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Original article

Autologous bone flap versus hydroxyapatite prosthesis in first intention in secondary cranioplasty after decompressive craniectomy: A French medico-economical study

Volet osseux autologue versus prothèse en hydroxyapatite en première intention dans la cranioplastie secondaire après craniectomie décompressive : une étude médicoéconomique française

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ABSTRACT

Background and purpose. – Decompressive craniectomy is the most common justification for cranioplasty. A medico-economial study based on the effective cost of the hydroxyapatite prosthesis, the percentage of autologous bone graft's loss due to bacterial contamination and the healthcare reimbursment, will allow us to define the best strategy in term of Healthcare economy management for the cranioplasties. A comparison was made between the two groups of patients, autologous bone flap versus custom-made prosthesis in first intention, based on the clinical experience of our department of neurosurgery.
Results. – No differences was shown between the two groups of patients, in terms of lenght of in-hospital stay and population's characteristics or medical codification. The mean cost of a cranioplasty using the autologous bone graft in first intention was € 4045, while the use of hydroxyapatite prosthesis led to a cost of € 8000 per cranioplasty.
Conclusion. – In term of Healthcare expenses, autologous bone flap should be used in first intention for cranioplasties, unless the flap is contaminated or in specific indications, when the 3D custom-made hydroxyapatite prosthesis should be privilegied.

Mots clés :
Cranioplastie
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RÉSUMÉ

Introduction. – Les craniectomies de décompression sont les principales indications secondaires à une cranioplastie. Une étude médico-économique permettra d'évaluer le coût de la cranioplastie par volet crânien autologue ou par prothèses en première intention pour la réalisation des cranioplasties. Nous avons comparé deux groupes de patients ayant eu une cranioplastie autologue ou un volet crânien sur mesure, dans notre service de neurochirurgie.
Résultats. – Aucune différence significative n'a été mise en évidence entre les deux populations en terme de durée d'hospitalisation et de caractéristiques de population. Le coût moyen d'une plastie crânienne est de 4045 € en utilisant le volet crânien autologue en première intention alors que la mise en place systématique d'une prothèse en hydroxyapatite revient à 8000 €.
Conclusion. – Il semble préférable en terme d'économie de santé, de reposer en première intention le volet crânien autologue, sauf en cas de contamination du volet ou dans des indications spécifiques, où l'on privilégiera la prothèse en hydroxyapatite.

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1. Introduction

A cranioplasty consist in the replacement of a defective or missing part of the cranial vault.

The interest of the cranioplasty lies in protecting the brain against injury, for aesthetic purposes, allowing a harmonious restoration of the cranial vault and treat post craniectomy symptoms like headaches.

Nowadays, three different type of cranioplasties are used: autografts, biomaterials shaped in the operating room and "custom-made" pre-fabricated prosthesis. The autologous cranial flap is removed during the craniectomy and then re-implanted, after storage in patient's abdominal fat or in a tissue bank. Moldable prostheses in the operating room are either metallic stents or surgical cements. Finally, since 2008, thanks to technological advances in radiology and biomaterials, allowing three-dimensional (3D) reconstructions with CT-scan and the discovery of new polymers, it is now possible to develop "custom-made" devices using 3D reconstruction of a patient's skull.

The aim of this retrospective study is to compare the cost of cranioplasty with autologous cranial flap over the cost of a hydroxyapatite-made prosthesis for cranioplasty in the context of a decompressive craniectomy. Prostheses moldable in the operating room being rarely used during decompressive craniectomies due to the large size of the component, they will not be considered in this study. The allograft and xenograft bone are no longer used, being more at risk for infection than the autograft, and less moldable than the custom prostheses (Moreira-gonzalez et al., 2003).

2. Material and methods

This article is a medico-economic study, based on a review of the literature about the different types of cranioplasty. We also conducted a short retrospective study based on the patients who underwent a cranioplasty after a decompressive craniectomy, hospitalized in our department of neurosurgery at the university hospital of Angers from January 2010 to September 2012.

A collaboration with the central pharmacy of the university hospital of Angers (Dr Martine Urban), and with the tissue bank of the French Blood Establishment (EFS) (Dr Marie Splingard), allowed the assessment of the actual cost of each of these two techniques of cranioplasty.

The custom-made prosthesis used in our department is the Custombone® by Codman®, consisting of porous hydroxyapatite. This is currently the only prosthesis that is authorized by the French national health authority (Haute Autorité de Santé, HAS), dated of July 8, 2008, for extensive cranioplasty.

