

Drone transportation of FFP maintained frozen using a vaccine refrigerated transport box

Abstract

Background: In cases of emergency injury, fresh frozen plasma (FFP) is necessary to compensate for the consumption of clotting factors. The emergent delivery of FFP can be critical to survival and reduction of complications. We hypothesize that drone transport of FFP under appropriate conditions below -30°C would be possible if we used a BioBox Cell® normally employed for COVID-19 vaccine transport.

Method: We transported FFP packs inside a BioBox Cell® that was continuously chilled by dry ice by an automobile-transport, to Tomi where a test location at a distance of approximately 200 km away from our laboratory. We transported FFP packs inside a BioBox Cell® by a drone (M1000) and, back to the laboratory by an automobile. For about a day, the FFP was transported car transport, and drone transport under low-temperature without power.

Results: The influence of drone flight on FFP clotting factor activity, such as fibrinogen, factors II, V, VIII, IX, X, XI, XIII, and von Willebrand factor (vWF), was minimal.

Conclusion: We transported FFPs at an adequate temperature using a drone and confirmed that there was little reduction in clotting factor activity. FFP can be transported easily and quickly using a drone using a low-temperature refrigerator.

Keywords: drone, FFP, vaccine transport box

Volume 10 Issue 1 - 2022

Fumiatsu Yakushiji,^{1,2} Koki Yakushiji,³ Mikio Murata,⁴ Miyuki Teratani,⁵ Hiroshi Fujita⁶

¹Department of Internal Medicine, Tokyo Metropolitan Bokutoh Hospital, Japan

²School of Medicine, Toho University School of Medicine, Japan

³Graduate School of Media and Governance, Keio University, Japan

⁴Department of Clinical Pharmacy, Yokohama University of Pharmacy, Japan

⁵Clinical Laboratory, Tokyo Metropolitan Bokutoh Hospital, Japan

⁶Department of Transfusion Medicine, Tokyo Metropolitan Bokutoh Hospital, Japan

Correspondence: Fumiatsu Yakushiji, Tokyo Metropolitan Bokutoh Hospital, 4-23-15, Koutoubashi Sumida, Tokyo 130-8575, Japan, Tel +81-3-3633-6151, Fax +81-3-3633-6173, Email clinic@nifty.com

Received: January 20, 2022 | **Published:** February 03, 2022

Introduction

Background

In cases of traumatic injuries, blood is usually needed for emergency intervention. Although whole blood transfusion contains clotting factors and is effective for hemostasis to some extent, fresh frozen plasma (FFP) transfusion is more commonly employed to cover the large consumption of clotting factors. The rapid delivery of FFP may aid survival and prevent further complications or injury.

We have been studying the rapid transport of blood by drones;¹ however, temperature control in FFP rapid transport was identified as a problem. The storage and transportation of FFP requires cryogenic temperatures, which usually entails the use of a large cryogenic refrigerator, making it difficult to achieve rapid transport by drones. Transport of COVID-19 vaccine has been achieved at a temperature of -70°C or lower using a BioBox Cell® (340 × 260 × 340 mm, 3kg, Sugiyamagen Co. Ltd., Tokyo Japan), and has been utilized previously in Japan. Therefore, we hypothesized that FFP could be transported at a similarly appropriate temperature using BioBox Cell®s. Red blood cells can be transported by drones under appropriate conditions of 2 to 6°C for emergency use. In this study, we report on the drone transport of FFP under appropriate conditions of -30°C or lower.

Material and methods

Preparation for packs of FFP and transport to the trial site

We produced two packs (BB-T020CJ; Terumo Co., Tokyo, Japan) of two phlebotomy-derived FFPs (FFP-A and FFP-B) in our laboratory, using the same standard methods used by the Japanese Red Cross. Each pack of FFP (FFP-A, FFP-B) was divided into two portions and stored at -80°C until the trial. In the trial, both FFP-A2

and FFP-B2 for drone flight were placed in a BioBox Cell® set below -75°C by inserting 2kg dry ice, and the FFP-A1 and FFP-B1 for control stored at -80°C in our laboratory. FFP packs for drone flight were stored in a BioBox Cell® and transported by automobile to Tomi City in Nagano Prefecture.

