



Special article

Ethical challenges of the finding of covert awareness with neuroimaging in vegetative states[☆]



Retos éticos del hallazgo de consciencia encubierta con neuroimagen en estados vegetativos

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Introduction

A patient's progression after a severe brain injury with impaired level of consciousness is very variable. After a period of coma which can last up to 3 or 4 weeks, some patients recover while others open their eyes and begin to breathe spontaneously, but show no voluntary response ("Vegetative State" or "Unresponsive Wakefulness Syndrome") or are able to demonstrate a voluntary response, but this is not sustained ("Minimally Conscious State"). In both cases, a clinical evaluation is difficult. Vegetative state diagnosis is based on detecting the absence of voluntary response signs to stimuli using validated clinical scales. Various published series report that these methods' sensitivity and specificity can be clearly improved.¹ The diagnosis of permanent vegetative state can activate limited therapeutic plans driven by an irreversible outcome assumption. Since 1994, following a consensus of several scientific societies, the previously mentioned diagnosis is considered when there are no signs of voluntary response one year after a traumatic brain injury or 6 months after non-traumatic brain injury.²

Recent neuroscientific findings³ show that brain-computer interfaces based on functional magnetic resonance imaging (fMRI), electroencephalography (EEG) and/or event-related potentials can be a viable strategy for detecting 'covert' conscious activity in patients who are in a sustained altered state of consciousness when

leaving a period of coma secondary to brain damage. Brain functions have been found intact in some of these patients (verbal comprehension, recent and autobiographical memory, orientation, etc.). These have been interpreted as conscious activity which goes unnoticed in validated clinical scales. There have even been cases of patients that were able to communicate assisted by fMRI and/or EEG.

Current situation

This debate was opened in 2006 when a fMRI study detected conscious activation to a verbal order in a 23-year-old female patient who met the clinical criteria for post-traumatic vegetative state.⁴ Despite not showing responses suggestive of voluntary behaviour in repeated clinical examinations, the authors interpreted that the patient could intentionally modulate her brain activity in response to verbal proposals. While inside a fMRI scan, it was asked verbally to imagine two activities: playing tennis or going from one room to another inside her home. Following the request, changes were observed in the transport of oxygen in blood, detectable by fMRI, in specific brain regions respectively involved in motor programming and spatial orientation, with a pattern comparable to healthy controls.

In 2012,⁵ another patient diagnosed with vegetative state during more than 12 years of progression could sustain a 'coherent' conversation with investigators by using the fMRI activation paradigms described above to establish a "yes"/"no" binary code. Among other things, the patient knew the current year and the name of his caregiver, unknown to him before the accident. Therefore, this demonstrated that the patient had (according to currently up to date clinical criteria, the condition was irreversible and deprived of

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any complex cognitive function) at least: verbal comprehension; ability to activate and voluntarily stop brain activation patterns using it to establish yes–no response codes; use old memories and store new ones, as well as time and space orientation.

fMRI paradigms have encouraged similar experiments based on EEG or evoked potential records. These cases and some more series published in the last decade have led to consider these advances as a possible solution to clinical diagnostic inaccuracy, even suggesting some prognostic correlation. Some authors argue that the detection of preserved covert cognition would predict a greater likelihood of functional recovery, although specific data on the latter are scarce, inconsistent and offer little information about the extent of long-term expected recovery.^{6,7} In fact, there is scientific consensus that, today, neither diagnosis nor prognosis can be based solely on ancillary tests.

In short, the new findings show that the clinical diagnosis of “vegetative state” in a patient that demonstrates conscious activity by other methods should be considered incorrect. How should we then call these patients who, clinically, do not express conscious responses but these are detected with imaging and/or neurophysiological technologies? The following term has been suggested: “*Non-behavioural minimally conscious state*”,⁸ but it may not be the most fitting because it seems clear that at least some of the patients reported show conscious activities that far exceed those observed externally in “states of minimal consciousness”: sustained attention, orientation, use and storage of memories and language comprehension.

