Alcor A-1033

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-1033 was a 91-year-old member with neuro cryopreservation arrangements. They were a long-term Alcor member and had been on the MRD Watch List for 19 months with chronic obstructive pulmonary disease (COPD). The cause of death shown on the death certificate was cardiopulmonary arrest subsequent to respiratory distress and chronic obstructive pulmonary disease.

Cardiac arrest was estimated to be at 06:33 hrs on T-0 days and the member was pronounced legally deceased in California at 06:35 hrs on T-0 days in September of 2023.

After stabilization and field washout, the patient was air transported to Alcor for cryoprotection. The patient arrived at Alcor on T+1 days. The cryogenic cooldown was initiated on T+1 days at 11:41 hrs and terminated on T+5 days at 04:44 hrs. The patient was transferred to long-term care at liquid nitrogen temperature on T+44 days at 14:35 hrs.

2. Member Assessment

This member had been on the Medical Response Director's (MRD) Watchlist for 19 months and was hospitalized approximately 4 months prior to cryoprotection for sudden worsening of chronic obstructive pulmonary disease (COPD). The member was sent to a skilled nursing facility from the hospital and was diagnosed with failure to thrive, which generally means weight loss, decreased appetite and poor nutrition, and inactivity, often accompanied by dehydration, depressive symptoms, impaired immune function, and low cholesterol.

T-22 days

The member was transferred back to the hospital for signs of aspiration pneumonia. The member's family did not notify the MRD of the hospital admission.

<u>T-14 days</u>

Alcor's MRD learned that the member had been admitted to the hospital on T-22 days, that a percutaneous endoscopic gastrostomy (PEG) feeding tube had been placed 6 days prior, and the member had recovered well from this. However, the pneumonia was worsening, and the member had an episode of respiratory decompensation on this date.

An Arterial Blood Gas test was done which resulted a blood oxygen (PaO2) of 44%, requiring an upgrade from hi-FLO (passive pressure high flow O2) to BiPAP (bi-ventilation with positive and negative pressure to assist with ventilation without invasive airways). Settings were minimal to maintain normal oxygen saturations. All other labs and findings were considered within normal limits. The member was reported to be alert and responsive. Twice daily the MRD spoke to the attending nurses for updates.



T-3 days

The MRD was unable to reach the nurse for the usual morning call around 06:00 hrs and was told the nurse would call back when available prior to shift change. The MRD attempted another call around 06:30 hrs with no success in speaking to the nurse. At 07:55 hrs the member's family called to inform the MRD that the member had again decompensated through the night and was transferred to ICU in the early morning where they were intubated.

3. Deployment

At 08:10 hrs, after consideration from the Alcor Deployment Committee, a Level-1 deployment was called. A withdrawal of care was planned for when the team arrived, and recovery and stabilization preparations were complete.

Sidebar:

The medical personnel on the Alcor Deployment Committee have established a list of medical indicators to assist in determining whether to call either a Level-1 standby, a high probability of death within seven days, or a Level-2 standby, a medium probability of death within seven days. The Deployment Committee voting members use these criteria when considering if a deployment is necessary.

Due to medical reasons, the MRD was not able to travel for this case. Suspended Animation (SA), one of Alcor's strategic partners for providing standby, stabilization and transport (SST) was consulted to assist onsite with this case with any logistical needs.

One of Alcor's Deployment and Recovery Team (DART) members and Alcor's Director of Development (DOD) departed by 12:15 hrs via Alcor's Mobile Recovery Vehicle (MRV) to the member's location. They arrived onsite at the member's location at 19:00 hrs.

4. Standby

Due to unfamiliarity with Alcor, the ICU nurse was not willing to give any information to the MRD over the phone initially. An update from the member's family confirmed the member was stabilized; however, the member required medication to keep the blood pressure from dropping, though the dose was unknown. The family was awaiting a call from the member's attending Critical Care physician for an update and prognosis.

At 16:55 hrs, SA secured a location for the procedure in the parking lot of a private funeral home, where the team could park the MRV and perform the surgical procedures in a safe, secure, and private location. At 18:23 hrs, the MRD received a call from the attending nurse, who was, with more information and permission from the member's family, now willing to give a proper medical update. Around 06:00 hrs that morning, the member had suffered respiratory failure, requiring a rapid response by hospital personnel to be called.

