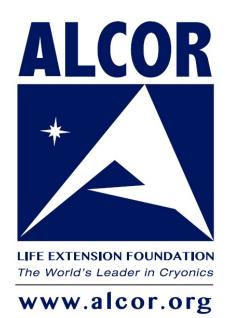
Alcor A-1931

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, T-X represents occurrences before T-0, and T+X represents occurrences following T-0.

A-1931 was a 77-year-old member with whole-body cryopreservation arrangements who suffered from pneumonia and Alzheimer's dementia. The cause of death per the death certificate was acute pulmonary embolus. Cardiac arrest was estimated to be at 07:03 hrs on T-0 days and the member was pronounced legally deceased in Texas at 07:05 hrs on T-0 days in 2022.

After neuro-on-whole-body <u>field cryoprotection</u> (FCP), the patient was air transported to Alcor for cryogenic cooldown. The patient arrived at Alcor at 07:30 hrs on T+3 days. The cryogenic cooldown was initiated on T+3 days at 08:48 hrs and terminated on T+7 days at 11:36 hrs. The patient was transferred to long-term care at liquid nitrogen temperature on T+21 days at 14:55 hrs.

2. Patient Assessment

The patient was admitted to the ICU on T-14 days due to aspiration. On T-7 days the member was discharged to inpatient hospice.

<u>T-5 days</u>

Alcor's Medical Response Director (MRD) received a call from the member's Medical Power of Attorney (MPOA) to report that the member had been in an intensive care unit (ICU) for seven days with aspiration pneumonia prior to being placed in an inpatient hospice facility two days prior. There was no surgical history, but the member did have a history of Alzheimer's disease.

The MPOA stated that the member had been responsive and talking the day before and eating good meals. However, this day the member was unresponsive and had not eaten. The hospice facility had placed the member on comfort care with as needed morphine for pain control and midazolam to relieve anxiety and promote sleepiness. The member had again aspirated so to increase comfort the physician gave orders for the member to receive nothing by mouth. The MPOA stated that she knew the member wanted to be cryopreserved but the member's neck medallion was no longer there, and she wanted to be sure Alcor was contacted. The MRD explained the standby and stabilization protocol that would be followed.

The MRD spoke to the member's hospice nurse by telephone at 11:33 hrs and received an assessment of the member that was consistent with the information given by the MPOA. The member's vital signs were heart rate (HR) 94/min, temperature (T) 37°C, blood pressure (BP) 127/70, respiration rate (RR) 18/min, and capillary oxygen saturation (SpO₂) at 96% on 6 L/min supplemental oxygen. The nurse was very cooperative and accommodating to Alcor's needs.

The MRD communicated with Alcor staff that a Level-1 deployment would likely be called soon, sent the Alcor paperwork to the hospice facility, and then at 11:43 hrs spoke with Alcor's Medical Advisor to discuss the member's condition. They both agreed that death was imminent, and a Level-1 deployment was called at 12:03 hrs.



Sidebar:

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

3. Standby

As this would be a whole-body field blood substitution procedure, Suspended Animation (SA), one of Alcor's strategic partners for providing standby, stabilization, and transport (SST) as well as remote blood substitution was alerted. They began the search for a funeral home with an embalming operating room available. They found a funeral home that was only 15 minutes from the member and had also worked with the hospice facility before. The Alcor staff began setting up the Alcor operating room (OR) for a whole-body perfusion.

At 08:58 hrs the MRD received the member's vital signs from the night nurse. The member's temperature (T) was 37°C, heart rate (HR) 92/min, respiration rate (RR) 18/min, blood pressure (BP) 128/68, capillary oxygen saturation (SpO₂) 93% on 6 liters (L) of oxygen (O2). The member was still receiving morphine 4 times/day and was unresponsive. The member was still not being given food or water by mouth and urine output was 400 cc for the whole day.

The SA team had arrived at the hospice facility at 10:36 hrs to set up their equipment and check on the member's status but were informed that per the MPOA they were not allowed in the facility, until the patient was declared legally deceased. This was surprising as the MPOA had previously been cooperative. Alcor's Social Services Director (SSD) arrived that evening.

<u>T-4 days</u>

The SA team leader called the hospice facility at 07:48 hrs to see when the team would be allowed access to the member. He was told that the manager was not yet in and would be given a message to call him. SA and Alcor staff discussed the confusing and sudden lack of cooperation on the part of the MPOA with no resolution. Alcor's MRD was enroute to the member's location. Alcor's General Counsel was alerted to the situation.

At 08:31 hrs the member's vitals were T still 37° C, HR 118/min, BP 142/64, RR 16/min, SpO₂ 85% on 6 L/min, urine output was 300cc during the last shift. The member was still unresponsive.

Alcor's MRD arrived at the member's location at 09:07 hrs. At 09:59 hrs the MRD called the MPOA to inform her she was enroute to the hospice facility and would like to meet in person. The MPOA agreed to meet and stated that she was looking forward to the meeting. At 10:30 hrs Alcor's MRD and SSD attempted to receive a patient update in person at the hospice.