Discussion

A deep ethical approach to the questions raised by these findings is not available to date, but it is unavoidable before any clinical practice implementation. It is from this perspective that we will consider the most significant issues.

Scientific soundness

There is no point in addressing a bioethical deliberation; that is, it is not worth discussing values unless we start from a solid foundation of scientifically proven facts. Today we are still far from a clinical applicability in healthcare practice of the neurophysiological tests and/or functional neuroimaging.⁹ The systematic clinical evaluation of behaviour and responses remains the “gold standard” despite its deficiencies. The main scientific objections proposed are:

Epidemiology

Some authors claim that 17–19% of patients who meet the clinical criteria for vegetative state maintain conscious activity undetectable by clinical observation, but these claims are based on small series, being the total number of patients who have reported these activations still very small (probably less than 20, if we consider only the vegetative state and neuroimaging). In addition, these findings have occurred, almost exclusively, in a very specific subgroup within these patients (those of traumatic aetiology with prevalence of axonal injury versus neuronal bodies). Therefore, it is unwise for the time being, to extend the diagnostic concern to all patients in a vegetative state, let alone the prognostic concern.

Validity, sensitivity and specificity of the experimental model

It is relevant to know if we find what we want to detect (validity), if we do it in all cases (sensitivity) and if whatever we observe with these methods always reflects conscious activity (specificity).

Despite impressive initial results, the scientific community reacted with scepticism at first, quickly objecting.

After the first case reported in 2006,⁵ critics argued that verbal stimuli can produce spontaneous neuronal activation, not necessarily “conscious”. Therefore, the changes found could simply amount to unconscious reflex activity or “conditional”, for example, to the last word in the order.¹⁰ Supporters of the use of neuroimaging counterargue that the activity is not observed in areas related with auditory processing but with the requested task and remains for prolonged periods, until the patient is asked to “relax”.¹ Isolated models that have allowed easy communication with patients, providing these up-to-date and/or autobiographical data, could not be easily explained just by unconscious processing.

These studies require a control group consisting of conscious healthy subjects. However, no research group, whether using fMRI or EEG, has managed cortical activation on verbal order in 100% of controls studied.^{11–13} For example, up to 25% of subjects were unable to perform and/or understand exactly the meaning of the task on mental images using EEG. This opens the door to both, false positives as well as false negatives, with the consequent secondary limitations for clinical applicability.

The technique itself has inherent limitations. Many of these patients have involuntary movements that prevent capturing signals and producing images or records. In some protocols, up to 91% of the subjects could not be properly evaluated for this reason.¹⁴

Applied statistical methods and established significance thresholds, essential in the interpretation of results in such small samples, are very heterogeneous, becoming an active focus of discussion in scientific literature.

All these considerations make it advisable to exercise caution regarding making the results and conclusions public, and highlight the need for standardization and coordinated effort among different research teams.

Media coverage

These results have been actively publicized in different mass media and have had a striking social impact (mainstream press, internet, television, social networks, etc.).¹⁵ Perhaps, too often, the visual impact of fMRI colour images has gone ahead of reflection, scientific rigour and prudence. False and/or premature expectations generated can contaminate the debate and the practical decisions derived from it.

Moral status

What moral considerations, rights and obligations do we owe to people who cannot express conscious capabilities, who, on the other hand, remain active as shown by neuroscientific findings? If confirmed, and from a philosophical point of view, we would be talking about a new state, affecting very important qualities for conceptualizing what the philosophical tradition means by “person” and “autonomy”.

Examining their quality of life

Beyond ontological debates, the real challenge would be to know what the patient thinks about his/her situation. In other words, it is important to know the perception of quality of life and/or suffering of people who, outside the experimental setting, cannot express behavioural patterns towards the external environment or use conventional language. It is already a challenge to measure such a subjective concept in the rest of the people, let alone these cases, where the difficulties grow considerably, as the only expression link the person has is the brain–computer interface conveyed by imaging or neurophysiological techniques. In fact, applying quality of life

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