The member was transferred to the ICU, where they were intubated, and a bedside bronchoscopy was performed. Severe mucus plugs were found, removed, and sent to the lab for cultures. The nurse confirmed that the member required Levophed, a medication to keep the blood pressure from dropping. The member required 15mcg/minute at that time. The



member showed signs of septic shock and the sepsis protocol had been prescribed and administered. Another Arterial Blood Gas test was performed, which resulted in a blood oxygen level (PaO2) of 65%. The member's vital signs were: blood pressure (BP) 80/47, mean arterial pressure (MAP) 59, heart rate (HR) 64, respiration rate (RR) 16, temperature (T) afebrile, and capillary oxygen saturation SpO2 97%.

The MRD explained in depth the process of cryopreserving the member, our requests for onsite staging and procedures, and asked what the hospital would allow. The nurse informed the MRD that a meeting had been set with the hospital administration, the member's family, and Alcor's onsite team for the next morning.

T-2 days

The hospital would not allow all onsite staging and procedures requested by Alcor. This decision was made by the hospital's Chief Financial Officer (CFO), who was the on-call weekend administration representative. Another meeting was planned for the following morning with the appropriate hospital administrators. The member's family planned to change the member's code status from Full Code, where all resuscitation procedures would be employed to keep a patient alive, to Do Not Resuscitate (DNR) the following day. The vital signs were: BP 96/54, HR 60, RR 24, T 37°C, SpO2 not given.

T-1 days

The meeting with the administrator had gone well and they would indeed allow the procedures at the bedside with onsite staging. Due to the member's status, it was mentioned that they would be attempting a breathing trial and, if successful, the member would be extubated that afternoon with the hope of recovery of unassisted breathing.

At 17:36 hrs, the member's family had spoken to the member's primary care physician and had made the decision to move forward with a withdraw of care, a.k.a. transition to comfort care, with the expectation that extubating the member would lead the member to pass away naturally with no further interventions, aside from comfort measures.

At 18:23 hrs the health care team removed the member from Levophed and started a morphine drip. At 19:58 hrs the member was extubated. The vitals were: BP 110/59, HR 101, RR 2-3, SpO2 75%.

5. Patient Recovery and Stabilization

T-0 days

At 06:16 hrs, the vitals were: BP 45/28, HR 65, RR 2-3, SpO2 80%. Time of cardiac arrest was reported as 06:33 hrs. The patient was pronounced legally deceased at 06:35 hrs.

With several team members conducting the stabilization procedures, it only took about 10 minutes from pronouncement to hospital exit. The patient was placed in the portable ice bath PIB at 06:37 hrs which already contained 100 lbs. of ice. At 06:36 hrs the EZ-IO intraosseous device was placed in the tuberocity of the left leg. The first stabilization medication (see the



below Table of Medications Administered for the names of the medications, the dosages, and the times of administration) was administered.

The King airway was placed at 06:38 hrs and the SaVE ventilator was started at 06:39 hrs to provide oxygen to the lungs. The nasopharyngeal thermocouples were placed in the patient's nares at 06:39 hrs and plugged with swimmer wax to keep water from entering the nares and compromising the temperature readings. The ROS-Q mechanical chest compression device was placed on the patient and started at 06:39 hrs to restart vascular circulation. At 06:41 hrs the surface conduction cooling device (SCCD) with the face mask was initiated to improve external cooling.

The patient was removed from the hospital at 06:45 hrs and placed in the MRV at 06:47 hrs. The MRV was then moved to the parking lot of a local funeral home. While enroute, an additional 100 lbs. of water ice was added to the PIB. The patient arrived at the funeral home at 07:13 hrs, but the funeral home was no longer willing to have the procedure done on their premises. Another funeral home, 25 minutes away, was secured and the surgery and cryoprotectant perfusion were performed there.

6. Field Surgery and Cryoprotectant Perfusion (FCP)

At 07:28 hrs the chest compressions were stopped, and the first surgical incision was made on the right side of the neck to isolate the carotid artery. The right jugular vein was severed at 07:30 hrs, causing bleeding that resulted in loss of the visual field, however, this was quickly clamped, and the surgery proceeded.

At 07:40 hrs 25,000 IU of streptokinase, a thrombolytic used to break up existing blood clots, was added to the first cryoprotectant perfusion bladder. The right carotid artery was found to have branched lower than is normal, so the right carotid artery was cannulated with a 14 French (Fr) cannula below the clavicle bone at 07:45 hrs.

The gravity-induced perfusion flow was initiated at 07:46 hrs with Bladder #1 containing nM22 cryoprotectant with a molarity of 07.47 and a concentration of 0.05 concentration needed to vitrify (CNV) (see the Table of Concentrations (Brix) of nM22 Solution for the precalculated concentrations of each bladder). The left carotid artery was cannulated with a 16 FR cannula at 07:58 hrs and perfusion flow was immediately started in the left carotid artery as well.