The Nurse Manager, and the hospice social worker, both greeted the MRD and the SSD at the door and stated that the MPOA requested Alcor personnel not be granted permission inside the hospice facility. The MRD called the MPOA who then came to the door and stated that she did not want the member to be disturbed, and Alcor and SA personnel were not to return unless called (see the Discussion section for more details).





At 11:55 hrs the MRD sent an email to the nurse manager with the requested Alcor documentation and then updated Alcor's Co-CEOs of the situation. They were advised to cease communication with the MPOA unless necessary until local legal counsel was identified and on board to assist. At 20:26 hrs the MRD received an update from the night nurse on the member's condition and vital signs HR 118, T 37°C, BP 142/64, RR 16/min, and SpO₂ 85% on 6 L/min of oxygen. The member's total urine output for the day was 300 ml. The hospice nurses remained cooperative and forthcoming with patient updates.

T-3 days

The member was taken off oxygen and the foley catheter was removed. The member was still unresponsive and receiving no food or water by mouth. No skin changes were observable. The member's vitals showed significant changes at 08:00 hrs with T at 39°C, HR 120/min, RR 20/min, BP 117/57, SpO₂ 80% on room air.

The nurses had all been friendly and helpful when the MRD called for updates, with no hesitation to give information and they all assured the MRD that they would call immediately if there were any changes in the member's condition. A hospice nurse called at 16:40 hrs to report that the member's vitals were HR 130/min, RR 20/min, SpO_2 58% on room air. The member's skin was showing signs of mottling throughout the body. However, Alcor and SA were still not allowed access to the building. This disparity was still not understood. The Alcor Board of Directors was notified of the possible legal obstacles and was agreeable to having local counsel intercede, as necessary.

At 19:20 hrs the team was at a hotel approximately four minutes from the facility, but the stabilization medications were being drawn up and as much advanced preparation as possible was being done. The team was only allowed to perform the ice bath in the facility, so the priority was to begin that and then move the member outside as soon as possible in order to start cardiopulmonary support and start administration of the stabilization medications. The SA surgeon and perfusionist were at the funeral home priming their perfusion equipment for the blood substitution.

The member's vitals were unchanged at 22:01 hrs. The MRD made the decision to send the entire team back to the hotel for the remainder of the night. The hospice had given assurances that they would call if the member was declining and near cardiac arrest.

T-2 days

A hospice nurse called at 08:02 hrs to report increased mottling of the skin and cyanosis on the member's fingertips, feet, and face. The SpO₂ reading was 74% but readings may not be as accurate due to the poor perfusion that was evidenced by the mottling and cyanosis. The team was standing by with everything set up ready to go. The member's other vitals were HR 140/min, BP 109/87, and RR 24/min.

At 12:03 hrs the MRD called the hospice for an update and was informed by the nurse that this patient had been made "private" by the MPOA. Hospice could not give any more information and asked for the phone calls for medical updates to stop. The MRD requested that Alcor be notified at time of death and the nurse confirmed that they would comply.



<u>T-1 days</u>

No medical updates were received from the hospice facility on this day. SA remained on standby at the hotel four minutes away.

T-0 days

The MRD received notification at 06:54 hrs that the patient had begun agonal breathing. The nurse manager had already notified the funeral home for pick up. The MRD notified the SA team on standby, who had also received a call from the funeral director. At 07:08 hrs the MRD received a call from the nurse manager that the time of cardiac arrest had been 07:03 hrs and the member was pronounced legally deceased at 07:05 hrs.

The MRD called the nurse manager at 07:26 hrs to request the body be released to SA, but the nurse manager stated that she had been advised by her general counsel that the body could only be released to the funeral home (see Discussion section). The MRD confirmed the understanding and notified SA. At 07:52 hrs SA confirmed that the funeral director was at the hospice facility and the body was being released.

4. Stabilization

The funeral director arrived at the hospice facility at 07:52 hrs to remove the patient, using his vehicle for patient transport to the funeral home which unfortunately was not large enough to allow use of the PIB. The hospice facility would not allow the patient to be transferred into the portable ice bath (PIB) on their property. At 08:02 hrs the patient was loaded into the funeral director's vehicle. Once the vehicle exited the hospice property, the patient was intubated with the SAVe Automed ventilator as well as the PCM-900 Capnograph and a Zoll impedance threshold device to monitor the success of ventilation. Additionally, the left and right nasopharyngeal temperature probes were placed at a depth of about 10 cm, and manual compressions were initiated.

At 08:02 hrs the funeral director was met by the SA stabilization vehicle. 35 lbs. of water ice were placed around the patient's head, an intraosseous device (IO) was placed in the tuberosity of the right leg, and the abbreviated medications protocol was administered while manual compressions were performed enroute to the funeral home. The decision to administer the abbreviated protocol was made at the last minute by the on-site Alcor representatives after consulting with personnel at Alcor. The medications Tempol and the initial 250,000 IU Streptokinase were not available for administration (see Discussion section).

