

Alcor A-1649

Case Report



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1. Personnel

Field Neurocryoprotection and Transport:

Josh Lado, Alcor Medical Response Director
Steve Graber, Alcor Technical Coordinator

Cryogenic Cooldown:

Hugh Hixon, Jr., Alcor Research Fellow; cooldown, data reduction
Steve Graber, Alcor Technical Coordinator; cooldown, data reduction

Deployment Committee:

Steve Harris, M.D., Alcor Chief Medical Advisor
Max More, Ph.D., Alcor Chief Executive Officer
Josh Lado, Alcor Medical Response Director

2. Summary

Information is derived from multiple sources and is all converted to Mountain Standard Time (MST).

Robert Whitaker, a 76 year old, non-confidential, neurocryopreservation Alcor member had been found deceased at home in Columbia, SC, by his family on June 3, 2017. He had been an Alcor member since 1997. The Alcor Deployment Committee decided that a [field neurocryoprotection](#) (FNC) protocol would be attempted. The County Pathologist and the Deputy Coroner were both cooperative and helpful.

An Alcor team was deployed to the patient's location. The patient was transported back to Scottsdale, the morning of June 6, 2017. Cooldown was initiated on June 7, 2017, and long-term maintenance commenced on July 22, 2017.

A CT scan was done on June 22, 2017. The blood-brain barrier (BBB) was compromised, resulting in no brain volume reduction. The patient's jugular effluent was over the terminal concentration of nM22 for over 45 minutes but the CT scan showed incomplete cryoprotection; the cortex had between 50% - 60% of full concentration cryoprotectant, indicating a microscopic mixture of ice crystals and vitrified tissue. The cerebellum received very little cryoprotectant. There was a very small isotherm in the pharyngeal record of the cooldown plunge to dry ice indicating that a small amount of freezing occurred during cooling.

3. Patient Assessment and Pre-Deployment

On June 3, 2017, at 16:25 hrs, Alcor received a TeleMed alert that Robert Whitaker, a non-confidential, neurocryopreservation Alcor member, was apparently deceased. He had been found unconscious and unresponsive by his family and his personal assistant when they arrived home from shopping. The family called 911 to request that police and paramedics respond as quickly as possible in order to pronounce legal death.

Approximately half an hour later the patient's assistant called to report that the police and medical personnel were on the scene and had pronounced the patient legally deceased at 16:53 hrs. Per the death certificate, the presumed time of death (cardiac arrest) was 15:00 hrs.

Alcor's Chief Executive Officer (CEO), Medical Response Director (MRD), Chief Medical Advisor (CMA) and staff discussed the possibility of doing a FNC procedure, which had only been approved by the Alcor Board of Directors for use in Europe where long transport times could cause extensive cold ischemic injury (see Discussion). The Alcor Deployment Committee and the Alcor Board of Directors made the decision to proceed with FNC.

Alcor's local funeral home was contacted to ask them for assistance with finding a cooperative funeral home in South Carolina. The Deputy Coroner in South Carolina was contacted and reported that he was going to transport the patient to the county morgue, which was located in a local hospital, where the patient would be placed in a refrigeration unit at 1.7°C to 2.3°C. The Deputy Coroner also stated that he would contact the County pathologist for clearance to do the neuroseparation at the morgue.

Alcor's CMA asked the team to have medical personnel in South Carolina to administer anti-coagulation drugs, such as heparin, if available. The County pathologist contacted Alcor to report that the FNC procedure could be done at his facility and that he could also assist with accessing and cannulating the carotid arteries. When asked about anticoagulation administration, he replied that he did not have any anti-coagulant drugs.

The patient's assistant called Alcor and was informed about the FNC protocol that was planned. She asked to meet with Alcor personnel after the procedure was completed.

The Deputy Coroner called Alcor at 20:34 hrs to advise that he would be at the procedure the following day to observe. The MRD asked the Deputy Coroner if he could acquire any anti-coagulation drugs to administer to the patient. The Deputy Coroner stated that regulations prohibited him from administering any drugs.

The Arizona funeral home called the MRD to discuss the paperwork that would be required by the South Carolina funeral home and the paperwork for the cremation of the remains after the neuroseparation, as all paperwork needed to be current with South Carolina state law.

4. Deployment

The Alcor team left Phoenix, AZ just before midnight on June 3, 2017, and arrived in Columbia, SC the next morning on June 4, 2017, at 07:30 hrs. They left the airport in the pre-arranged rental truck with the equipment needed for the field neurocryoprotection. After stopping at a local store for a cooler and ethylene glycol-based anti-freeze for the field cryoprotection heat exchanger, they arrived at the hospital where the morgue was located at 08:30 hrs.

