Umbilical Cord Blood Collection: Ethical Aspects
Leanza V, Genovese F, Marilli I, Carbonaro A, Vizzini S, Leanza G and Pafumi C*
Institute of Pathology, Obstetrics and Gynecology, University Hospital - Vittorio Emanuele, Catania, Italy

Introduction

Treatments with stem cells are used today with very promising results. Three sources of cells are used for hematopoietic reconstitution: bone marrow (BM), peripheral blood (PB) and umbilical cord blood (UCB) [1,2]. The first UCB transplantation was performed in 1988 in a patient affected by Fanconi anemia (FA), using his brother’s cord blood who had a compatible human leukocyte antigen (HLA) [3]. His umbilical cord blood was collected at birth, cryopreserved and used after thawing for transplantation [4]. After the first UCB transplant more than 20,000 have been performed, mainly in children and adolescents [5,6].

The umbilical cord blood has been used successfully as a source of stem cells for hematopoietic reconstitution as an alternative to bone marrow or peripheral blood progenitor cells [7]. Related and unrelated transplants of umbilical cord blood have been used for children with malignant and non-malignant diseases [8-10]. Transplantation of UCB has been used with successful outcomes for the treatment of leukemia, lymphoma, myelodysplasia, aplastic anemia (AA), hemoglobinopathies, metabolic storage diseases and immunodeficiencies [11]. Several research groups are studying the usefulness of cord blood for other hematologic diseases, in particular to repair damage caused by heart disease and stroke, diabetes mellitus, traumatic brain and spinal cord injury [12].

Cord as a source of stem cells has important advantages over human leukocyte antigen (HLA)-matched unrelated bone marrow transplants. These advantages include a lower incidence of graft-versus-host disease, without the loss of a graft-versus-malignancy effect [13] no risk and pain for the donors, ready for immediate access and use, with minimal cell manipulation and a better long-term immune recovery leading to similar long-term survival rates [14]. Several studies in patients with hematologic malignancies showed that cryopreserved CB contains a sufficient number of hematic stem cells in order to obtain the engraftment in the majority of pediatric patients [15,16]. However, the low cell content of CB units may be its major limitation. In adults, the use of double unit graft, as a strategy to increase the dose, is associated with the improvement of graft cell engraftment, with a low transplant-related mortality (TRM) and with the opportunity of transplanting of CB at lower dose [17].

According to the Eurocord registry data, this strategy has been applied in about 993 adult patients with hematological diseases and stroke, diabetes mellitus, traumatic brain and spinal cord injury [12].

Materials and Methods

A review of the literature was undertaken using the Medline and Popline CD Rom considering articles published between 2004 and 2012; additional sources were identified from references cited in relevant research articles. We studied articles concerning umbilical cord donation, conservation, transplant, stem cells.

Collection and preservation

To provide adequate CB units for transplantation, there are special banks created to collect, process and cryopreserve CB. There are 3 main ways to collect and store CB [20]: CB units donated for public use in a public bank [21]; CB units collected from a healthy baby and kept for another family member who suffers from a disease which is known to be treatable [22] and CB units collected from a healthy baby and pay to be kept in a private bank for possible future use as a therapy for the donor, or a family-member. Therefore, two main options are available for parents who want to preserve umbilical cord blood: public and private banks [23-26]. In 2011, the Bone Marrow Donor Worldwide site reported that a total of 497,501 units of cord blood were stored with 43 banking networks in 26 countries [27]. These free and anonymous donations led to more than 20,000 transplants worldwide of unrelated umbilical cord blood [28]. Currently the procedure for CB collection involves a relatively simple venipuncture, followed by gravity drainage in a sterile anticoagulant-filled bag, using a closed system. After aliquots are removed for routine testing, the units are frozen and stored in liquid nitrogen [29]. Cell count and volume are key parameters for the eligibility of cord blood units for storage. National regulatory agencies and transplant centers have to follow international standards, with the aim of reaching a stable production of high quality UCB units for transplantation.

Banks

Public banks: The first public cord blood bank was established in 1991 at the New York Blood Center [30]. These banks are generally “not-for-profit” and have as main purpose to create an inventory of UCB units for independent use. UCB is donated to the bank, and the units are made available to suitably matched regional, national or international recipients. This type of program generally is partly or wholly funded by public funds. When the requirements for therapeutic use are satisfied, the blood unit is screened with a series of tests, reported in international registers and made available for national or international transplants [31]. The cord blood unit becomes public property for subsequent clinical use. About 20% of all cord blood units satisfy the storage criteria [32]. If the sample is considered inadequate it may be used for research [33].