Once at the funeral home at 08:22 hrs the patient was transferred into the PIB. Three SA team members were present to perform the rest of the stabilization so many procedures could be performed concurrently. At 08:25 manual compressions were resumed after the patient transfer. An additional 70 lbs. of water ice were added to the PIB, along with 2 gallons of water. The pump and the cooling mask on the surface conduction cooling device (SCCD) were then activated to further improve external cooling, and the Autopulse mechanical chest compression device was initiated at 08:31 hrs for better cardiopulmonary support.



5. Field Surgery and Blood Substitution

An additional 35 lbs. of water ice was added to the PIB. The patient was moved to the operating table in the funeral home at 08:33 hrs.

At 08:35 hrs the patient's nasopharyngeal temperature (NPT) was 27°C and the Autopulse was stopped to begin surgical preparation. Manual compressions were applied until the surgery commenced at 08:39 hrs. The first incision in the chest was made at 08:41 hrs and a Stryker electrical saw was used to access the chest. The ascending aorta was cannulated at approximately 08:51 hrs with a 21 French (Fr) curved tip Edwards EZ Glide cannula and the inferior vena cava was canulated through the right atrium with a 29/37 CalMed tri-stage venous return canula.

At 09:06 hrs open circuit perfusion was initiated with a left NPT temperature of 21°C. 250,000 IU streptokinase was administered through the patient circuit at 09:07 hrs. Closed circuit perfusion began at 09:24 hrs with a left NPT of 10°C. At 10:15 hrs perfusion was terminated. The left NPT was 2°C.

Throughout the entire procedure the patient circuit was attached to a room air pump delivering 5L/min into the oxygenator. Additionally, the perfusion pressure never exceeded 100 mm/Hg at the head of the arterial canula. The perfusate used was 30 liters of MHP2. The surgeon closed the patient leaving the heart cannulae secured and accessible from outside the patient's chest cavity. This had been requested by Alcor for future cryoprotectant perfusion procedures to reduce ischemic damage to the patient during a re-cannulation of the patient at the Alcor OR.

The patient's head was then covered in an additional 35 lbs. of water ice at 10:17 hrs and left with the recirculation pump and cooling mask active. The patient remained in the functioning PIB while the team attempted to find the hospice physician to sign off on the death certificate.

At about 14:00 hrs the decision was made (see the Discussion section) to perform the cephalic FCP procedure and place the patient on dry ice for ground transport to Alcor once the transit paperwork was processed.

6. Field Surgery and Cryoprotectant Perfusion (FCP)

Work to set up the perfusion heat exchanger, gravity tripod, and surgical instruments started at 15:05 hrs. The patient was extubated at 15:10 hrs.

The left carotid cutdown procedure began at 15:11 hrs and the funeral director assisted with location of the carotid arteries to save time. The left carotid artery was canulated at 15:21 hrs with an 18 Fr. curved tipped canula. At 15:24 hrs the right carotid cutdown procedure started. The right carotid artery was canulated with another 18 Fr. Curved tipped canula at 15:39 hrs. The right and left jugular veins were severed to facilitate effluent drainage.

As this was a cephalic-perfusion-on-whole-body procedure, the vertebral arteries could not be accessed for cannulation or clamping off. Also, since SA had not done this type of field cryoprotection procedure in the past, their kit did not have the equipment to make burr holes.



The gravity-induced perfusion flow was initiated at 15:22 hrs with Bladder #2 containing nM22 cryoprotectant with a concentration of 0.05 percent concentration needed to vitrify (CNV), with a molarity of 0.47 (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 an elevated tripod, a smoother transition of increasing concentrations of cryoprotectant can be achieved.

The gravity feed system for FCP uses a tripod that can be adjusted for height to control the arterial pressure. The pre-mixed cryoprotectant was in a series of bladders with graduated concentrations [measured by the refractive index (RI) in Brix units]. The height of the bladders on the teeter totter was approximately 48 inches which is (48" x 2.054 mmHg per inch of height =) a maximum arterial pressure of 98 mmHg 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.

This process allows for a smoother curve in the increasing concentrations of cryoprotectant. The gravity feed system for FCP uses a tripod that can be adjusted for height to control the arterial pressure. The pre-mixed cryoprotectant was in a series of bladders with graduated concentrations [measured by the refractive index (RI) in Brix units].

Sidebar:

Per the cryoprotection protocol, the ramp is to be paused at 30 Brix (50% of the desired terminal concentration) to allow the patient to come to osmotic equilibrium. When the bladder system is used, bladders 6 & 7 represent the pause. The cephalic/patient enclosure and the chiller are switched from $+3^{\circ}$ C to -3° C operation. At the end of the 30-minute pause, the ramp is resumed at the maximum addition rate (maximum without losing total volume in the circuit) to go to 105% of the desired end concentration (52.5 Brix) and held between 102% and 105% concentration until the terminal concentration is obtained.

Bladder #6 was started at 16:04 hrs and this marked the start of the 30-minute pause for equilibration. Ethylene glycol antifreeze was added to the water in the heat exchanger approximately 10 minutes after bladder #6 was started to bring the perfusate below 0°C. At 18:28 hrs the refractive index (RI) of the effluent was 50 Brix (100% of perfusate concentration needed to vitrify (CNV), and the one-hour countdown to termination of cryoprotectant perfusion was started. Cryoprotectant perfusion was terminated with bladder #18 at 19:25 hrs. The final RI concentration was 51.3 Brix (103% of CNV).

