Alcor A-1404
Case Report

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1. Summary

Information was derived from multiple sources and was all converted to Mountain Standard Time (MST). For de-identification, dates are not shown. T-0 represents the date of cardiac arrest (if more than a few moments before pronouncement) or pronouncement of legal death, T-X represents occurrences on dates before T-0, and T+X represents occurrences on dates following T-0.

A-1404 was a 59-year-old member with neuro cryopreservation arrangements. The member had a history of cancer; the cause of death on the death certificate was congestive heart failure after years of cardiomyopathy. Two out-of-state standby operations were held for this patient; one held and terminated without death, and then another ending in death. After the second standby, the member was pronounced legally deceased in June in Texas at 00:23 hrs on T-0 days in 2020.

After field stabilization and blood washout, the patient was transported to Alcor for cryoprotectant perfusion and cryogenic cooldown. The cooldown was initiated at 21:06 hrs on T-0 days, and terminated at 11:28 hrs in June, T+5 days. CT scans of the cephalon in liquid nitrogen were obtained on T+80 days and the patient were then transferred to long-term maintenance.

2. Patient Assessment and Pre-Deployment

T-206 days

The member was placed on Alcor's Watch List when admitted to a hospital for heart surgery. The member had suffered from cancer for several years and had been admitted to the hospital for fluid on the heart, due to chemotherapy infusions. Medical care had also included a lymphadenectomy.

T-192 days

The member was discharged from the hospital. Recovery had taken longer than the physicians felt was normal.

T-46 days

A heart valve replacement surgery had been planned. A team member with one of Alcor's strategic partners, Suspended Animation (SA), was dispatched to assess the situation. Alcor's Medical Advisor was also on alert.

T-45 days

The procedure had gone well. An Impella device, a percutaneously inserted ventricular assist device (VAD), had been placed in the heart. The member was on bypass for approximately one hour. The ejection fraction (EF) heart failure measurement was at 10%. The member was in the intensive care unit (ICU) and was expected to remain there for the next few days. The SA team member and a member of the family (who had previous standby, stabilization, and transport experience) were on standby.

T-44 days

The member's heart was labored and the response to the earlier procedure was no longer positive. The member's family had authorized a left ventricular bypass to be done that morning. Considering the member's medical history and terminal condition, a Level-2 deployment (medium risk of death within 7 days) was officially called. An additional member of the SA team, who was in Texas, was deployed to the member's location.

Sidebar:
The medical personnel on the Alcor Deployment Committee have determined a list of medical indicators that have either a Level-1, or a high probability of death within seven days, or a Level-2, a medium probability of death within seven days. The Deployment Committee voting members use these criteria when considering if a deployment is necessary.

3. The First Standby

T-40 days

Vital signs had improved, and it was planned for the member to be weaned from the ventilator. That did not happen because the member had become febrile. The member was on epinephrine, dobutamine and Milrinone for cardiac support, the diuretic Lasix, insulin to regulate blood sugar, the sedative propofol, fentanyl for pain relief, and the blood thinner heparin. The Impella level was dropped to P5 from P6 (providing less support). A spontaneous breathing trial was done in the morning. Periods of apnea prevented extubation and the home PICC line was removed due to fever.

T-37 days

The member underwent a pericardiocentesis procedure that morning to remove fluid and blood clots from the heart. The member was febrile again and was diagnosed with pneumonia in one lung. The physician changed the antibiotics.

T-29 days

The member had been gradually improving and the crisis was over. The Level-2 (medium risk of death within one week) deployment was officially terminated.

4. The Second Standby

T-1 days

Alcor received notification at 04:56 hrs that the member was again hospitalized. The member experienced chest pain for three days and was hypotensive at the rehabilitation facility. Blood pressure was 90/60 upon arrival, BNP (a protein produced by the heart which is higher than normal during heart failure) was abnormal, COVID-19 negative, with an ejection fraction of 15 to 20%. Overnight, the member had gone into ventricular fibrillation. The pulse could not be found, so cardiopulmonary resuscitation (CPR) was given for approximately 15 minutes.

At 06:23 hrs Alcor's Deployment Committee called a Level-1 (high risk of death within one week) deployment. One of Alcor's Strategic Partners, Suspended Animation, Inc. (SA) in California, was deployed to perform standby, stabilization and transport (SST) as well as a blood washout if the member were to go into cardiac arrest.

While making travel arrangements, it became apparent to SA team members that due to the COVID pandemic going on across the country, flights were extremely limited, and the quickest arrival time would not be until late that night (see the Discussion section). SA contracted the funeral director that was to be used on the first standby. Alcor also deployed their Readiness Coordinator (RC) with an SST kit that included the medications for the abbreviated medications protocol as well as the full protocol in case SA could not make it to the member's bedside before the RC. This would end up being helpful, as the RC was able to speak to the hospital staff and the funeral director to make sure everything was in order before SA's arrival, which saved the limited time that SA had before the member went into circulatory arrest.

The SA team had not yet arrived but later learned from the hospital staff that the member had been without a sustainable heartbeat despite the revival efforts of the ICU team and at 08:06 hrs the member had been revived by the hospital staff but was not stable. The member was placed on a ventilator at the maximum setting (no more detail available). The SA team members who were enroute from separate locations were in communication with each other via Alcor's internal communication system (ICS) to coordinate steps necessary for a smooth SST operation. The member's family and the hospital personnel agreed to have the member revived in the event of another cardiac arrest rather than initiate a Do Not Resuscitate (DNR) order until SA was on site, after which they would authorize the withdrawal of care.

At 13:34 hrs the Charge Nurse on duty confirmed that the team would be allowed to set up their equipment in the member's room before pronouncement of legal death. The hospital was very cooperative. They agreed to conduct withdrawal of care procedures and then step back and let the SA team begin stabilization procedures. The RC contacted the funeral director to provide the information needed for the death certificate and transit permit.

Alcor's RC arrived at the hospital at 16:53 hrs. Two SA team members were on a layover at 18:13 hrs and were being delayed due to a mechanical problem with their aircraft. They did not know how long the delay would continue.

The patient received blood thinners at 18:44 hrs. At 19:52 hrs the SA team reported that there were problems with their replacement plane and a third aircraft would be used. They landed at 20:51 hrs and expected to be at the hospital an hour later.

At 21:35 hrs the SA team had arrived and were engaged in a conversation with the family and the member's physician, giving them details about the stabilization procedures. It was decided that after the contract surgeon and contract perfusionist had their equipment set up, the member would be placed on do not resuscitate (DNR) status and the ventilator would be removed. The contract surgeon and perfusionist relocated to the funeral home (FH) to set up their equipment for the blood washout surgery.

5. Field Stabilization

T-0 days

The member was taken off the ventilator at 00:14 hrs; morphine was administered for pain control and Ativan for anxiety. The member was pronounced legally deceased at 00:23 hrs.

There was no delay between cardiac arrest and pronouncement, but the SA team had to wait five minutes for the nursing staff to disconnect the patient from all monitoring and I.V. lines before they could transfer the member into the portable ice bath (PIB). They also had to wait for confirmation from the attending physician regarding the release of the remains. This took about five minutes. During that time the rectal occlusion device was placed. The patient already had multiple lines in place, including an intraosseous (I.O.) device for access to the member's vasculature that had been placed by hospital staff in the right tuberosity. The hospital staff had agreed to leave the airway in place as this would speed up the stabilization protocol.

The member was placed into the PIB at 00:28 hrs and manual chest compressions were initiated while the AutoPulse mechanical chest compression device was set up. Mechanical cardiopulmonary support (CPS) was initiated at 00:31 hrs. At the same time, the administration of stabilization medications was initiated (see the below Table of Medications Administered for the names of the medications, the dosages, and times of administration).

Concurrently, the team placed nasopharyngeal temperature (NPT) probes in both of the patient's nares and the ventilator was placed. Additional ice was placed over the patient. At 00:32 hrs the surface conduction cooling device (SCCD) was initiated to circulate the ice water in the PIB and optimize the cooling of the patient. The $EtCO_2$ detector was placed on the airway at 00:34 hrs to evaluate the effectiveness of the CPS but it only worked for five minutes (see the Discussion section).