Drone flight

We used an M1000 quadcopter (Load capability of up to 24.9 kg on take-off. Maximum speed of 58 km/h, Mazex Corp. Osaka, Japan) to transport FFPs for drone flight using a hang-up method, which is suspending the BioBox Cell® from a rope.

Temperature monitoring

We recorded temperature continuous monitoring using a FlashLink® Deep Freezer USB PDF Data Logger Model 40555, DeltaTrak, Inc., California, USA) inside of the BioBox Cell®, which was continuously chilled with dry ice.

For about a day, the FFP was transported car transport, and drone transport under low-temperature without power.

Macroscopic findings

The macroscopic findings of the flown FFPs were checked for deformation and melting due to external forces.

Measurement of clotting factor activity levels

We evaluated clotting factor activity for all phlebotomist-derived FFPs.

Clotting tests (plasma fibrinogen, activated partial thromboplastin time (aPTT), and prothrombin time (PT)) and activities of clotting factors (factors II, V, VII, IX, X, XI, XIII, and vWF (von Willebrand factor [vWF])) were measured by BML Inc. (Tokyo, Japan).

Numerical evaluation

We compared the activity of clotting factors in blood after travel, including drone flights, with control FFP stored at -80°C in a cold refrigerator in the laboratory. The rate of change was calculated by dividing the clotting factor activity of FFP after transport, including drone flight, by that of the control FFP for both FFP-A and FFP-B. Furthermore, the mean, standard deviation, and 95% confidence intervals were calculated from the results of the two rates of change. If there is no change in the clotting factors of FFPs between the flown FFP and the control, then the rate of change should be 100%; if there is a difference, the confidence interval for the rate of change cannot include 100%.

Results

Drone flight

M1000 transported FFPs under visual supervision at a height of approximately 1060 m in Tomi City, Nagano Prefecture. The flight information was a 7 min 11 s flight time, approximately 1 km distance, cruising altitude 10m on April 3, 2020. The weather was hot and sunny, with a temperature of 32.3°C .

Temperature monitoring inside of the BioBox cell

The temperature inside the BioBox Cell® was always below -75°C .

Measurement of level of clotting factor activities

There seemed to be no clear difference in clotting factor activity between the preserved control and the drone flight FFP since the 95%

Macroscopic findings

There were no macroscopic findings of damage or thawing in the FFP after drone transport (Figure 1). There was no remarkable difference between the drone-transported FFP and the control.



Figure 1 Macroscopic finding of FFPs after the transport involving drone flight.

FFP-A2 derived from FFP-A is on the left, and FFP-B2 derived from FFP-B is on the right after transport. No macroscopic damage or thawing was observed.

confidence interval for the mean of the rate of change included 100% in almost all cases, except for factors VII and X, which were slightly reduced in the FFP transported by drone (Table 1).

Table 1 Change of clotting factors between FFPs after drone transport and laboratory storage

