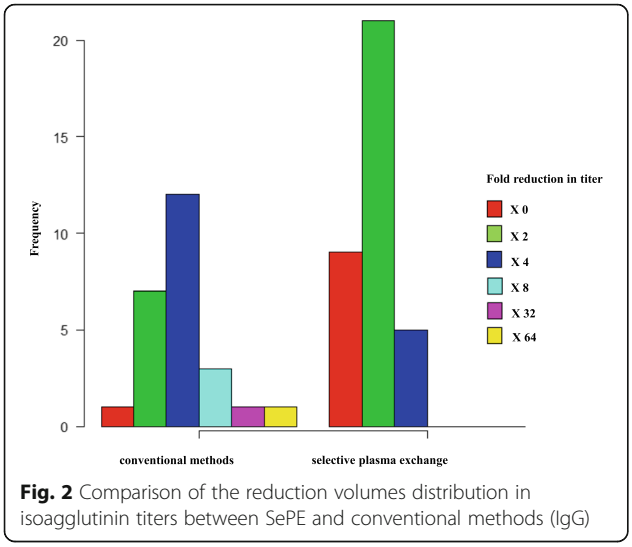

Fig. 2 Comparison of the reduction volumes distribution in isoagglutinin titers between SePE and conventional methods (IgG)

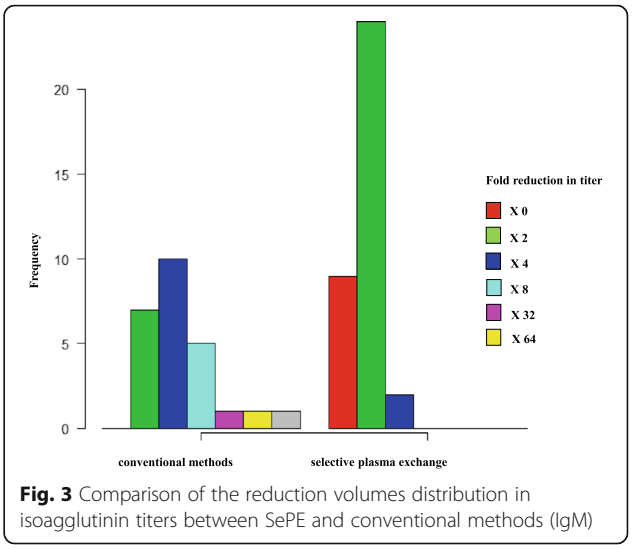

Fig. 3 Comparison of the reduction volumes distribution in isoagglutinin titers between SePE and conventional methods (IgM)

Neither titer decreased after SePE in about 30% of the sessions (IgG; 10/29, IgM; 9/29).

Comparison of the reduction volumes in anti-blood group antibody titers between SePE and conventional methods (PE, DFPP) (Table 3).

The reduction volumes of isoagglutinin titers of patients with SePE ($n = 29$) were significantly less than those of patients with conventional methods (PE, DFPP) ($n = 25$) ($P < 0.001$ for both IgG and IgM).

Discussion

Since 2015, we have performed SePE as an apheresis modality for ABOi kidney transplantation. In 29 SePE sessions performed in 15 KTRs without any incidence of antibody-mediated rejection, we were able to control isoagglutinin titers (IgG, IgM) to ≤ 1:16 [8, 25–27] in all except 2 KTRs with high antibody titers. There was a median twofold decrease in isoagglutinin titers in our patients undergoing SePE. The median removal rate of fibrinogen was 25.5%. Side effects occurred in only 4 of the 29 sessions. However, the reduction in isoagglutinin titers in patients undergoing SePE was significantly less than that in patients treated with conventional methods. This study is the first report of the use of SePE for isoagglutinin removal in pre-transplant desensitization for ABOi kidney transplantation.

Initially, we performed SePE in KTRs with high isoagglutinin levels, but we found that this was not as effective as conventional methods (PE, DFPP) for removal of isoagglutinins, even when using 2 PV of substitution fluid (cases 1 and 2). Therefore, we subsequently decided to first perform DFPP or PE in KTRs with high isoagglutinin levels, followed by SePE after these levels were reduced sufficiently. A median twofold decrease in isoagglutinin titers was obtained using SePE (Table 2), but the titers did not decrease at all in 30% of the sessions (Figs. 2 and 3) and the reduction in isoagglutinin titers in SePE was significantly less than that with conventional methods (Table 3). These results suggest that SePE alone is sufficient for KTRs with isoagglutinin titers ≤ 1:32, but in KTRs with titers ≥ 1:64, it is preferable to first perform PE or DFPP and decrease isoagglutinin to ≤ 1:32 before performing SePE.

