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How to compare clinical results of different neurosurgical centers? Is a classification of complications in neurosurgery necessary for this purpose?

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INTRODUCTION

A classification of complications in neurosurgery, to be approved and validated by the scientific community, has been advocated as the main vehicle for comparing different series of patients having undergone surgery in different centers and/or at different times.[12] The ultimate goal of such a classification would be-in the long period and from the point of view of healthcare policy-the quality improvement of health services to be offered to patients. Such improvement (which would also be relevant with regard to saving economic resources) could be achieved through an analysis-with quantitative (or at least objective) data-to establish which medical center guarantees the best clinical results in a specific surgical procedure.

If a simple, practical-and therefore applicable in any medical center-classification of complications could achieve this purpose, it would be logical that all efforts should be made toward developing it. Should this aim not be pursued, or should it be achieved through different tools, the effort of defining a complications' classification would be a mere intellectual exercise lacking any practical usefulness.

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Historical overview: The refinement of the definition of surgical complications and of classification of complications in general surgery

The question of how to define negative results following invasive therapeutic procedures has been a matter for discussion for many years now in the field of general surgery.

A classification of complications to be accepted by the entire scientific community has not been developed yet, even starting from the definition itself of complication; any proposed definition of complication,[4-6,16,17] as a matter of fact, has not been approved by those authors who later dealt with this subject. Sokol and Wilson,[17] for example, define as a complication "any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped;" the authors themselves admit, however, that establishing in each case if a negative event could or could not be considered as a complication entails wide margins of subjectivity.

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The attempt to precise a classification of complications faces even harder obstacles, in as much the clarification of categories within which to classify the innumerable unexpected events that might occur in the surgical field will necessarily be either too generic or too specific. In the former case, such classification will include many different negative events not strictly homogeneous with regard to the cause of the complication; in the latter one, such classification will appear fastidious and not handy because of the excessive number of categories to be detailed.

The most thorough paper in this field-dealing with cholecystectomies-was published by Clavien in 1992.[4] In this paper, a fundamental concept is introduced, that is, the grading of complications based on patients' morbidity on the basis of the severity of any residual or lasting disability. Other authors also[8,9] stated that life quality measures should be used to evaluate surgery outcomes.

Clavien,[4] moreover, recommended considering as "complications" only unexpected negative events; any predictable unfavorable outcome caused by a specific surgical risk inherent to the procedure being on the contrary a "sequela." This idea, also approved by other authors,[2,16,10] logically introduces the concept of a definition of surgical risk (i.e., the likelihood that a patient might develop a disability following a technically irreproachable surgical procedure). In the field of general surgery, Dindo *et al*., in 2004,[5] specified the complexity of surgery in three main categories as follows. Type A: surgical procedures without opening of the abdominal cavity; type B: abdominal procedures except liver surgery, representing instead type C procedures. Complications have been classified in five grades according to the importance of the therapy necessary to treat them. Grade I complications, requiring only routine drugs, include transient atrial fibrillation, atelectasis, transient elevation of serum creatinine; grade II complications, requiring specific drug treatment, include tachyarrhythmia, pneumonia, urinary tract infection; grade III complications, treated with invasive procedures, include bradyarrhythmia requiring pacemaker implantation, bronchopleural fistula, and stenosis of the ureter treated surgically. Grade IV includes single or multiorgan dysfunction and life threatening complications requiring intensive care unit management. Grade V represents the death of the patient. For each of the three classes of risk in which complications have been grouped, every type of negative event occurred much more frequently in group C patients ($P < 0.0001$).

The definition of surgical complications and of classification of complications in neurosurgery

In the neurosurgical field, the first author who felt the need to give a definition of complication was Black in 1993.[1] Lebude, in 2010,[13] proposed a binary but too generic assessment of complications in spinal surgery, that is, major and minor complications (adverse events that produce permanent or only transient detrimental effects, as postoperative myocardium infarction in patients with coronary artery disease or supericial wound infection, respectively).