3. Results

3.1. Description of the population

From January 2010 to September 2012, fourteen patients underwent a decompressive craniectomy. Twelve were done for an extensive sylvian infarction, ten due to a primary cerebrovascular stroke, and two following a vasospasm after subarachnoidian haemorrhage caused by an aneurysm rupture. The two other were done after a severe brain traumatism, and one after an extended cerebral venous sinus thrombosis.

Until the end-date of this study, twelve of these patients underwent a cranioplasty, five with their native bone flap and seven with the use of a custom-made hydroxyapatite. The two remaining patients are waiting for their cranioplasty.

Both groups were compared. The sex-ratio was the same and the mean age of 53.6 years ± 6,3 in the autologous group versus 41 years ± 16.7 in the custom-made group, with a p-value of 0.1.

No postoperative complication required the removal of the cranioplasty.

3.2. Mean duration of hospitalisation for the two techniques

For the allograft group, the mean length of postoperative hospital stay was of 6.4 ± 0,9 days for the autograft group and 5,71 days ± 1,1 for the custom-made prosthesis group (p = 0,27).

We observed that the mean duration of hospital stay, regardless of the type of cranioplasty, decreased with the time from seven days to four days, probably due to the increasing experience of the surgeons.

3.3. Medical codification

For each cranioplasty, the codification is similar, using the code LAMA009 "vault's cranioplasty" which corresponds to an amount of € 209. The code LAGA007 is also used sometimes in addition with the previous code, corresponding to "vault's cranioplasty removal" for an amount of € 167.20.

3.4. Cost of the different techniques

For the autologous cranial bone flap, there are two methods of preservation of the cranial components: the oldest technique consists in placing the cranial flap into the patient's abdominal fat during the same procedure than the craniectomy. This technique is less used because of the deformity associated with the presence of an abdominal scar and the gradual deterioration of the bone flap's size and quality. There is also a significant risk of subcutaneous hematoma following the major peeling of the skin needed to insert the bone graft (Inamasu et al., 2010). The second method, used nowadays, is the transportation and preservation of the autologous bone flap in a tissue bank.

The packaging component, consumables, transport containers and transportation costs are charged € 134.24. Conditioning of the flap, microbiological controls and blood samples from the patient, and preservation of the cranial flap are charged € 630.76. Overall, the storage of the graft is charged € 765 all cost included.

The distribution of the graft, if validated, is charged € 150, including product traceability, packaging for transport of frozen graft and transportation costs.

In case of destruction of cranial flap after contamination, there is no additional billing. The cost of destroying these cranial components was estimated by statistical studies and was included within conditioning cost, causing no overcharge.

In total, the cost of a sterilized cranial flap autologous, used to make a cranioplasty is € 915.

If the cranial flap is destroyed due to contamination, support costs are € 765, corresponding to the storage in tissue bank of the cranial flap. To this cost we should add the cost of a hydroxyapatite prosthesis, € 8000, for a total cost of € 8765.

Concerning the custom-made prosthesis, two prosthesis are delivered for a global cost of € 8000 per patient.

The shape of the prosthesis is calculated to provide a symmetrical reconstruction of the cranial vault. After approval by the neurosurgeon on a prototype of the component and its adjustment compared to a reconstruction of the skull of the patient, two permanent prostheses are delivered in sterile packaging.

4. Discussion

4.1. Indications of decompressive craniectomy

The main diseases that can lead to a delayed cranioplasty are grouped into four broad categories. The main providers of cranioplasty are decompressive craniectomies performed generally after a malignant sylvian ischemic stroke, whose indication has been codified by the European Stroke Organization (ESO) in 2008 (Servadei, 2011). Another potential vascular indication described is the cerebral venous sinus thrombosis.

The cranioplasty can be considered in a post-traumatic context (defect of the cranial vault, decompressive cranial flap).

The cranioplasty may be indicated remotely from an infectious osteitis that resulted in the removal of the bone flap previously replaced (Baumeister et al., 2008).

Finally, the cranioplasty may be proposed following the removal of a tumor lesion invading the skull.

The usual delay for performing of cranioplasty is 2 to 3 months after the acute episode. This delay reduces the risk of infection and postoperative morbi-mortality. However, recent studies suggest that this period can be shortened safely to less than one month, with less complications (Beauchamp et al., 2010).

4.2. Medico-economic study: autologous cranial flap versus "custom-made" hydroxyapatite prosthesis as first-line cranioplasty

Data obtained from the tissue bank allowed us to estimate the rate of skull graft lost due to bacteriological contamination from 40 to 45%, meaning that for four patients out of ten, the use of a cranioplasty using a hydroxyapatite prosthesis will be needed, leading to an additional cost for the hospital.

