



Complete nationwide survey on umbilical cord blood freezing bag breakage in Japan

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Abstract

Background aims. Although umbilical cord blood (UCB) has now become a common stem cell source, UCB bag breakage is a known risk in UCB transplantation (UCBT). This survey provides the first comprehensive data on the frequency and causes of UCB bag breakage in Japan. **Methods.** Data regarding UCB bag breakage from all causes, identified between April 1, 2010, and September 3, 2013, were collected from all transplant centers registered for UCBT (209 hospitals) and all public cord blood banks (CBBs) (8 CBBs) in Japan. **Results.** Seventeen incidents of UCB bag breakage at CBBs were confirmed, none of which resulted in bags being shipped to transplant centers. From among 3836 UCBT, 16 incidents (0.4%) of UCB bag breakage were confirmed at transplant centers. Although all these bags were used for transplantation, no direct health hazard was reported. The major cause of UCB bag breakage confirmed at transplant centers was considered to be external force (75%). In addition, 11 incidents of unexplained UCB bag breakage at sealing between compartments were reported. **Conclusions.** UCB bag breakage was confirmed at both CBBs and transplant centers. UCB bags should be handled with particular care and attention.

Key Words: cord blood bank, cord blood transplantation, nationwide survey, umbilical cord blood bag breakage

Introduction

Umbilical cord blood (UCB) has now become an indispensable cell source for hematopoietic stem cell transplantation [1–5]. Because UCB will be transplanted into an immunocompromised host, UCB should be aseptically processed [6,7]. Shortly after harvesting from the donor, UCB is sealed in a sterile freezing bag and cryopreserved in a liquid nitrogen tank at -196°C . Although for more than 2 decades, freezing bags have been manufactured to withstand extremely low temperatures [8], deep-frozen materials are inevitably fragile, and it is difficult to ensure that no breakage occurs [9,10]. To date, no comprehensive survey has been reported regarding UCB bag breakage.

A frozen UCB bag is thawed in a bath at 37°C with a rapid increase in temperature just before infusion at the transplant center. If the bag is damaged, blood leakage will be observed at the time of thawing. To minimize contamination from a broken bag, it is placed within a sterile bag before thawing [11]. This precautionary measure is supposed to minimize contamination of UCB from breakage during transportation from cord blood

banks (CBBs) or during thawing at transplant centers. UCB bag breakage during processing or cryopreservation at CBBs is not acceptable from a quality control perspective [12].

Because inflation of UCB bags at CBBs from unknown causes has been reported, there are concerns regarding damaged UCB units being released to transplant centers. Therefore, we performed a nationwide survey in Japan on UCB bag breakage to address concerns regarding this aspect of UCB transplantation (UCBT).

Methods

Collection of data

Reports of UCB freezing bag breakage were provided by all transplant centers registered for UCBT (209 hospitals, 266 departments, all over Japan) and all public CBBs (8 CBBs, all over Japan). Data regarding UCB freezing bag breakage from all causes identified between April 1, 2010, and September 3, 2013, were collected. This survey was conducted by the Ministry of Health Labour and Welfare of the Government of Japan.

Storage and shipping of UCB units

UCB units are stored in liquid nitrogen storage tanks. In general, UCB units are cryopreserved for up to 10 years in Japan. On request from transplant centers, UCB units are removed from liquid nitrogen storage tanks for human leukocyte antigen typing and are tested for infection through the use of one or two attached tubes; thereafter, they are re-stored in the tank. Before conditioning, in general, UCB units are

shipped to transplant centers in liquid nitrogen dry-shippers that ideally maintain the temperature below -150°C . All CBBs use the same UCB bags, which are made of polyvinyl chloride and manufactured and distributed by Nipro Corporation in Japan (F-025, Nipro, Osaka, Japan). The UCB bags have small and large compartments, and these two compartments connect to each other through two tunnels at the ends of compartments. Sealings between

Table I. Details of UCB bag breakage: 17 cases of UCB bag breakage confirmed at CBBs.

No.	CBB	Time of breakage confirmation	Time of UCB processing	Description of UCB bag breakage	Site of breakage	Probable cause	Use for UCBT
A1	A	5/2010	5/2005	At the time of lab examination for release, tube breakage was confirmed.	Tube	Imperfect adhesion of the tube end	No
A2	B	3/2012	3/2005	Dropped during transportation.	Unknown	External force	No
A3	C	4/2010	4/2008	Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A4	C	4/2010	8/2008	Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A5	C	4/2010	10/2008	Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A6	C	7/2010	5/2006	Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A7	C	7/2010	5/2007	Liquid nitrogen infiltration from the break at SBCs. Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A8	C	2/2011	7/2002	Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A9	C	4/2011	4/2007	Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A10	C	4/2011	3/2007	Liquid nitrogen infiltration from the break at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A11	C	5/2011	2/2005	Liquid nitrogen infiltration from the break at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A12	C	6/2011	2/2001	Liquid nitrogen infiltration from the break at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A13	C	9/2011	1/2004	Liquid nitrogen infiltration from the break at SBCs. Inflation of the UCB bag was observed at the time of test on request.	Unknown	Unknown	No
A14	C	2/2012	9/2010	Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A15	C	3/2012	6/2005	Liquid nitrogen infiltration from the break (pinhole) at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A16	C	5/2013	8/2011	Liquid nitrogen infiltration from the break (pinhole) at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No
A17	C	6/2013	7/2009	Liquid nitrogen infiltration from the break (pinhole) at SBCs. Inflation of the UCB bag was observed at the time of test on request.	SBCs	Unknown	No

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