At 00:38 hrs the left NPT was 34.0°C and the right NPT was 35.0°C. A privacy drape was placed over the patient and at 00:42 hrs the hospital release of remains form had been signed and the team had begun transporting the member to the funeral home for blood washout. While moving the patient to the transport vehicle, the AutoPulse shut off when ice became lodged in the body bands securing the device to the patient (see the Discussion section). Manual CPS was initiated until the problem was resolved and mechanical CPS was again initiated at 00:47 hrs. The administration of high-volume medications continued during the trip to the funeral home. The patient and the team arrived at the funeral home at 00:59 hrs and the patient was moved onto the surgical table at 01:01 hrs. The left NPT was 28.8°C and the right NPT was 30.1°C. The SA team finished administering the stabilization medications while the surgeon prepped the patient for the blood washout surgery.

6. Field Surgery and Washout

The perfusion circuit had been set up in advance by the perfusionist and included a room air aquarium pump that runs at 5L/min to the circuit oxygenator. Since the patient had had numerous heart surgeries, the surgeon decided to use the femoral route for access to her vasculature. The AutoPulse was terminated at 01:14 hrs to allow the surgeon to begin the cannulation of the vessels. The patient's NPT was 29˚C. The procedure was performed with the patient in the PIB. The right groin was prepped and draped, and a longitudinal incision was made at 01:09 hrs. There was an extensive hematoma in the area, making vascular exposure tedious and the femoral artery was small; therefore, the surgeon decided to abort this approach and instead use a thoracic approach.

The chest was prepped, and sterile drapes were placed. The previous median sternotomy incision was reopened at 01:41 hrs and deepened to the level of the sternum, which was divided with an oscillating saw. The surgeon noted that there was no evidence that the sternum had ever been divided: there were no sternal wires or signs of a sternal repair and the mediastinal structures appeared undisturbed and without any evidence of prior grafts or other surgical sites.

The pericardium was opened, and the cardiac structures were noted to appear grossly normal. Purse string sutures of 3-0 Prolene were placed in the distal ascending aorta and the right atrial appendage. The tubing pack in the field neuro kit had 18 Fr. red rubber Robinson catheters that were too small for this patient (see the Discussion section). 20 French [FR] Sarns aortic cannula and 29/37 dual-stage venous catheter were inserted and connected to the cardiopulmonary bypass circuit.

The open-circuit washout was initiated at 02:10 hrs. 250,000 IU streptokinase was added to the washout perfusate. The closed-circuit washout was initiated at 02:22 hrs, and cooling continued until the patient reached a core temperature of 3°C at 03:19 hrs.

The surgeon concluded that a good washout had resulted based his participation in prior washouts, the fact that there were no complications during washout and the patient had been

cooled to 3˚C. The cannulae were removed and the sternum was reapproximated with three #5 stainless steel wires. The tissues were closed with running 4-0 Vicryl, followed by staples for the skin.

7. Patient Transport

Once the surgeon completed suturing the thoracic cavity, the patient was moved into a double body bag with approximately 100 pounds of double-bagged water ice at 05:17 hrs. The team was waiting for the funeral director to acquire a Ziegler case from a nearby funeral home. After the Ziegler case, arrived the funeral director worked on the acquisition of the transit permit and flight arrangements while the SA team loaded the patient into the Ziegler case and covered the patient with bagged water ice (see the Discussion section).

Once these arrangements were finalized, the patient was loaded into the funeral director's transit vehicle and taken to the cargo area at the airport. The SA team members and the patient were all on a direct flight leaving Texas at 09:00 hrs, to arrive at Phoenix Sky Harbor Airport at 13:40 hrs. The official weight of the shipper was 333 lbs. The Arizona funeral director had not been put in touch with the remote funeral director (see the Discussion section).

8. Cryoprotectant Perfusion Surgery at Alcor

This case took place during the COVID-19 pandemic. To protect the operating room (OR) staff the Field Cryoprotection (FCP) procedure was used in the OR and staff was limited (See the Discussion section).

The patient arrived at Alcor at 14:58 hrs. The nasopharyngeal temperatures (NPTs) were 3.3˚C from the patient's left nare and 2.9˚C from the right nare. Additional ice was added around the patient at 15:05 hrs while still in the body bag. A polyethylene support block was placed under the patient's shoulders at 15:28 hrs to raise and expose the neck for the cephalic isolation. The patient was draped for surgery.

The first incision was made in the patient's neck at 15:35 hrs for cephalic isolation. The left carotid artery was isolated at 15:39 hrs. The surgeon noted that the carotids were soft and without disease. At 15:44 hrs both the left and right NPTs read 1.1˚C. The right carotid artery was isolated at 15:48 hrs and the trachea was transected with scissors at 15:49 hrs.

The left burr hole was drilled at 15:52 hrs using chilled saline to cool the Codman perforator and the skull. The right burr hole was drilled at 15:54 hrs using the same cooling method. The burr holes were cleaned and opened. At 15:58 hrs one temperature probe was placed in each

burr hole and sutured to the scalp to prevent them from being dislodged. The left burr hole temperature (BHT) reading was 1.9˚C at 15:59 hrs and the right BHT reading was -0.3˚C.

Cephalic isolation was completed at 16:01 hrs. The cephalon weighed 4.8 kg. The right carotid artery was cannulated at 16:18 hrs and ligated to secure in place. Sufficient fluid came out of the vertebral arteries to suggest that the Circle of Willis was intact. Therefore, the vertebral arteries were not clamped off. Due to the patient' history of heart surgery, consideration was given to cannulate via the femoral route (see the Discussion section), but it was decided to use the carotid arteries. Both carotid arteries were cannulated with the red rubber Robinson catheters attached to the tubing.

During washout, the thermocouple recording the temperature in the venous line was damaged. An SST team member was able to fix the temperature probe to record the final minutes of the procedure (see the Discussion section).

9. Cryoprotectant Perfusion at Alcor

Due to the patient' history of heart surgery, consideration was given to cannulate via the femoral route (see the Discussion section), but it was decided to use the carotid arteries. Both carotid arteries were cannulated with the red rubber Robinson catheters attached to the tubing, and cryoprotectant perfusion was initiated in both carotid arteries at 16:21 hrs. The gravity-induced perfusion flow was initiated with Bladder #2 containing nM22 cryoprotectant with a concentration of 0.05 concentration needed to vitrify (CNV) (see the Table of Concentrations (Brix) of nM22 Solution, for the times the bladders were started, the precalculated concentrations of each bladder, and the refractive index of effluent samples taken).

By hanging two bladders with different cryoprotectant concentrations on a teeter-totter atop the tripod, a smoother transition of increasing concentrations of cryoprotectant can be achieved (see the Discussion section for a more detailed explanation). This procedure was used for the rest of the bladders.

The height of the bladders on the teeter totter was 36 inches to 38 inches which is (36" x 2.054 mmHg per inch of height =) 74 to 78 maximum arterial pressure at the infusion site. The goal is to have the pressure between 70 and 80 mmHg and the bladders can be raised or lowered as needed to optimize flow and protection of the vasculature.

At 16:26 hrs the cephalon was placed into a flexible blue cooling enclosure containing water ice. At 16:33 hrs the left BHT was 4.9˚C and the right BHT was 3.4˚C, the perfusate temperature (PT) was -0.4 ˚C, and the arterial pressure (AP) was measured at 60 mmHg.

Cryoprotectant perfusion was terminated at 21:00 hrs. The initial criterion for termination was 50 Brix for over 30 minutes, but this case was terminated because the length of time of perfusion (from 16:21 hrs to 21:00 hrs) had already been 4 hours and 39 minutes without reaching 50 Brix.

This was more than the three hours recommended by Alcor's science advisors to limit the toxicity of the cryoprotectant.

The weight of the cephalon at 21:03 hrs (after cryoprotectant perfusion) was 4.66 kg which was a loss of (4.8 kg – 4.66 kg) = 0.14 kg, or a 2.9% weight loss due to dehydration from exposure to the cryoprotectant. Problems were experienced with the 40-liter drainage bladder and the cord for the electric razor (see the Discussion section).

10. Cooling to Liquid Nitrogen Temperature

The cephalon was moved into the patient care bay at 21:05 hrs and lowered into the cooldown dewar. The temperature probes and other lines were connected to the cooldown computer and the liquid nitrogen source was connected.

A computer program was used to initiate cryogenic cooldown at 21:06 hrs in June, T-0 days. plunging to -110˚C, and subsequent cooling of -1˚C /hr. to -190˚C, followed by a slow approach to LN2 temperature over 10 hours. An uneventful cooldown was terminated at 11:28 hrs in June, T+4 days. CT scans were obtained on T+80 days while the patient was at liquid nitrogen temperature and the patient was then transferred to long-term maintenance at liquid nitrogen temperature.

