



POINT OF VIEW

Cranioplasty with bandaging: New forms of limitation of life support and organ donation[☆]

D. Escudero^{a,*}, L. Cofiño^a, D. Gracia^b, M. Palacios^c, M. Casares^d, L. Cabré^e, P. Simón^f, P. Miranda^g, K. Martínez^h, S. Iribarrenⁱ, I. Saralegui^j, R.M. Simó^k, B. de León^l, V. Español^m

^a Servicio de Medicina Intensiva, Hospital Universitario Central de Asturias, Oviedo, Spain

^b Profesor Emérito de la Universidad Complutense de Madrid, Madrid, Spain

^c Presidente del Comité Científico de la Sociedad Internacional de Bioética – SIBI, Miembro del Comité de Bioética de España, Spain

^d Nefrólogo, Magister en Bioética, Presidente del CEAS del Hospital Universitario de Getafe, Madrid, Spain

^e Jefe Servicio Medicina Intensiva Hospital de Barcelona, SCIAS, Presidente de la Associació de Bioètica i Dret de la Universitat de Barcelona, Miembro del Comité de Bioètica de la Generalitat de Catalunya, Presidente del CEA del Hospital de Barcelona, SCIAS, Spain

^f Profesor de Bioética, Escuela Andaluza de Salud Pública, Granada, Spain

^g ex Jefe de Servicio de Ginecología y Obstetricia, Hospital Universitario 12 de Octubre, Madrid, Máster en Bioética, Spain

^h Presidente de la Asociación de Bioética Fundamental y Clínica. Servicio de Medicina Intensiva, Hospital Navarra, Pamplona, Spain

ⁱ Jefe de Servicio Medicina Intensiva, Hospital Universitario de Araba Sede Txagorritxu, experto en Bioética, Spain

^j Presidente Comité Ética Asistencial, Unidad Medicina Intensiva, Hospital Universitario Álava-Santiago, Vitoria, Spain

^k Presidenta Comité de Ética Asistencial del Área Sanitaria IV, Hospital Universitario Central de Asturias, Oviedo, Spain

^l Servicio de Medicina Intensiva, Instituto Nacional de Silicosis – HUCA, Miembro del Comité de Ética Asistencial del Hospital Universitario Central de Asturias, Oviedo, Spain

^m Servicio de Medicina Intensiva I HUCA, Miembro del Comité de Ética Asistencial del Hospital Universitario Central de Asturias, Oviedo, Spain

KEYWORDS

Ethics;
Organ donation;
Brain death;
Life-sustaining
treatment limitation

Abstract Most of the transplanted organs are obtained from brain death (BD) donors. In neurocritical patients with catastrophic injuries and decompressive craniectomy (DC), which show a dreadful development in spite of this treatment, DC could be a futile tool to avoid natural progress to BD.

We propose whether cranial compressive bandage (*cranioplasty with bandage*) could be an ethically correct practice, similar to other life-sustaining treatment limitation (LSTL) common methods.

Based on a clinical case, we had contacted the Assistance Ethics Committee and some of the bioethics professionals and asked them two questions: 1) Is ethically correct to perform a *cranioplasty with bandage* in those patients with LSTL indication? 2) Thinking in organ donation possibility, is this option preferable?

[☆] Please cite this article as: Escudero D, et al. Craneoplastia con vendaje. nuevas formas de limitación del tratamiento de soporte vital y donación de órganos. Med Intensiva. 2013. <http://dx.doi.org/10.1016/j.medint.2012.12.008>

* Corresponding author.

E-mail addresses: dolores.escudero@sespa.princast.es, lolaescudero@telefonica.net (D. Escudero).

PALABRAS CLAVE

Ética;
Donación de órganos;
Muerte encefálica;
Limitación del
tratamiento
de soporte vital

Conclusions: (1) *Cranioplasty with bandage* could be considered an ethically acceptable LSTL practice, similar to other procedures. (2) It facilitates organ donation for transplant, which provides for value-added proposition because of its own social good. (3) In these cases, it is necessary to know previous patient's will or, in absentia, to obtain family consent after a detailed procedure report.

