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Research Article

Cord Blood and Tissue Banking in Lebanon: The First National Experience

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Abstract

Umbilical Cord Blood Transplantation (UCBT) has been performed in the clinic for over 30 years. UCBT has several advantages over other methods, including no harm to mothers and donors, an off-the-shelf product for urgent use, less stringent HLA match, lower incidence and severity of chronic Graft-Vs-Host Disease (GVHD) and probably a stronger graft-vs-leukemia effect. UCB has also been used as source for regenerative medicine and immune modulation. Hence, collection and banking of UCB-derived cells have become a popular option. 1992 was the first public cord blood bank, the Act Regarding the Promotion of the Appropriate Supply of Hematopoietic Stem Cells for Transplant regulates only how public banks store and provide Umbilical Cord Blood (UCB) for research or transplantation. Lebanon had no laws to regulate how the cord blood banks manage the procedures, harvesting, preparation and storage of such blood. As a result, the status of UCB storage distribution in Lebanon remains unknown. In our article and in particular, we will introduce Reviva Regenerative Medicine Center known as the first and only cord blood bank based in Lebanon, our strategy in collection, processing and long-term storage, the challenges it faces and the strategies for future improvement. This is the first article to determine the status of UCB provision to private banks in Lebanon. Given these considerations, the trend toward UCB will continue to provide growing assistance to health care worldwide.

Keywords: Umbilical Cord Blood; Private Biobank; Umbilical Cord Blood Transplantation; Reviva Regenerative Medicine Center; Lebanon

Introduction

Umbilical cord blood has become an established source of hematopoietic stem cells following early clinical evidence demonstrating its capacity to restore hematopoiesis in inherited bone marrow failure syndromes, leading to its broader application in both malignant and non-malignant hematologic conditions [1]. Cord-blood banks have developed worldwide [2]. Eurocord, a group of physicians, was established to standardize methods of collecting, testing and cryopreserving cord blood from both related and unrelated donors [1]. Stem cells are defined by their capacity for long-term self-renewal combined with the ability to generate differentiated progeny that acquire specialized biological functions [3]. These are cells that have the ability to build different tissues of the body, therefore can play a central role infuture therapies called stem cell therapies [4]. Stem cells derived from the blood in the remaining segment of the Umbilical Cord and Placenta are known as 'Umbilical Cord Blood (UCB) stem cells' [5]. This blood, which is of no use to the mother or the baby and has been treated as a medical waste for centuries [5,6]. However, currently, it is estimated that 800,000 units of cord blood stored in public

banks and 5,000,000 units stored in private banks [7]. UCB has emerged as a potentially promising source of hematopoietic stem cells, which can be used for hematopoietic reconstitution [8]. HSC are adult stem cells that can differentiate into specialized blood cells that control immune function, homeostasis balance and responses to microorganisms and inflammation [9]. This beneficial role, in addition to the procedure of collection and storage of these UCB stem cells is called UCB banking [10]. In 1982, using UCB as a source of transplantable Hematopoietic Stem Cells (HSC) and Hematopoietic Progenitors Cells (HPC) was first suggested by Hal Broxmeyer in a private meeting with the late Edward A. Boyse and Judith Bard [11]. Cord blood storage banks were established to maintain and supply umbilical cord cells [12]. UCB banking has grown significantly over the past two decades [13]. Given the increasing demand and need for cord blood cells to perform transplants, the increased number of cord blood banks is reasonable. These banks are currently growing in many countries around the world [12,14,15]. The option was first made available in the 1990s following the discovery that cord blood is a rich source of stem cells. These cells can be used to treat blood diseases and immune system disorders [13].

Biocyte funded Broxmeyer with a grant to study the biology and cryopreservation of UCB cells [11]. These studies established the possibility of using UCB as a transplantable source of HSCs and HPCs, which then led to the first UCB Transplant (UCBT) and subsequent UCBTs. The first UCBT, performed in October 1988, was made possible by an international collaboration between Arleen Auerbach from the Rockefeller University in New York,who described a method of prenatal diagnosis in Fanconi Anemia (FA), Broxmeyer from the Indiana University School of Medicine IUSM and Eliane Gluckman from the Saint-Louis Hospital in Paris as Gluckman had the best clinical results at that time using Bone Marrow Transplant (BMT) to treat patients with FA [11,16]. The recipient was a 5-years old patient with severe aplastic anemia due to FA, whose condition necessitated an urgent HCT. On day 22, the patient had complete hematological reconstitution and donor chimerism [11,17].