A seemingly more elaborated suggestion relating to complications' classification in neurosurgery was elaborated by Landriel Ibanez, in the paper published in 2011.[12] The definition of complication chosen by Landriel ("any deviation from the normal post-operative course") presumes a non-existing agreement, within the scientific community, about what should be considered a "normal" postoperative course. The suggested classification follows the codification introduced in general surgery by Dindo in 2004,[5] which divides adverse events in four steps not on the basis of patients' postoperative life quality but on the relevance of the different treatments necessary to treat the complication. [As already described in the previous paragraph].

In such papers, the detail of complexity of surgery cases is lacking (only the percentage of patients who underwent cranial or spinal surgery is known); thus, the presented clinical records, failing the purposed goal, cannot be compared with other clinical records in other clinical centers.

It is obvious that, with no assessment of surgery complexity, a hospital where only simple surgical procedures are performed will appear much more reliable as opposed to a center of excellence where many complex surgical procedures such as skull base procedures are conducted, for which an incidence of morbidity and a not negligible mortality is even expected. For example, and remaining in the field of meningioma surgery, in a recent paper 112 patients who underwent surgery for grade I convexity meningiomas over the past 20 years were retrospectively reviewed; no worsening of preoperative deficit was reported, whereas mortality rate was 0.9%.[14] On the other hand, in a series of 226 patients operated on for skull base meningiomas, morbidity was reported to be as high as 32% (with permanent neurological deficits in 3.5% of the patients), whereas mortality rate was 2.7%.[15]

As in the field of general surgery, it is really difficult to come to a shared definition of what a complication in neurosurgery is.

On the other hand, many ideas springing from the debate among those authors who dealt with the topic of negative events in general surgery must be considered as a guide for an objective evaluation of neurosurgical procedures' results, which is the essential prerequisite for the purpose of comparing surgical treatments' quality in different medical centers.

The concept to discriminate negative events occurring after surgery between complications and sequelae, introduced by Clavien,[4] in which the term of complication has been specified as any postoperative event deviating from an ideal course, whereas sequelae have been defined as a subgroup of complications producing "an accepted alteration in structure or function of the body that is embodied in the procedure" because they are caused by factors "inherent to the procedure." This idea has been indeed taken into consideration by Clark and Spetzler[3] who stated that a classification of complications "would have to be able to differentiate between complications and normal outcomes, without being distracted by whether or not the outcomes are favorable." In other words, implying the relevance of surgical risk intrinsic in many neurosurgical procedures, they suggest that any postoperative worsening of a patient's neurological condition, if expected because of surgery complexity, should not be considered as a complication.

For example, a hemiparesis occurring to a patient operated for a large arteriovenous malformation (AVM) located in the motor cortex will be classified as a sequela, whereas the same neurological deficit occurring after the removal of a frontal AVM reaching the Silvian fissure (secondary, that is, to coagulation of a middle cerebral artery branch feeding the corticospinal bundle) should be considered a complication.

Similarly-according to the definition provided-a facial paresis occurring after the complete removal of a large acoustic neuroma should be considered a sequela, whereas a cerebellar infarction should be be classified as a complication. In many cases, anyway, which factors should be considered "inherent" to a specific surgical procedure-so that a postoperative neurological deficit would be accepted-can be a matter of discussion.

Similarly, as reported in one of the previous paragraphs, Sokol and Wilson[17] exclude from the definition of complication an expected undesirable result of an operation. While it appears easy to classify negative events in procedures with very high or very low chances of success, on the other hand, "deciding whether an expectation is reasonable will be harder when the likelihood falls between the two extremes of certainty."

Our proposal concerning the possibility to compare surgical results in different medical centers-as described in the following paragraphs-does not require, therefore, connections to any classification of complications in neurosurgery, lacking even a shared definition of the word complication-in the scientific community-in general surgery as well as in the neurosurgical field.

The need of definition and classification of surgical complexity in neurosurgery

The definition of complexity in neurosurgical procedures (corresponding to the likelihood that the patient develops a neurological deficit following a technically irreproachable surgical procedure), seeming necessary in the light of previous argumentations, is not an easy task. What should be done, following the teaching of Dindo[5] in the field of general surgery, is to specify the complexity of surgery in different categories on the basis of the correlation between the class of surgical risk and the occurrence of postoperative negative events.