© 2012 Elsevier España, S.L. and SEMICYUC. All rights reserved.

Craneoplastia con vendaje. Nuevas formas de limitación del tratamiento de soporte vital y donación de órganos

Resumen La mayoría de los órganos trasplantados proceden de donantes fallecidos en muerte encefálica (ME). En pacientes neurocríticos con lesiones catastróficas y craniectomía descompresiva (CD) que tienen una pésima evolución a pesar de todo el tratamiento, la CD puede llegar a ser una medida fútil que impida la evolución *natural* hacia la ME.

Planteamos si realizar un vendaje compresivo pericraneal (*craneoplastia con vendaje*) puede ser una práctica éticamente correcta y comparable a otras formas habituales de limitación del tratamiento de soporte vital (LTSV).

A partir de un caso clínico, realizamos una consulta al Comité de Ética Asistencial y a expertos bioéticos, formulando las siguientes cuestiones: 1) En pacientes que se decide la LTSV ¿es éticamente correcto realizar una craneoplastia con vendaje? 2) ¿Es preferible esta opción considerando una posible donación de órganos?

Conclusiones: 1) La *craneoplastia con vendaje* puede ser considerada una forma de LTSV éticamente aceptable y similar a otros procedimientos 2) Facilita la donación de órganos para trasplante, lo que aporta valor añadido por el bien social correspondiente 3) En estos casos, es necesario conocer las instrucciones previas del paciente y en su ausencia, obtener el consentimiento familiar por delegación tras un informe detallado del procedimiento.

© 2012 Elsevier España, S.L. y SEMICYUC. Todos los derechos reservados.

"The fact that things are so does not mean that they have to stay that way". Bertolt Brecht. The life of Galileo.

Organ transplantation is a consolidated treatment for terminal organ failure. It clearly improves patient's quality of life, and in the case of vital organs constitutes the only possible treatment option. Transplantation currently offers excellent results, reaching a survival rate of 48% after 20 years in the case of liver transplantation¹ and of 53% after 10 years in the case of heart transplantation.² Spain, with 35.3 donors per million of population (ppm) in the year 2011,³ has the highest donor rate in the world, while the United States has a rate of 26.3 ppm and the European Union has an average donor rate of 18.1 ppm. Up until 1 January 2012, a total of 81,909 organ transplants had been carried out in Spain.

Globally, the main problem facing transplantation is the scarcity of organs—a situation causing the death of about 10% of all patients while on the waiting list. The demand for organs moreover increases every year, since transplantation has become a routine and generalized practice. Approximately 90% of all organs transplanted in Spain come from brain death (BD) donors, but this source has a limited potential for producing candidate organs. In order to satisfy the demand on the part of patients on the transplant waiting list, the Spanish National Transplant Organization (*Organización Nacional de Trasplantes*, ONT) and other international organizations have developed strategies designed to increase the donor pool by harvesting organs from non-heart beating donors (Maastricht types II and III) and live donors.⁴

The age of BD donors has gradually increased in this country. In the year 2011, 53.7% of the donors were over 60 years of age, 27.9% were between 45 and 59 years of age, and only 18.4% were under 45 years of age.⁵ This means that a large proportion of donors are of the "expanded" type, resulting in a shortage of thoracic organs in particular, since these are the transplants that prove most demanding in terms of donor age.

