Innovation in neurosurgery response to: “Ideal”, the operating microscope, and the parachute

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We are glad that our editorial generated interest and did not go unnoticed [1].

Cappabianca and Zada write that “...a meticulous and tailored informed consent process must always be carried out...” [2]. We would be satisfied with a simple informed consent when a planned new procedure is offered to a patient. It is a fact that none of the reports on Endoscopic Endonasal Approaches for Skull Base Meningiomas (EEMS) quoted in Muskens' paper had an informed consent, let alone ethical approval or outside evaluation of results [3]. On the other hand, the Woven Endobridge (WEB device) reports quoted in the same paper had ethical approval and informed consent in four studies and outside independent result evaluation in two of the four studies [3].

This is clear evidence that minimal common sense requirements for the introduction of new procedures are not hampering innovation, rather making it more robust while at the same time attempting to protect patients.

Regarding the “parachute” comment, we would remand to what is written in one of the Ideal papers where it is clearly stated that nobody would question the validity nor would advocate a randomised trial, for example, for tracheostomy for tracheal obstruction; this is again a common sense issue. *“Trials might be unnecessary when an advance that cannot be explained by either chance or bias is clear and substantial. For example, tracheostomy for tracheal obstruction, suturing for repairing large wounds, and ether for anaesthesia were such clear advances that trials were not needed. Most operations, however, are smaller advances prone to overoptimistic*

assessment by their developers and, therefore, need controlled randomised studies, when possible” [4].

As far as the introduction of the operating microscope in Neurosurgery to treat intracranial aneurysms, it was rather quickly accepted because an overwhelming number of reports from different part of the world, from different neurosurgeons, described superior outcomes especially when dealing with anterior communicating artery aneurysms. In the end, we do not think that asking for ethical approval or informed consent is a constraint on offering putative innovative treatment that has a basis for being potentially beneficial to the patient; doing away with it may be more practical and less time consuming, but certainly not always safer for the patients, in addition to raising ethical concerns.

References

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