In fact, only few of these diseases, the most well-known example concerns arteriovenous malformations,[18] have been classified in different classes of risk. However the preliminary data published by a high-volume neurosurgical center[7] show that, among several risk factors taken into consideration, a few (major brain vessel manipulation, surgery on eloquent area, posterior fossa, brainstem-deep location, and cranial nerve manipulation) were found to be statistically significant independent predictors for the appearance of new postoperative neurological deficit.

Our suggestion for the future is that centers of excellence, after considering the published mentioned data and retrospectively elaborating their own clinical records, should develop and suggest classifications not of complications but rather of surgery complexity (this being based on the number and/or relevance of identified risk factors) for any of the diseases treated in planned neurosurgery (glioblastomas, low grade gliomas, meningiomas, epidermoids, etc., with a restriction to cranial procedures); such classification should unequivocally specify, with numerical parameters, the class of risk of any patient. Evidence should be provided, as suggested by Kwock-chu Wong,[11] of increasing severity of long-lasting morbidity (and increasing of mortality) with the increase in the class of risk.

Is it possible to compare clinical results of different neurosurgical centers?

The availability of such a classification should make it possible to identify homogeneous groups of patients from a surgical risk point of view. In each group, the postoperative neurological status of every patient should be converted through a performance scale into a number; thus, it will be possible to elaborate simple statistical data, as the average, which would show in a numerical parameter, the overall neurological status of any group of patients. These parameters can be compared with the same data obtained from groups of patients belonging to the same class of risk who had surgery in other medical centers. The data regarding mortality (should there have been any) should also be specified for each class of risk and compared among the different hospitals. In fact, as reported in one of the previous paragraphs, a mortality rate of approximately 3% is expected in skull base meningioma surgery, whereas the same data is unacceptable in a series of patients operated on for grade I convexity meningiomas.

Should the results of a single clinical center be significantly worse compared with others, would be the responsibility of the hospital management to identify the causes of such unsuitableness, and to strive for improving the quality of health services offered to patients.

Use of numerical health scales for postoperative evaluation of the patients' quality of life

Evaluation of outcomes after surgery must consider only patients' quality of life, as it was suggested by Clavien[4] over 20 years ago.

To the purpose to quantitatively specify both any lasting disability and, symmetrically, patients' quality of life, many scales could be used. One of them is the well-known Karnofsky scale, basically employed in oncology, which grades patients' clinical status in 10 categories. Health status may, in any case, also be measured through other scales such as the modified Rankin scale (which grades life quality in only six steps); other scales such as SF-36 or life quality scales do not seem to be as handy to be easily used in the neurosurgical field.

In any case, the adopted performance scale should be simple, handy, and possibly already validated in clinical practice in order to conform to the strong suggestion of Clark and Spetzler,[3] who consider it essential to assign "objective measurements to a patient's overall level of health after surgery."

Because the need to treat patients with preoperative neurological deficits is not exceptional, we think that middle-term postoperative evaluation should not be expressed on the basis of absolute values, but rather on any modification compared with preoperative scores: To a patient without neurological deficit before surgery presenting a postoperative score of 60 in Karnofsky scale will be assigned 40 worsening points; in a patient who suffered from a preoperative hemiparesis (with a score of 80) presenting the same postoperative Karnofsky score of 60, the worsening score will be evaluated at 20 points.

How to reduce the bias due to multiple variables, comparing surgical results of different clinical centers?

In the case of surgical procedures for neoplasms or vascular malformations, information regarding the entity of tumor removal or angioma, respectively, should be provided; patients with complete or partial removal of a cerebral lesion should belong to different subgroups in the postoperative clinical evaluation.

Treatment of different diseases requiring neurosurgical procedures often includes further therapies, such as steroids or, in the case of malignant tumors, chemo and radiotherapy. These treatments themselves might induce complications and worsening of patients' life quality, not depending on the execution of the surgical procedure but on the unpredictable interaction between the individual patient and such additional treatments; to the purpose of comparing surgery quality in different centers, patients' health status evaluated after surgery must rely only on the effects of surgical procedures. Therefore, it would seem appropriate, for example, to evaluate patients having undergone surgery for malignant neoplasms before the beginning of oncologic treatment (which is usually administered, anyway, only after postoperative stabilization). In other cases of worsening of neurological patients' conditions after surgery, the appropriate time for the follow-up should be in our opinion approximately 3 months later, when any neurological deficit, if it had occurred, is supposed to have improved or stabilized. Should the worsening of the patient's health status be attributed to accessory treatments, specification would be made in the report and the patient would be excluded from the statistical analysis.