The sieving coefficient of IgM was 0, according to the manufacturer's reported value for Evacure Plus EC-4A10 [20], and the actual removal rate was approximately 10%, with the isoagglutinin (IgM) titers decreasing in the same manner as the isoagglutinin (IgG) titers (Figs. 2 and 3). This may have been caused by adsorption to the membrane, but the precise mechanism remains unclear.

Regarding coagulation factors, although the sieving coefficient of fibrinogen is reported to be 0 [20], the actual removal rate was about 25%. Based on scanning electron microscopy imaging, Ohkubo et al. [31] found that fibrinogen reduction by SePE using EC-4A10 is due to membrane fouling by substances such as fibrinogen fibrils. When DFPP is performed repeatedly, the fibrinogen levels decrease considerably [15, 16], such that 25%

Table 3 Comparison of decrease volumes in isoagglutinin titers between SePE and conventional methods (PE, DFPP)

Variable	IgG titers		IgM titers	
	Odds ratio (95%CI)	*P* value	Odds ratio (95%CI)	*P* value
SePE or not	0.059 (0.017–0.205)	$P < 0.0001$	0.014 (0.002–0.091)	$P < 0.0001$

These odds ratios and *P* values were adjusted for pre-isoagglutinin titers. *SePE* selective plasma exchange, *PE* simple plasma exchange, *DFPP* double-filtration plasmapheresis, *IgG* immunoglobulin G, *IgM* immunoglobulin M, *CI* confidential interval

removal by SePE becomes disadvantageous. In such cases, aggressive FFP transfusions are desirable.

With respect to side effects, we were able to perform SePE safely with only a few minor side effects, due to the use of albumin rather than FFP [18, 19]. In addition, because 5% albumin solution was used, there were few incidences of hypotension, even though fluid removal was performed in tandem with HD.

The study has some limitations. First, our sample size was small and there was no control group, and a further study with a larger sample size and a control group is needed to confirm the results. Second, with respect to the graft function, investigation of the long-term impact of this protocol may be necessary. Third, further studies are needed to compare the therapeutic efficacy of SePE monotherapy with conventional methods (PE, DFPP, IA).

In conclusion, because SePE is less efficient in removing isoagglutinins compared to conventional methods, the use of SePE alone should be limited to patients with low isoagglutinin titers, and SePE in combination with conventional methods should be used for patients with high isoagglutinin titers. SePE may be a useful treatment option, if applied in appropriate cases, due to its lower cost (about half the price of PE using fresh frozen plasma in Japan) and fewer side effects. However, care is required with the use of SePE because about 25% of fibrinogen is removed.

Abbreviations

ABO-i: ABO-incompatible; DFPP: Double-filtration plasmapheresis; FFP: Fresh frozen plasma; HD: Hemodialysis; Ht: Hematocrit; IA: Immunoadsorption; KTRs: Kidney transplant recipients; MMF: Mycophenolate mofetil; PE: Simple plasma exchange; PV: Plasma volume; RR: Removal rates; SePE: Selective plasma exchange

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Availability of data and materials

The data and materials were all included in the manuscript.

Authors' contributions

A.H. (first author) and T.N. (corresponding author) contributed to the concept, design, data acquisition, interpretation, and writing. D.K. and A.S. contributed to the data analysis and interpretation. Y.T., U.J., and T.N. reviewed and revised the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study protocol was conducted in accordance with the Principles of the Declaration of Helsinki and the Declaration of Istanbul, and was approved by the ethics committee of the Osaka City University Graduate School of Medicine (No. 4009). Opt-out consent was obtained instead of written informed consent; i.e., we provided the patients with information explaining the proposed research project (the purpose, required individual data and duration of the study) by means of an information sheet or hospital website and gave them the opportunity to opt out.

Consent for publication

For publication of this manuscript, opt-out consent was obtained by means of an information sheet or hospital website.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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