In September 2019, the UCBT and newborn stem cell banking communities celebrated the 30th anniversary of the first Hematopoietic Stem Cell (HSC) transplant using cord blood as a graft for a patient with FA [18]. The successful demonstration that cord blood is capable of reconstituting a patient's blood and immune system, coupled with the confirmation that cord blood can be cryopreserved for later use, led to the establishment of cord blood banks and thus the newborn stem cell banking industry in the early 1990s [19].

Hematopoietic Cell Transplantation (HCT) is a life-saving procedure for the treatment of malignant and non-malignant blood disorders like leukemia, lymphoma, thalassemia, sickle cell disease, bone marrow failures, inherited metabolic disorders, immunological defects and other genetic diseases [20,21]. Cord blood cells have been used successfully as an alternative to Bone marrow or peripheral blood progenitors cells, benefits include immediate availability of banked UCB units, lower incidence of Graft-Versus-Host Disease (GVHD), minimal risk to the donor and a lower requirement for HLA compatibility between the donor and the recipient [20,22].

The facile nature of Mesenchymal Stem Cells (MSC) acquisition in relatively large numbers from different tissue compartments of the umbilical cord with a non-invasive procedure makes it a promising MSC source of regenerative medicine at clinical settings [23].

Numerous cryobanks, previously engaged in UCB storage, now offer UC tissue cryopreservation and storage services [24]. MSCs are of interest to the regenerative medicine field due to their ability to enhance tissue repair [23,25]. They have been shown to act through paracrine signaling, whereby the cells respond to the injury and then secrete factors that enhance tissue repair or through engraftment and differentiation into blood vessels, smooth muscles, fibroblasts and osteogenic lineages [26]. Additionally, MSCs have been used in a wide range of clinical trials to treat diabetic wounds, peripheral vascular disease and osteoarthritis, to name just a few [26].

Public banks are often operated by government agencies, free of cost to the donor but the collected blood and tissue can be used to treat other patients or for research purposes. Private banks are profit-driven, but the collected samples can only be used by the donor himself or his family [13].

The Lebanese government has always overlooked this matter, which explains the absence of public banks. There's only one private cord blood bank that processes and freeze the cells in Lebanon which limits the patients' options to private banking. The

increasing burden of inherited and acquired hematologic diseases has contributed to the sustained expansion of cord blood banking activities worldwide. This growth has resulted in a large global inventory of cryopreserved cord blood units, managed through heterogeneous regulatory frameworks that address donor consent, quality systems, manufacturing practices, product release criteria, logistics and long-term outcome monitoring. These criteria are minimum requirements for national-level regulations that govern cord blood banks. The quality of UCB units stocked worldwide has become an important issue, which is why some major banks are trying to introduce GMP or ISO systems for the quality assurance of UCB.

The presence and development of Bone marrow transplantation programs, together with the persistent challenge of identifying compatible donors, highlighted the need for alternative and readily available sources of Hematopoietic stem cells. In this context, the therapeutic potential of Umbilical cord blood stem cells became increasingly evident. From this perspective emerged the idea of creating the cord blood banking initiative under Reviva Regenerative Medicine Center.

Reviva operates in accordance with the regulations established by Foundation for the Accreditation of Cellular Therapy-NetCord, internationally recognized organizations setting standards for cellular therapy and cord blood banking. Locally, the center is monitored by Apave, ensuring that our equipment, facilities and processes comply with the highest standards of quality and patient safety. Reviva provides comprehensive local services ranging from the collection to the cryopreservation of Umbilical cord stem cells, improving proximity, accessibility and optimal cell quality.

Although Reviva has achieved important milestones, the challenging circumstances in Lebanon have temporarily slowed its expansion. Nevertheless, the center remains operational and continues to function in accordance with Good Clinical Practice.