Clotting factor	aPTT	%PT	INR	fibrinogen	II	V	VII	VIII	IX	X	XI	XIII	vWF
FFP-A1 : Laboratory-stored control derived from FFP-A	39.8	86.9	1.08	186	81.8	52.2	127.3	54.4	85	114.9	70.6	144	60
FFP-B1 : Laboratory-stored control derived from FFP-B	33.5	109.8	0.95	228	102	86.3	107.3	109	84.2	107.3	93.2	109	176
FFP-A2: FFP after travel with drone flight derived from FFP-A.	38.4	82.6	1.11	191	81.8	52.9	125.2	51.9	77.3	112.3	67.2	163	58.1
FFP-B2: FFP after travel with drone flight derived from FFP-B.	33.7	109.8	0.95	228	98.9	85.1	106.1	109	87.4	106.1	93.2	108	176.5
On FFP-A Rate of clotting factor change between travel with drone flight vs stored in the laboratory (%)	96.5	95.1	102.8	102.7	100.0	101.3	98.4	95.4	90.9	97.7	95.2	113.2	96.8
On FFP-B rate of clotting factor change between travel with drone flight vs stored in the laboratory (%)	100.6	100.0	100.0	100.0	97.0	98.6	98.9	100.0	103.8	98.9	100.0	99.1	100.3
Average for rate of clotting factor change between travel with drone flight vs stored in the laboratory (%)	98.5	97.5	101.4	101.3	98.5	100.0	98.6	97.7	97.4	98.3	97.6	106.1	98.6

Table Continued...

Clotting factor	aPTT	%PT	INR	fibrinogen	II	V	VII	VIII	IX	X	XI	XIII	vWF
Standard deviation for rate of clotting factor change between travel with drone flight vs stored in the laboratory (%)	2.1	2.5	1.4	1.3	1.5	1.4	0.3	2.3	6.4	0.6	2.4	7.1	1.7
Upper limit of 95% confidence interval for rate of clotting factor change (%)	102.6	102.4	104.1	104.0	101.5	102.7	99.1	102.2	110.0	99.4	102.3	120.0	101.9
Lower limit of 95% confidence interval for rate of clotting factor change (%)	94.5	92.7	98.7	98.7	95.5	97.3	98.1	93.2	84.8	97.2	92.9	92.3	95.2

aPTT, activated partial thromboplastin time; %PT, % prothrombin time; INR, PT-international normalized ratio; vWF, von Willebrand factor; FFP, fresh frozen plasma

Discussion

This trial suggests that the FFP in a BioBox Cell® was not significantly affected by automobile transportation with drone transportation in terms of macroscopic observation and clotting factor activity changes. This method appears to be effective for FFP transportation without a heavy refrigerator to increase the cryogenic temperature.

In terms of temperature control, it was proven that the BioBox Cell® could be used to control temperature for a long period of time by inserting dry ice, which provides the markedly low temperatures required for blood transport.

Considering the use of blood transfusion products in Japan, the use of whole blood is relatively low. The usual transfusion is a red blood cell (RBC) solution. Naturally, it does not contain any clotting factors. In addition, it is common for medical institutions to perform surgical procedures to store red blood cell fluid for the duration of its useful life at an appropriate temperature of 2 to 6 °C. However, only a few medical institutions have refrigerators to store FFPs. Furthermore, if the patient needed to be replenished with clotting factors, thawed FFP could be used within 3 h.² If thawed FFP is not used, it must be discarded. Therefore, the ability to transport FFP under the guidelines of the Japanese Red Cross requires the instructions of -30°C or lower for storage of FFP.³ The presence of a convenient form of transport that fulfills this requirement is highly significant. To this end, we have shown that the BioBox Cell® can transport FFP while maintaining its frozen state, and that FFP can be transported by drones even in emergency situations, such as the area where the emergency is happening is not rapidly accessible.

Furthermore, although the data are not shown, we conducted experiments with thawed FFP using both car and drone transportation, although the clotting activity of thawed FFP decreased with time.

Acknowledgments

None.

Competing interests

The authors report no competing interest.

Funding information

The study was not funded.

References

1. Yakushiji F, Yakushiji K, Murata M, et al. Quality of blood is not affected by drone transport: An evidential study of the unmanned aerial vehicle conveyance of transfusion material in Japan. *Drones*. 2020;4:4.
2. Japan Red Cross, Transfusion Information 0902-117 “How to Thaw Fresh Frozen Plasma (FFP)”.
3. Moog R. Temporary storage of fresh frozen plasma above -30°C has no negative impact on the quality of clotting factors and inhibitors. *Transfus Altern Transfus Med*. 2020;11(1):8–9.