11. Timeline and Time Summaries

Timeline

T-0	00:23	Cardiac arrest and pronouncement of legal death
T-0	00:28	Start of ice bath cooling
T-0	00:29	Start of manual chest compressions
T-0	00:31	Start of mechanical chest compressions
T-0	00:31	The hospital left the I.V. in the patient
T-0	00:31	Placement of ventilator; patient already intubated
T-0	00:31	Administration of first medication (200 mg propofol)
T-0	00:42	Transport patient to MOV in hospital parking lot
T-0	00:43	AutoPulse stopped (ice stuck in the bands)
T-0	00:47	AutoPulse restarted
T-0	00:59	Patient arrived at funeral home
T-0	01:03	Administration of final medication (250 mL Hetastarch)
T-0	01:09	Start of field surgery, femoral approach
T-0	01:14	Termination of cardiopulmonary support (L NPT 28.6˚C, R NPT 30.2˚C)
T-0	01:41	Switched to median sternotomy
T-0	02:10	Start of open circuit washout
T-0	02:22	Start of closed circuit perfusion
T-0	03:19	Completion of closed circuit perfusion
T-0	09:00	Transport of the patient to air cargo department
T-0	14:58	Arrival of patient at Alcor (L NPT 3.3˚C, R NPT 2.9˚C)
T-0	15:35	Start of surgery at Alcor (cephalic isolation)
T-0	15:52	Start of burr hole surgery
T-0	15:58	Completion of burr hole surgery
T-0	15:59	NPT probes attached to data acquisition system (L NPT 1.9˚C, R NPT -0.3˚C)
T-0	16:01	Completion of cephalic isolation
T-0	16:02	Weight of cephalon (4.8 kg)
T-0	16:21	Start of cryoprotectant ramp (bladder system)
T-0	17:17	Pause at 50% of concentration necessary for vitrification (CNV) (bladders 6 & 7)
T-0	18:00	Start of sub-zero terminal concentration ramp (off pause)
T-0	21:00	Termination of cryoprotection (final RI = 49.2 BRIX)

Time Summaries

Event Duration hr:min		days	time	
FIELD STABILIZATION				
14:35	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	14:58	Arrival of patient at Alcor (L NPT 3.3˚C, R NPT 2.9˚C)
00:05	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	00:28	Start of ice bath cooling
00:06	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	00:29	Start of manual chest compressions
00:08	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	00:31	Administration of first medication (200 mg propofol)
00:32	From:	T-0	00:31	Administration of first medication (200 mg propofol)
	Till:	T-0	01:03	Administration of final medication (250 mL Hetastarch)
FIELD SURGERY AND WASHOUT				
00:46	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	01:09	Start of field surgery, femoral approach
01:00	From:	T-0	01:09	Start of field surgery, femoral approach
	Till:	T-0	02:09	End of field surgery
01:47	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	02:10	Start of open circuit washout
01:09	From:	T-0	02:10	Start of open circuit washout
	Till:	T-0	03:19	Completion of closed circuit perfusion
02:56	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	03:19	Completion of closed circuit perfusion
CRYOPROTECTANT SURGERY AT ALCOR				
00:37	From:	T-0	14:58	Arrival of patient at Alcor (L NPT 3.3˚C, R NPT 2.9˚C)
	Till:	T-0	15:35	Start of surgery at Alcor (cephalic isolation)
00:26	From:	T-0	15:35	Start of surgery at Alcor (cephalic isolation)
	Till:	T-0	16:01	Completion of cephalic isolation
00:46	From:	T-0	15:35	Start of surgery at Alcor (cephalic isolation)
	Till:	T-0	16:21	Start of cryoprotectant ramp (bladder system)
05:25	From:	T-0	15:35	Start of surgery at Alcor (cephalic isolation)
	Till:	T-0	21:00	Termination of cryoprotection (final RI = 49.2 BRIX)
CRYOPROTECTANT PERFUSION AT ALCOR				
15:58	From:	T-0	00:23	Cardiac arrest and pronouncement of legal death
	Till:	T-0	16:21	Start of cryoprotectant ramp (bladder system)
01:23	From:	T-0	14:58	Arrival of patient at Alcor (L NPT 3.3˚C, R NPT 2.9˚C)
	Till:	T-0	16:21	Start of cryoprotectant ramp (bladder system)
04:39	From:	T-0	16:21	Start of cryoprotectant ramp (bladder system)
	Till:	T-0	21:00	Termination of cryoprotection (final RI = 49.2 BRIX)

CRYOGENIC COOLDOWN AT ALCOR				
00:06	From: Till:	T-0 T-0	21:00 21:06	Termination of cryoprotection (final RI = 49.2 BRIX) Start of cryogenic cooldown
20:43	From: Till:	T-0 T-0	00:23 21:06	Cardiac arrest and pronouncement of legal death Start of cryogenic cooldown
06:08	From: Till:	T-0 T-0	14:58 21:06	Arrival of patient at Alcor (L NPT 3.3˚C, R NPT 2.9˚C) Start of cryogenic cooldown

12. Table of Medications Administered

TIME	MEDICATION	DOSE	PURPOSE
00:31 hrs	Propofol	200 mg	Anesthetic; reduces cerebral metabolic demand; reduces the theoretic possibility of increased awareness during aggressive CPS.
00:32 hrs	Sodium citrate	20 g total (1st dose 60 cc) Note 1	Anticoagulant; prevents blood clot formation.
00:33 hrs	Sodium citrate	(2nd dose 40 cc) Note 1	Anticoagulant; prevents blood clot formation.
00:34 hrs	Heparin	50,000 IU	Anticoagulant; prevents blood clot formation.
00:36 hrs	Antacid	250 mL total (1st dose 70 cc) Note 8	A buffer used to protect the stomach from acid erosion.
00:36 hrs	Vasopressin	40 IU total (1st dose 20 IU) Note 2	Vasopressor; increases blood pressure during CPS.
00:36 hrs	Minocycline	200 mg	Antibiotic and neuroprotectant
00:36 hrs	Antacid	(2nd dose 70 cc) Note 8	A buffer used to protect the stomach from acid erosion.
00:36 hrs	Antacid	(3rd dose 70 cc) Note 8	A buffer used to protect the stomach from acid erosion.
00:37 hrs	Antacid	(4th dose 40 cc) Note 8	A buffer used to protect the stomach from acid erosion.
00:37 hrs	SMT (S-methyl-isothiourea)	400 mg Note 3	Neuroprotectant (iNOS inhibitor); protects the brain from ischemic injury; raises blood pressure.
00:39 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	400 cc total (1st dose 60 cc) Note 4	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.

00:40 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(2nd dose 60 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
00:47 hrs	Vital Oxy	180 cc total (1st dose 60 cc) Note 5	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
00:52 hrs	Vital Oxy	(2nd dose 60 cc)	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
00:54 hrs	Vasopressin	(2nd dose 20 IU) Note 2	Vasopressor; increases blood pressure during CPS.
00:55 hrs	Vital Oxy	(3rd dose 60 cc)	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
00:56 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(3rd dose 60 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
00:57 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(4th dose 60 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
00:58 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(5th dose 60 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
00:59 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(6th dose 40 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
01:00 hrs	Decaglycerol/THAM [tris(hydroxymethyl) aminomethane]	(7th dose 60 cc)	Decaglycerol inhibits cerebral edema. THAM is a buffer to mitigate acidosis.
01:03 hrs	Hetastarch	250 mL Note 6	A volume expander used to restore volume in dehydrated patients and increase cerebral perfusion during CPS
02:10 hrs	Streptokinase	250,000 IU Note 7	A thrombolytic used to break up existing blood clots.

Notes:

1. The standard formulation for sodium citrate is 20% w/v, in sterile packaging provided by the manufacturer. This patient received 20 grams of sodium citrate as per protocol because his weight was over 40 kg.

2. Vasopressin is a fixed dosage of 40 IU, the second 40 IU dose to be administered concurrently with Vital-Oxy, I.V. Vasopressin is to be administered intermittently and only if

the patient’s temperature is above 20°C. The patient's nasopharyngeal temperature was 29.84°C and met the requirement for the second dose.

3. SMT (S-methyl isothiourea) is a powder, (1 vial = 400 mg) dissolved in 10 mL of saline and injected through a 0.2 µ filter. SMT is unstable in solution with a useful life of approximately six hours.

4. Decaglycerol/THAM is administered as a custom formulation of 20% w/v decaglycerol and 4.5% w/v THAM (tromethamine) in water and was administered in seven 60 cc syringes.