5. Field Surgery and Washout

Field surgery started just after 09:30 hrs on June 4, 2017, and was finished, including the cephalic isolation, at approximately 10:45 hrs. Open circuit field cryoprotection was started immediately. This FNC protocol utilized a series of individual bladders made up in advance with different and gradually increasing concentrations of nM22 cryoprotectant (see the below Table of Concentrations (Brix) of nM22 Solution). Gravity was used to infuse the perfusate into the patient as an open circuit procedure.

The open circuit FNC perfusion was completed at 12:55 hrs with perfusate bladder number 12 (53.72 Brix) as the concentration of nM22 was over 50 Brix (target concentration being 53.72 Brix) from both jugular veins for over 45 minutes. No burr holes were made and the cephalon was not weighed.

The cryoprotective procedure was unremarkable. Pressure had been maintained at approximately 60 mmHg, the temperature was well controlled at approximately +1°C until approximately midway in the procedure at a concentration of 35.48 Brix, and then at approximately -3°C until the end of the cryoprotective perfusion. The team achieved terminal concentration by bladder number 9 but ran all the way to the end of bladder number 12. Initially, a large number of clots were observed, but by bladder number 2, the perfusate was clear again. The flow was fast, approximately 10-15 minutes per bladder, slowing to 20 minutes per bladder with bladder number 9. Dry ice was placed around the cephalon in the shipping container at 13:01 hrs and the cooldown to -80°C (dry ice temperature) was begun.

During cryoprotectant perfusion there were indications of tanning on the cheeks from the uptake of the cryoprotectant, but not to the level seen in the operating room (OR) at Alcor and the patient's eyes had not collapsed from dehydration (the time these observations were made were not recorded).

6. Transport

At 08:15 hrs on June 5, 2017, after reviewing different transport options, the team concluded that it would be better to ship by FedEx. At 08:40 hrs Alcor staff called the remote team to discuss the pros and cons of the different shipping options. It was decided to use FedEx and ship from the Columbia, SC FedEx central office to be shipped that afternoon.

At 11:09 hrs the neuro shipping container was delivered to FedEx in Columbia, SC. At 21:29 hrs the neuro shipping container arrived in Indianapolis, IN and at 07:34 hrs on June 6, 2017, FedEx delivered the neuro shipping container at Alcor and at 07:38 hrs the shipping container was topped off with additional dry ice.

7. Cooling to Liquid Nitrogen

An eyebolt was placed in the patient's vertebra and at 12:17 hrs on June 7, 2017, the patient was placed into the cooldown dewar and cryogenic cooldown from -80°C (dry ice temperature) to liquid nitrogen (LN₂) temperature was initiated. Cooldown was terminated on June 11, 2017. On July 22, 2017, the patient was placed into long-term maintenance at LN₂ temperature (-196°C).

8. Timeline and Time Summaries

June 3, 2017

- 15:00 Estimated time of death on the death certificate
- 16:53 Patient legally pronounced by police and medical personnel

June 4, 2017

- 08:30 Alcor team arrived at the hospital morgue where the patient was located
- 09:30 Field surgery was started
- 10:45 Cephalic isolation completed and field surgery terminated
- 10:45 Start of open circuit cryoprotection
- 12:55 End of open circuit cryoprotection; final Brix readings over 50 from both jugulars for over 45 minutes
- 13:01 Start of dry ice cooling

June 5, 2017

- 11:09 Neuro shipping container delivered to FedEx in Columbia, SC

June 6, 2017

07:34 FedEx delivered the neuro shipping container at Alcor

June 7, 2017 - Start of patient cryogenic cooldown to LN₂ temperature

June 11, 2017 - Cryogenic cooldown terminated

July 22, 2017 - Transfer of patient to long-term maintenance at LN₂ temperature

Time Summary - Field Cryoprotection through Cryogenic Cooldown

hrs: mins

18:30 From estimated time of cardiac arrest (ETOCA) to start of field surgery:
15:00 hrs (6-3-17) to 09:30 hrs (6-4-17)

01:00 From start of surgery to end of surgery: 09:30 hrs to 10:30 hrs

19:45 From ETOCA to start of open circuit washout: 15:00 hrs (6-3-17) to
10:45 hrs (6-4-17)