Intensive Care Units (ICUs) constitute a key element in any transplant program, since it is in the ICU where BD is diagnosed,⁶ and where the multiorgan donor is maintained. In Spain, almost 80% of all transplant coordinators are intensivists.⁷

In neurocritical patients with intracranial hypertension syndrome (ICH), the European Brain Injury Consortium⁸ and the American Association of Neurological Surgeons⁹ propose decompressive craniotomy (DC) as a second level management measure. In recent decades, DC has been the subject of controversy, and although it clearly reduces intracranial pressure (ICP) and shortens the stay in the ICU, there is debate regarding the functional outcome of the technique.¹⁰⁻¹⁵ In any case, and despite the controversies, extensive DC (frontal-subtemporal-parietal-occipital) is increasingly being used in the ICU. This in turn is one of the explanations given for the decrease in BD donors, which in Spain have dropped from 32 ppm in the year 2001 to 29.2 ppm in 2010.¹⁶

In patients with devastating neurological injuries and an extremely poor prognosis, the maintenance of DC prevents ICP from reaching levels high enough to produce cerebral circulatory arrest and therefore BD. In these cases,

life-sustaining treatment limitation (LSTL) may be considered—this being a frequent practice in our ICUs and regarded as a quality standard by the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (*Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronarias, SEMICYUC*).¹⁷ When LSTL is performed through terminal extubation, the possibility of organ harvesting is exclusively limited to controlled non-heart beating or Maastricht type III donation.¹⁸ This type of donation is only exceptionally performed in Spain, and because of its inherent limitations, the harvesting of organs for grafting cannot always be guaranteed.

Based on the case of a patient admitted to the ICU of the Central University Hospital of Asturias (Oviedo, Spain), we have postulated suppression of therapeutically futile DC involving cranioplasty with bandage as a form of LSTL. All aspects related to transplantation have an important bioethical dimension,¹⁹ and despite the fact that this practice, and withdrawal of ventricular drainage, are performed occasionally, there are no literature references in this respect. Consequently, *a posteriori*, we commented the case with the Clinical Ethics Committee of our hospital and consulted reputed national and international experts in bioethics. In order to obtain a broader range of impressions, we consulted experts from different settings. All of them were especially dedicated to medical ethics: Dr. Diego Gracia, Dr. Marcelo Palacios, Dr. Pablo Simón and Dr. Pilar Miranda. Others were specifically ascribed to the world of Intensive Care Medicine, as members of the SEMICYUC and experts in ethics applied to the critical patient: Dr. Luis Cabré, Dr. Iñaki Saralegui, Dr. Koldo Martínez and Dr. Sebastián Iribarren. In turn, another consulted expert, likewise dedicated to medical ethics, was more closely related to organ donation and transplantation: Dr. Miguel Casares.

The consulted experts came from different parts of the country; consultation was therefore made by e-mail. The authors of the present article summarized and structured all the replies obtained. Posteriorly, the manuscript was forwarded to all the consulted experts (as co-authors) for reading and approval. The pertinent modifications were made, and the paper was then again forwarded to the experts with a view to obtaining final consensus. The paper was then submitted for publication.

Clinical case

A 38-year-old male was admitted due to traumatic brain injury. Upon admission, the Glasgow coma score was 3, with bilateral non-reactive mydriasis (6 mm) and the absence of corneal reflexes. The brain computed tomography scan showed multiple hemorrhagic contusions, massive brain edema with compression of the peri-mesencephalic cisterns, and left subdural hematoma with mass effect. Given the Glasgow score and the absence of brainstem reflexes, Neurosurgery decided against surgical intervention. After three hours without sedation, the patient remained with bilateral non-reactive mydriasis (6 mm) but had recovered the corneal reflexes and showed decerebration rigidity motor responses. Upon re-evaluation by Neurosurgery, and despite the bilateral non-reactive mydriasis and dire prognosis, surgery with evacuation of the subdural hematoma was