5. The dose of Vital-Oxy was adjusted to the patient’s weight of 73 kg; 180 mL was combined with 115 mL of sodium chloride and administered in three 60 cc syringes. Each mL of Vital-Oxy contains 194 mg Sigma Cremophor EL (or Sigma Kolliphor EL), 155 mg ethanol, 19.4 mg PBN, 3.24 mg carprofen, 1.55 mg melatonin, and 198 IU vitamin E.

6. Hetastarch is a volume expander used to restore volume in dehydrated patients and increase cerebral perfusion during CPS. It is administered 250 mL as a fixed dosage by I.V./I.O.

7. Streptokinase is not administered with stabilization medications but is put in the first batch of washout solution. The standard administration of streptokinase is 250,000 IU dissolved in 5 mL of 9% sodium chloride. This medication previously needed to be infused through a 0.2 µ filter. The medication now in use is already sterile filtered and can be reconstituted in the vial.

8. An antacid is given in several doses, totaling 250 mL, and inserted through the nasogastric tube in an airway.

13. Table of Concentrations (Brix) of nM22 Solution

A-1404 step-ramp, nM22						
Preferred endpoint is over 49.9 Brix from both jugulars for 1/2 hr.						
2-liter bag labeled	[nM22], CNV	Brix (calc)	bag started, hr:min MST	bag started, hr:min post-pro-nouncement	bag flow rate, ml/min	Brix, jugular Sampling line
2	0.05	11.81	16:18	15:55		
3	0.08	13.14	16:42	16:19	83	
4	0.14	15.35	16:57	16:34	133	
5	0.23	19.03	17:15	16:52	111	17.2
6	0.50	29.85	17:40	17:17	80	21.2
7	0.50	29.85	18:03	17:40	87	26.3
8	1.06	52.31	18:23	18:00	100	32
9	1.06	52.31	19:18	18:55	36	40.3
10	1.06	52.31	20:27	20:04	29	48.9
END			21:00	20:37	61	49.2

Note: The bladders of pre-mixed concentrations of cryoprotectant are made up in advance and kept on hand. At the time the bladders used on this case were made up the protocol was to have bladder #1 contain only B1 washout solution. It has been learned on recent cases that starting perfusion with a low concentration of cryoprotectant, and not just washout solution, keeps the perfusion ahead of developing edema in the patient. For this reason, the protocol is now to always start with bladder #2 which does contain cryoprotectant. Since there is still a stock of bladders where there is a bladder marked #1, those perfusions are noted as having been initiated with bladder #2.

14. Discussion

Standby, Stabilization and Transport

Airline flights were an issue; both mechanical issues causing delays and limited flight options. This presented challenges but did not compromise this patient. However, due to the COVID-19 situation, these problems are likely to persist and standby, stabilization and transport (SST) personnel need to be aware and factor this into logistics planning during times like these. It is usually better to try to get on the quickest non-stop flight for deployment. However, other transportation options may need to be considered

The AutoPulse mechanical chest compression device stopped operating during the stabilization procedure at the hospital. Nurses who were assisting but not familiar with the device, accidentally and unknowingly, allowed ice to get into the body bands causing the device to stop. It was restarted but stopped again while moving the patient down the hallway. The SA team

continued to move the patient while using manual compressions, but there may have been as many as 3 minutes without cardiopulmonary support. Alcor's strategic partner will investigate how they may be able to eliminate this equipment problem.

The EtCO2 device on the patient only logged data for about 5 minutes. This device was old and Alcor's strategic partner will look into better equipment options.

The AZ funeral director has requested that in the future when a remote funeral home is contracted for services, the AZ funeral director should be put in contact with the remote funeral director as early as possible so that he can organize the logistics to better benefit Alcor and the patient.

Field Surgery and Blood Washout

The surgeon thought the femoral route would be better for accessing the vessels because of the patient's recent heart problems and surgeries. But that route turned out to be too problematic and cannulation was not possible. The surgeon went back to using a median sternotomy. This cost an additional 40 minutes during surgery. About 30% of people do not have a femoral system that is compatible with our cannulation needs. The surgeon was correct to explore a femoral approach if the patient had a history of recent cardiac surgeries, and this would be a good approach for the future as well.

For pressure monitoring, the practice at the time of this case was to connect a transducer to the head of the arterial cannula to give the closest pressure reading (in mmHg) to the patient. The protocol was set the target pressure at approximately 100 mmHg once the patient reached 20°C.

During washout, the thermocouple recording the temperature in the venous line was damaged. If one of the temperature probes is damaged during SST, there is a backup probe available in the kit. The damage to the temperature probe happened during the washout and when the damage was noticed the procedure was almost complete. An SST team member was able to fix the temperature probe to record the final minutes of the procedure. Going forward, more attention will be placed on monitoring the temperature logging.

Cryoprotectant Surgery and Perfusion

This was the first case that took place during the COVID-19 pandemic. To protect the operating room (OR) staff from the aerosols that are produced when using the standard OR pumps, the Field Cryoprotection (FCP) procedure using gravity to perfuse from sealed bladders containing pre-mixed and graduated concentrations of cryoprotectant was used in the OR.

Another precaution was to limit the number of staff physically in the OR, all of whom wore appropriate personal protective equipment (PPE).Two persons were on-call but outside the OR and the scribe was telecommuting over Zoom. Due to the limited staff and other precautions, the OR data collection system was not set up, so data collection on this case was that of a field case.

The gravity feed (field neuro cryoprotection) system uses a tripod that can be adjusted for height to control the arterial pressure. The pre-mixed cryoprotectant is in a series of bladders with graduated concentrations [measured by the refractive index (RI) in Brix units]. By hanging two bladders with different RI concentrations on a teeter-totter atop the tripod, as the bladder with the lower RI runs out and becomes lighter, the teeter-totter will allow both bladders to flow, mixing the two concentrations and creating a smoother transition from one concentration to the next. When the bladder with the lower RI runs out, the full concentration of the bladder with higher RI then flows exclusively. This concentration smoothing process repeats as successive bladders are hung.

When the patient was first brought into the OR at Alcor, additional ice needed to be added around the patient while still in the body bag. There was enough ice for this case, but if there had been as much as a 6 to 8 hrs delay (and those are increasingly possible, see #1 above), it might not have been enough. In the future, SST personnel should try to purchase more ice than is felt is needed and get as much ice into the neuro case as possible.

When the patient arrived, the ice had shifted during transport and was no longer packed around the patient's head. Transport personnel need to pack the case such that the ice is kept around the patient's head. The body temperature upon arrival at Alcor was 2.7°C so the heat loss was mostly external. Different airlines have different maximum weight limits, over which they will have extra fees. Alcor would prefer to pay extra to have more ice.

The older gurney that was used in the operating room on this case had had the sides removed. Since the patient was in a body bag, sides on the gurney would have been beneficial. The Alcor technical staff will build sides for this gurney.

The tubing pack in the field neuro kit had 18 Fr. red rubber Robinson catheters that were too small for this patient. In the future, it will be more convenient if the catheters are not pre-attached to the tubing, and there are several sizes of catheters in the kit. Alcor technical staff will make this change.

The 40-liter drainage bladder in the OR did not have wheels and was heavy and difficult to discard. Alcor technical staff will use existing equipment and see that the drainage bladder has wheels in the future.

