Innovation in neurosurgery-response to: "IDEAL", the operating microscope, and the parachute

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LETTER TO THE EDITOR (BY INVITATION) - BRAIN TUMORS

Innovation in neurosurgery—response to: "IDEAL", the operating microscope, and the parachute

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We read with great interest the editorial by Ammirati [2] and the letter to the editor by Capabianca and Zada, and value the discussion that has followed our publication [7].

Innovations are at the heart of neurosurgery and without technical advances such as the microscope we could not provide the level of care that is today considered standard. Unfortunately, (level I) evidence that a specific innovation results in improved patient outcomes is often lacking or non-existent. Low incidence and high disease burden may further hinder systematic evaluation of any new technique in neurosurgery [7].

Because of these challenges, we agree with Capabianca and Zada that neurosurgeons often have no choice but to resort to personal judgment and clinical intuition, which inherently introduces a level of personal bias. Nevertheless, we think that, regardless of the difficulties, it is vital that new neurosurgical procedures and medical devices undergo—when possible—a structured and ethical clinical introduction. At the same time, this should not stifle innovation. The general lack of evidence should not stop but rather stimulate neurosurgeons to innovate and encourage them to provide evidence for their daily practice.

The IDEAL Framework provides a "roadmap" for the ethical and methodologically sound introduction of surgical innovations [6]. If an innovation is introduced in the manner as proposed by the IDEAL Framework, future decision-making could be aided as procedural efficacy and safety are well evaluated, and the innovation has been compared to the current practice.

Capabianca and Zada correctly point out that it is often not possible to evaluate neurosurgical innovations in this manner, as they are usually the result of continuous adjustment and improvement by several neurosurgeons over a long period of time, as seen with endoscopic meningioma surgery [7]. However, this may result in a lack of equipoise needed to ethically conduct a study with a form of randomisation. It may also lead to greatly varying opinions regarding the feasibility and safety of the procedure among the neurosurgical community due to different personal experiences. This could result in patients being subjected to a potentially suboptimal treatment, as some innovations that had not been introduced in a systematic way turned out to be non-beneficiary or even harmful after rigorous evaluation. For example, the very commonly performed percutaneous coronary intervention (PCI) was recently found to be non-superior to a sham procedure for stable angina [1].

We argue that if a study with a form of randomisation is deemed viable, it should be conducted, because we owe it to our patients to provide evidence for the care we provide. We agree, therefore, with Ammirati [2] that if a procedure is paradigm changing the innovation should be evaluated in a structured manner.

Capabianca and Zada also argue that medical devices are already subject to a form of structured evaluation because of regulation in the USA and Europe. Even though current regulations are aimed at limiting harm to patients and insuring that the medical device in question is of benefit to patients, they are far from perfect. European regulations are in general considered even less strict than the US regulations [5]. This is one of the reasons why devices are introduced earlier in Europe, often with scarce evidence supporting (long-term) efficacy of the device. An example is the WEB device, which has been available in Europe since 2011 and is still under investigation in the USA [3, 4]. Medical devices often do not require a comparative trial, may be approved based on

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similarity to other devices and off-label use allows for virtually any application as long as the aim is to "practice medicine" [8].

Therefore, it is important to be aware of the limitations of the regulations of the introduction of medical devices, which may not be as rigorous as presumed.

Despite the many challenges that come with the implementation of a framework like IDEAL, conducting a randomised trial and approval of medical devices, there are clinically viable solutions to these both practical and ethical problems. The use of alternative trial design, "big data", registries, patient reported outcome measures (PROMs) and comparative effects research (CER) can also provide further insight into the efficacy and safety of neurosurgical treatments. They can provide clinically relevant data that can guide decision-making and ensure the best possible outcome for patients.

In the end, we owe it to our patients to provide optimal care with the highest possible level of evidence that can be acquired. We believe that structured approaches, such as the IDEAL Framework, and other structured forms of evaluation can help achieve this goal.

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