02:10 From start to end of open circuit washout: 10:45 hrs to 12:55 hrs

21:55 From ETOCA to end of open circuit washout: 15:00 hrs (6-3-17) to
12:55 hrs (6-4-17)

22:01 From ETOCA to start of dry ice cooldown (79°C): 15:00 hrs (6-3-17) to
13:01 hrs (6-4-17)

64:34 From ETOCA to patient arrival at Alcor (at 79°C): 15:00 hrs (6-3-17) to
07:34 hrs (6-6-17)

28:43 From patient arrival at Alcor (at 79°C) to start of cooldown to LN₂: 07:34 hrs (6-6-17) to
12:17 hrs (6-7-17)

93:17 From ETOCA to start of LN₂ cooldown: 15:00 hrs (6-3-17) to 12:17 hrs (6-7-17)

9. Discussion

Published on the Alcor website (<https://alcor.org/Library/html/fieldcryoprotection.html>) is a discussion of the pros and cons of FNC. That article says in part: “Perhaps the most difficult question of all is: At what distance and transport time from Alcor do the disadvantages of current field cryoprotection procedures (especially when no cryoprotection can be given for whole body patients when there is not sufficient advance notice) become outweighed by the advantages of avoiding long transport times at 0°C?”

To approve the use of FNC for this domestic case, the Deployment Committee and the Alcor Board of Directors had to make a difficult decision. The unexpected arrest was a daunting complication compounded by the nearly impossible difficulty of obtaining a death

certificate and a transit permit to transport the patient out of South Carolina on a Saturday evening for cryoprotection at Alcor in Arizona. The logistical problems limited the options to either cryopreservation without cryoprotection (straight freeze) protocol or the use of the FNC protocol.

The plan to use the FNC protocol was based partially on the calculation that the time from the estimated time of death to the start of the cryoprotective ramp would be approximately 19 hours, which would compromise perfusion too much relative to doing a field cryoprotection. The decision was made that an FNC would be the best option for this patient.

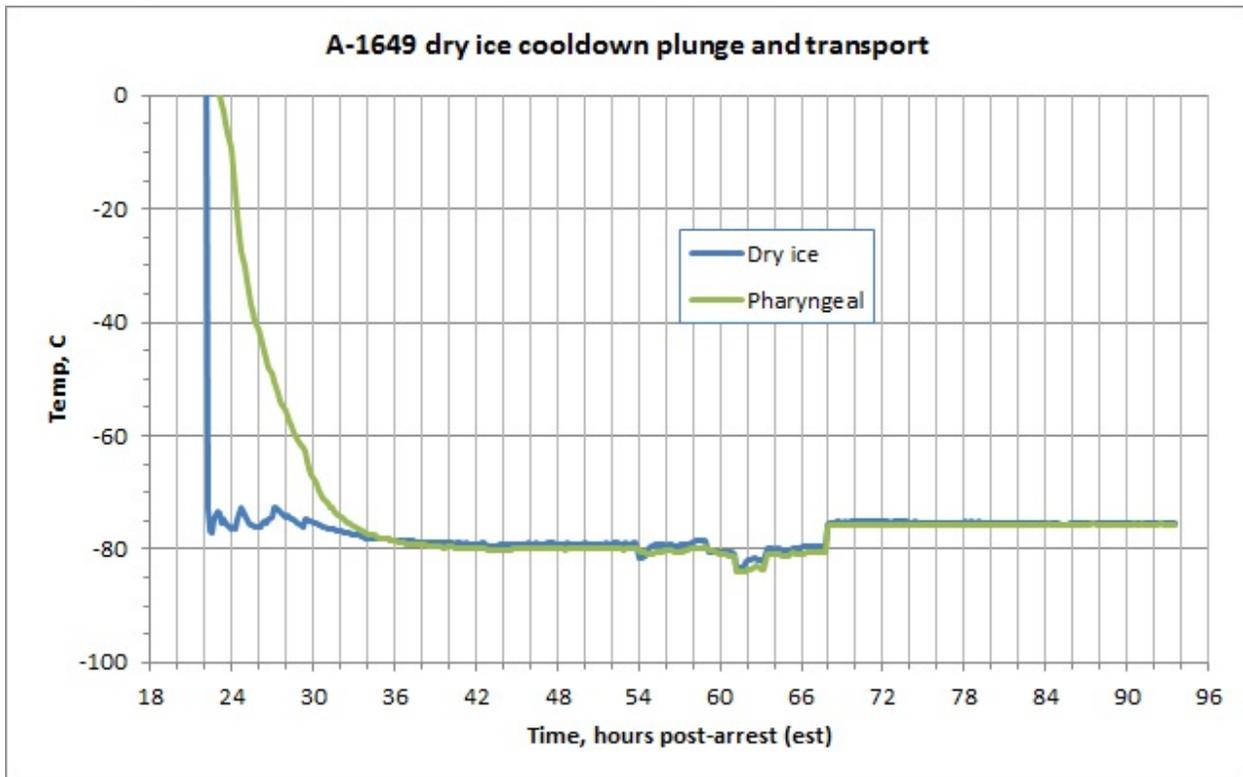
The Alcor Board of Directors was contacted to update them about the case and to inform the Board about the plan by the Deployment Committee to send a team to perform an FNC procedure. The decision was made by the Board to proceed with FNC and to deploy the MRD and one other Alcor staff member as soon as flights could be booked.

