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"Focus on Practice"-Clinical Ethics Consultation on an Orthotopic Liver Transplant Case

"Centrarse en la práctica": ética clínica de consulta en un caso de trasplante hepático ortotópico

"Centralizar-se na prática": ética clínica de consulta num caso de transplante hepático ortotópico

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Abstract

The contribution describes a case report addressed in 2011 by the clinical ethics consultation service team of the Institute of Bioethics and Medical Humanities at the "Agostino Gemelli" School of Medicine of the Università Cattolica del Sacro Cuore, Rome (Italy). The clinical case regards ethical dilemmas about the patient's prospects for receiving an orthotopic liver transplant, because she was a non-resident and lacked a caregiver to assist her during the follow-up period, as well as a place to stay after liver transplant surgery.

Keywords: Clinical ethics consultation; ethical dilemmas; orthotopic liver transplant; ethical evaluation (Source: DeCS, Bireme).

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Resumen

El artículo presenta un caso clínico, dirigido en el año 2011 por el equipo de servicio de consulta ética clínica del Instituto de Bioética y Humanidades Médicas de la Facultad "Agostino Gemelli" de Medicina de la Universidad Católica del Sacro Cuore en Roma (Italia). El caso clínico se refiere a los dilemas éticos sobre las perspectivas del paciente para recibir un trasplante hepático ortotópico porque no era residente del país y carecía de un cuidador para asistirlo durante el periodo de seguimiento, así como de un lugar para quedarse después de la cirugía.

Palabras clave: ética clínica de consulta; dilemas éticos; trasplante hepático ortotópico; evaluación ética (Fuente: DeCS, Bireme).

Resumo

Este artigo apresenta um caso clínico dirigido em 2011 pela equipe de serviço de consulta ética clínica do Instituto de Bioética e Humanidades Médicas da Faculdade de Medicina Agostino Gemelli, da Università Cattolica del Sacro Cuore (Roma, Itália). O caso clínico se refere aos dilemas éticos sobre as perspectivas da paciente para receber um transplante hepático ortotópico porque não era residente do país, carecia de um cuidador para assisti-la durante o período de observação e de um lugar para ficar depois da respectiva cirurgia.

Palavras-chave: ética clínica de consulta; dilemas éticos; transplante hepático ortotópico; avaliação ética (Fonte: DeCS, Bireme).

INTRODUCTION

The incidence of risks after *Orthotopic Liver Transplantation* (OLT) in a non-resident patient raises compelling ethical dilemmas that require deep reflection. Today, it is common knowledge that the worldwide availability of organs through cadaveric donation does not meet the demand (1) and, for this reason, liver transplantation (LT) can be the only solution for the end-stage pathology. Indeed, since the 1960s, LT has offered a real last chance of a new life for those patients.

However, post-OLT ethical assessment is fundamental, because follow-up economic costs must be considered in addition to hospitalization costs. Indeed, the patient —after hospital discharge— will be subject to follow up with different degrees of regularity, according to clinical conditions and the medical protocol adopted (2).

Clinical outcomes for patients submitted to OLT have improved over the years. This is due to several factors, such as the advance of surgical techniques, the careful selection of compatibility between donors and recipients (3) and the improvement in post-operative care and management to guard the recipient against infection (4). Moreover, OLT patients are administered immunosuppressive therapy for life. Even so, the continued use of immunosuppressant drugs can cause inevitable clinical consequences for the patient's life, such as increased risk of infection or metabolic complications (e.g. diabetes mellitus) and cancer (3). All these complications change over time, after the person receives the organ.

