

THE DECISION OF REFUSING COCHLEAR IMPLANTATION IN CHILDREN: BIOETHICAL CONSIDERATIONS

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Abstract: Starting from the observation that the cochlear implantation represents a “therapeutic frontier” that has radically changed the scenarios of irremediability in the most serious cases of deafness and, above all, of deep congenital deafness that cannot be compensated with hearing devices, the article aims at clarifying the ethical and legal problems arising by the application of the method in the case of young children. With the intent to address and unravel the problematic issue of refusing intervention by some parents, proponents of the “deaf culture”, the benefit for the child is highlighted, in terms of protection of psycho-physical health, and not only of the protection of life, as a criterion intended - according to the law in force in Italy - to shape (and limit) the choices that the parental responsibility holders are called to make on behalf of the child. Because of this criterion, it is stressed that the parent’s conviction that their child's life is at their disposal has no legal and ethical justification. On the contrary, the emphasis is placed on the fact that parents have the duty to not compromise their child's quality of life based on their choices, as is the case when an intervention has proven positive effects on cognitive and relational development. However, it is argued that the removal of parents’s right to decide in order to put it back to the tutelary judge (Guardianship) should be the last resort, in the hope that, thanks to the adoption of the most appropriate communication strategies and an open approach to confrontation, it will be possible to overcome resistance and make shared decisions.

27

Keywords: Cochlear implants, Children, Informed consent, Bioethics.

Resumo: Partindo da observação de que a implantação coclear representa uma "fronteira terapêutica" que mudou radicalmente os cenários de irreversibilidade nos casos mais graves de surdez e, sobretudo, de surdez profunda congênita que não pode ser compensada com aparelhos auditivos, o artigo objetiva esclarecer os problemas éticos e legais decorrentes da aplicação do método no caso de crianças pequenas. Com a intenção de abordar e de desvendar a problemática da recusa de intervenção por alguns pais defensores da "cultura surda", destaca-se o benefício para a criança, em termos de proteção da saúde psicofísica, e não apenas da proteção da vida, como critério destinado - de acordo com a lei vigente na Itália - a moldar (e a limitar) as escolhas que os detentores da responsabilidade parental são chamados a fazer em nome da criança. A partir desse critério, enfatiza-se que a convicção dos pais de que a vida de seus filhos está à sua disposição não tem justificativa legal e ética. Pelo

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contrário, enfatiza-se o fato de que os pais têm o dever de não comprometer a qualidade de vida de seus filhos com base em suas escolhas, como é o caso quando uma intervenção tem efeitos positivos comprovados sobre os desenvolvimentos cognitivo e relacional. No entanto, argumenta-se que a remoção do direito dos pais de decidir, devolvendo-o ao juiz tutelar (Guardião), deve ser o último recurso, na esperança de que, graças à adoção das estratégias de comunicação mais apropriadas e a uma abordagem aberta à confrontação, seja possível superar a resistência e tomar decisões compartilhadas.

Palavras-chave: Implantes cocleares. Crianças. Consentimento livre e esclarecido. Bioética.

Introduction

Cochlear implantation (C. I.) also termed “cochlear prosthesis” is an articulated prosthetic-rehabilitative procedure that can be counted among the biomedical methods. Its development (made possible by the increasing knowledge in the field of electrophysiology and of how neurosensory apparatus works), has, for some decades now and, in any case, since the second half of the last century, given medicine the feature of a “context of success”¹, increasing the capacity of therapeutic responses, often resolute, for diseases that could not be effectively treated in the past.

It is a method - with distant roots in intuitions and experiments by leading figures in modern science, starting with Alessandro Volta - which, like other methods (e.g organ transplants ²), has experienced a pioneering phase. During this phase, it appeared as an experimental procedure, which should be evaluated with great caution or even excluded, especially in children³, because of the uncertainty in determining the auditory threshold, the unpredictability of clinical results and, in particular, the impact on language learning, as well as because of the high threshold of exposure to risks of a psychological as well as physical nature, due to intra- or post-operative surgical complications or bacterial infections.

Thanks to the improvement of techniques and to the increased ability to cope with possible side effects, C.I. has, however, for about thirty years now, become an effective intervention strategy in the case of subjects suffering from total or profound deafness that cannot be compensated by the use of a hearing device. The Food and Drug Administration has approved its clinical application in pre-school children since 1990. Nowadays the C. I. is a therapeutic “frontier”, whose development has required that clinical and surgical problems, technical problems related to the devices used and, again, problems of an organizational nature be faced and solved. Moreover C.I. encourages collaboration among professionals

whose skills (otology, audiology, speech therapy) are indispensable for the success of the intervention⁴.

These problems of a clinical, technical and organizational nature are and will continue to be in the foreground also in the development from which the C. I. may be interested in the future, but they certainly do not exhaust the problems that this method raises and, I would add, the problems with which health professionals must be confronted in clinical scenarios that would require their adoption.