This case will add to the data regarding the use of FNC and help future cases be better informed in making a determination about 1) at what distance and transport time from Alcor do the disadvantages of current field cryoprotection procedures become outweighed by the advantages of avoiding long transport times at 0°C, 2) whether FNC should or should not be limited to cases from Europe, and 3) what criteria should be used to make the decision to use FNC.

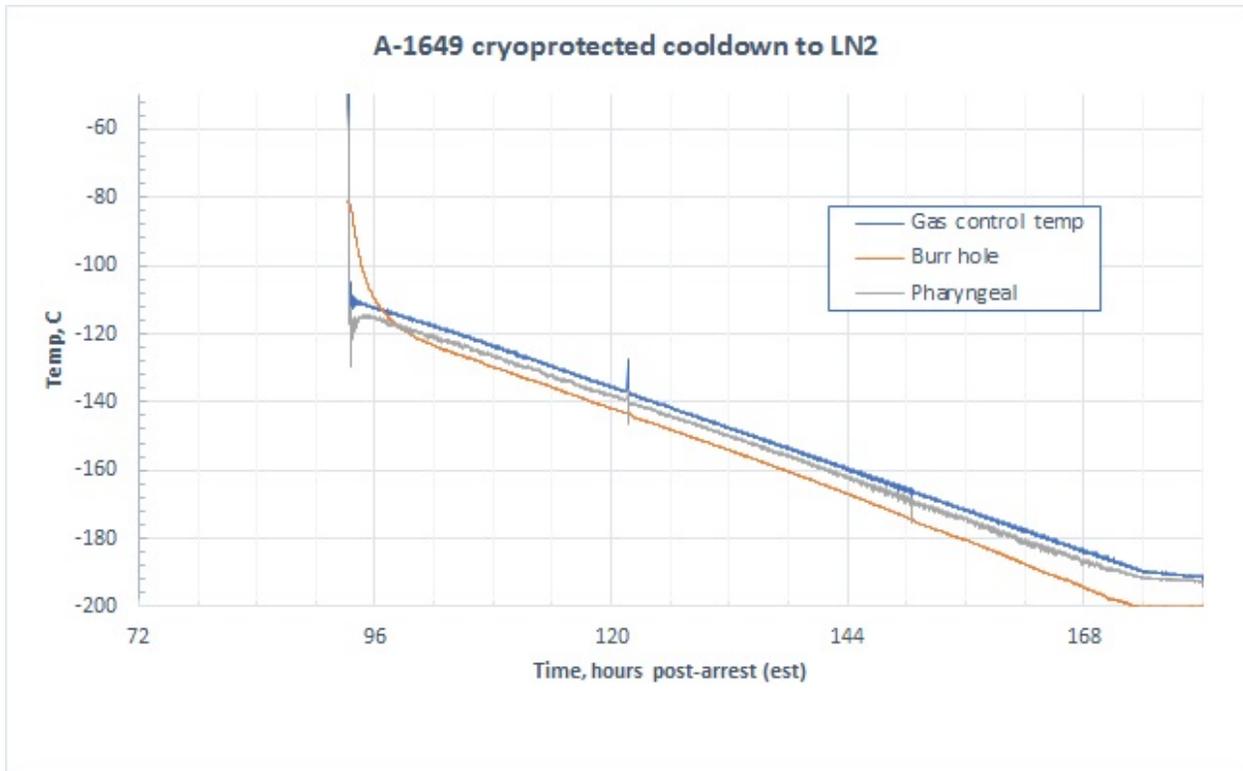
10. Table of Concentrations (Brix) of nM22 Solution

