

Stem cell therapy in spinal trauma: Does it have scientific validity?

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Sir,

I read with interest the article “stem cell therapy in spinal trauma: Does it have scientific validity?”¹ in Indian Journal of Orthopaedics. I tend to agree with the authors when they say that due to the complexity of spinal cord injuries (SCIs) a single approach may not be successful in achieving SCI repair. As they have highlighted in Table 2 of their article¹, majority of the studies in literature worldwide have shown no or poor results of stem cell therapy in SCI patients; although a few isolated case reports claim to have good results but, unfortunately, refrain from disclosing the surgical technique and themselves advice further research to reach any conclusive evidence in favor of stem cell therapy.²

One very interesting aspect other than scientific validity I would like to emphasize in this letter is the question of legal sanctity of stem cell therapy in SCI in India. Indian Council of Medical Research has stated that “at present, there are no approved indications for stem cell therapy other than the hematopoietic stem cell transplantation for hematological disorders. Accordingly, all stem cell therapies other than the above shall be treated as investigational and conducted only in the form of a clinical trial after obtaining necessary regulatory approvals. Use of stem cells for any other purpose outside the domain of clinical trial will be considered unethical and hence is not permissible. National guidelines for stem cell therapy-2013 states that any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial shall be considered as malpractice. These guidelines apply to all stakeholders including individual researchers, organizations, sponsors, oversight/regulatory committees and any others associated with both basic and clinical research on all types of human stem cells and their derivatives.”³

This piece of information in my view is must know for every spine surgeon in India to prevent them from going overboard with the “lucrative” stem cell therapy. I wish authors had covered this important aspect of legal sanctity of the procedure in their manuscript.

REFERENCES

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