For this reason, follow up after OLT is fundamental to preventing risk factors and guaranteeing a real change of life for the patient, as well as a positive outcome for transplantation. The American Association for the Study of Liver Diseases and the American Society of Transplantation have approved a *Practice Guideline* (5) aimed at supporting patient management beyond the first 90 days after LT. The idea is to identify the barriers to maintaining their health and to make recommendations on how to best prevent or manage these barriers. Providing follow-up proves to be more difficult when the patient is a non-resident or a non-citizen, since this often means the patient does not have a residence near the healthcare organization where they received the OLT and does not have a caregiver nearby who can assist the patient in the post-operative phase and during the entire follow-up period.

In this paper, we will describe a clinical ethics consultation (CEC) case – provided by the CEC Service of the Institute of Bioethics and Medical Humanities at the "Agostino Gemelli" School of Medicine, Università Cattolica del Sacro Cuore, Rome-Italy - regarding ethical dilemmas about post-surgical management for a non-resident OLT candidate. We will demonstrate that the concrete possibility for the patient to receive the appropriate follow-up, after the transplantation procedure, has clinical and organizational value, as well as ethical merit.

THE CASE

The case under examination was addressed in 2011. It concerns a Polish woman, 49 years old, who was affected by acute hepatitis that evolved into chronic liver disease and hepatic failure. From a medical anamnestic point of view, the patient was treated at the "Agostino Gemelli" Teaching Hospital five years earlier for cervical cancer,

We will demonstrate that the concrete possibility for the patient to receive the appropriate follow-up, after the transplantation procedure, has clinical and organizational value, as well as ethical merit.

and submitted to surgery, chemotherapy and radiotherapy. At the time of the CEC request, her cancer was in remission.

On 29 July 2011, the patient came to the Emergency-Acceptance Department (DEA) of "A. Gemelli" Hospital with marked jaundice. The initial medical examination resulted in a diagnosis of acute hepatitis with chronic liver disease.

Her clinical situation likely was determined by the following causes: she ate mushrooms 30 hours before access to the DEA, during a drug regimen in recent months with acetylsalicylic acid and diclofenac in recent months.

The patient was admitted to the Internal Medicine Unit of our hospital and promptly treated. During her hospitalization, the patient experienced congestive gastropathy, a duodenal ulcer and right common femoral thrombosis. A central venous catheter (CVC) was placed to facilitate vascular access.

An analysis of the patient's clinical situation and the *quod vitam* prognosis indicated a liver transplantation (*Orthotopic Liver Transplantation* - OLT) . After adequate counselling with clinicians, the patient was introduced to the screening procedures for inclusion in the OLT waiting list. All required medical investigation indicated there were no clinical contraindications for including the patient at the top of the list, due to the severity of the disease. All the while, the patient maintained good autonomy.

From the perspective of the transplantation procedure, the CEC involved the possibility for the patient to pursue all post-surgical follow-up medical treatments/examinations: i.e. the woman should have a place to stay, possibly close to the hospital, and a caregiver who could assist her during the entire follow-up period. The absence of these requirements would have compromised the benefit of the LT. This was ascertained during the screening procedures for the waiting list and in further counselling shared with staff of the Internal Medicine Unit and the transplant surgeons.

Indeed, it was learned the Polish patient did not have immediate accommodation in Rome, because she lived in another region of Italy. Moreover, the patient had been widowed several years before and her only daughter was married, with a baby, living in Poland and unavailable to assist her mother in Italy. In other words, the patient did not have a caregiver available immediately available to assist her outside of her home country, nor did she have people nearby.

The ethical concerns arising from the clinical situation justified the request for CEC by physicians.

DISCUSSION ON THE CLINICAL ETHICS CONSULTATION

From a methodological point of view, our CEC Service applies the four criteria (indications for medical intervention; patient's preferences; Quality of Life (QoL), and contextual aspects) proposed by A.R. Jonsen et al. (6), integrating them into (ontologically founded) personalist bioethics, which first of all protects respect for physical human life (7). Integration is carried out as follows: for clinical indications: consideration is given to the parameters for moral action, "moral absolutes" and the double effect doctrine; for patient preferences: the meaning of patient autonomy is taken into account; for QoL: the proportionality of treatment is considered, and for contextual aspects: the rule of prudence and other moral virtues.

