ORIGINAL ARTICLE

Ethical Challenges with Awake Craniotomy for Tumor

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ABSTRACT: ***Background:*** Awake brain surgery is useful for the treatment of a number of conditions such as epilepsy and brain tumor, as well as in functional neurosurgery. Several studies have been published regarding clinical results and outcomes of patients who have undergone awake craniotomy but few have dealt with related ethical issues. ***Objective:*** The authors undertake to explore broadly the ethical issues surrounding awake brain surgery for tumor resection to encourage further consideration and discussion. ***Methods:*** Based on a review of the literature related to awake craniotomy and in part from the personal experience of the senior author, we conducted an assessment of the ethical issues associated with awake brain tumor surgery. ***Results:*** The major ethical issues identified relate to: (1) lack of data; (2) utilization; (3) conflict of interest; (4) informed consent; (5) surgical innovation; and (6) surgical training. ***Conclusion:*** The authors respectfully suggest that the selection of patients for awake craniotomy needs to be monitored according to more consistent, objective standards in order to avoid conflicts of interest and potential harm to patients.

RÉSUMÉ: Défis éthiques concernant la craniotomie en état vigile pour traiter une tumeur. ***Contexte :*** La chirurgie du cerveau en état de vigile est utile pour traiter certaines pathologies telles l'épilepsie et les tumeurs cérébrales ainsi qu'en neurochirurgie fonctionnelle. Plusieurs études ont été publiées sur les résultats cliniques et l'issue chez des patients qui ont subi une craniotomie en état vigile, mais peu d'études ont traité des aspects éthiques. ***Objectif :*** Les auteurs ont exploré d'une façon large les questions éthiques entourant la chirurgie en état vigile effectuée pour l'ablation de tumeurs dans le but de favoriser un examen plus approfondi du sujet et de susciter la discussion. ***Méthode :*** Nous avons procédé à une évaluation des questions éthiques associées à la chirurgie en état vigile pour l'ablation d'une tumeur cérébrale, en nous basant sur une revue de la littérature sur la craniotomie en état vigile et en partie sur l'expérience de l'auteur principal. ***Résultats :*** Les principales questions éthiques identifiées concernent : 1) le manque de données ; 2) son utilisation ; 3) les conflits d'intérêt ; 4) le consentement éclairé ; 5) l'innovation chirurgicale et 6) la formation chirurgicale. ***Conclusion :*** Les auteurs suggèrent avec considération que la sélection des patients soumis à la craniotomie en état vigile doit être surveillée selon des standards plus constants et plus objectifs afin d'éviter des conflits d'intérêts et des préjudices potentiels pour les patients.

Can. J. Neurol. Sci. 2012; 39: 78-82

The frequency and indications for use of modern awake craniotomy are increasing.[1] The first "contemporary" application was for the treatment of epilepsy in the early 17th century.[2,3] It was followed by resection of tumors from eloquent brain regions,[1-6] and then to routine, nonselective tumor resection regardless of the involvement of eloquent cortex.[1,7] Faster resumption of normal activity by the patient and more efficient use of medical resources has led to its performance with less regard to tumor location, and even on an outpatient basis in some neurosurgeons' practices.[8-10] Awake brain surgery is also used for neuromodulation in the treatment of idiopathic Parkinsonism, essential tremor, dystonia and chronic pain,[11,12] and has been experimentally applied in a number of non-movement disorders such as depression, obsessive compulsive disorder, Tourette's disorder, Alzheimer disease, chemical addiction and obesity.[12] We explore some of the factors that influence whether to recommend awake brain surgery to tumor patients and the associated ethical implications; excluded from this discussion are the ethical issues relating to psychiatric neurosurgery and epilepsy surgery.

Results

Lack of data

Clinical research is usually conducted to answer the question of whether a new treatment is better than the standard.[13] Unfortunately, after nearly a century of experience, there is no

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Received June 1, 2011. Final Revisions Submitted July 22, 2011.
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definitive data that awake craniotomy for brain tumor resection is better or worse for patients. To our knowledge there has been just one small prospective randomized study. In 2007, Gupta et al[14] demonstrated higher blood loss, increased neurological deficits and less cytoreduction in patients undergoing awake craniotomy versus surgery under general anesthesia for resection of tumors in eloquent cortex. However, based on the small cohort and "steep learning curve" involved in performing awake craniotomy the authors further reported, "[f]rom the results of this study, it would be very difficult to conclude which of the procedures [sic] is superior." Indeed, these results have not been reproduced and should not be generalized. It is implied by the paper that they are not representative of neurosurgeons with large experiences with awake craniotomy nor are the results statistically significant.