Furthermore, it is necessary to specify if any persistent worsening of a patient's health status after surgery is due to medical complications (as infections or thromboembolisms); these patients must be presented in the report but excluded from statistical analysis for the purpose of avoiding bias due to the occurrence of negative events not directly related to surgery. It is evidently true that a pulmonary thromboembolism is related to surgery because it is more likely to happen in bedridden patients whose neurological conditions presented a transient postoperative worsening (and for that reason correctly treated with antithrombotic drugs); however, it is equally true that not all bedridden patients will develop this complication, consequent to many contributory causes. Our goal is to compare the surgical results of different hospitals (that is to say the surgical ability of the neurosurgical team working in a specific clinical center) so it appears more appropriate, in our opinion, not to take in consideration any worsening of patients' quality of life due to random variables and only indirectly related to surgery. The same argument is valid for infections-systemic or circumscribed to the operative bed-obviously assuming that adequate perioperative antiseptic procedures and correct antibiotic prophylaxis have been undertaken by the medical team taking care of the patient.

These arguments lose their significance in case of patients with persistent and serious impairment of their neurological conditions where a delayed medical complication has resulted in death. In these cases, the fatal medical negative event occurred just because the patients were bedridden or presented a respiratory failure due to a bulbar damage after surgery. We think that in these circumstances, medical complications should be considered directly related to surgery and classified as such. In any case, the causes of death of any patient should be accurately detailed.

Another bias is related to the possible underestimation of the postoperative patient's clinical problems if the evaluation is performed by the surgical team. We think that assigning to the patient the task of a self-evaluation, as hypothesized by some authors,[17] would introduce a bias due to an emotional involvement of the person whose quality of life could be changed after the surgical procedure. The better solution, in our opinion, is that the evaluation is undertaken by the neurologist working in the hospital where the operation has been performed, but who is not directly involved in the surgical procedure.

Postoperative medical complications and preoperative patients' global health status. The need for a global health scale

The occurrence of postoperative medical complications is sometimes facilitated by preexisting diseases (diabetes, obesity, previous phlebitis of inferior limbs, malignant neoplasms of internal organs), whose accurate analysis would have had relevance in the decisional process of selecting the more appropriate treatment (for example choosing less invasive kinds of surgical procedures or even avoiding surgery, if too dangerous for fragile patients). These arguments introduce the idea of the need for a more accurate preoperative study of the global health status of the patients, more precise and structured compared with American Society of Anesthesiology score. What should be done is to develop a health scale taking into account before surgery, in addition to the neurological status, all systems; cardiac, respiratory, gastrointestinal, renal, endocrine functions should be considered and expressed in a numerical form, as well as hematologic and laboratory values. In addition, the extent of dysfunctions in dermatologic or gynecologic field (should there have been any) should be specified. The entity of pain (if present) should also be evaluated by means of numeric values.

This global evaluation of patients before surgery is essential and should be standardized, with the aim of selecting a "custom-made" treatment for every patient and reducing life-threatening medical complications.

CONCLUSION

To the purpose of judging neurosurgical treatments quality in different medical centers, the complexity of any neurosurgical procedure should be defined, through numerical parameters, before surgery; it should thus be possible to identify-in different hospitals-homogeneous groups of patients in relation to surgical risk and to compare their overall life quality (even through a quantitative definition, by using numerical performance scales) a few weeks after surgical procedure.

In this context, any definition and classification of complications in neurosurgery in our opinion does not seem to be really relevant.

We hope that our Editorial will encourage a constructive debate within our scientific surgical community on this critical theme, whose ultimate purpose consists in optimizing the treatment of patients suffering from intracranial lesions or other diseases requiring neurosurgery. We welcome suggestions, comments, and contributions in order to define in a combined effort a classification of surgical complexity in neurosurgical procedures, as well as a health scale allowing standard evaluation of patients before surgery.

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Conflicts of interest

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