Cord Blood: Learn & Share

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Quality evaluation of umbilical cord blood cells in a AABB accredited cord blood bank in Hong Kong

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Background

It is important and critical to monitor the cryopreservation procedures of umbilical cord blood (UCB) in a Cord Blood Bank according AABB requirement; Standard 5.17B Processing Tests for HPC, Cord blood Products, part 3. The quality of (UCB) after cryopreservation should be tested periodically. It is ensured that the thawed UCB is suitable for clinical transplantation upon client' request.

Objective

This retrospective study used initial UCB and cryopreserved UCB quality control (QC) samples to assess the quality process in our cord blood bank.

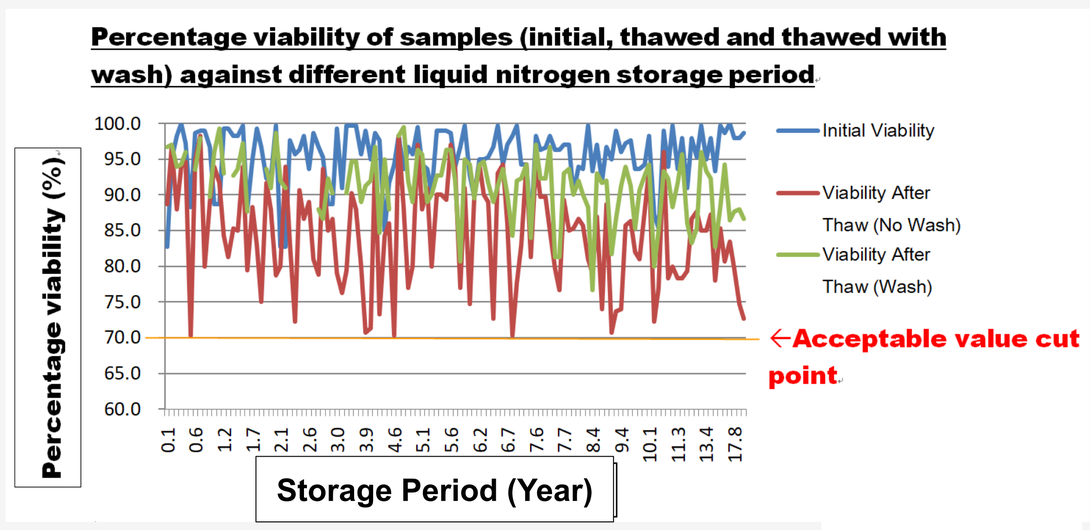
Materials and Methods

A total of 123 UCB samples were collected between March 1998 and March 2013. The samples were processed and cryopreserved according to validated standard operating procedures (SOP). The total nucleated cell count and cell viability of QC samples were measured and recorded. The total nucleated cells (TNC) and cell viability were determined by and cell counter (Beckman Coulter) and manual counting method (Trypan blue) respectively. The final product (UCB with freezing medium containing 10% DMSO) were cryopreserved in the liquid phase of liquid nitrogen tank. The QC samples were then thawed for testing over different duration of cryopreservation (0.09-18.2 years). According to our SOP, the acceptable criteria for the quality check point was determined as TNC recovery and cell viability of thawed UCB QC sample was >70%. The storage period of the cryopreserved UCB was further derived into five groups: Less than 3 years, 3-5 years, 5-8 years, 8-12 years and more than 12 years. The Turkey's honest significance test was used to evaluate the effect of different time of storage on TNC recovery rate and thawed cell viability.

Results

The mean TNC recovery rate was 99.4% (70.5% to 136.1%), and the mean cell viability of thawed UCB QC was 88.7% (71.4% to 113.7%). The thawed TNC and cell viability was not affected by duration of storage (p value >0.05). The quality of cryopreserved UCB was stable up to 18.2 years as all 123 QC samples were well within the predetermined acceptable criteria.

Parameters	Mean	Median	SD	Min	Max
Volume (ml) collected. Defined at Cord Blood Bank	14.5	12.6	5.03	5.0	26.5
Nucleated cell concentration (10^6/ml) in initial product without freezing solution	19.9	13.4	15.3	4.3	74.5
Initial TNCs X 10^8 (/mL)	4.9	3.6	4.0	0.83	24.0
Total volume (ml) product with freezing solution	25.6	22.9	9.2	6.2	53.0
CD34+ cells initial count (cell/ul), total 104 samples	2.7	1.3	3.6	0.14	19.8
Total CD34+ cells initial concentration (cell/ul), total 104 samples	36.7	16.4	46.7	1.3	213.3
Nucleated cell concentration (10^6/ml) in thawed sample	20.6	13.3	15.9	4.5	78.4
Thawed TNCs X 10^8 (/mL)	4.8	3.6	4.0	0.84	24.1
TNCs recovery % (post thaw v.s. initial), total 123 samples	98.2	99.4	14.9	70.5	136.1
TNCs recovery % (post thaw v.s. initial), before June 2007, total 85 samples	105.2	104.5	11.3	136.1	74.8
TNCs recovery % (post thaw v.s. initial), after June 2007, total 38 samples	82.6	81.9	8.8	105.3	70.5
% viability of initial sample collection	95.5	96.7	4.1	82.7	100
% viability of thawed QC samples	84.5	85.3	7.3	70.3	98.3
% viability recovery (post thaw v.s. initial)	88.6	88.7	8.3	71.4	113.7
% viability of thawed QC samples after wash, total 109 samples	91.3	92.0	4.5	76.7	99.5
% viability recovery (post thaw after wash v.s. initial), total 109 samples	95.8	95.9	6.1	82.2	116.9
% viability recovery (post thaw v.s. initial), before June 2007, total 85 samples	95.2	96.3	4.1	82.7	100.0
% viability recovery (post thaw v.s. initial), after June 2007, total 38 samples	96.2	97.0	3.9	85.0	99.7
Thaw QC sample time (second)	107.2	95.0	46.3	12	290
Total CFU after thawed (10^4/ml)	43.2	18.8	61.0	0.40	353.7



Conclusion

The objective data as generated from thawed QC samples demonstrated the stability of the stored UCB products over time. Thus, the processing and cryopreservation were well maintained in our cord blood bank. The prospective validation of the UCB products stability should be carried on to find out the longer storage duration of the cryopreserved UCB in the liquid phase liquid nitrogen tank.