According to the first criterion of clinical ethics, to understand the indications for a specific medical intervention, it is necessary to analyze all the details of the particular situation. Regarding the indications for medical intervention, the indication for OLT is clear, due to the urgency of patient's clinical situation. Therefore, ensuring the patient the highest position in the waiting list is warranted.

During a dialogue in a CEC setting, the patient clearly expressed her wish to have transplantation surgery. For this reason, the patient's preference for LT is very clearly addressed .

The QoL criterion is the result of an individual evaluation by the patient about how she can envision/perceive her life after OLT, combined with the best scientific literature on the matter. In light of the foregoing criteria

Obviously, since an organ is a very scarce resource that is not be to wasted, the patient selection criteria are rooted firstly in medical factors, but personal (preferences) and contextual (organizational, family, social) factors also have to be included.

(medical indication and patient's preferences), LT will definitely give our patient the possibility for a good QoL. However, , one question stands out from a contextual point of view; that is, since the patient is a non-resident and possibly does not have accommodation near the hospital, adequate follow up might be difficult. The resulting ethical question represents a dilemma, considering the shortage of available organs (8). Specifically, if the patient does not have the possibility for follow up —in accordance with medical protocols— there is the possibility the transplanted organ might be wasted. In our particular case, after a dialogue, the patient claimed her countrymen residing in Rome would have been able to assist her during the time requested for follow-up controls/treatments.

Obviously, since an organ is a very scarce resource that is not be to wasted, the patient selection criteria are rooted firstly in medical factors, but personal (preferences) and contextual (organizational, family, social) factors also have to be included. Indeed, in the case under examination, the social or contextual factors cannot be ignored, as the possibility of providing adequate follow-up is crucial. The literature shows that when non-citizens

do not have a permanent place to live or have other social and personal conditions that are prohibitive for LT, this difficulty results in a refusal to list a potential recipient for an organ donation, in order to maximize the benefit from available organs (9). Moreover, there are different approaches in different areas. For example, ethical problems were found in the United States, where there are certain discrepancies between citizens and non-citizens. The American Board ,founded by the United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN, recently approved revisions of the liver allocation policy, so as to guarantee wide access to organs for possible recipients. OPTN states: "The Board also approved a series of amendments to policy regarding the transplantation of candidates who are not residents of the United States. The amendments included refined definitions for more precise data collection of resident status, as well as new processes for review of transplants involving non-resident recipients and public reporting of such transplants" (10). On the other hand, in Europe, various directives were enacted on Living Organ Donation (LOD) from a legal point of view, and are applied differently in the member countries (11). For this reason, the Commission of European Communities adopted a Communication from the Commission in 2008, which that constitutes an *Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States*. This EU Action Plan was intended to encourage cooperation between EU member states in coordinating their policies and programs on organ transplantation (12).

In the case under examination, the physicians —who requested CEC— and the CEC Service team came up with an alternative; namely, staying in a foster home near Rome, not too far from "Gemelli" Hospital. The patient accepted this option. Having considered the patient's preferences, the QoL she would acquire with LT, and the contextual aspects, given the possibility of overcoming the lack of an immediate accommodation in Rome, the transplant was given the go ahead, pending valid, free and informed consent.

CONCLUSIONS

The role of clinical ethics consultation, applied in this case to facilitate a clinical decision on a transplant and conducted in line with the aforementioned methodology, seems to be an effective tool.

The prudent choice that a personalist bioethics approach implies for the most appropriate decision was applied in line with the real possibility of being able to perform the scheduled follow-up, making it possible to combine the medical indications, patient preferences, and the proportionality of the intervention with the possibility of follow-up. This is a case in which the circumstances /contextual aspects are crucial to making the best decision, specifically one that accomplished the required contextual feasibility for the first three criteria.

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