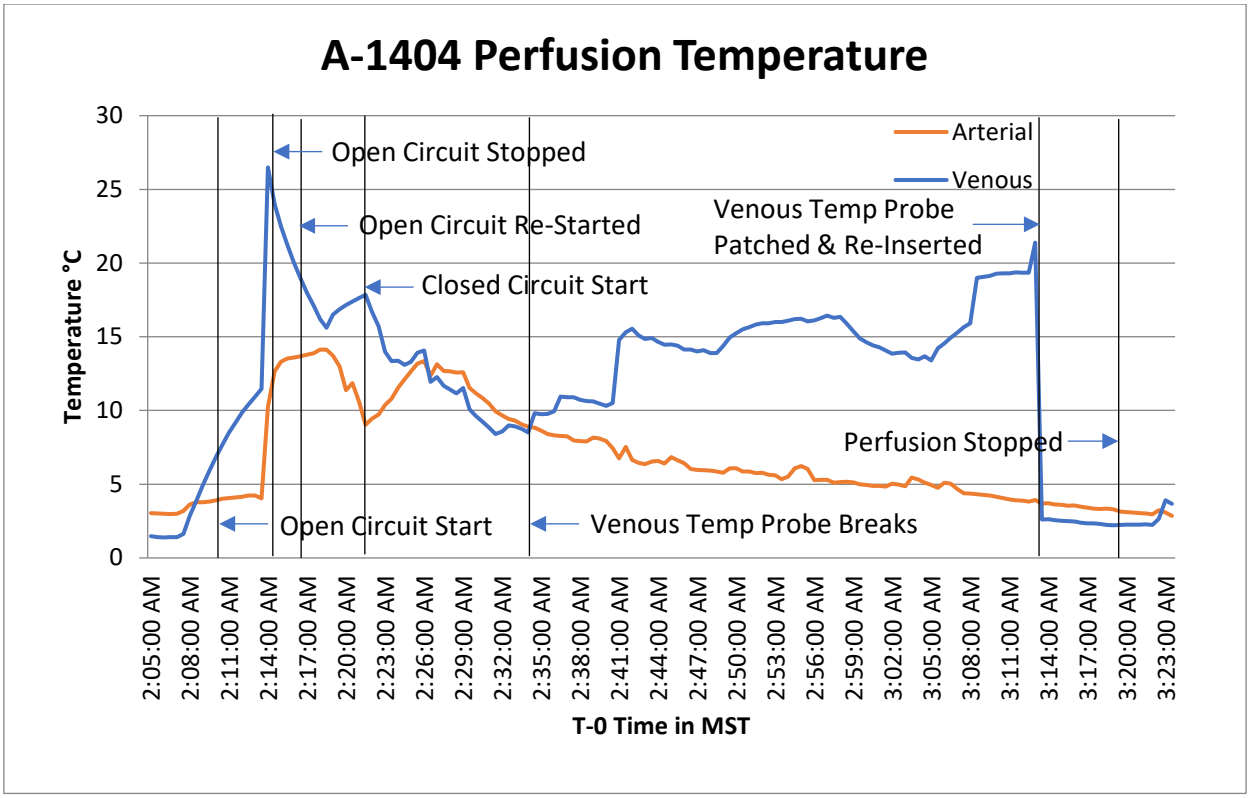
The cord to the electric razor in the OR was too short, even with an extension cord. A longer extension cord will be placed in the OR.

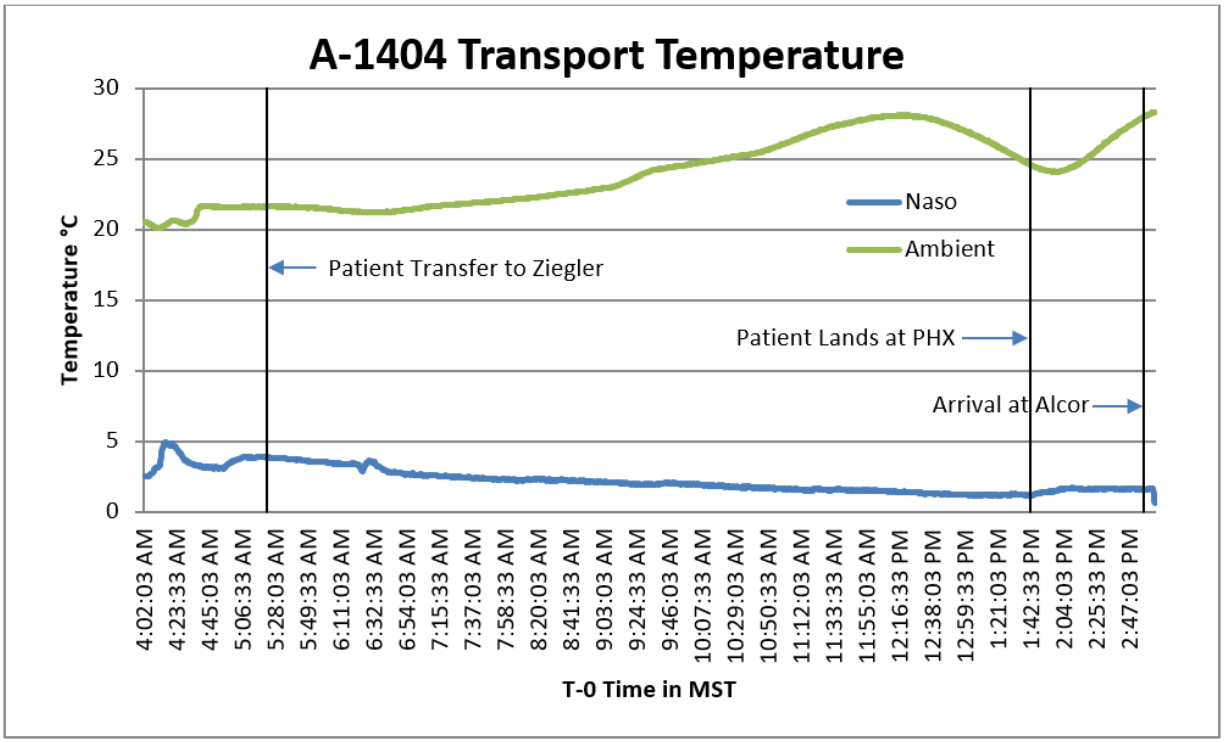
The calculated S-MIX for this case is 02:24 hrs. More than half of the calculated normothermic ischemia exposure was produced during hypothermic transport of the patient from a remote location.

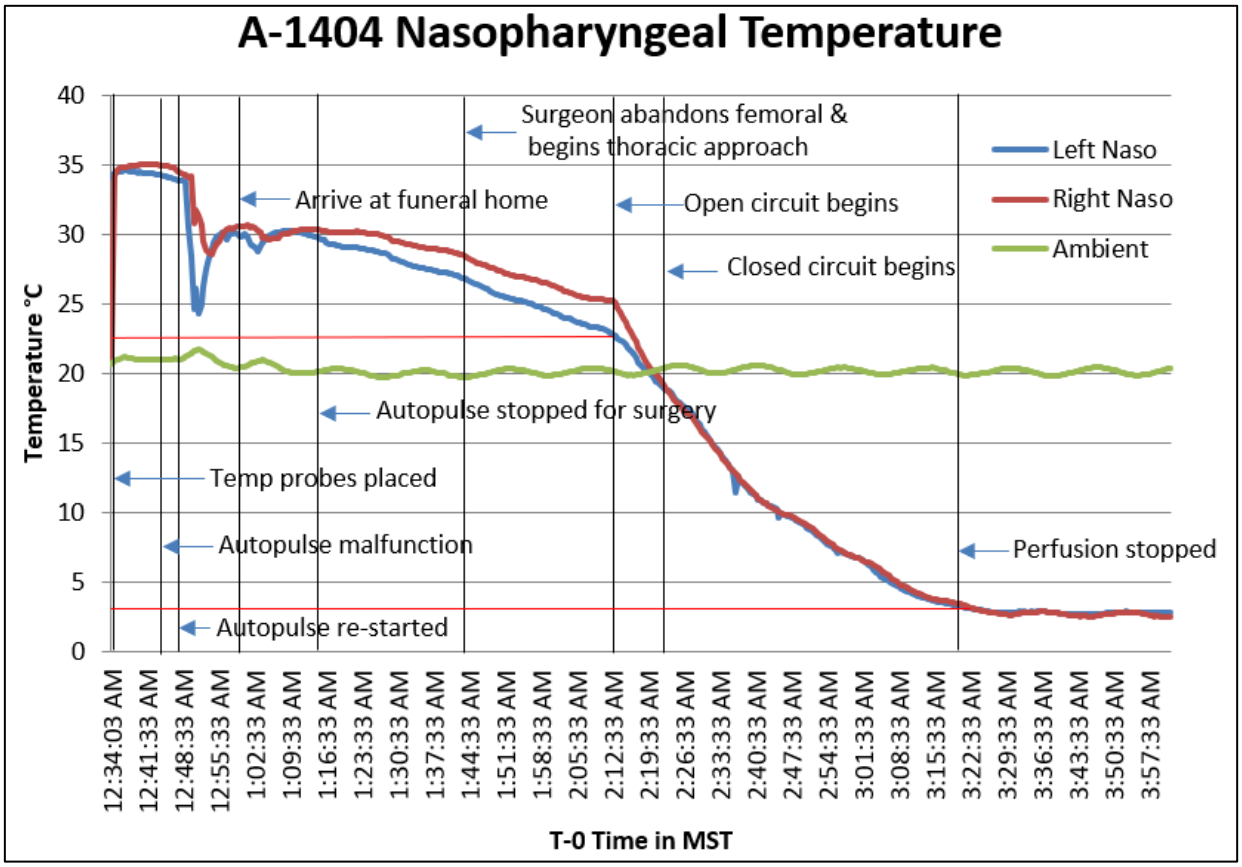
The post-cryopreservation CT scans show that no part of the brain had concentrations of M22 sufficient for ice-free cryopreservation and some parts appear to mostly have frozen blood.