It is a conspicuous deficiency, both scientific and ethical, in the field of neurosurgery not to have prospective evidenced-based support for performing awake craniotomy (and many other procedures). Even though there are no randomized prospective studies demonstrating that awake craniotomy is superior to craniotomy under general anesthesia in terms of patient outcome, many different studies have determined it to be safe, well-tolerated and efficient.[1,2,4-7] The benefits of awake craniotomy include the avoidance of general anesthesia and its potential for complications,[15] as well as fewer intensive care admissions and shorter overall hospital stays.[1] In addition, it cuts operating times, and less frequently requires the use of a Foley catheter, endotracheal tube, and central venous or intra-arterial lines than does general anesthesia.[1,4,7,16] The most common intraoperative complications of awake craniotomy are seizure, respiratory depression, emotional stress and physical discomfort.[17]

From the perspective of the senior author, who feels awake craniotomy is an excellent option for patients and the healthcare delivery system, the randomization of patients in the face of overwhelming circumstantial evidence of safety and efficacy is ethically questionable. In any event, in an evidence-based medical culture the lack of data does raise questions about the ethics of advocating for the expanded use of awake brain surgery, as well as its performance on an outpatient basis. Without prospective comparative information it is impossible to objectively measure the risk-benefit ratio of awake craniotomy versus general anesthesia and therefore, to provide entirely unbiased recommendations to patients.

Utilization

It is reasonable for patients to expect there to be evidence-based standardization of care in tumor surgery but regrettably there is no uniform code to provide guidance for most neurosurgical problems. Overutilization of awake craniotomy (and any other procedure) is likely to be an unavoidable problem for "champions" of a procedure – those surgeons who either truly believe it is superior to other operations and/or those with a personal interest in the operation. While some surgeons may prefer operating under general anesthesia, others, like the senior author, are strongly inclined to perform awake craniotomy whenever possible. An important ethical issue is whether neurosurgeons under or over select patients for awake brain surgery based on personal preference.

Fairness requires that patients should have access to awake craniotomy where appropriate and that the procedure not be denied to individuals without good scientific evidence and/or medical contraindication.[11] Decision-making with respect to the selection of candidates for awake craniotomy for brain tumor based on the strengths and preferences of a given neurosurgeon is not optimal medical practice. For example, should a young person with a low-grade glioma in the speech cortex agree to craniotomy under general anesthesia because his or her surgeon prefers it and/or is not part of a team where awake craniotomy is comfortably and routinely performed? Of course, we would be remiss not to acknowledge the existence of a global inequity whereby neurosurgeons in the developing world are generally not trained in awake craniotomy techniques and thus their patients have minimal opportunity to access this surgical option.

On the other hand, it is ethically questionable whether patients should be subjected to routine use of awake craniotomy for non-eloquent tumor resection, when an alternative surgery under general anesthesia is available and possibly better suited to their individual needs. Established exclusion criteria to awake craniotomy include patients unable to cooperate because of severe dysphasia, language barrier, cognitive impairment, emotional instability or delirium, as well as patients with low occipital tumors (requiring prone positioning) or tumors involving significant dural attachment (due to the probability of significant dural pain on resection).[4,7] It has further been recommended that patients under the age of 11 not be considered for awake craniotomy.[18] From the experience of the senior author, attention to these principles combined with experienced surgical and anesthesia teams who communicate well, results in smooth awake craniotomies in the overwhelming majority of cases with intraoperative problems significant enough to call into question whether awake craniotomy was the best choice for a particular patient occurring in approximately 1% of cases.

Nevertheless, several elements of the criteria for exclusion are subjective and as a consequence variation in the procedure selected is wide in comparison to other aspects of neurosurgery, other medical specialties, and even other professions (e. g. accountants, airline pilots or engineers who must follow set guidelines).[19] While a standard of care for deciding when to perform awake craniotomy would be optimal, the persona of neurosurgeons as individualists is a difficult obstacle to overcome.[18] This raises questions about the objectivity of reasons given when recommending or denying awake craniotomy. A literature review ascribes diversity of treatment approach amongst neurosurgeons to age,[20] experience,[21] and training background.[20,21] In the best interests of patients and neurosurgeons, we encourage the future development of comprehensive guidelines.