At 19:34 hrs the patient was removed from the ice bath, placed on a mega mover inside two body bags, and transferred into a Ziegler case with R-19 insulation and approximately 300 lbs. of dry ice. At 19:50 hrs the patient was moved into a cold storage room at the funeral home that was kept at approximately 3°C.



7. Patient Transport

T+1 days

Dry ice was replenished in the morning. The death certificate and transit permit were not issued until 16:30 hrs and a van for patient transport could not be sourced until 10:30 hrs.

T+3 days

The patient was driven to Alcor and arrived at approximately 07:30 hrs. The nasopharyngeal temperature was not recorded as the thermistor probe appeared to be giving false data (see the Discussion section).

8. Cooling to Liquid Nitrogen Temperature

Computer controlled cryogenic cooldown was initiated at 08:48 hrs on T+3 days, plunging to -110° C and descending thereafter at -1° C/hour to liquid nitrogen temperature. On T+7 at 11:36 hrs an uneventful cooldown was terminated. On T+21 days at 14:55 hrs, the patient was transferred to long-term care at liquid nitrogen temperature.



9. Timeline and Time Summaries

Timeline

	1	
Т-0	07:03	Estimated time of cardiac arrest
Т-0	07:05	Time of pronouncement of legal death
T-0	07:57	Started ventilation
Т-0	08:02	Ice placed on patient
Т-0	08:02	Placement of intraosseous device (IO)
Т-0	08:04	Start of manual chest compressions
Т-0	08:04	Administration of first medication (sodium citrate)
T-0	08:22	Arrive at funeral home and start of ice bath cooling
Т-0	08:31	Start mechanical chest compressions
T-0	08:31	Termination of mechanical chest compressions (27°C)
T-0	08:32	Administration of last medication (antacid)
T-0	08:41	Start of field surgery (median sternotomy)
Т-0	09:05	End of field surgery
Т-0	09:06	Start open circuit washout (LNPT 10°C, RNPT 2°C)
Т-0	09:22	End open circuit blood substitution
Т-0	09:24	Start closed circuit perfusion
Т-0	10:15	End closed circuit perfusion (2°C)
Т-0	14:00	Decision to perform field cryoprotection (FCP)
Т-0	15:21	Start of carotid artery cannulation
Т-0	15:39	End of carotid artery cannulation
Т-0	15:22	Start of bladder system field cryoprotection
Т-0	16:04	Start 30-minute pause for equilibration (bladders #6/#7)
Т-0	19:25	End of cryoprotection (RI = 51.3 Brix)
Т-0	19:34	Start dry ice cooling
T+2	09:37	Departure of patient from funeral home
T+3	07:30	Arrival at Alcor
T+3	08:48	Start of cryogenic cooldown
T+7	11:36	End of cryogenic cooldown
T+21	12:00	Transfer patient into long term care



Time Summary

FIELD				
STABILIZ	ATION			
00:02	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	07:05	Time of pronouncement of legal death
00:59	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	Т-0	08:02	Ice placed on patient
01:19	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	08:22	Arrive at funeral home and start of ice bath cooling
01:01	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	08:04	Start of manual chest compressions
01:01	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	08:04	Administration of first medication (sodium citrate)
00:28	From:	T-0	08:04	Administration of first medication (sodium citrate)
	Till:	T-0	08:32	Administration of last medication (antacid)
FIELD SU	IRGERY AN	D CRYO	PROTECT	ION (FCP)
01:38	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	08:41	Start of field surgery (median sternotomy)
06:58	From:	T-0	08:41	Start of field surgery (median sternotomy)
	Till:	T-0	15:39	End of carotid artery cannulation
02:03	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	09:06	Start open circuit washout (LNPT 10°C, RNPT 2°C)
01:09	From:	T-0	09:06	Start open circuit washout (LNPT 10°C, RNPT 2°C)
	Till:	T-0	10:15	End closed circuit perfusion (2°C)
03:12	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	10:15	End closed circuit perfusion (2°C)
04:03	From:	T-0	15:22	Start of bladder system field cryoprotection
	Till:	T-0	19:25	End of cryoprotection (RI = 51.3 Brix)
12:22	From:	T-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	19:25	End of cryoprotection (RI = 51.3 Brix)
06:41	From:	T-0	08:41	Start of field surgery (median sternotomy)
	Till:	T-0	15:22	Start of bladder system field cryoprotection
10:44	From:	T-0	08:41	Start of field surgery (median sternotomy)
	Till:	T-0	19:25	End of cryoprotection (RI = 51.3 Brix)
	AND LIQUI	D NITRO		OLDOWN AT ALCOR
00:09	From:	T-0	19:25	End of cryoprotection (RI = 51.3 Brix)
	Till:	T-0	19:34	Start dry ice cooling
01:01	From:	Т-0	07:03	Estimated time of cardiac arrest
	Till:	T-0	08:04	Administration of first medication (sodium citrate)
72:27	From:	Т-0	07:03	Estimated time of cardiac arrest
	Till:	T+3	07:30	Arrival at Alcor
01:18	From:	T+3	07:30	Arrival at Alcor
	Till:	T+3	08:48	Start of cryogenic cooldown