Materials and Methods

A. Reviva Overview

Reviva Regenerative Medicine Center, established in 2011 in Lebanon, is the first dedicated stem cell therapy laboratory in the region. The center operates a fully integrated Current Good Manufacturing Practice (cGMP) facility, encompassing cord blood and tissue banking, cellular therapy including bone marrow transplantation, clinical research and regenerative medicine applications. All laboratory operations from collection to cryopreservation adhere to international quality and safety standards, including FDA-approved and CE-marked equipment. Clinical trials and research activities are conducted under ethical oversight by the Institutional Review Board and regulatory compliance is ensured locally through Acute Physiology and Chronic Health Evaluation (APAVE). Through this infrastructure, Reviva provides high-quality, GMP-compliant stem cell services to patients in the Middle East and North Africa, supporting both therapeutic applications and translational research.

B. First National Cord Blood Banking:

1. Data collection:

We have collected data from 2011 to 2019. We took into consideration various parameters such as operating mode, way of collection, storage time and temperature, transportation, processing and freeze, thawing techniques, number of cells and viability. These parameters have been reported to affect the quality and quantity of CBUs, which we aimed to investigate in this study.

2. Consent and Collection

a. Consent Form

Cord blood units are collected from all across Lebanon. All hospitals were non partner hospitals. Written informed consent was obtained prior to any collection and patients were reassured aboutthe safety of the procedure on both the mother and the newborn. Furthermore, patients were required to sign a contract that runs for 25 years before obtaining the kit in which the cord blood and tissue would be collected.

b. Collection

After giving birth, the umbilical cord is cleaned with betadine and alcohol then clamped and the cord blood is collected by gravity from the umbilical vein into the bag (Grifols, Barcelona, Spain) containing 25 ml of Citrate-Phosphate-Dextrose anticoagulant. The physician is free to collect the blood before or after the placenta is released from the body, depending on their

background. When done, a part of the umbilical cord is cut and put into a cup containing PBS with antibiotics provided with the kit. Along with this, three blood tubes are collected from the mother's blood (2 plain tubes and 1 EDTA tube).

c. Specimen arrival
Upon receiving the specimen, a checklist should be completed to ensure the conformity of the sample (leaks, temperature, blood clots, hemolyzed blood, labeling of the product, accident during transportation and picture of the bag).

3. Processing
a. Volume reduction
The bag is later on sent to the processing room where it is weighed and filtered using the blood filter: (Haemonetics Australia, PTY. Ltd) and 1ml for quality control is collected. The filtered bag is then labeled and connected to the SEPAX 530.4 single use kit (Biosafe, SA - Eysins, Switzerland) and mounted into the SEPAX 2 machine. After manually checking the parameters and initiating the process, SEPAX 2 will automatically check the conformity of the kit and start the procedure. The final volume of Buffy coat is set to 20 ml. Under the safety cabinet, 1ml of the final product is collected for quality control tests.

b. Cord tissue processing
After being chopped into 3-5 mm^3 blocks, cord tissue is added to chilled cryotubes containing the freezing solution. The cryotubes are then kept at 4°C until freezing.

c. Blood Freezing
DMSO/Dextran (Origen Biomedical, Austin-USA) is used as a freezing solution. It is added using cool-mix machine at a rate of 1 ml/min. Once the process is over, the report of the procedure will be printed and the blood is kept on a cold pad and a sample for blood culture and security tubes is taken.

d. Controlled rate freezing
The final bag, along with the tubes, is inserted into the controlled-rate freezer and the process is initiated. The freezing curve should be monitored throughout the procedure. When the process is complete the standard report is printed and the samples are moved to the quarantine tank until receiving the mother's tests results.

e. Mother's tests
The mother's blood collected is sent to the lab in order to perform the serology tests (HIV, HBS ag, HCV, VDRL, HTLV, CMV, EBV), blood typing and indirect coombs test. 0.5 ml of mother's serum is kept at -80°C if needed for future tests.

f. Quality Control
For the initial and final product specimens, quality control testing is performed. CBC, CFU-GM, flow cytometry analysis for viable CD34+ and CD45+ cells, manual count and manual viability using Trypan Blue are the required tests.

