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Controlled clinical trials and efficacy: report of a neurosurgical study[☆]

Estudios clínicos controlados y eficacia: a propósito de una investigación en neurocirugía

Dear Editor:

I was particularly interested by a recent article published in your journal, on the “efficacy” and safety of microsurgical treatment of trigeminal neuralgia.¹ Without discrediting the valuable results reported, the article opens a debate on the importance of proper reporting of research by the type of results obtained. Talking about efficacy in a retrospective,



observational study using data from medical histories and comparing different age groups is certainly the result of poor comprehension and interpretation of methodological rigour, a pillar of clinical research, which enables us to distinguish between different types of research according to their validity. It is widely known that the efficacy of an intervention is assessed with clinical studies conducted in “controlled conditions,” whereas the effectiveness of an intervention is shown in observational studies in “real conditions,”^{2–4} as in the mentioned study.

In the field of neurosurgery, there has been a considerable decrease in the use of rigorous analytical designs to assess the efficacy of an intervention, as used in controlled clinical trials; the trend over the past 20 years shows that there has not been a proportional increase in the disciplines of neurology and neurosurgery, as is clear from the statistical figures obtained from studies included on the MEDLINE

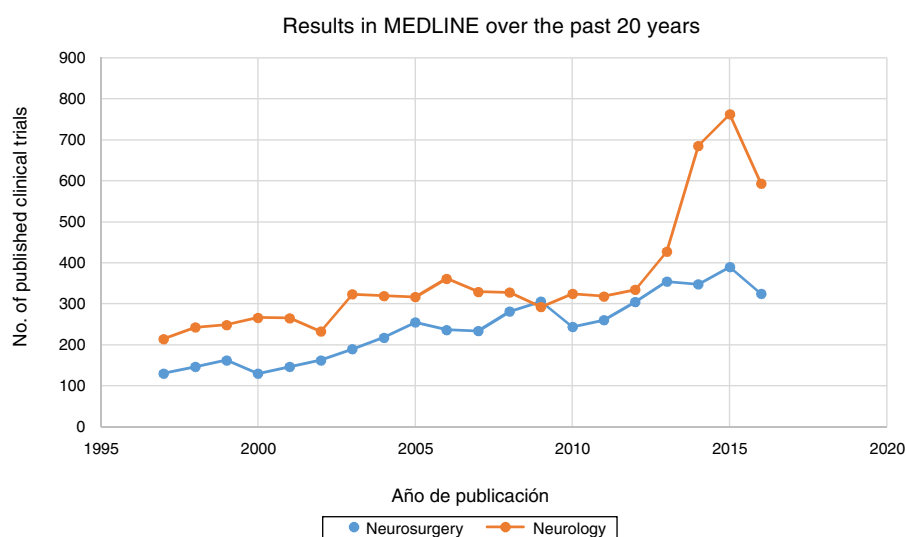


Figure 1 Clinical trials in neurology and neurosurgery published on MEDLINE over the past 20 years.

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database (Fig. 1) (Source: data obtained from MEDLINE, available from: <https://www.ncbi.nlm.nih.gov/pubmed/>).

One of the causes related to this poor progression may be the inherent difficulty of performing adequately controlled and randomised trials with this type of patients⁴; however, this justification should not diminish the quality of the limited number of efficacy studies in neurosurgery; rather, it should help us improve the quality of the reports from observational studies. In this respect, we should mention the promotion work carried out by the EQUATOR network, an international initiative to improve the reliability and value of healthcare research literature.⁵ The proposed guidelines include the STROBE initiative,⁶ aimed at reporting observational studies; this is an appropriate tool for the published study, which should be reviewed by the authors.

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Reply to the letter to the editor «Controlled clinical trials and efficacy: Report of a neurosurgical study»[☆]



Réplica a la carta al editor «Estudios clínicos controlados y eficacia: a propósito de una investigación en neurocirugía»

Dear Editor,

We would like to make some comments regarding the Letter to the Editor “Controlled clinical trials and efficacy: report of a neurosurgical study.”¹ The author of this article refers to our article “Microsurgical treatment of trigeminal neuralgia in patients older than 70 years: an efficacy and safety study,” criticising the use of the term “efficacy” in an observational study aiming to assess the outcomes of microsurgical treatment of trigeminal neuralgia (TN) in elderly patients vs. in younger patients.² Although it is true that the usefulness of a treatment in clinical practice is called “effectiveness,” randomised controlled clinical trials are considered the paradigm in the assessment of both “efficacy” and “effectiveness.”³ Our study is far from providing this type of evidence, and like many studies on the surgical treatment of TN, it is merely observational; while this criticism of the title is indeed correct, we consider this merely to be a question of semantics. Furthermore, the author critiques the lack of randomised controlled clinical trials

in neurosurgery and questions the usefulness and validity of the results obtained by retrospective observational studies.

In neurosurgery, there are many questions for which no class I evidence is available, and obtaining this evidence would be ethically questionable, prohibitively expensive, or so complex that the neurosurgical field of knowledge itself may solve the problem in question through technological or scientific advances before class I trial results could be obtained. Therefore, although neurosurgery is not an isolated case, it does constitute a clear example of a medical discipline that is continuously limited by the lack of cases, ethical questions, and the costs involved in obtaining high-quality evidence.^{4,5} For this reason, several authors signal the need to integrate lower-level evidence, mainly from pragmatic observational studies based on prospective registries, but also from case series, observational studies, meta-analyses of heterogeneous studies, expert opinions, and ultimately from personal experience, in order to create a corpus of evidence that would enable us to propose acceptable neurosurgical solutions where no class I evidence is available for a given question.^{6,7}

In the specific case of TN, one outstanding question is whether surgical treatment is equally or more effective than pharmacological treatment, and, should the latter be the case, whether it should be proposed immediately after diagnosis is established, instead of waiting for the failure of pharmacological treatment.⁸ A systematic review of the Cochrane database identified only 11 randomised controlled studies of TN.⁹ However, most studies presented bias and none included microvascular decompression (MVD). However, there is evidence from other studies demonstrating the effectiveness of surgical treatment, which completely resolves pain in the long term in 70% of the patients treated.¹⁰ Furthermore, although practically all patients with TN continue with pharmacological treatment until pain becomes refractory to several combinations of drugs, Spatz et al.¹¹ report a preference for early surgery in their

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