15. Cryoprotection and Temperature Graphs

Graphs from SA:

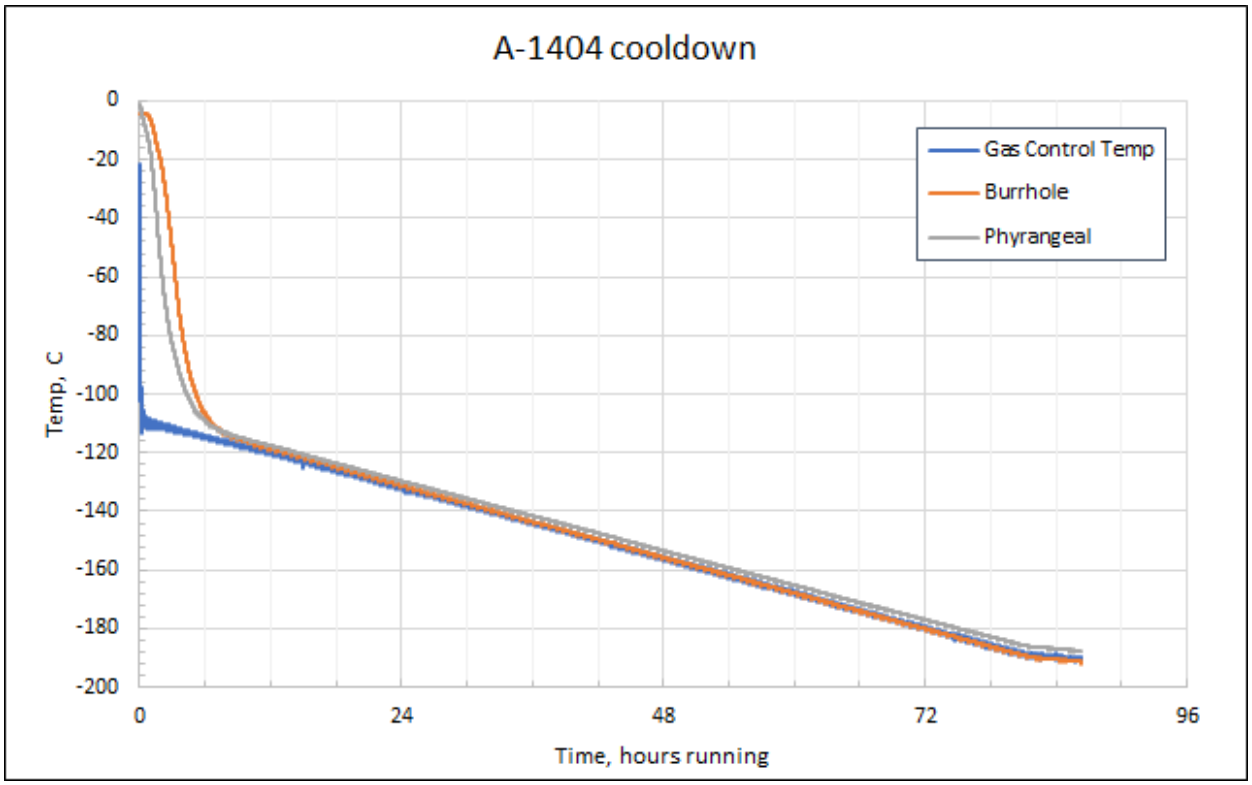


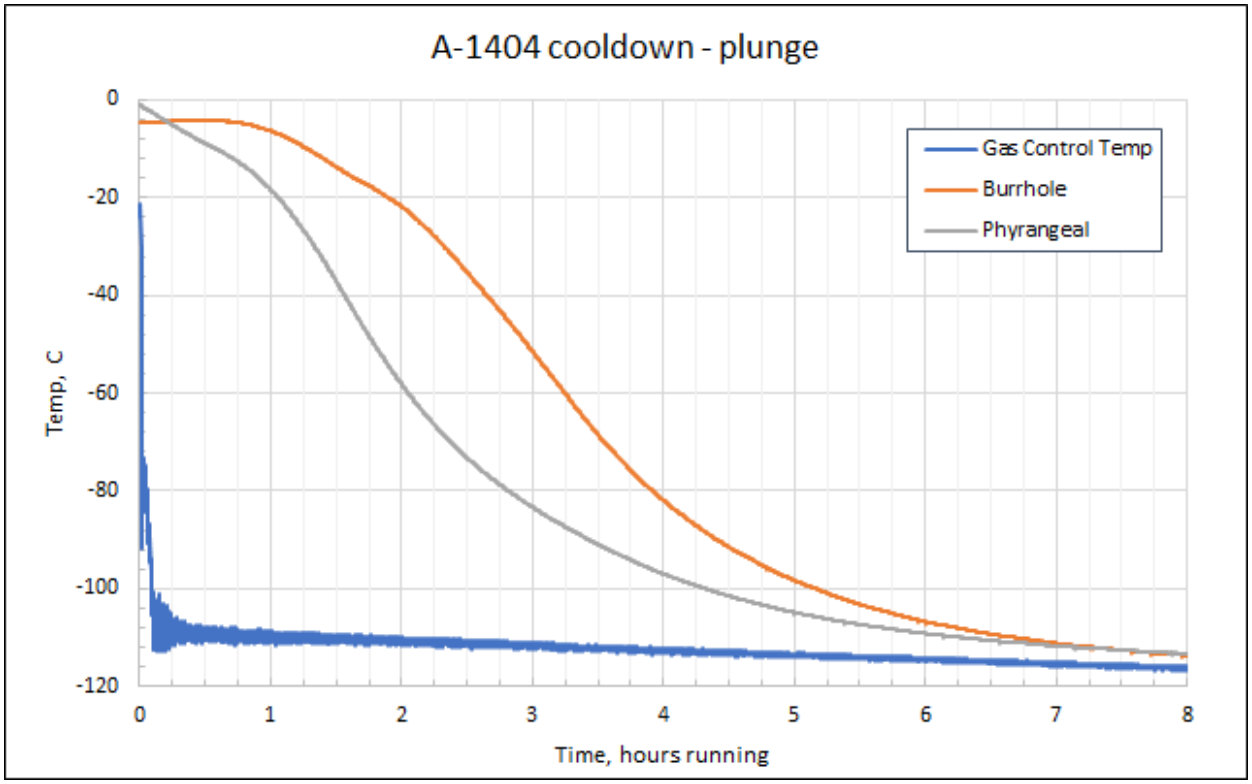


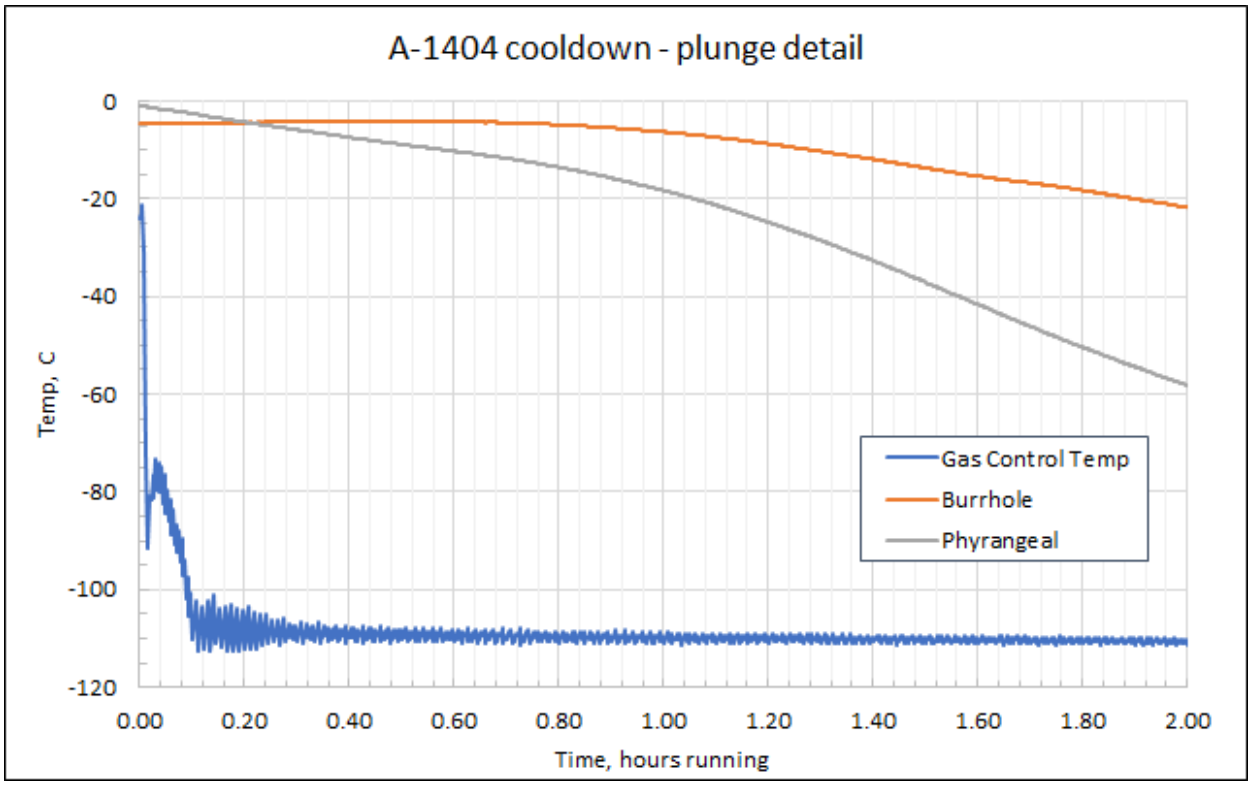

A-1404 Nasopharyngeal Temperature
Temperature °C
40
35
30
25
20
15
10
5
0
Surgeon abandons femoral & begins thoracic approach
Arrive at funeral home
Open circuit begins
Closed circuit begins
Autopulse stopped for surgery
Temp probes placed
Autopulse malfunction
Perfusion stopped
Autopulse re-started
Left Naso
Right Naso
Ambient
12:34:03 AM
12:41:33 AM
12:48:33 AM
12:55:33 AM
1:02:33 AM
1:09:33 AM
1:16:33 AM
1:23:33 AM
1:30:33 AM
1:37:33 AM
1:44:33 AM
1:51:33 AM
1:58:33 AM
2:05:33 AM
2:12:33 AM
2:19:33 AM
2:26:33 AM
2:33:33 AM
2:40:33 AM
2:47:33 AM
2:54:33 AM
3:01:33 AM
3:08:33 AM
3:15:33 AM
3:22:33 AM
3:29:33 AM
3:36:33 AM
3:43:33 AM
3:50:33 AM
3:57:33 AM
T-0 Time in MST

Graphs from Alcor:

This case was done in the Alcor operating room but due to Covid-19 precautions the field neuro cryoprotection system of bladders and gravity feed perfusion was used. Therefore, there is no perfusion