Conflict of interest

Doctor and patient preference may not be aligned. Although medicine is supposed to be a patient-centered system, there are doctor-centered nodal points along the decision-making tree. A multidisciplinary team, such as a tumor board, can be useful in ensuring ethical conduct and optimum treatment decisions.[12] Surgeons uncomfortable with awake craniotomy should consider referring patients to colleagues or outside institutions for additional opinions.

Expectations of colleagues

There is an expectation among medical professionals and often patients that in order to deliver the best possible results surgeons must utilize the most advanced procedures available. A belief that the patient or the neurosurgeon's colleagues and/or trainees might be disappointed or critical if surgery is performed under general anesthesia constitutes an external influence that should be considered.

Hospital resources

Priority setting is the art of medical resource allocation. It involves finding the appropriate balance between individual patient rights and the greater good of the healthcare delivery system. Awake craniotomy reduces the need for postoperative intensive care monitoring,[4] and decreases operating times and hospital stays.[22-24] It is difficult to weigh the efficacious use of hospital resources against an individual patient's needs, and therefore important for neurosurgeons to remain sensitive to the opportunity for patient exploitation if procedures are performed when the greater good of the system/hospital is prioritized over an individual patient's best interests.[13]

Financial/reputational benefits

The potential impact of financial inducements on the clinical judgment of individual neurosurgeons, as well as its influence on patient perception, is largely self-evident. Ethical issues related to reputational benefit, which can raise a surgeon's profile and lead to academic promotion, may be more prevalent but also are more subtle and difficult to monitor.[25] Nonetheless, reputational and financial conflicts of interest are not necessarily harmful to the patient. When making an ethical assessment, it is worth considering that surgical performance may be improved by either of these incentives.

Teaching opportunities

An important role of the neurosurgeon is that of mentor and educator to medical students, residents, fellows and peers. The decision of whether to perform one surgical procedure over another can be influenced by a desire to teach and to leave a legacy for others to follow. Neurosurgeons should be careful to prioritize the patient's interests over providing learning opportunities when these objectives conflict and should remain mindful of any tendency to inappropriately proselytize students to a favored surgical approach.

Additional effort/personal bias

Performing awake craniotomy demands learning new techniques and using different surgical technology. Furthermore, keeping patients awake adds an element of complexity to any neurosurgical procedure, as even the best patients can be difficult to manage (e. g. may develop an intraoperative cough or unexpected anxiety). Consequently, for a given neurosurgeon, the practical inconvenience of awake craniotomy may trump any perceived gains to patient safety. It is debatable whether inconvenience to the surgeon, which can affect outcome, is an appropriate factor for consideration when deciding whether to perform an awake craniotomy.

Legal liability

For several reasons, awake craniotomy may increase the risk of litigation, deterring neurosurgeons from performing the procedure. Patients might misinterpret normal intraoperative discussion or inadvertently confabulate their recollection of the surgery as a result of the administration of sedatives or cortical manipulation. Furthermore, patients may assert that the procedure was more painful or emotionally challenging than the surgeon described. Alternately patients operated upon under general anesthesia who incur complications may later feel angry that an awake craniotomy was not done, especially if this option was not discussed with them. The impact of selecting a surgical procedure based on the probability of litigation must be actively minimized by the medical profession – if we concern ourselves with this, patient outcomes will suffer because of bad decisions being made for the wrong reasons.

Informed consent

Fully informed consent requires an explanation of all surgical options, including a detailed review of possible outcomes and complications,[26] and disclosure of the reasons for any recommendation provided. Neurosurgeons should keep in mind the possibility that a patient may feel coerced into consenting to a given procedure in order to avoid introducing perceived negativity into the relationship.[25] Furthermore, there may be cultural differences in the acceptance by patients of awake brain surgery.[2]

Unique to awake surgery, consent can be revoked during the procedure. Although rare, occurrences have been documented where a patient competent to decide and willing to accept the consequences has halted his/her awake brain surgery.[11,27,28] Rules should be put in place to deal with this situation. These include guidelines regarding advanced directives, appropriate intraoperative measures of persuasion and the possibility of returning to surgery at a later date. Patients may be more likely to suspend a surgery once informed of the option, and surgeons should consider discussing how requests for discontinuation will be handled.[11]