carried out, with left DC and ICP monitoring with a Camino® catheter, in view of the age of the patient. The course proved negative, with a sustained ICP of over 40 mmHg, refractory to all kinds of treatment (deep sedation, analgesia, neuromuscular block, controlled hyperventilation, hypertonic saline infusion, mannitol and DC). The computed tomography scan showed ischemic areas in the brainstem, territory of the right anterior cerebral artery and left brain hemisphere (territory of the middle and posterior cerebral arteries). After 5 days, and with the suspicion of BD, sedation was suspended. After 48 h without sedation, the patient presented a Glasgow score of 3, bilateral non-reactive mydriasis and the absence of photomotor, cranial, oculocephalic and cough reflexes, maintaining only spontaneous breathing. The electroencephalogram (EEG) showed the absence of brain bioelectrical activity in the left brain hemisphere, and minimum activity with suppression phases in the right hemisphere. The neurological exploration, the computed tomography findings and the EEG tracing confirmed that the patient suffered catastrophic and irreversible brain damage, with no chance of recovery. The supervising physician made the following assessment: the natural course of these injuries is towards BD, though this is impeded by DC initially intended to help save the life of the patient, but which has failed and now artificially prolongs a terminal situation. In this case two options were considered:

- (A) Decompressive craniotomy no longer improves the situation and only prolongs a terminal condition. It therefore would be acceptable to cancel its effects by means of a cranioplasty with bandage. In this case, death would occur according to neurological criteria.
- (B) The application of LSTL through terminal extubation, likewise considering that intubation and mechanical ventilation are futile and only prolong a terminal patient condition. In this case, death would occur according to cardiorespiratory criteria.

The case was discussed in clinical session, and since patient recovery was considered impossible, all the physicians in the Department agreed to apply LSTL. Of the two abovementioned options, the supervising physician chose cranioplasty with bandage, with the criterion that this would ensure a course more consistent with the natural evolution of the initial injury. The relatives of the patient were informed in detail of the reasons for this decision and of its possible consequences. Twenty-four hours later, after obtaining consent from the family, and in the absence of prior wills, the patient donated 6 organs (seventh day of admission).

Ethical consultation

All the consulted experts in medical ethics were asked the following question:

In a patient with catastrophic and irreversible brain damage, in which LSTL is decided, is it ethically correct to perform cranioplasty with bandage in order to facilitate evolution towards BD? Should this option be preferred over other forms of LSTL, taking into account the possibility of organ donation?

Responses

The experts agreed on the following points:

- (1) From the scientific and ethical perspective, in the event of catastrophic neurological damage, it is advisable to adapt treatment to the expectations for recovery and the wishes of the patient, if these have been previously expressed.²⁰ Maintaining futile treatment is regarded as poor clinical practice, since it goes against human dignity. The physician should always avoid unwarranted insistence upon treatment. Limiting life support measures that only serve to artificially prolong life without possibilities for recovery of the patient, having established consensus among the attending physicians and relatives, constitutes correct practice consistent with the recommendations referred to end of life care, Spanish legislation, and the accepted ethical standards.²¹ LSTL in these situations avoids undue suffering for the family and also the unnecessary consumption of healthcare resources. In the present case, cranioplasty with bandage is considered good medical practice.
- (2) Reverting the effect of decompressive surgery when the latter is no longer effective and indeed proves futile cannot be assumed in terms of surgical replacement of the bone flap, since this would constitute an unjustified consumption of resources. Reverting the effect of decompressive surgery through cranioplasty with bandage may be regarded as ethically similar to other forms of LSTL, since it does not violate the principles of beneficence and non-maleficence.
- (3) Attending the principle of autonomy, it must be determined whether the patient expressed or left instructions referred to LSTL and organ donation. If not so, then the relatives or legal representatives should make the decisions on the basis of what they know. In this respect, it is necessary to provide the family with exhaustive, detailed and transparent information on the entire process.
- (4) If the patient expressed a wish to donate his or her organs, or in the event of family consent through delegation, the implicated healthcare professionals must do everything possible to satisfy the expressed wish—preserving the principle of autonomy and abiding with the principles of social solidarity. In the present case it would be indicated to apply LSTL involving cranioplasty with bandage, since a fatal outcome under conditions of brain death would facilitate organ donation. In this context it must be remembered that donation under non-heart beating donor conditions (in cases of death according to cardiorespiratory criteria after terminal extubation) is exceptional, and is unable to guarantee organ harvesting for transplantation.