TIME	MEDICATION	DOSE	PURPOSE
T-0 days 08:04 hrs	Sodium citrate	100 mg Note 1	Anticoagulant; prevents blood clot formation.
08:05 hrs	Sodium citrate	100 mg Note 1	Anticoagulant; prevents blood clot formation.
08:05 hrs	Heparin	50,000 IU	Anticoagulant; prevents blood clot formation.
08:06 hrs	Minocycline	200 mg	Antibiotic; reduces microbial overgrowth during long transport times.
08:06 hrs	Decaglycerol/THAM	60 ml Note 2	Decaglycerol inhibits cerebral edema.
08:07 hrs	Decaglycerol/THAM	60 ml Note 2	Decaglycerol inhibits cerebral edema.
08:08 hrs	Decaglycerol/THAM	60 ml Note 2	Decaglycerol inhibits cerebral edema.
08:09 hrs	Decaglycerol/THAM	20 ml Note 2	Decaglycerol inhibits cerebral edema.
08:32 hrs	Antacid	250 ml Note 3	A buffer used to protect the stomach from acid erosion.
09:07 hrs	Streptokinase	250,000 IU Note 4	A thrombolytic used to break up existing blood clots.

10. Table of Medications Administered

Notes:

1. The standard formulation for sodium citrate is 20% w/v, in sterile packaging provided by the manufacturer. 10 grams of sodium citrate are given to patients who weigh less than 40 kg, and 20 grams are given to patients who weigh over 40 kg. This patient received 20 grams of sodium citrate because the patient's weight was over 40 kg.

2. Decaglycerol/THAM is administered as a custom formulation of 20% w/v decaglycerol and 4.5% w/v THAM (tromethamine) in water (pH = 10.4 and pKa = 8.3).

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

4. With the abbreviated medications protocol, streptokinase is not administered with the 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, and 25,000 IU for the abbreviated medications protocol. 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.



Preferred end	point is ov	ver 49.9 Brix f	rom both jug	gulars for 1/2	hr.			
2L Bag label number	[nM22], CNV	Molarity of penetrating CPAs*	Brix (calc)	Bag start hh:mm, MST	hrs post pronounc- ement	Bag avg. flow rate, mL/min	Sample time hh:mm, MST	Effluent Conc., Brix
2	0.05	0.47	11.81	15:22	8.28	111.1	17:03	41.9
3	0.08	0.78	13.14	15:40	8.58	153.8	17:19	41.4
4	0.14	1.29	15.35	15:53	8.80	333.3	17:22	43.4
5	0.23	2.15	19.03	15:59	8.90	400.0	17:36	38.2
6	0.50	4.67	29.85	16:04	8.98	125.0	17:48	44.2
7	0.50	4.67	29.85	16:20	9.25	250.0	17:55	46.9
8	1.06	9.91	52.31	16:28	9.38	166.7	18:08	46.4
9	1.06	9.91	52.31	16:40	9.58	500.0	18:22	49.2
10	1.06	9.91	52.31	16:44	9.65	80.0	18:28	50.5
11	1.06	9.91	52.31	17:09	10.07	400.0		
12	1.06	9.91	52.31	17:14	10.15	64.5		
13	1.06	9.91	52.31	17:45	10.67	111.1		
14	1.06	9.91	52.31	18:03	10.97	90.9		
15	1.06	9.91	52.31	18:25	11.33	33.3		
END				19:25	12.33			

11. Table of Concentrations (Brix) of nM22 Solution

Note: When the bladders with precalculated concentrations of cryoprotectant are made up in the lab, the first bladder in the series contains only the B1 carrier solution with no cryoprotectant and is intended to be used for purging air bubbles. Bladder #2 contains the lowest concentration of cryoprotectant. Limited experience with the bladder system, however, has shown that better edema control is provided when the initial perfusion is done with cryoprotectant. As a result, cryoprotectant perfusion is initiated with Bladder #2. When there is sufficient experience to make this the standard protocol, the lab procedure for creating the bladders will be changed so that Bladder #1 will contain cryoprotectant.



12. Discussion

Standby and Stabilization

The member's Medical Power of Attorney (MPOA) was cordial on the phone prior to Alcor/SA arrival at the member's site but was hostile and noncompliant once Alcor/SA arrived. Neither Alcor nor SA were allowed access to the hospice facility. This seems to be an ongoing issue and often related to family or MPOA desire to acquire the funding provided to Alcor for cryopreservation. Alcor personnel will continue to investigate means of eliminating or minimizing this, such as looking into types of legal standing that can better assert Alcor's and the member's rights.

Communication with the hospice or medical facility as to who will be transporting the patient needs to be made abundantly clear. In this case the MRD stated the funeral home would pick up and transport the patient but did not clarify that the SA team would be acting as an agent for the funeral home. This created miscommunication that resulted in the hospice facility not releasing the patient to SA/Alcor until the funeral director was present for transport. They also claimed that SA could not use their vehicle and that the remains had to be transported in the funeral director's vehicle. This decision was made by the hospice administration who are not legally allowed to dictate this decision.

