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ARTICLE SUMMARY: SAFETY OF PLASMA EXCHANGE THERAPY IN PATIENTS WITH MYASTHENIA GRAVIS

OVERVIEW
To assess the safety of PLEX in patients with moderate-to-severe myasthenia gravis (MG) and provide guidance for patient selection.

AUTHORS
Ebadi H, Barth D, Bril V

TERUMO BCT
10811 West Collins Avenue, Lakewood, Colorado 80215-4440 USA

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BACKGROUND

Multiple reports regarding plasma exchange (PLEX) in patients with myasthenia gravis (MG) have indicated that it is safe and effective, but it is still considered to be a complicated treatment with difficulties such as prescribing PLEX, vascular access, and a requirement for vascular access. There is also concern about the use of PLEX in elderly patients and in those with significant clinical comorbidities.

TREATMENT AND DATA COLLECTION

These investigators collected data prospectively from 42 patients with MG randomized to PLEX treatment in a comparison study versus intravenous immunoglobulin (IVIG) (Gammunex 10%; Talecris Biotherapeutics). All patients had worsening moderate-to-severe MG as determined by Quantitative Myasthenia Gravis Score (QMGS) > 10.5.

PLEX treatments were performed on an apheresis device (Spectra Optia® Apheresis System and COBE® Spectra Apheresis System; Terumo BCT, Lakewood, Colorado). Each patient received up to 5 PLEX procedures with one plasma volume exchanged per procedure. Treatments were given every other day with breaks allowed for weekends for most patients.

Five percent albumin was used as the replacement fluid and 0.5 g of 10% calcium gluconate was added to each 500-mL 5% albumin bottle to prevent citrate reactions. An acid citrate dextrose solution was used for anticoagulation.

Peripheral and central venous access was performed.

GRADING OF ADVERSE EVENTS

Adverse events with PLEX were rated as follows:

- Grade I, mild (no treatment required)
- Grade II, moderate (intervention required, but treatment completed)
- Grade III, severe (procedure interrupted or abandoned)
- Grade IV, fatal

RESULTS- SAFETY

- Forty-two patients, including 19 men (45%) and 23 women (55%), were treated with PLEX for a total of 203 procedures.
- PLEX was performed in the outpatient apheresis clinic in 38 patients (90%) and as an inpatient procedure in 4 patients (10%).
- Twenty-three patients (55%) had no complications during 115 PLEX treatments.
- Adverse events in the remaining 19 patients (88 PLEX treatments) are summarized in Table 1.

Table 1. Adverse Events With PLEX*

Grade I	▪ Tingling in lips and hands (citrate reaction)–3 ▪ Re-siting of IV line–5 ▪ Cold and numb hands (vasospasm)–5
Grade II	▪ Abdominal cramps and nausea (vasovagal)–1 ▪ Tingling in hands and feet (citrate reaction)–3 ▪ Hypotension and numbness in extremities (vasospasm)–1 ▪ Vomiting and hypotension (vasovagal)–1 ▪ Leg swelling–1 ▪ Clot in tube–1
Grade III	▪ Poor IV access–4 ▪ Severe tingling and numbness in distal limbs (vasospasm)–1 ▪ Unilateral facial weakness and hypotension (vasospasm)–1

*Numbers indicate numbers of adverse events.

- The complication rate was the same in patients with and without comorbid disease.
- Thirty-five patients (83%) completed all PLEX treatments using peripheral venous access. Four patients (10%) completed all PLEX treatments using a central venous line due to poor venous access. Three patients (7%) switched from peripheral venous access to central venous access after the first PLEX was done peripherally. Two of these switches were due to poor venous access, and one was due to vasovagal reaction during peripheral venous access.

EFFICACY

- Patients treated with PLEX had baseline QMGS ranging from 11 to 30. There was a reduction in the mean (± standard deviation) QMGS score by 4.7 ± 4.9 units at day 14 after the end of PLEX treatment (Barth et al, *Neurology* 2011). This benefit was maintained through day 28 (mean reduction 4.7 ± 5.7 units).
- Overall, 57% of the patients treated with PLEX responded based on a minimum QMGS improvement (decrease) of ≥ 3 units.
- Post-intervention patient evaluation indicated that 65% improved, 31% remained stable, and 2% worsened.
- No patient required additional treatment after PLEX until day 14.
- After the end of the study, 8 patients required additional treatment; 4 patients received additional PLEX. Three of these patients continued to worsen, were withdrawn from PLEX, and treated with other modalities.

AUTHORS' CONCLUSIONS

- Side effects were observed in about 50% of patients, but most were mild, readily treated, and did not interfere with ongoing treatment.
- The PLEX procedure can be performed safely in the outpatient setting by peripheral venous access in the majority of patients with MG and the duration of treatment is about 2 hours.
- These results show that PLEX is safe and effective for patients with MG.

REFERENCES

Ebadi H, Barth D, Bril V. Safety of plasma exchange therapy in patients with Myasthenia Gravis. *Muscle Nerve*. 2013;47(4):510-514.

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Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

Terumo BCT Asia Pte. Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

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