To the Editor:

A main finding in the study by Idei et al was that patients who underwent bone marrow mononuclear cell (BM-MNC) implantation had a highly significantly higher major amputation-free survival rate than patients who did not undergo BM-MNC implantation.

A major amputation is not a spontaneous event such as stroke or myocardial infarction. Before reaching a decision concerning amputation, there is interaction between the patient and a surgeon. A surgeon nonblinded to type of treatment may have been more prone to recommend amputation in control patients who had not received a promising new therapy, and a patient who has undergone a painful but promising new therapy may be more prone to delay an amputation in a hope that the new therapy will alleviate ischemic symptoms and promote wound healing.

A 100% amputation rate within 8 months for the 30 patients in the atherosclerotic peripheral arterial disease control group is higher than reported in previous reports. At least some of the 24 patients in this group who were in Rutherford category 4 and 5 would be expected not to have undergone amputation within 8 months.

Only patients in the control group and not those in the BM-MNC implantation group were reported as being considered candidates for major amputation, indicating that the treatment of the BM-MNC implantation group was different from that of the control group in ways not dictated by the experimental design. Also, patients reportedly stopped smoking before treatment with BM-MNC implantation, but no account is given of the smoking status of the no-implantation groups, and no follow-up report of smoking status is given, although smoking status may be of importance for limb survival.

It is not reported whether the visual analog pain scores were assessed by the patients or by an examiner. Results could have been biased by an examiner enthusiastic about the new therapy or by a placebo effect in patients eager to improve after receiving a new and promising but invasive treatment.

Diabetes mellitus and hemodialysis were found to correlate with major amputation in patients with critical limb ischemia. It is unclear why this finding made the authors conclude that critical limb ischemia patients with diabetes mellitus who are undergoing hemodialysis may not be eligible for cell therapy.

Limb ischemia is usually diagnosed by the observable effects the ischemia has on the tissues and not by angiography as stated in the Methods section. Angiography is used to diagnose the cause of the ischemia.

In the legend to Table 1, the meaning of “versus before (0 days) in the same group” is unclear.

Disclosures

None.

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References

Letter by Dregelid Regarding Article, "Autologous Bone-Marrow Mononuclear Cell Implantation Reduces Long-Term Major Amputation Risk in Patients With Critical Limb Ischemia: A Comparison of Atherosclerotic Peripheral Arterial Disease and Buerger Disease"
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Circ Cardiovasc Interv. 2011;4:e12
doi: 10.1161/CIRCINTERVENTIONS.111.961375

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