Clear and concise communication needs to be made with the hospice or medical facility about who is obtaining possession of the patient upon legal pronouncement of death. Documents will be drawn up and signed by the funeral director that the SST team has legal authority to function as the agent for the funeral home to pick up the human remains.

The decision to administer the abbreviated medications protocol was made at the last minute by the on-site Alcor representatives when delays caused by the circumstances described above resulted in it taking close to an hour before the medications could be administered. The medications Tempol and the initial 250,000 IU Streptokinase were not available for administration. The streptokinase had been located with the perfusionist at the funeral home because this is the procedure when using the full medications protocol. The SA kit did not contain Tempol which is shown on the protocol to be administered "if available". SA will start including Tempol in their kits for possible future use, but for this case it would not have been drawn up prior to the stabilization as expectations were that access to the patient would have been quicker.

Field cryoprotection (FCP)

The onsite Alcor representatives had had the forethought to ship out the Alcor Field Cryoprotection (FCP) kit. Due to the delays in getting the death certificate signed, SA and on-site Alcor personnel decided that an FCP procedure on the cephalon of the whole-body patient would reduce ischemic damage to the brain. This was discussed with technical staff at Alcor and at about 14:00 hrs the decision was approved by both Alcor Co-CEOs to perform the cephalic FCP procedure and place the patient on dry ice for ground transport to Alcor once the transit paperwork was processed.



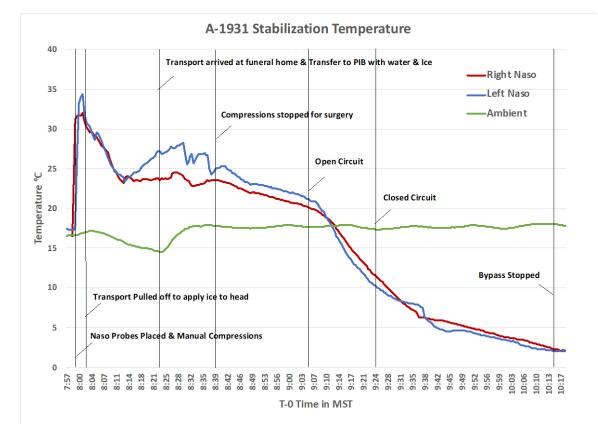
Cryogenic Cooldown at Alcor

When the patient arrived at Alcor the nasopharyngeal temperature was not recorded because the thermistor probe appeared to be giving false data. The first recorded temperature in the cooldown file was -87.62°C, which does not make sense given that dry ice temperature is -78.5°C. However, SA's transport graph below also shows their temperature probes were reading about -85°C as soon as the patient transport began.

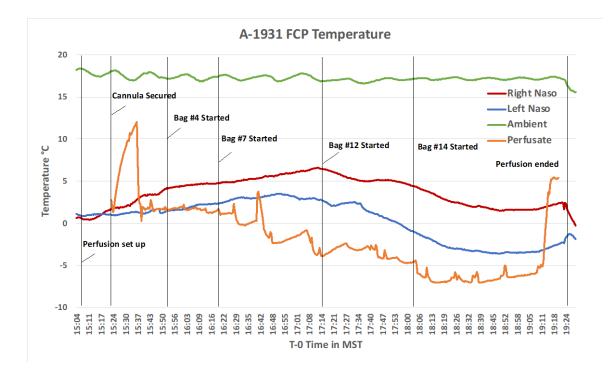
There is no known explanation for this, but it is possible that the thermistor itself was defective since it was reading the same temperature from SA's logger as it was on the Alcor cooldown system.

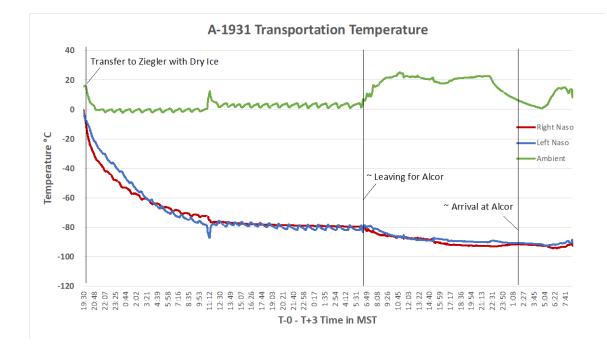
13. Cryoprotection and Temperature Graphs

Graphs by SA:

