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Allison Gandey is a journalist for Medscape. She is the former science affairs analyst for the Canadian Medical Association Journal. Allison, who has a master of journalism specializing in science from Carleton University, has edited a variety of medical association publications and has worked in radio and television. She can be contacted at agandey@webmd.net.

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Immunoglobulin Similar to Plasma Exchange in Myasthenia Gravis

Allison Gandey

April 26, 2011 (Honolulu, Hawaii) — A new study comparing intravenous immunoglobulin to plasma exchange in patients with myasthenia gravis has found the 2 approaches comparable.

Presenting at plenary here at the American Academy of Neurology 63rd Annual Meeting, investigators unveiled the results of the study, scheduled to be published in *Neurology* later this year.

"The duration of treatment effect and the tolerability of both treatments is very similar," Vera Bril, MD, from the University of Toronto in Ontario, Canada, said at the meeting. "Either treatment may be offered to patients, depending on availability of resources."

Dr. Vera Bril

The results are considered to provide Class 1 evidence, she added. The field has been limited by a lack of evidence from adequately powered randomized clinical trials. This study was funded by Talecris Biotherapeutics, which markets intravenous immunoglobulin as *Gamunex.*

Investigators randomized 84 patients with moderate to severe myasthenia gravis, defined as a Quantitative Myasthenia Gravis Score for disease severity of greater than 10.5 and worsening weakness. The score is a validated summary score ranging from 0 to 39 points assessing various functions, such as head lifting, grip strength, and vital capacity.

Patients received intravenous immunoglobulin, 1 g/kg/day for 2 consecutive days, or 1.0 plasma volume exchanges for 5 exchanges. Investigators evaluated patients at day 14 after treatment.

Interestingly, Dr. Bril noted that she and another colleague had a bias going into the study toward plasma exchange. However, they found that both approaches reduced the Quantitative Myasthenia Gravis Score.

A difference of 5 points was required between treatments to conclude one was superior to the other, but the decline between groups did not reach that threshold, Dr. Bril said.

Table 1. Change in Quantitative Myasthenia Gravis Score for Disease Severity

Change	Immunoglobulin	Plasma Exchange	*P* Value
Baseline score	14.2 ± 4.0	14.4 ± 3.8	.83
Change from day 0 to 14	3.2 ± 4.1	4.7 ± 4.9	.13

Patients were considered responders if their score improved by 3.5 points or more. When they limited consideration to responders, the difference again was not significant between groups. "If you do a numbers needed to treat on this, you'd need to treat 14 people to find 1 person who might do better with" plasma exchange vs intravenous immunoglobulin, she noted.

Table 2. Responders

Measure	Immunoglobulin	Plasma Exchange	*P* Value
Percentage	51	57	.50

Table 3. Postintervention Status at Day 14

Outcome	Immunoglobulin	Plasma Exchange	*P* Value
Improved	69	65	.74
Stable	10	31	.07
Worse	17	2	.10

"The dropout rate was the same in both treatment arms, and both treatments were well tolerated," Dr. Bril said. In all, 15 patients withdrew — 10 patients receiving immunoglobulin therapy and 9 receiving plasma exchange.

"It's hard to think that one of these treatments had a better and longer-lasting effect than the other given this disposition of patients," she noted.

A total of 18 patients needed additional treatment after day 14 — 10 of these were receiving immunoglobulin therapy and 8 were receiving plasma exchange.

Dr. Bril pointed out that patients with greater baseline disease severity had a greater response to therapy ($P = .005$). The presence of antiacetylcholine receptor antibody also predicted a better response ($P < .001$).

The most common adverse events with immunoglobulin therapy were headache, nausea, vomiting, fever, and chills. For plasma exchange, vasospasm was seen, as well as citrate reactions, she noted. "One patient had an episode of heart failure that was thought not related to treatment, and 1 patient had a myocardial infarction that was thought possibly related to treatment," she added.

During the question period following the presentation, Robert Miller, MD, from the California Pacific Medical Center, in San Francisco, congratulated Dr. Bril and her team for taking on such a challenging area of study.

"Isn't it interesting how similar these results are to those in Guillain-Barré syndrome, where we've seen the same story of comparable efficacy and very similar adverse events," Dr. Miller commented. "Bravo for doing it because I think in myasthenia gravis we've had much less evidence until now."

This study was funded by Talecris Biotherapeutics. Dr. Bril has worked as a consultant for the company. She has also worked as a consultant for Lilly, Eisai, Pfizer, and CSL.

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