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 39 inches which produced (39" x 2.054 mmHg per inch of height) a maximum arterial pressure of 80 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.



A single burr hole was drilled at 08:04 hrs and a thermocouple was placed to measure brain temperature. The cephalic isolation was started at 08:07 hrs and completed at 08:14 hrs.

The left vertebral artery was cannulated at 08:19 hrs with a 12 Fr cannula. The right vertebral artery was not found. A branch of the carotid was cannulated with a 12 Fr cannula using the secondary vertebral line.

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 5 & 6 represent the pause. The cephalic/patient enclosure and the chiller are switched from +3°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.

Ethylene glycol anti-freeze was added to the heat exchanger at 09:05 hrs to allow for perfusate temperatures of -3°C and the pause for patient equilibration was started with bladder #6.

Field cryoprotectant perfusion (FCP) was terminated at 10:56 hrs. The final refractive index (RI) reading was 51.2 Brix, and the molarity was 9.91.

7. Patient Transport

The patient was moved into the dry ice shipper at 10:57 hrs and covered with approximately 30 lbs. of dry ice. The patient was then driven to Alcor for cryogenic cooldown.

8. Cooling to Liquid Nitrogen Temperature

T+1 days

The patient arrived at Alcor at 11:28 hrs. The nasopharyngeal temperature was -80°C.

Computer-controlled cryogenic cooldown was initiated at 11:41 hrs on T+1 days, plunging to -110°C and descending thereafter at -1°C/hour to liquid nitrogen temperature. On T+5 days at 04:44 hrs, an uneventful cooldown was terminated. On T+44 days at 14:35 hrs, the patient was transferred to long-term care at liquid nitrogen temperature.



9. Timeline and Time Summaries

Timeline

T-0	06:33	Time of cardiac arrest			
T-0	06:35	Pronouncement of legal death			
T-0	06:36	Placement of IV and/or intraosseous device			
T-0	06:36	Administration of first medication (propofol)			
T-0	06:37	Start of ice bath cooling			
T-0	06:38	Placement King airway			
T-0	06:39	Start of chest compressions and ventilation			
T-0	06:42	Administration of final medication (antacid)			
T-0	06:45	Start transport of patient to funeral home			
T-0	07:13	Arrive at funeral home			
T-0	07:28	End cardiopulmonary support			
T-0	07:28	Start of field surgery			
T-0	07:46	Start of field cryoprotect and perfusion (FCP)			
T-0	08:04	Drilled burr hole and placed thermistor (end of surgery)			
T-0	08:07	Start of cephalic isolation			
T-0	08:14	Complete cephalic isolation			
T-0	09:05	Start 30-minute pause for equilibration (bladders #5 and #6)			
T-0	10:56	End of FCP (final RI = 51.2 Brix)			
T-0	10:57	Start of dry ice cooling			
T+1	11:28	Arrival of patient at Alcor (-80°C)			
T+1	11:41	Start of patient cryogenic cooldown			
T+5	04:44	End of cooldown			
T+44	14:35	Transfer of patient to long-term care at LN2 temperature			



Time Summaries

Event Duration				
hr:min		days	time	
111.111111		days	time	
00:02	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	06:35	Pronouncement of legal death
00:04	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	06:37	Start of ice bath cooling
00:06	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	06:39	Start of chest compressions and ventilation
00:03	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	06:36	Administration of first medication (propofol)
00:06	From:	T-0	06:36	Administration of first medication (propofol)
	Till:	T-0	06:42	Administration of final medication (antacid)
00:55	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	07:28	Start of field surgery
00:36	From:	T-0	07:28	Start of field surgery
	Till:	T-0	08:04	Drilled burr hole and placed thermistor (end of surgery)
01:13	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	07:46	Start of field cryoprotect and perfusion (FCP)
03:10	From:	T-0	07:46	Start of field cryoprotect and perfusion (FCP)
	Till:	T-0	10:56	End of FCP (final RI = 51.2 Brix)
04:23	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	10:56	End of FCP (final RI = 51.2 Brix)
00:36	From:	T-0	07:28	Start of field surgery
	Till:	T-0	08:04	Drilled burr hole and placed thermistor (end of surgery)
00:18	From:	T-0	07:28	Start of field surgery
	Till:	T-0	07:46	Start of field cryoprotect and perfusion (FCP)
03:28	From:	T-0	07:28	Start of field surgery
	Till:	T-0	10:56	End of FCP (final RI = 51.2 Brix)
00:01	From:	T-0	10:56	End of FCP (final RI = 51.2 Brix)
	Till:	T-0	10:57	Start of dry ice cooling
04:24	From:	T-0	06:33	Time of cardiac arrest
	Till:	T-0	10:57	Start of dry ice cooling
28:55	From:	T-0	06:33	Time of cardiac arrest
	Till:	T+1	11:28	Arrival of patient at Alcor (-80°C)
00:13	From:	T+1	11:28	Arrival of patient at Alcor (-80°C)
	Till:	T+1	11:41	Start of patient cryogenic cooldown