Private banks: The alternative approach is the “for-profit” companies that encourage parents to preserved UCB for use of their family. In this case the cryopreserved CB will be will be used by either

*Corresponding author: Pafumi Carlo, Institute of Pathology, Obstetrics and Gynecology, University Hospital - Vittorio Emanuele, Catania, Italy, E-mail: pafumi@unict.it

Received May 16, 2012; Accepted June 13, 2012; Published June 16, 2012


Copyright: © 2012 Leanza V, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.
the donor (autologous transplant) or by a family member (related allograft). For a fee, the UCB is processed and stored as a form of “biological insurance”. In promotional material, the private banks indicate that UCB stored can serve as a source of stem cells for autologous and allogeneic transplants and these cells can be modified through gene transfer and targeted differentiation to treat some degenerative diseases like Alzheimer, Parkinson and myocardial infarction [34]. In fact, in many of these situations the effectiveness of CB transplantation is speculative and not used currently [35]. Prospective families may be vulnerable to this approach; with emotional pressure, many parents decide to collect and store UCB, despite estimates for future use being in the range of more than 1:1000 to 1:200.000 [36-38]. The private banks store CB for private use, and the blood remains property of the child under the care of the parents. Samples of UCB stored in private banks for autologous or allogeneic (for the donor child or a related family member) transplants allogeneic are not searchable by the public [39]. Their number is increasing all over the world, exploiting the idea that the indications for the use of CB is expanding every day. Even though this assertion is not justified by currently available scientific information and despite the probability for needing it being between 1 in 25.000 to 1 of 200.000 in the first 20 years of life [40].

Scientific and clinical data show that the estimated probability that an individual will develop a disease treatable with their saved CB is between 0.04% and 0.05% [41]. More than 780.000 units of cord blood are stored in more than 130 private cord blood banks worldwide [42]. According to many authors, this impacts the opportunity to discover future or additional indications for CB use and fuels the scientific community attitude against private cord blood banking [43,44].

Reasons for the academic and scientific community lack of support of private (for profit), the banks of include the lack of clinical justification for autologous banking sector, poor quality standards regarding the collection and storage of CB, no guarantee in case of failure, and false advertising by CB private banking companies [45]. Recent surveys of European countries suggest a strong preference for public over private CB banking [46,47]. Hybrid banks are also gaining popularity, in which firms are collecting units for a fee for the private use of the donor’s family, and at the same time collect units for public use. This allows the local health authority to cover some of the costs of storing the public CB units [48].

Ethical aspects

The expansion of UCB banking has led to the establishment of quality standards by professional groups [49]. There are numerous international registries that publicly list units of CB in searchable databases such as Bone Marrow Donors Worldwide (BMDW), the NETCORD Foundation, the National Marrow Donor Program (NMDP) to provide access to all patients in need. The group NETCORD was created in 1998 to establish best practices in stored umbilical cord blood, to facilitate the search for donors, improve the quality of the grafts, standardize excellence criteria on an international scale and, above all, establish procedures for the bank accreditation process [50]. Collaborations between NETCORD-Eurocord and NMDP have been established with the aim of providing the most appropriate and highest quality CB units for a specific patient.

There are unique ethical issues related to private banking of UCB. Politicians cannot help shape the future of the UCB banking sector in their country without taking into account the existence of private banks and their potential role in meeting future clinical needs, as well as their contribution, actual and potential, to research in this field. Now is the time to address prospectively the socio-ethical and legal issues surrounding UCB banking and customs [46].

The National Bioethics Committees are unanimous in accepting the statements in the cord blood banking issued by the EGE (European Union Group on Ethics).

On July 21, 1998, the EGE issued opinion number 11: “Ethical aspects of human tissue banks” [51] that emphasizes values such as integrity of the body, respect for privacy and confidentiality of data, the promotion of solidarity, equity of access to health care and informed consent of donors stating that “the information provided to the woman or couple must clearly explain the potential new treatments, but they are still experimental.” The principles listed by the EGE in its opinion number 19 “Ethical aspects of umbilical cord blood bank”, published March 16, 2004 [52] are:

- The principle of respect for human dignity and integrity, which enshrines the principle of non-commercialization of human body.
- The principle of autonomy or the right of self-determination on the basis of complete and correct information.
- The principles of justice and solidarity, with regard to equal access to health services.
- The principle of beneficence, or the obligation to do well, especially in health care.
- The principle of non-maleficence, or the obligation to do no harm, including the obligation to protect vulnerable groups and people, and to respect their privacy and confidentiality.
- The principle of proportionality, which implies a balance between means and goals”.

Committee of Ministers Council of the European Parliament recommended that “if the cord blood banks are established, they should be based on altruistic and voluntary cord blood donation and used for allogeneic transplantation and related research.”

Conclusion

In conclusion is evident that the promotion of donation for autologous use and the establishment of cord blood banks for autologous use is not supported by the Member States or by their health services. Clinical utility of autologous UCB storage is said to be limited because of very low probability that autologous hematopoietic stem cells will be required the individual in his/ her lifetime. Precise information should be available to the public on the advantages and disadvantages of cord blood banks, where autologous cord blood banks are being established. The promotional material or information provided to families must be accurate, and fully informed consent for the storage of cord blood must be obtained [53]. The National Marrow Donor Program estimates that by 2015 there will be 10,000 worldwide UCBT year using publicly banked cord blood. Therefore, it is vital to create repositories of public cord blood donations around the world [54].

However, in the final section 1.27, the EGE acknowledges that if in the future regenerative medicine using autologous stem cells develops, then having your own umbilical cord blood stored at birth could increase the likelihood of having access to new therapies [55]. It is hoped that UCB autologous stem cells will be of particular value for cell therapy and regenerative medicine, but, once again, many uses currently remain speculative.
References


51. www.coe.int/tc/vm/home_en.asp