Step-ramp calculator			
sixth root of [% CNV]/5 =		1.6688	
bag #	contents	[M22], %CNV v/v	Brix (calc)
1	washout	0.00	8.20
2		0.05	10.31
3		0.08	11.72
4		0.14	14.07
5		0.23	17.99
6		0.39	24.55
7		0.65	35.48
8		1.08	53.72
9		1.08	53.72
10		1.08	53.72
11		1.08	53.72
12		1.08	53.72

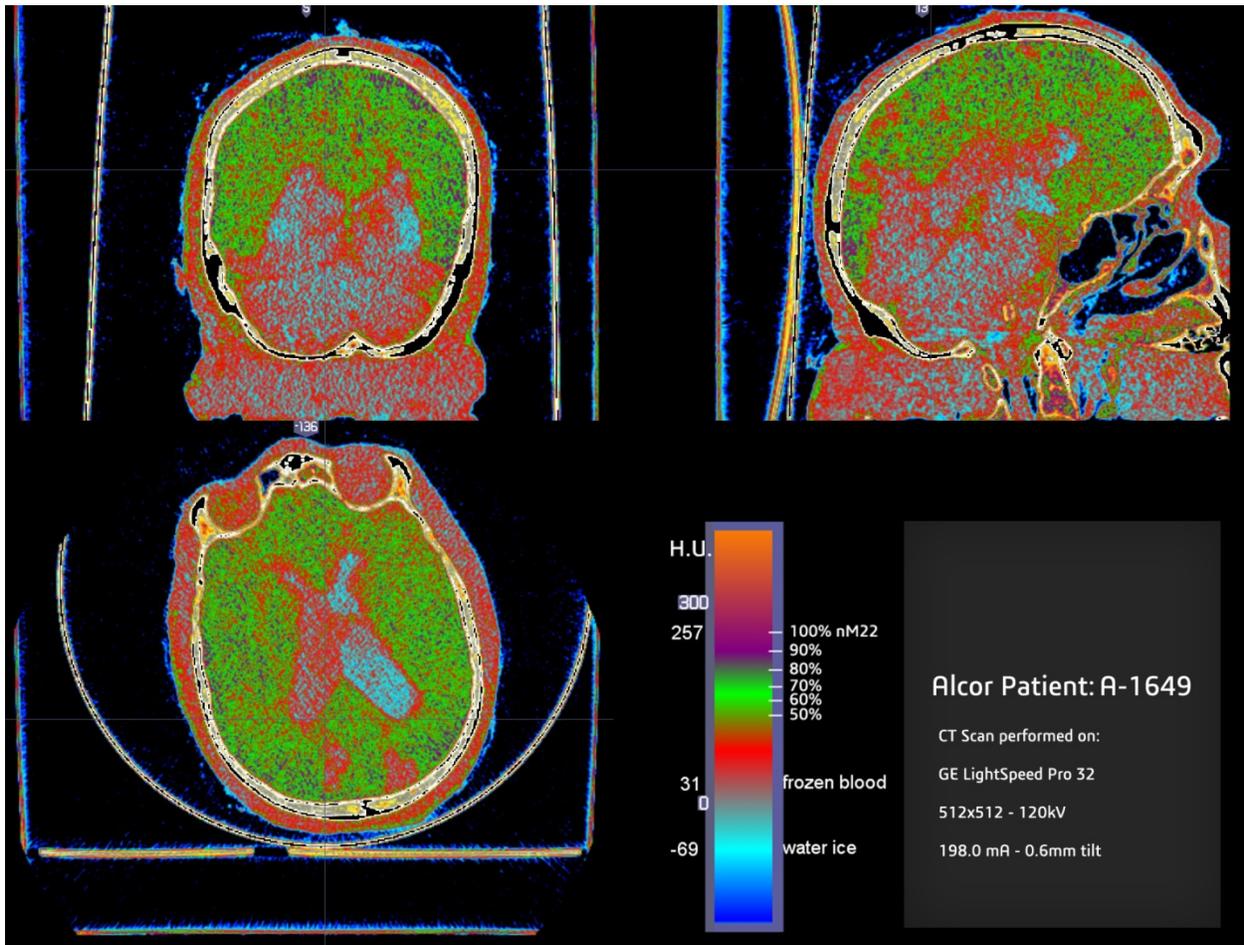
11. Graphs and CT scans



Note: the box indicates when ice formed.



Cryoprotectant Distribution (CT scan)



Note: This CT scan was taken on July 22, 2017 while the patient was at -196°C .