control or computer temperature data from which graphs could be made. Temperatures and other data were recorded manually and are noted in the narrative section of this report.






A-1404 cooldown - plunge detail
0
-20
-40
-60
-80
-100
-120
Temp, C
0.00
0.20
0.40
0.60
0.80
1.00
1.20
1.40
1.60
1.80
2.00
Time, hours running
Gas Control Temp
Burrhole
Phyrangeal

16. S-MIX

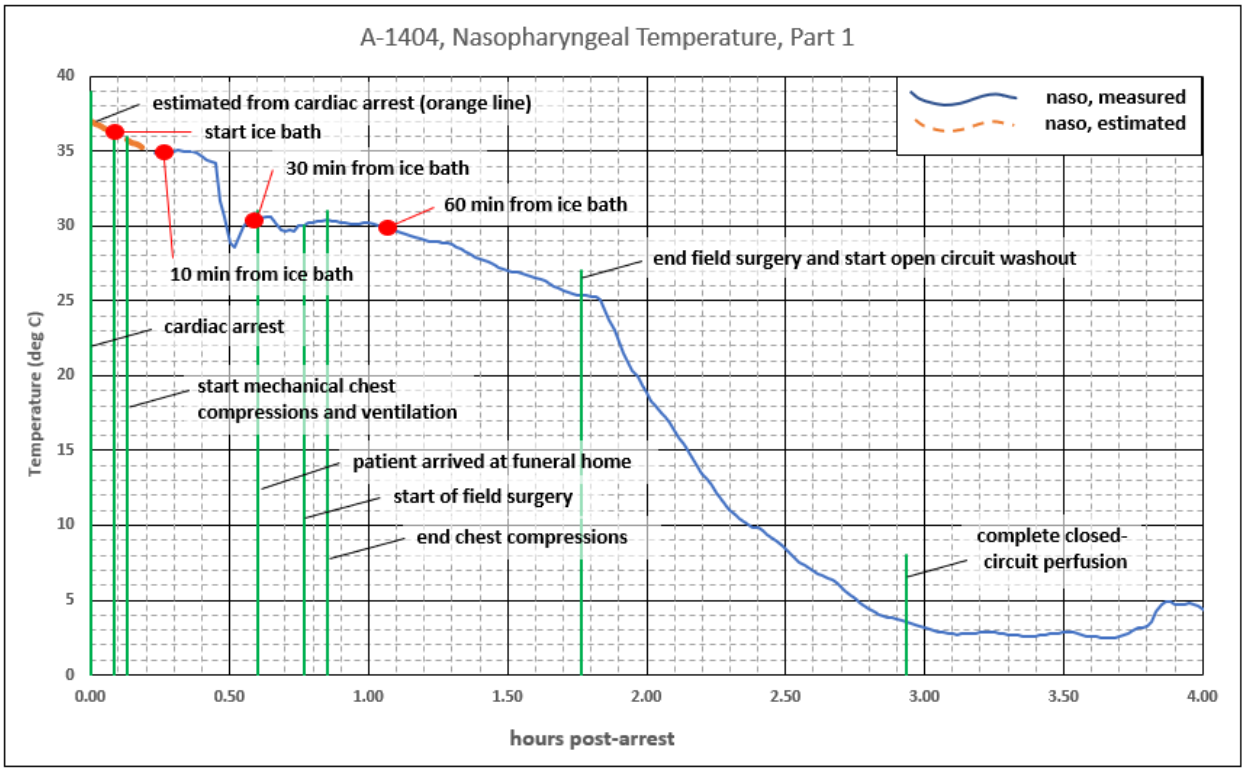
The Standardized Measure of Ischemic Exposure (S-MIX) expresses the total ischemic exposure prior to the start of cryogenic cooling as the equivalent duration of normothermic ischemia. An S-MIX of 00:00 (hh:mm) is the ideal case of no ischemic damage. The higher the S-MIX time, the more damage. Factors that improve the S-MIX, and that are quantitatively accounted for in the below table are: shorter times at higher temperatures, ventilation during cardiopulmonary support (CPS), and oxygenation during blood washout. The duration from cardiac arrest to 0 C is 16:46. As shown below, and due to lowering of the body temperature, SMIX duration is shorter, at 02:08.