From the ethical perspective, we are obliged to contemplate organ donation, since there are many patients on the transplant waiting list who could benefit as a result. Some authors²² have estimated that a multiorgan donation comprising 6 organs generates 55.8 years of life for the different recipients, and thus represents an important social benefit consistent with the principles of justice. The World Health Organization,²³ the Spanish

national medical organization (article 48 of the Code of Medical Ethics and Deontology²⁴), and the ethical code of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC)²⁵ consider it an obligation of all health professionals to encourage and promote organ donation. Moreover, the family members of the patient can find certain consolation in donation, since by doing so, they are contributing to save the life or improve the quality of life of other people. It must be remembered that organ donation contributes greatly to a fairer society, with values such as solidarity, altruism, compassion, or the correction of inequalities. On the other hand, transplantation practice has been shown to be very efficient in terms of healthcare resource utilization.

- (5) In the ICU, the disconnection of mechanical ventilation and/or terminal extubation is a common element in LSTL. The fact that protocolized extubation is traditionally and most frequently decided does not mean that this LSTL modality should prevail over other options such as cranioplasty with bandage, particularly in those cases where there is a possibility for organ donation.

Therefore, cranioplasty with bandage can be regarded as good clinical practice, consistent with the general aims of medical practice as defined by the Hastings Center.²⁶

In many cases, decompressive craniotomy can save the life of neurocritical patients, and our obligation as intensivists is to offer our patients all possible opportunities for recovery. Unfortunately, in cases characterized by a very poor course and devastating injuries, DC may prove futile and can moreover impede natural evolution of the patient condition towards brain death.

After pondering this clinical case, it can be concluded that cranioplasty with bandage is an ethically acceptable form of LSTL. Its application is of undeniable social value, since it facilitates organ donation. In these cases, it is necessary to know the existence of prior instructions and to adequately inform the family of the patient with a view to obtaining consent.

Social and professional practices change slowly, and good reasons, profound reflection and broad knowledge are needed to facilitate change. We are therefore obliged to continue our research and specific training of health professionals in relation to the new forms of LSTL and organ donation.

Conflicts of interest

The authors declare that they have no conflicts of interest.

References

1. Registro español de trasplante hepático (RETH). Memoria de resultados 2010. Available from: <http://www.ont.es> [accessed on 9.09.12].
2. XIX Informe Oficial de la Sección de Insuficiencia Cardíaca. Trasplante Cardíaco y Otras Alternativas Terapéuticas de la Sociedad Española de Cardiología (1984–2007). Registro español de trasplante cardíaco. Rev Esp Cardiol. 2008;61:1178–90.