Cochlear implantation as an ethically problematic clinical procedure

Not unlike other therapeutic procedures made available by the extraordinary scientific and technological progress made in the biomedical field since the second half of the last century, the C. I. presents, in fact, also relevant profiles of ethical problems, in addition to the problems of a technical-clinical nature, in relation to which have already been, and will continue to be, of primary importance the specialized skills of health care workers, as well as technological advances of a bio-engineering nature.

This means that the availability of a therapeutic strategy, such as the one offered by the C. I., which has radically changed the scenario in which deafness, even in its most serious forms, is faced with choices, in order to make which the scientific knowledge and organizational skills acquired by operators during their training are undoubtedly a necessary, albeit not sufficient, condition. Indeed, the reference to further factors able to best guide concrete actions is needed. These factors include rules, principles and values on which criteria of acceptable practices are based.⁵ In other words, the constitutive elements of ethics: morality, law, and deontology. Given that ethics comes into play when there are problems of choice and “identification of regulatory criteria on the basis of which to resolve them, it can be said that ethics has found a privileged context in the health sector, as the idea has emerged that the availability of a treatment does not always and in any case justify its implementation, nor does it make irrelevant the question of who is affected by the decision to implement it. A trend which has been gradually consolidated in Italy not only in the bioethical field, but also at the deontological and legal level, before being stated by Act no. 219/2017 “Rules concerning informed consent and advance directives⁶.

It is true, therefore, that ethics concerns almost all health interventions, since there is no treatment in respect of which the question is not asked whether or not its implementation

has been carried out in compliance with the fundamental ethical principles of reference for clinical practice, starting from the traditional principles that require therapies to be based on the best interests of the patient (principles of non - maleficence and beneficence), and from the principle that, as a rule, requires the involvement of the patient, or those who represent him, in decisions on treatment (principle of autonomy)⁷.

It is, however, also true that the treatments present more or less high rates of ethical problems in relation to their impact on the recipients and/or other subjects and, therefore, in consideration of their greater or lesser invasiveness and impact on the psycho-physical integrity of those who receive them. In addition, and more generally, ethical profiles of particular relevance are, above all, involved by the interventions that most contribute to transforming the scenarios of human life in the different phases, making it possible to control and, therefore, removing from chance and necessity, situations and conditions that have long been considered “natural” . Let us think of those techniques applied to the procreative process⁸ or to interventions that modify the genetic heritage^{9,10} or end of life decisions (non-activation and suspension of life support treatments¹¹), which modulate the times and ways of dying¹² .

Ethically problematic are also, in particular, the interventions that, in consideration of those who are the addressees make it far from easy to identify the most suitable subjects to be invested with decisions. This is the case when choices are to be made in relation to minors and incapacitated persons^{1, 13}. Now, the C. I. is one of the methods with relevant ethical profiles because it is likely to affect a condition of sensory deprivation that can no longer be considered irremediable and, due to the ineluctability, “natural”. It also presents additional ethical problems when it is directed towards young children as it has an invasive nature and decisions cannot be taken by the individual directly concerned.

For these characteristics, the C. I. deserves to be analyzed from a bioethical reflection that, giving evidence to the regulatory criteria of reference in the field of relationship and care mandate, can assess whether there are ethical reasons (in the broad meaning that includes also deontological and legal ones) to consider implementation of the C. I. in children not only justified but even due, and can also dissolve doubts and uncertainties regarding the role to be recognized to the subjects involved in the clinical decision-making process, as well as the directions of ethically approvable choices.

Normative criteria for the care relationship, with particular reference to minors

What are the normative criteria that frame decisions on treatments in general and specifically decisions concerning implementation of the C. I. ?

These criteria can be inferred from increasingly widespread moral principles, deontological rules, and legal provisions emerged from an incisive rethinking of assumptions and attitudes long rooted in traditional medical ethics¹. These criteria state that any treatment must be based on therapeutic appropriateness, evaluated also in relation to psycho-physical well-being and quality of life, to the further essential condition of respect for the will expressed by the patient, the recipient of adequate information in the context of a communicative relationship, and to the condition of the prevalence of patients' rights, safety, well-being and dignity over all other interests.

These criteria regulated by Act no. 219/2017 as referred to earlier, thanks to which Italy now has an advanced regulation of health care relationship, adopted in implementation of the principles enshrined in the Constitution (in particular the principle of voluntary treatment enshrined in art. 32) and in continuity with the jurisprudential guidelines which, as stated in the Constitutional Court's ruling no. 438/2008, have attributed to informed consent the value of a true and proper right of the person, indeed, a synthesis of two fundamental rights of the person, the right to self-determination and to health, rooted in the principles enshrined in articles. 2, 13 and 32 of the Constitution.