Surgical innovation

Surgical innovation is needed to benefit both individuals and society. Ethical conflicts can arise between a neurosurgeon's desire to explore different applications for awake craniotomy and the maintenance of patient safety and comfort. Innovative patient care sometimes involves uncertainty about risks and benefits, and outcome data are not always available.[12] Advancements involving the translation of a procedure indicated in one set of circumstances to another raises ethical issues as it involves potentially placing some patients at risk for the benefit of others.[13]

The performance of awake craniotomy on patients with tumors in non-eloquent brain regions is one area where such consideration is warranted. Some of the benefits of performing awake craniotomy are societal and do not accrue to the patient. It is problematic to determine the appropriateness of research where third party benefits may exceed those accruing to the patient and there is no established framework for balancing those interests where they conflict.[13]

A related ethical dilemma arises with regard to the performance of awake brain surgery on an outpatient basis. Outpatient awake craniotomy has been demonstrated to maximize resource utilization and increase patient satisfaction.[7] Furthermore, it likely reduces the potential for infection, thromboembolic events, and other hospital-based complications.[29,30] Patients have reported that having brain surgery done as outpatients made their disease seem less serious, which contributed to emotional well-being and aided in the recovery process.[15] Although a strong argument can be made for performing awake craniotomy on tumors regardless of the proximity to eloquent cortex, as well as on an outpatient basis, to do so means some patients will form a part of the neurosurgeon's learning curve. In other words, they will be used as practice for the benefit of others.

Surgical training

There are additional ethical concerns associated with academic hospitals. It is important to consider how to adapt the teaching model in circumstances where the patient remains awake during surgery. An awake patient will be more sensitive to the degree of involvement of the attending surgeon in comparison to the fellow or resident and this may cause emotional distress. Thus, the intraoperative role of each member of the healthcare team should be thoroughly explained in advance. It has already been shown that patients are quite unaware of the intimate role surgical trainees play in their care.[31] Delegation of the performance of surgical procedures under appropriate supervision to surgical trainees is ethical but deception in concealing the fact that the neurosurgeon is doing so is not.

Other changes to the teaching model need to be considered for awake craniotomy as well, including consideration of the appropriate amount and substance of intraoperative discussion. Just as the sterile operating environment can be contaminated by a careless act, the patient's emotional state can be disturbed by a thoughtless or insensitive comment (e. g. discussions about another patient).[32] The appropriateness of humor and conversation in the operating room will need to be assessed on a patient-by-patient basis and all new personnel to awake brain surgery such as new nurses and new residents should be instructed about appropriate behavior in this special environment.

Limitations

This paper may be limited in its scope and may not adequately address the wide-variety of ethical issues surrounding awake brain surgery. Those that have been discussed are arguably not examined in as much depth as desired. There is also some overlap and thus repetition among the discussion points.

Conclusion

The asymmetry of power between surgeons and patients is important to keep in mind when advising on the appropriateness of awake craniotomy for brain tumor. Doctors must be careful to maintain awareness of their biases and conflicts of interest and avoid unduly influencing patients based on their own priorities.[33,34] Patients who undergo awake surgery would presumably like to do so because they believe it will improve outcomes and minimize complications.[15] Undoubtedly, they would be surprised and dismayed to learn that factors never disclosed to them influenced their surgeon to recommend the procedure. Most patients trust their surgeon and follow the recommended course of action so the responsibility is the surgeon's to be open and fair with his/her recommendation.

The usefulness of awake craniotomy has been established, as has its safety and efficacy, though it has not been proven superior in terms of outcome to surgery under general anesthesia by a prospective randomized study. As a result, extension of awake craniotomy to new patient populations raises ethical questions and addressing them is an evolving process. Similar issues arise with respect to its performance on an outpatient basis. Greater exploration of the opinions of neurosurgeons is needed. As more patients undergo or become eligible for awake craniotomy more comprehensive guidelines will need to be developed. The next step is to develop generally applicable and objective eligibility criteria for patient selection.

Acknowledgments

Supported in part by the Medical Student Training and Research Experience in Aging and Mental Health (MSTREAM) Program of the National Institute of Mental Health.

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