4. Final Storage
Upon receiving mother's blood tests results, the specimens (Blood bag, security tubes and cord tissue tubes) are moved to their final storage location as per rack number and position depending on the Freeze System. The product is to be discarded in case of any positive results in any of the mother's tests.

Results

Cord Blood Component Parameters Before and After Volume Reduction

We analyzed umbilical Cord Blood (CB) units received at Reviva over a 9-year period. Due to the ongoing financial crisis and the challenging circumstances in Lebanon since 2020, the collection of new specimens was temporarily suspended to ensure the quality and safety of stored units. By applying the current criteria, we found that our banking efficiency was 57.5%. The initial analysis revealed a direct correlation in volume, absolute TNC counts and the total number of CD34+ and CD45+ cells. The TNC content had the most significant correlation with the number of CD34+ cells ($r = 0.681$; $P<01$), compared with the CD45+ count ($r = 0.655$; $P <.01$) and volume ($r = 0.581$; $P < .01$). A TNC count of 8.32×10^8 was the optimal point analysis that most accurately

allowed for the selection of CB units meeting the CD34+ cell content of 5 × 10^6 (sensitivity, 78.7%; specificity, 70.7%). The characteristics of the CB units meeting a CD34+ cell content between 5 × 10^6 or more (n = 500 [58.7%]) were noted. The median volume obtained was 85 mL (range, 48.0-213.2 mL) with a median TNC content of 721.875 × 10^6 (range, 2.5 × 10^8-36.6 × 10^8), a median CD34+ cell count of 2.64 × 10^6 (range, 2.0 × 10^6- 4.0 × 10^6) and a median viability of 98% (range, 97 - 99%) after volume reduction and before cryopreservation. Total nucleated cells are important as well as the viability. Before processing we obtained a mean number of 600x10^6. The results after processing a mean number 500x106. Before and after processing through the years, we preserve up to 80% of the TNC, the outcome is statistically significant with a p<0,001. Cell viability is an important indicator of the quality of cord blood units. Before and after processing, we preserve about 99% of the viability which is satisfactory. CD34 is used to identify and isolate hematopoietic stem cells for clinical use in bone marrow transplantation. Before processing, we saw that the value of CD45+/CD34+ was 5x10^6. Through the years, the value has decreased (in to: 2,5x10^6. We observed consistent results with up to 80% retention, with a statistically significant p-value <0,001. After processing we saw that the value of CD34+/CD45+ was 1,3x106 and we have preserved the same value through the years. So, according to our results, we consider that we have preserved roughly the same value of CD34+ before and after processing Table 1, Fig. 1.

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Number of cases	47	53	84	93	120	120	74	48	0	9	13	21
Mean Initial Volume (ml)	66.00	67.20	67.13	69.88	72.50	75.33	82.88	80.67	0	76.62	84.53	88.30
Mean TNC (x10^6)	518.00	676.00	677.00	668.48	675.85	766.75	847.22	788.37	0	963.26	890.97	1036.80
Mean CD45 (x10^6)	343.56	549.36	306.60	390.94	455.76	382.46	401.3	540.2	289.3	399.2	421.2	387.3
Mean CD34 (x10^6)	2.63	3.37	3.00	2.37	2.48	2.36	2.5	3	0	2.89	3.01	3.1

Table 1: Summary of all cord blood data collected.

