Sciatica Helped Little by IV Methylprednisolone

BY TIMOTHY F. KIRN
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SAN ANTONIO — A single, intravenous injection of methylprednisolone performed just slightly better than placebo in alleviating pain from acute discogenic sciatica, Axel Finckh, M.D., said at the annual meeting of the American College of Rheumatology.

Dr. Finckh presented a study in which 59 patients with radiographically confirmed discogenic sciatica were randomized to either a single, 500-mg, intravenous bolus of methylprednisolone or to placebo, and then followed for 10 days.

Both groups had significant improvement in pain on the first day, as shown with a 100-point, visual analog scale, with a greater mean improvement for the methylprednisolone group.

However, mean scores in both groups were about the same by the third day and remained comparable through day 10.

Both groups had gradual diminishment of pain from day 3 onward, said Dr. Finckh, of Brigham and Women's Hospital, Boston.

Nor were response rates significantly different on a straight leg test for radicular irritation, a McGill Pain Score for global pain, a flexibility score, and a functional disability questionnaire, Dr. Finckh explained.

The patients in the study had all had sciatica for at least 1 week, and not more than 6 weeks, prior to being treated.

Use of nonsteroidal anti-inflammatory drugs was permitted.

The use of corticosteroids in sciatica is controversial, Dr. Finckh said.

Most studies of oral administration have not demonstrated any benefit.

Some studies of epidural administration, however, have shown positive findings.

His group conducted the study because they hypothesized that giving the corticosteroid intravenously might be a way to achieve high drug levels quickly, without the risks and pain typically associated with epidural administration.

Despite the negative results, Dr. Finckh seemed unwilling to give up completely on intravenous injection for sciatica.

He noted that 48% of the steroid-treated patients had pain improvement, versus 28% of the placebo patients.

Long-term treatment using the technique might have more of an effect, he said. ■

Scleroderma Responds to Stem Cell Transplant

BY NANCY WALSH
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SAN ANTONIO — A small group of patients with severe systemic sclerosis have shown a durable response to autologous hematopoietic stem cell transplantation, with 8 of 13 transplanted patients remaining alive after a mean follow-up of 44 months, Zora Marjanovic, M.D., reported at the annual meeting of the American College of Rheumatology.

Stem cell transplantation has in recent years been investigated for use in diseases such as scleroderma following observations that some patients with autoimmune disease who undergo transplantation for hematopoietic or other malignancies also may experience a remission of the autoimmune disease after the procedure.

In the first sequential open phase I-II study assessing the feasibility of autologous stem cell transplantation for systemic sclerosis with early visceral involvement, patients were eligible if they had rapidly progressing disease with heart, lung, or kidney involvement, Dr. Marjanovic said in a poster session.

The transplant protocol involved mobilization with cyclophosphamide plus recombinant human granulocyte colony-stimulating factor (GCSF) or GCSF alone if the left ventricular ejection fraction (LVEF) was less than 40%.

Subsequent conditioning, which took place at least 4 weeks after mobilization, used cyclophosphamide, 200 mg/kg, or melphalan, 140 mg/m^2 if the LVEF was less than 40%.

Outcomes following reinjection of CD34+ and hematopoietic stem cells were classified as major response, partial response, no response, disease progression, or relapse. Patients were assessed every 3 months.

Of the 14 patients enrolled in the nonrandomized trial, 13 were transplanted; 1 withdrew after mobilization.

One procedure-related death occurred, she said.

Six months following transplantation, nine patients responded to treatment—six had major responses and three had partial responses.

After a mean follow-up of 44 months, 8 of the responding patients were alive, 4 have died from disease progression. One nonresponding patient remains alive.

During the follow-up period, five patients relapsed but eventually responded to reintroduction of immunosuppression by mycophenolate mofetil. Four of these were partial responses, and one was a major response, said Dr. Marjanovic of University Hospital Center Saint-Louis, Paris, France.

This trial demonstrated that autologous hematopoietic stem cell transplantation is feasible in severe scleroderma, with low toxicity and significant clinical benefits, she said.

In a report published earlier and based on 12 of the patients, toxicity associated with the procedure included infections occurring during the neutropenic period of mobilization; these were managed with antibiotics (Br. J. Haematol. 2002;119:726-39).

There were also two episodes of mucositis and three cases of mild hepatic toxicity during intensification.

Stem cell transplantation is now being compared with monthly cyclophosphamide in an ongoing phase III trial, Dr. Marjanovic said.

In the Autologous Stem Cell International Scleroderma (ASTIS) trial, patients with diffuse systemic sclerosis and visceral involvement who are at risk for severe organ dysfunction and premature mortality are being prospectively randomized to the experimental transplant procedure or standard monthly intravenous pulse therapy with cyclophosphamide.

As of October 2004, 41 patients from 16 centers in eight European countries have been enrolled. The primary end point is event-free survival during 2 years of follow-up. Information is available at www.astistrial.com. ■

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