When using an autologous bone graft in first intention, the average cost of cranioplasty, taking into account a rate of graft loss of 40% is of € 4055 per case. This cost takes into account the cranioplasties with autologous cranial flap, of a standard cost of € 915 and cranioplasties where the autologous bone flap could not be relocated due to contamination, which therefore required the realization of a hydroxyapatite prosthesis, causing additional costs (765 € + 8000 €).

The use of the Codman® Custombone® as first line implies a permanent cost of 8000 € by cranioplasty, due to the price of the prosthesis.

4.3. Comparison to reference

In terms of health cost, it is cheaper to harvest, preserve and reimplant an autologous cranial flap in first line, with an average cost per cranioplasty 45% lower than the use of a hydroxyapatite-made cranial prosthesis. The systematic use of hydroxyapatite in cranial flap will represent an average additional cost of 3945 € per cranioplasty. We decided to calculate the cost of the use of autologous bone graft replacement in first intention taking into consideration the graft's contamination rate and the cost of the custom-made prosthesis.

It would become advantageous from an economic standpoint to use the prosthesis as first-line if the rate of loss of bone flaps exceeded 90%.

Taking into account the current rate of bone flap loss, around 40%, the price of the hydroxyapatite prosthesis should be less than 1425 € to make it financially advantageous to use these prosthesis in the first intention in cranioplasties.

4.4. Advantages and inconvenients of the two types of cranioplasty

The autologous cranial flap is considered as the gold standard for cranial flap. Biocompatibility is optimal due to the presence of the patient's cells in the bone, the lower risk of infection than with any other type of prosthesis and the low cost of conservation (Artico et al., 2003). The major drawback of autologous cranial flap is its method of harvesting, most often made in emergency situations, by unexperienced people in this task, which results in approximately 40% of cases of bone flap loss due to contamination during harvesting or packaging, leading to an over-cost of € 7850 for a replacement using a custom-made prosthesis.

The advantages of "custom-made" prosthesis consist in providing a satisfactory cosmetic result and a good biocompatibility due to the components used. Moreover, hydroxyapatite is recolonized by osteoblasts from the surrounding skull, allowing ossification and integration of the prosthesis with an excellent stability (Staffa et al., 2007, 2012). The main drawback of this prosthesis is its price, which is 8000 € for two prostheses for the same patient. The prosthesis being made in biocompatible material, the risk of poor tolerance of the prosthesis and the risk of infection are low but still higher than the autologous cranial flap. To achieve a minimum level of resistance, hydroxyapatite prosthesis must be at least 7–8 mm thick, making its use difficult in areas of low thickness bone defect, as the temporal bone. It may be noted that the minimum amount of time needed for making a "custom-made" prosthesis is quite long, about 1 or 2 months.

4.5. Indications of the custom-made hydroxyapatite prosthesis

The indications for reimbursement of Custombone® are well-defined in guidelines of the HAS. The marketing authorization was given for patient with favorable oncologic and neurologic prognosis after the failure of an autologous cranial transplant, if the bone defect is large (more than 35 cm^2) or if located in the frontotemporal area (Staffa et al., 2007, 2012).

4.5.1. Perspectives to decrease the cost of cranioplasties

One way to reduce the cost of cranioplasties will be to improve our sampling methods, sterilization and decontamination of autologous skull flaps to lower infection rate. It could be possible to soak the grafts in a solution of antibiotics such as rifamycin, or in an iodine antiseptic during the time of surgery before their storage and transportation. It could be advantageous to sterilize the samples upon arrival at the tissue bank by irradiation or decontaminate by dipping in successive baths of antibiotics. This could decrease the rate of loss of cranial flaps, while increasing the overall cost of conservation of cranial components.

In such protocol, it could be of interest to evaluate the quality of bone grafts. Adopting such practice may altogether reduce the risk of contamination but expose to a detrimental effect on cells natively present in the graft (Yadla et al., 2011).

Lowering the infection rate may also be achieved by teaching to the emergency staff and surgical team the sampling techniques.

Other prostheses are under development and accreditation from the HAS, as Bioverit®, a vitroceramic alloy that offers an alternative to the custom-bone (Balossier et al., 2011).

Finally, it is very likely that the arrival of new prosthesis will allow lower prices, making, in the near future, the use of a bioprosthesis as first-line use in cranioplasty a viable economical choice.

5. Conclusion

In terms of overall cost of health, and given the current state of our knowledge and ongoing technological developments, the cost of performing a cranioplasty with autologous cranial flap is less than that is achieved using a "custom-made" hydroxyapatite prosthesis. The findings of this medico-economic study are similar to those made by the report of the Haute Autorité de santé (HAS) of 8 July 2011 concerning the marketing authorization of custombone. The HAS stated that this device has no room in the first-line use of cranioplasties, except in specific indications, because of its cost higher than the first-line autologous flap.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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