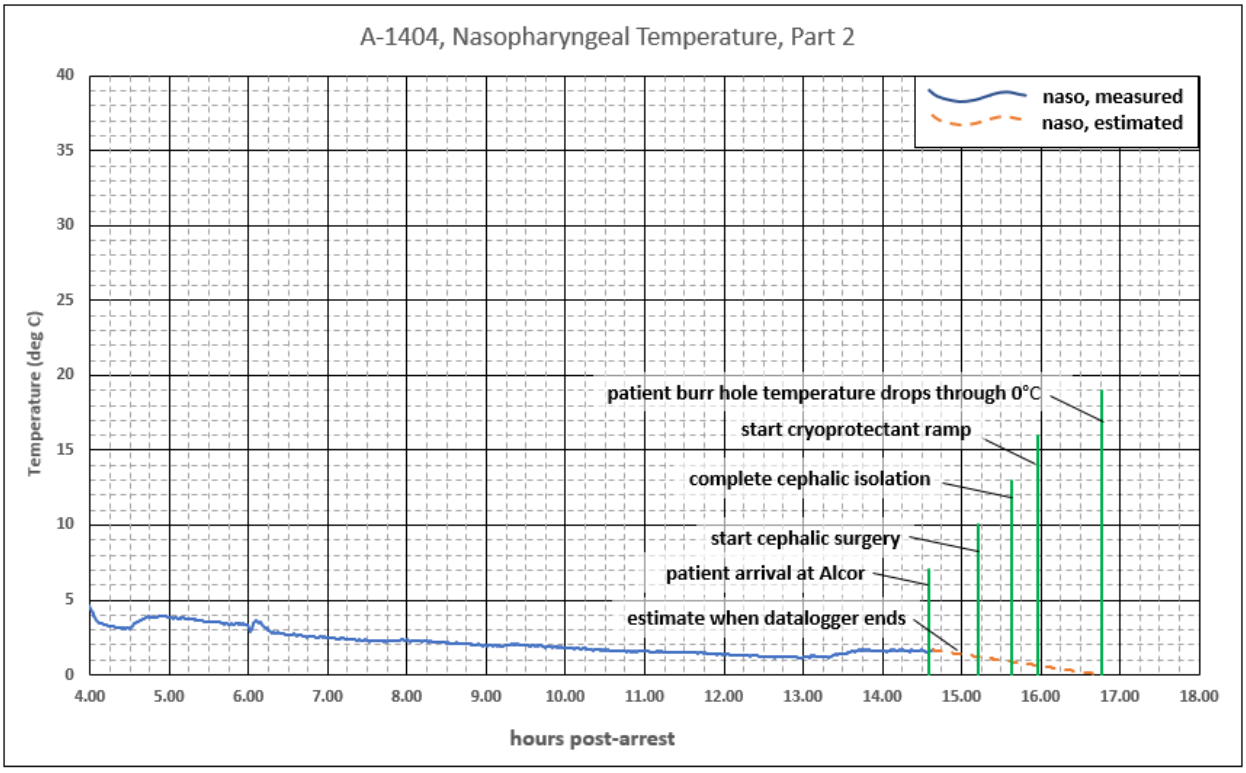
event	segment #	days (T+X)	time (MST) duration	post-arrest	Tnaso (deg C)	CPS w/ ventil.	washout oxygen.	S-MIX (hh:mm)
Cardiac arrest and pronouncement of legal death		T-0	00:23	00:00	37.0			
	seg 1		00:05	00:05	-0.8	no	no	00:05
Start of ice bath cooling		T-0	00:28	00:05	36.2			
	seg 2		00:03	00:03	-0.5	no	no	00:03
Start of mechanical chest compressions & ventilation		T-0	00:31	00:08	35.8			
	seg 3		00:28	00:28	-5.3	yes	no	00:11
Patient arrived at funeral home		T-0	00:59	00:36	30.4			
	seg 4		00:10	00:10	-0.3	yes	no	00:03
Start of field surgery, femoral approach		T-0	01:09	00:46	30.1			
	seg 5		00:05	00:05	0.3	yes	no	00:02
Termination of cardiopulmonary support		T-0	01:14	00:51	30.4			
	seg 6		00:55	00:55	-5.1	no	no	00:30
End field surgery & start open circuit washout		T-0	02:09	01:46	25.4			
	seg 7		01:10	01:10	-21.7	no	yes	00:00
Completion of closed circuit perfusion		T-0	03:19	02:56	3.7			
	seg 8		11:39	11:39	-2.1	no	no	01:03
Arrival of patient at Alcor		T-0	14:58	14:35	1.6			
	seg 9		00:37	00:37	-0.3	no	no	00:03
Start of surgery at Alcor (cephalic isolation)		T-0	15:35	15:12	1.2			
	seg 10		00:26	00:26	-0.3	no	no	00:02
Completion of cephalic isolation		T-0	16:01	15:38	0.9			
	seg 11		00:20	00:20	-0.3	no	no	00:02
Start of cryoprotectant ramp (bladder system)		T-0	16:21	15:58	0.6			
	seg 12		00:48	00:48	-0.6	no	no	00:04
patient temperature drops thru 0 deg C		T-0	17:09	16:46	0.0			
totals:			16:46	16:46	-37.0			02:08

The below plots show events related to the S-MIX calculation. There is an estimated section starting at cardiac arrest at normal body temperature (37°C) and extending about 15 minutes until the datalogger came online. There is a second estimated section at the end when nasopharyngeal data was not available. The time for the patient's temperature passing through 0°C was estimated by using the time when the burr hole temperature passed through 0°C.

The red dots provide a metric for how fast the patient is initially cooled. This is a critical period since body temperature is highest and ischemic damage most rapid. The below table provides cooling data for 10, 30, and 60 minutes after the team first applies water ice.

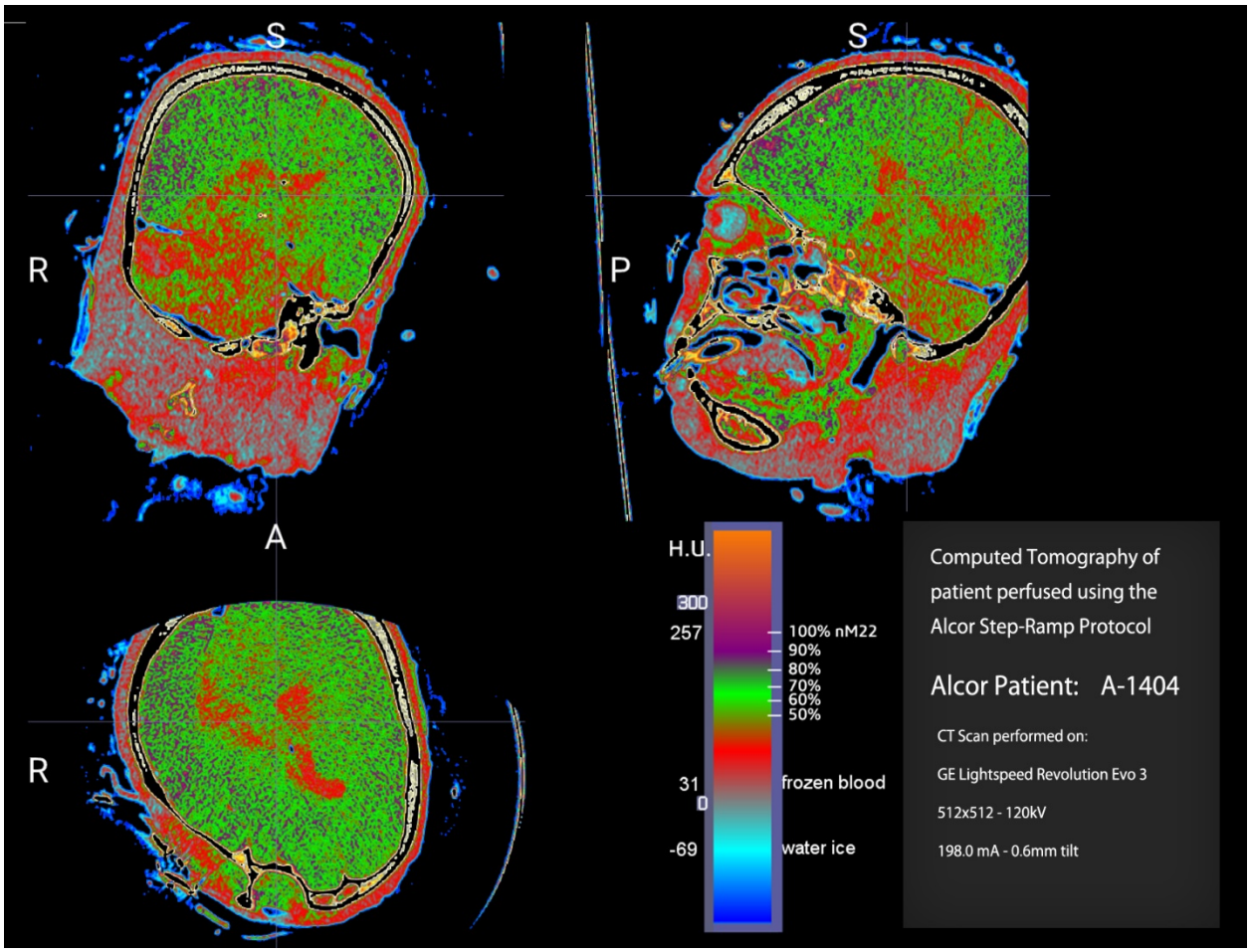
Patient Cooling Rate				
Note: time = 0 at start of ice bath	0 min elapsed	10 min elapsed	30 min elapsed	60 min elapsed
Naso temperature (°C)	36.3	34.9	30.4	29.9
Temperature drop (°C) from t = 0	0.0	-1.4	-5.9	-6.4
Cooling rate (°C/min) from t = 0	N/A	-0.14	-0.20	-0.11





17. CT Scans

Cryoprotectant Distribution (Post-cryopreservation CT scan)



The post-cryogenic cooldown CT scans were obtained on T+80 days; the patient was at liquid nitrogen temperature (-196°C).