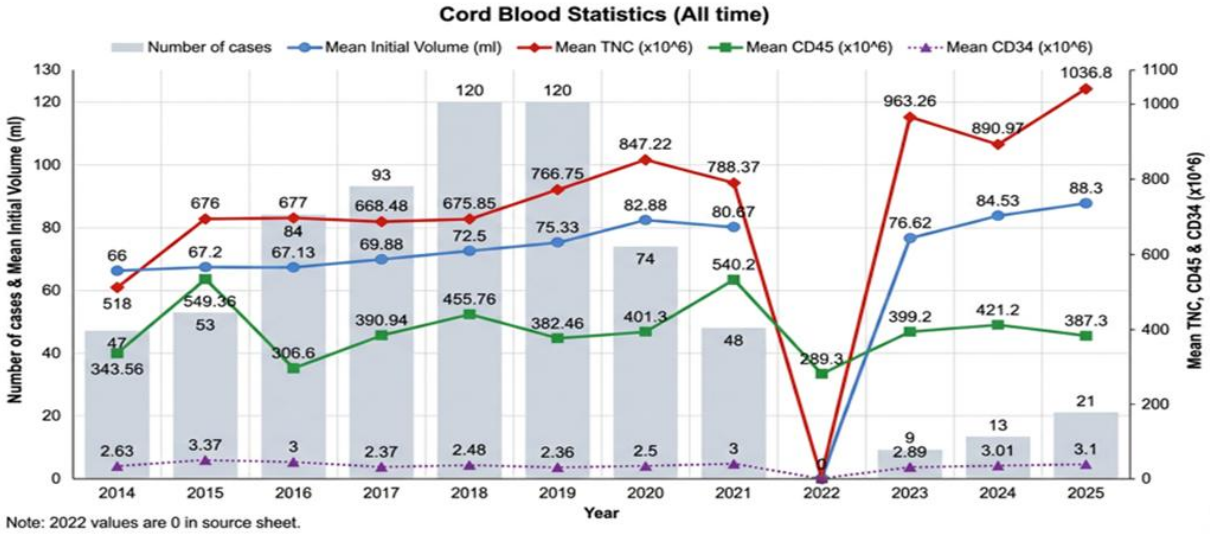

Figure 1: Cord blood units collected between 2014 and 2025 are presented in the graph. A noticeable decline in number of cord blood stored unit is observed after 2019, corresponding with the onset of the economic crisis. In 2022, at the peak of the crisis, laboratory activity was temporarily halted in order to restructure pricing policies and maintain patient safety standards.

Discussion

Recognition of Umbilical Cord Blood (UCB) as a clinically relevant source of hematopoietic stem cells has driven the development of sophisticated banking infrastructures to ensure the availability of high-quality grafts for transplantation. From a clinical perspective, cord blood offers logistical and immunological advantages, including rapid access to cryopreserved units, minimal donor-associated risk and increased donor availability compared with conventional sources such as bone marrow or peripheral blood. The first operational CB banks were established in the early 1990s, with pioneering facilities in New York, Milan and Düsseldorf, providing the foundation for standardized collection, processing and cryopreservation for transplantation purposes. Since then, cord blood banking has expanded globally, with hundreds of public and private banks now operating across multiple continents. Current estimates indicate that public banks collectively store over 800,000 units, while private and family banks maintain several million units, reflecting the growing clinical and research demand for this resource.

The establishment of these banks, along with international coalitions and accreditation standards, addressed multiple operational and regulatory challenges, including donor recruitment, collection protocols, processing, cryopreservation and quality control. Although substantial progress has been made, ongoing debates remain regarding harmonization of procedures, standardization of cell quality and optimization of transplantation outcomes.

Within the global landscape of Cord Blood (CB) banking, Reviva Regenerative Medicine Center occupies a unique and strategic position as the first and only dedicated stem cell therapy laboratory in Lebanon. In 2011, we undertook the challenge of establishing the first national cord blood bank in the country, addressing the complex logistical, regulatory and operational issues inherent to such an endeavor challenges comparable to those faced during the establishment of conventional blood banks. The construction and operational setup were completed under the supervision of APAVE, enabling the creation of the first cGMP-compliant stem cell laboratory in the region.

Operating a fully GMP-compliant platform, Reviva provides high-quality CB units that support both hematopoietic stem cell transplantation and broader regenerative medicine applications. Despite the ongoing economic and political crises in Lebanon since 2019, the center has maintained operational excellence, ensuring adherence to international quality and ethical standards while contributing to regional transplantation programs. This experience positions Reviva as a model for the successful implementation of stem cell therapy infrastructure under challenging conditions, demonstrating that robust, clinically reliable CB banking is achievable even in resource-limited settings.