The regulatory framework, mandatory for all actors involved in health care, including Act no. 219/2017, is characterized by the central position attributed to the patient, whom is granted decision-making autonomy, that is, the prerogative to decide whether to accept or refuse treatment. The competent and adult patient can also decide whether to include or exclude family members in the decision-making process. In affirming the importance of the communicative relationship, the law highlight the competence of healthcare professionals, to whom it reserves the prerogative to identify and propose diagnostic and therapeutic options which, in relation to the diversified situations of illness, are considered appropriate, on the basis of the clinical-scientific evidence and/or the consensus reached within the community of healthcare professionals.

There is no doubt that the administration of the C. I. or of any other treatment in case of an adult and competent patient is subject to the patient's consent as legally stated. Consequently, the refusal by the patient after being informed represents an insurmountable obstacle¹⁴. In this scenario, the correct identification of the conditions of appropriateness in a

specific clinical situation as well as the duty of the doctor to establish an adequate communication with the patient to allow the understanding of information about the nature of the intervention, as well as its hypothetical benefits and risks is ascertained.

But what happens in case of interventions on children?

Paragraph 1 prescribes that a person who is under the age of 18 or incapacitated has the right to the enhancement of his or her ability to understand and make decisions, with due respect for the rights set out in Article 1.1, and that he or she must receive information on choices relating to his or her health in a manner appropriate to his or her abilities in order to be put in a position to express his or her will. In addition, the second paragraph of Article 3 provides that informed consent to the medical treatment of the child shall be expressed or refused by the parental guardian or guardian taking into account the will of the minor, in relation to his or her age and degree of maturity, and having as its purpose the protection of the child's psychophysical health and life in full respect for his or her dignity.

Finally, it is important to underline the provision of paragraph 5: “in the event that . . . the legal representative of the minor refuses the proposed treatment and the doctor believes that it is appropriate and necessary, the decision is referred to the tutelary judge on appeal by the legal representative of the person concerned or the persons referred to in Articles 406 et seq. of the Civil Code or the doctor or the legal representative of the health facility”.

From these provisions emerges a discipline which maintains, on the one hand, that parents or, in their absence, the guardian, have the right/duty to give or deny consent to administration of an intervention, in accordance with the traditional perspective which requires legal representation for the execution of any act before acquiring the capacity to act. On the other hand, the child is no longer seen as a passive object of choices and decisions concerning his or her health and life. The child becomes a subject of rights and freedoms, whose personal development ought to be sustained by the legal representatives by removing obstacles and creating opportunities. This new understanding of the role of the child is testified by the emphasis on the right of children to have their understanding and decision-making skills enhanced, as required by important supranational documents, such as the Convention on the Rights of the Child (1989) and the Charter of Fundamental Rights of the European Union (2000) (Art. 24, Rights of the child),.

This is the perspective according to which the capacity of discernment^{15,16} is the appropriate criterion to replace or supplement the criterion of legal representation, linked to

the age threshold - that of reaching the age of 18 - considered by law a necessary condition for the acquisition of the capacity to act ¹⁷.

This is not, however, a perspective limited only to minors with a sufficient degree of maturity, but rather a rethought of the concept of minors in general, which will have an impact on the way in which decisions reserved for legal representatives are understood and shaped, even if the recipients of care are children of a few years or a few months of age. In parallel with the changed consideration of the minor, the legal representation of the parents (and guardian) has also been reshaped, which has gradually lost the connotation of right/power, to assume that of power/duty, or, even better, of responsibility/duty. These qualifications of responsibility are attributed to those who represent the minor not in their personal interest, nor in the interest of the family or a wider group to which they belong, but exclusively in the interest of the minors themselves, with the strong implication that the only possible decisions ought to be directed towards protection of the psychophysical health and life of the minor in full respect of his/her dignity as the law states.

The limitation of the decisions of the representatives to those functional to the interests of the child is confirmed by the provision that, in the event of refusal of treatment deemed appropriate and necessary by the doctors, the decision is referred to the tutelary judge (Guardianship).

Refusal of treatments for minors in general and cochlear implantation in particular: criteria and limits

Therefore, the provisions of the law in force and, in the same line, the provisions emerging from the Code of Medical Ethics (Art. 37), provide a sufficiently sound basis for considering any action taken by health professionals to not maintain the decision at the sole disposal of the parents in the case of treatment whose refusal may put the child's life at risk. And what about treatments such as C.I whose omission does not put life at risk, but adversely affects its quality?

It would be a serious misunderstanding to think that the law endorses overriding the will of the parents, putting the so-called “therapeutic privilege” back into play. This expression refers to the idea that the availability of a treatment, which a doctor considers appropriate, should always be carried out. The involvement of parents (or guardian) continues to play a major role, with the aim of achieving shared decisions as far as possible, even when

life-saving treatment is at stake^{14,19}. But the law decisively emphasizes the benefit of the child as a guiding criterion for the clinical decision, re-qualifying the benefit in terms of health protection in a broad psychophysical sense, and not just life protection.