3. Matesanz R, Domínguez-Gil B, Coll E, de la Rosa G, Marazuela R. Spanish experience as a leading country: what kind of measures were taken? *Transpl Int.* 2011;24:333–43.
4. Matesanz R, Marazuela R, Domínguez-Gil B, Coll E, Mahillo B, de la Rosa G. The 40 donors per million population plan: an action plan for improvement of organ donation and transplantation in Spain. *Transpl Proc.* 2009;41:3453–6.
5. Resultados donación año, 2011. Available from: <http://www.ont.es> [accessed on 9.09.12].
6. Escudero Augusto D. Diagnóstico de muerte encefálica. *Med Intensiva.* 2009;33:185–95.
7. Matesanz R. El modelo español de donación y trasplante de órganos: la ONT, páginas 11-26 en El Modelo español de coordinación y trasplantes. Matesanz R, editor. Madrid, Aula Médica; 2008.
8. Maas AI, Dearden M, Teasdale GM, Braakman R, Cohadon F, Iannotti F, et al. Guidelines for management of severe head injury in adults. European Brain Injury Consortium. *Acta Neurochir (Wien).* 1997;139:286–94.
9. Guidelines for management of severe head injury. Brain Trauma Foundation. *J Neurotrauma.* 2007;24:S1–106.
10. Cooper DJ, Rosenfeld JV, Murray L, Arabi YM, Davies AR, D'Urso P, et al. Decompressive craniectomy in diffuse traumatic brain injury. *N Engl J Med.* 2011;364:1493–502.
11. Lubillo S, Blanco J, López P, Molina I, Domínguez J, Carrera L, et al. Papel de la craniectomía descompresiva en el enfermo neurocrítico. *Med Intensiva.* 2009;33:74–83.
12. Sahuquillo J, Arikan F. Decompressive craniectomy for the treatment of refractory high intracranial pressure in traumatic brain injury. *Cochrane Database Syst Rev.* 2006;25:CD003983.
13. Hutchinson PJ, Corteen E, Czosnyka M, Mendelow AD, Menon DK, Mitchell P, et al. Decompressive craniectomy in traumatic brain injury: the randomized multicenter RESCUE study. *Acta Neurochir Suppl.* 2006;96:17–20.
14. Pompucci A, De Bonis P, Pettorini B, Petrella G, Di Chirico A, Anile C. Decompressive craniectomy for traumatic brain injury: patient age and outcome. *J Neurotrauma.* 2007;24:1182–8.
15. Aarabi B, Hesdorffer DC, Ahn ES, Aresco C, Scalea TM, Eisenberg HM. Outcome following decompressive craniectomy for malignant brain swelling due to severe head injury. *J Neurosurg.* 2006;104:469–79.
16. De la Rosa G, Domínguez-Gil B, Matesanz R, Ramón S, Alonso-Álvarez J, Araiz J, et al. Continuously evaluating performance in deceased donation: the Spanish quality assurance program. *Am J Transplant.* 2012;12:2507–13.
17. Rubio O, Sánchez JM, Fernández R. Criterios para limitar los tratamientos de soporte vital al ingreso en unidad de cuidados intensivos: resultados de una encuesta multicéntrica nacional. *Med Intensiva.* 2012 [Epub ahead of print].
18. Koostra G, Daemen JH, Oomen AP. Categories of non-heart-beating donor programs. *Transplant Proc.* 1995;27:2893–4.
19. Gracia D. Trasplantes de órganos: medio siglo de reflexión ética. *Nefrología.* 2001;21:13–29.
20. Saralegui Reta I, Monzón Marín JL, Martín MC. Instrucciones previas en Medicina Intensiva. *Med Intensiva.* 2004;28:256–61.
21. Monzón JL, Saralegui I, Abizanda R, Cabré L, Iribarren S, Martín MC, et al., Grupo de Bioética de la SEMICYUC. Recomendaciones de tratamiento al final de la vida del paciente crítico. *Med Intensiva.* 2008;32:121–33.
22. Schnitzler MA, Whiting J, Brennan D, Lentine K, Desai N, Chapman W, et al. The live years saved by a deceased organ donor. *Am J Transplant.* 2005;5:2289–96.
23. Recomendaciones de la 44 Asamblea Mundial de la Salud en materia de Trasplante de Órganos. *Rev Esp Trasplant.* 1992;1/2:168–83.
24. Código de Deontología Médica. Guía de Ética Médica. Organización Médica Colegial de España; 2011. Available from: <https://www.cgcom.es/> [accessed on 9.09.12].
25. Cabré L, Grupo de Trabajo de ética de la SEMICYUC. Código ético de la Sociedad Española de Medicina Intensiva. Crítica y Unidades Coronarias (SEMICYUC). *Med Intensiva.* 2006;30:68–73.
26. The Hastings Center. The goals of medicine. Setting new priorities. An International Project of the Hastings Center. Hastings Center Rep. 1996;26 Suppl 6:S13.