Techniques to efficiently and safely select donors, collect, store, process and distribute CB units were developed by our professional team, with ongoing assessment of ways to improve these techniques is being followed by the center. Although different studies have been performed regarding selection, collection and processing of CB, improvements in methods are needed to maximize resource utilization without compromising quality for clinical use, to increase efficacy and to reduce the cost of CB transplantation. This is why we have decided at Reviva to follow the FACT NetCord guideline, in order to have the best outcome from each stored CB unit.

This is the first analysis to evaluate the TNC, CD34+ and viability content of Reviva CB inventory. Our findings do require detailed validation, however and could be limited by changes in post-processing, pre-freeze TNC, CD34+ cell enumeration assays over time. They also do not account for variations in unit quality as reflected by the post-thawing of CD34+ cell viability. From a practical standpoint, these data clearly reinforce incorporating both TNC and CD34+ cell dose into CB unit selection, because units with an adequate TNC dose do not necessarily have an adequate CD34+ cell dose.

Throughout the years from 2011 to 2019, the TNC count had the largest area confirming that it is the primary driver of the CD34+ cell content in CB. Combining two parameters to select CB did not lead to an improvement in the relationship between sensitivity and specificity; therefore, the TNC count as a single criterion seems to be sufficient for selecting CB units for cryopreservation. Most of the CB units not meeting the CD34+ cell content of 2×10^6 or more had a TNC count below the selected value. These units would not have been processed for CD34+ cell content had this cutoff point been applied. It is worth mentioning that from of all CB units with a TNC count more than the ROC-selected value, only 20% had a CD34+ cell count of less than 2×10^6. All received units at Reviva were stored without any selection. However, they reached number of cells was confirmed with the international requirements.

The potential clinical implications of the CD34+TNC content ratios are unknown and require further investigations. It is critically important that if transplant centers incorporate CD34+ dose into unit selection, the pre-cryopreserved CD34+ dose must approximate what will be recovered after thawing [27]. Current guidance states that centers should request unit reports and CB bank verification of units with a CD34+ dose much higher than expected based on both the TNC dose and the CD34+TNC ratio (e.g., >1%) [28]. Our analysis highlights the fact that we have a large inventory of CB units with adequate TNC and CD34+ doses for patients of low to intermediate weight. This has major implications for pediatric transplantation because these units can be obtained quickly and high survival rates have been achieved with pediatric CB transplant. Our analysis also supports the need for intensive efforts and ongoing funding to enrich the CB inventory with units that have high cell doses.

In the Arab region, five countries Jordan, Saudi Arabia, Qatar, Egypt and the United Arab Emirates (UAE) have implemented notable CB banking programs, reflecting diverse policies, emerging initiatives and significant investments. Although private CB banks predominate, several public banks also operate and additional programs are under development. Within this context, Reviva was established as the first and only private CB bank in Lebanon, navigating significant operational challenges posed by the ongoing economic crisis and political instability since October 2019. Despite these constraints, the systematic collection, processing and analysis of CB units at Reviva have produced a high-quality inventory, aligning with international standards for hematopoietic stem cell transplantation. These outcomes underscore the center's resilience and its capacity to provide clinically reliable CB products, demonstrating that robust cord blood banking is achievable even under extreme economic and national crises.

Conclusion

The demonstrated successes so far of the public and private CB programs in the world are positive trends for the region. Major investments to create new private CB banks in Lebanon, in order to stop the shipment of the cord blood units outside the country are being considered. Programs require a commitment to training, education, research and facilities to ensure their full integration into the national health care infrastructure. Lebanon is in need of robust policies and programs for HSC transplants, CB banks and research, especially so that it does not fall behind as these fields continue to progress internationally. Governments should engage experts in medicine, to create guidelines for sustainable and effective CB banking programs. Several factors in Lebanon, including population demographics and accessibility of medical treatments, strongly incentivize the widening of public CB storage capabilities with family-directed donation programs. In addition, the lack of knowledge about public opinion and level of awareness concerning these topics makes research, educational initiatives and medical staff training even more critical.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore was exempt.

Informed Consent Statement

Informed consent was obtained from all participants included in the study.

Authors' Contributions

All authors contributed equally to this paper.

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