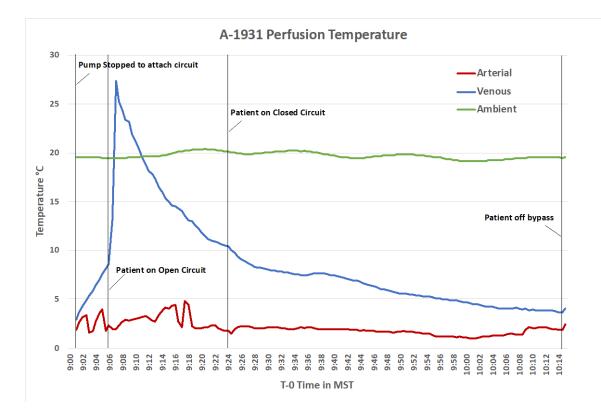


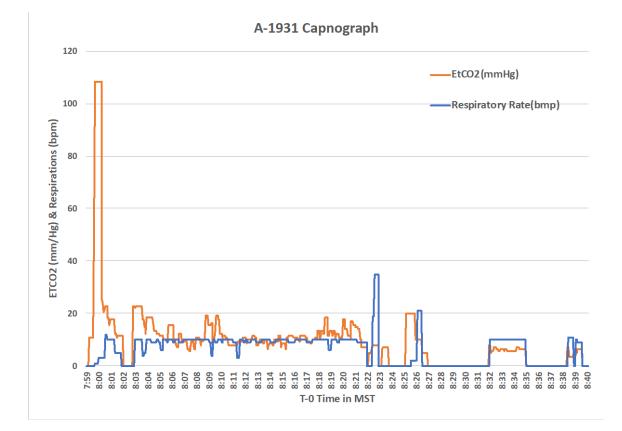






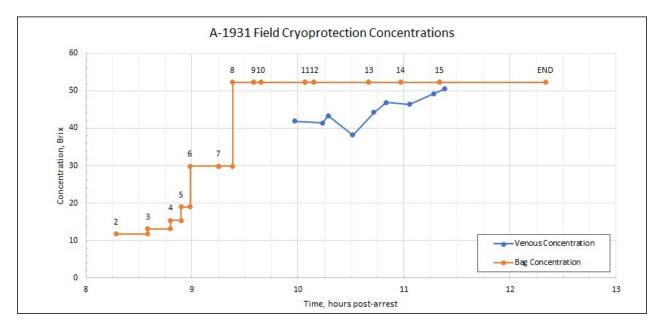


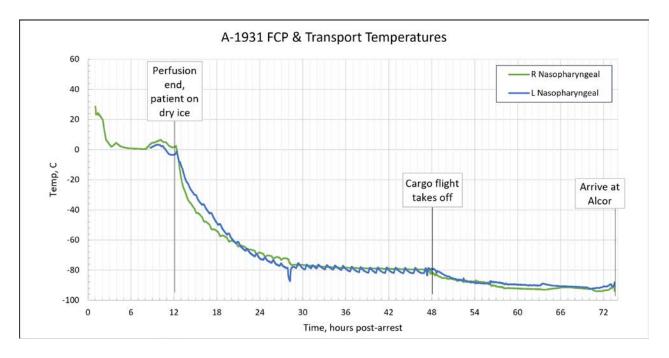




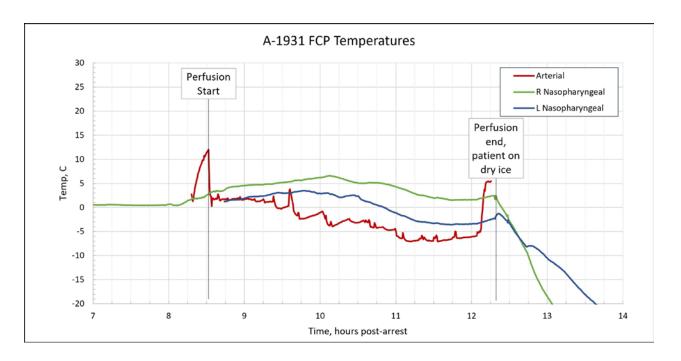


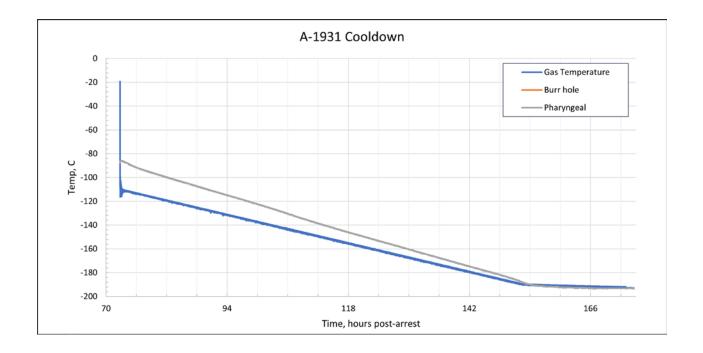
Graphs by Alcor:













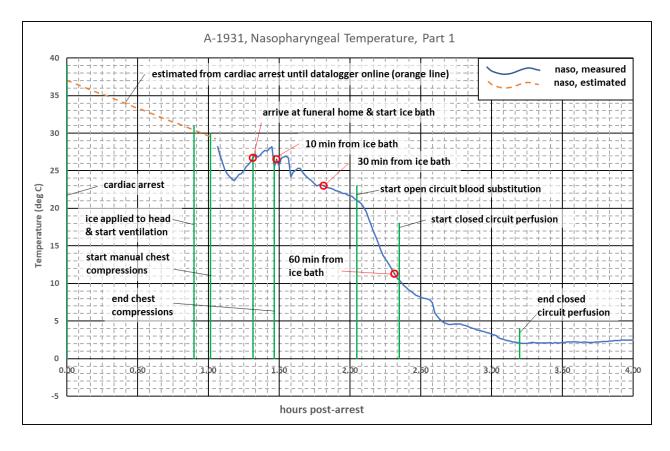
14. S-MIX

The <u>Standardized Measure of Ischemic Exposure</u> (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 °C is 10:52. As shown below, and due to lowering of the body temperature, S-MIX duration is shorter, at 01:55.

