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 patients[4]; 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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patients. The lack of randomised controlled studies on TN is explained by several reasons[12]: (1) difficult recruitment in a rare disease with exclusively clinical diagnostic criteria; (2) ethical problems of comparing against sham treatment when effective medical and surgical therapies are available; (3) patients' preferences when comparison is against a standard medical treatment, since being assigned to the control group creates a drop-out bias (drop-out or change to the experimental group) or deception bias; (4) lack of equidistance of professionals towards different treatments due to the consequences of ablative surgery vs. MVD; (5) unequal experience with several surgical procedures at a single centre or by the same surgeon; (6) inability to blind to surgical procedures; and (7) measurement of outcomes with extrapolable scales (the Barrow Neurological Institute scale was designed to evaluate the outcomes of radiosurgery, and its correlation with the visual analogue scale is not clear)[13] and treatment objectives, since for pharmacological treatment, a 50% decrease in pain intensity and frequency was required vs. 100% relief with surgery. Given all these limitations, there is a need for new alternatives to perform pragmatic trials on effectiveness. Designing cohort multiple randomised controlled trials may be one such avenue of research.[14]

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The Brugada pattern in a patient treated with amitriptyline☆

Patrón de Brugada en paciente tratada con amitriptilina

Dear Editor:

Brugada syndrome is an autosomal dominant inherited channelopathy that affects the sodium channels of cardiac cell membranes. It is more frequent in young patients, and diagnosis is based on electrocardiographic (ECG) criteria and clinical history of syncope, or family history of sudden death due to malignant ventricular arrhythmias. Three different Brugada ECG patterns have been described: 1) type I, characterised by a coved-type ST-segment elevation ≥ 2 mm in more than one right precordial lead (V1-V3), followed by negative T wave; this is considered the only diagnostic type of pattern; (2) type II, characterised by an ST-segment elevation ≥ 2 mm in right precordial leads followed by positive or biphasic T wave resulting in a saddle-back configuration; and 3) type III, defined as either of the 2 previous types with ST-segment elevation ≤ 1 mm.[1,2]

Furthermore, several situations and drugs are reported to trigger an ECG pattern of Brugada syndrome.

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