Thereby the law reinforces initiatives to enable decision-making processes based on that criterion also in case of treatments whose significant impact on the quality of life of those who are subject to them can no longer justifiably be considered controversial. There are, therefore, valid ethical and legal reasons to oppose the family's claim to be able to reject the implementation of the C. I. on young children with profound congenital deafness. They have no decision-making power that meets limits or conditions. In other words, parents cannot dispose of their child's life at will, without having to worry about compromising his/her quality with the choices made.

There is also resistance against the C. I. on the basis of alleged factual reasons. That is, the argument is used that it is still an experimental procedure, whose results are uncertain, thus exposing the child to a high risk. These reasons are unfounded: far from being an experimental procedure, the C.I. presents itself today as a method of which, together with the introduction of measures to control risks, the areas and conditions of application and, conversely, the contraindications have been well defined. It is, instead, a method of which, in relation to a well-defined population of very young children with profound deafness not differently treatable, it is now proven, despite the variability of results, the effectiveness in the recovery of auditory function and language skills, with the related positive effects on cognitive and relational development.

Testing other arguments against the cochlear implant

We cannot end this paper without briefly considering two further arguments of advocates of the deaf culture against the C. I. The two arguments are: protection of cultural diversity and deafness as a “natural” condition deserving to be preserved.

As for the first argument, the question is: is it true that C.I. represents a threat to the maintenance of the cultural identity of a minority group entitled to protection from any form of interference? And the second question is: does it really represent an undue interference in a natural condition?

The answer to both questions can only be negative, based on the following considerations. Starting with the second question, to the advocates of the intangibility of what

is natural, one can oppose the point that - like David Hume¹⁸ had already affirmed very well in the eighteenth century - the value judgement about the merits of a situation, a condition, a way of being cannot be derived from the simple observation of the presence of such situations, conditions, phenomenal manifestations, in general, in reality. Even the most devastating oncological pathologies or the coronavirus epidemic that has spread globally in recent months - to give just two examples - present themselves as natural, but not such that they cannot or must be fought! Without, on the other hand, neglecting that, if one recognizes in naturalness the connotation of what is taken away from the possibility of human control, then one can go so far as to argue that deafness can no longer be considered “natural”, as it is no longer unchangeable, thanks precisely to the biomedical safeguards available today.

As far as the subject of the threat that the C. I. would pose to the cultural identity of the deaf community is concerned, it is a subject that deserves to be taken into consideration, but on the basis of which misunderstandings can be glimpsed, which frequently arise when dealing with the very important issue of the protection of cultural diversity and the rights of cultures^{1, 20}.

In fact, to recognize cultural diversity as a value, taking all the necessary actions to guarantee the right of the members of a given community to live by making the best use of practices, starting with the linguistic ones (in this case sign language), which are typical of their culture, does not mean to impose, in fact, membership of a community, in the name of the defense of the culture that characterizes it, on individuals who, due to their age, can neither make autonomous choices nor would be they able to choose, in the future, whether or not to make the linguistic practices of that community their own, being deprived of the opportunity of functional recovery and the acquisition of further modes of communication offered by the C. I.

Conclusions

The considerations proposed in this paper argue in favour of the thesis that cochlear implantation in very young children can be considered ethically justified and dismiss the main argumentative modalities used by those who oppose its implementation. But what can be the strategies to overcome resistance and encourage shared decisions?

The healthcare professionals who, faced with the refusal of the family, finds themselves in the frustrating situation of not being able to make available to some of their

young patients a therapeutic treatment without which the acquisition of verbal language will be compromised and cultural development, as well as social interaction, will be significantly limited, will have to adopt all the communicative strategies useful to facilitate the meeting between the caregivers and representatives of the minor, so as to hopefully maintain the decision within the care relationship, rather than resorting to external requests, in consideration, among other things, of the fundamental role that the family is called to play for the success of the educational-rehabilitation path necessary after the intervention.

Therefore, it suggests open dialogue, in which the perception of the deaf community to be stigmatized or devalued is not fed, albeit indirectly and unintentionally. On the other hand, the advantages that members of the hearing society, as well as deaf people, could derive from the availability of the amplified communication modalities allowed by the C. I. should be highlighted. These requirements presuppose respect for sign language as a communication tool for those who have no alternative, as well as the possibility of a special bilingualism (verbal/sign language) for those who can be offered this opportunity.

In case of refusal of treatments that can be envisaged as appropriate and necessary for the protection of the psychophysical health, as well as for the life of the child, the law provides that the decision is taken by the tutelary judge. This possibility should be the last option to be chosen, although not totally excluded.

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