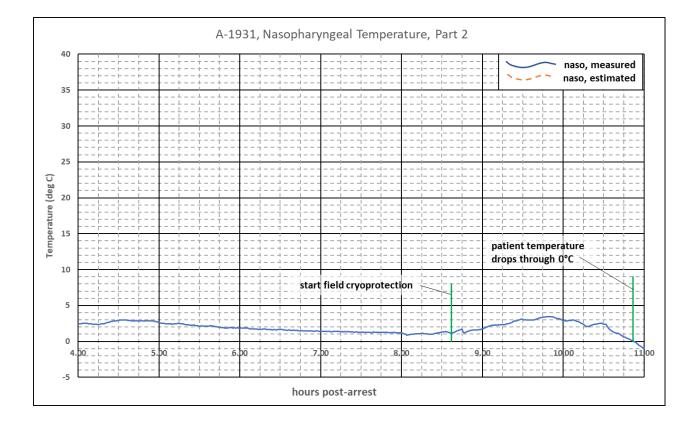
	seg-	days	time (MST)	post-	Tnaso	CPS w/	washout	S-MIX
event	ment #	(T+X)	duration	arrest	(deg C)	ventil.	oxygen.	(hh:mm)
Estimated time of cardiac arrest		T-0	07:03	00:00	37.0			
	seg 1		00:59	00:59	-7.2	no	no	00:46
Ice placed on patient & start ventilation		T-0	08:02	00:59	29.8			
	seg 2		00:02	00:02	-0.2	no	no	00:01
Start of manual chest compressions		T-0	08:04	01:01	29.6			
	seg 3		00:18	00:18	-2.9	yes	no	00:04
Arrive at funeral home and start of ice bath		T-0	08:22	01:19	26.7			
	seg 4		00:09	00:09	-1.2	yes	no	00:02
Termination of chest compressions		T-0	08:31	01:28	25.5			
	seg 5		00:35	00:35	-4.5	no	no	00:14
Start open circuit blood substitution		T-0	09:06	02:03	21.0			
	seg 6		00:18	00:18	-10.6	no	yes	00:00
Start closed circuit perfusion		T-0	09:24	02:21	10.5			
	seg 7		00:51	00:51	-8.4	no	no	00:06
End closed circuit perfusion		T-0	10:15	03:12	2.1			
	seg 8		05:25	05:25	-0.9	no	no	00:29
Start of bladder system field cryoprotection		T-0	15:40	08:37	1.2			
	seg 9		02:15	02:15	-1.1	no	no	00:12
patient passses thru 0C		T-0	17:55	10:52	0.1			
totals:			10:52	10:52	-36.9			01:55



The below plots show events related to the S-MIX calculation. The red dots can be used to construct a metric for how fast the patient is initially cooled (see the Patient Cooling Rate table below). This is a critical period since body temperature is highest and ischemic damage most rapid.



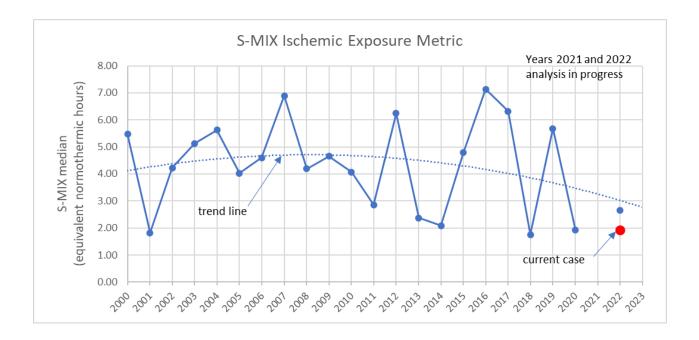




The below table provides cooling data for 10, 30, and 60 minutes after the team starts the ice bath.

Patient Cool	(patient weight 68 kg; 150 lb)				
Note: time = 0 at start of ice bath	0 min	10 min	30 min	60 min	
Note: time = 0 at start of ice bath	elapsed	elapsed	elapsed	elapsed	
Naso temperature (°C)	26.7	26.5	23.0	11.3	
Temperature drop (°C) from t = 0	0.0	-0.2	-3.7	-15.4	
Cooling rate (°C/min) from t = 0	N/A	-0.02	-0.12	-0.26	





The following plot shows the trend of S-MIX achieved since 2000.

15. CT Scans

As this was a neuro-on-whole-body cryopreservation, no post-cryopreservation CT scans were obtained. When the in-house scanner is functional and whole-body patients are being scanned, additional information will be added to this report.