10. Table of Medications Administered

T-0 days

TIME	MEDICATION	DOSE	PURPOSE
06:36 hrs	Propofol	200 mg	Anesthetic; reduces cerebral metabolic demand; reduces the theoretic possibility of increased awareness during aggressive CPS.
06:37 hrs	Sodium citrate	10 g Note 1	Anticoagulant; prevents blood clot formation.
06:38 hrs	Heparin	50,000 IU	Anticoagulant; prevents blood clot formation.
06:38 hrs	Vasopressin (1st dose)	40 IU Note 2	Vasopressor; increases blood pressure during CPS.
06:368hrs	Minocycline	200 mg	Antibiotic and neuroprotectant
06:39 hrs	SMT (S-methyl-isothiourea)	400 mg Note 3	Neuroprotectant (iNOS inhibitor); protects the brain from ischemic injury; raises blood pressure.
06:39 hrs	Decaglycerol/THAM	200 ml Note 4	Decaglycerol inhibits cerebral edema.
06:42 hrs	Vasopressin (2nd dose)	40 IU Note 2	Vasopressor; increases blood pressure during CPS.
06:42 hrs	Vital Oxy (w/ saline)	32 mL Note 5	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
06:42 hrs	Antacid	250 ml Note 6	A buffer used to neutralize stomach acid.
07:40 hrs	Streptokinase	25,000 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. 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.
- 2. Vasopressin is a fixed dosage of 40 IU, per dose for two doses. The second 40 IU dose is to be administered concurrently with Vital-Oxy, I.V. Vasopressin is to be administered only if the patient's temperature is above 20°C as it is ineffective at cold temperatures.
- 3. SMT (S-methyl isothiourea) is a powder, (1 vial = 400 mg) dissolved in 10 mL of saline and injected through a $0.2~\mu$ filter. SMT is unstable in solution with a use 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 (pH = 10.4 and pKa = 8.3). It is a fixed dose of 200 ml.
- 5. The medications protocol dilutes 70 mL or less, based on body weight, of Vital-Oxy into 150 mL of saline for a total of 220 cc of diluted Vital-Oxy saline. 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. An antacid can be given in several doses, totaling 250 mL, and inserted through the nasogastric tube in an airway.

7. The standard administration of streptokinase is 250,000 IU fixed dose, dissolved in 5 mL of 9% sodium chloride, to be added to the blood washout solution prior to remote blood washout, or to the first cryoprotection flush in the OR. The dosage is reduced to 25,000 IU in field neuro (FCP) cases and added to the first bladder). 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.

11. Table of Concentrations (Brix) of nM22 Solution

Preferred endpoint is over 49.9 Brix from both jugulars for 1/2hr										
		Molarity of		Bag start	hrs post	Bag avg.		Effluent		
2L Bag label	[nM22],	penetrating		hh:mm,	pronounc-	flow rate,	Sample time	Conc.,		
number	CNV	CPAs*	Brix (calc)	MST	ement	mL/min	hh:mm, MST	Brix		
1†	0.05	0.47	11.81	7:46	1.22	105.3				
2	0.08	0.78	13.14	8:05	1.53	133.3				
3	0.14	1.29	15.35	8:20	1.78	133.3				
4	0.23	2.15	19.03	8:35	2.03	125.0				
5†	0.50	4.67	29.85	8:51	2.30	142.9				
6	0.50	4.67	29.85	9:05	2.53	133.3				
7	1.06	9.91	52.306	9:20	2.78	133.3				
8	1.06	9.91	52.306	9:35	3.03	133.3				
9	1.06	9.91	52.306	9:50	3.28	133.3				
10	1.06	9.91	52.306	10:05	3.53	133.3				
11	1.06	9.91	52.306	10:20	3.78	133.3				
12	1.06	9.91	52.306	10:35	4.03	133.3				
13	1.06	9.91	52.306	10:50	4.28	333.3	10:21	49.9		
END†				10:56	4.38		10:56	51.2		
does not ac										

The surgery and field cryoprotection (FCP) were performed in the mobile recovery vehicle (MRV). Because of this, a minute-by-minute log was not made, so the timeline of the FCP was reconstructed from multiple data sources including video, instant messages, and manual recordings. Times that are known precisely are indicated were available.

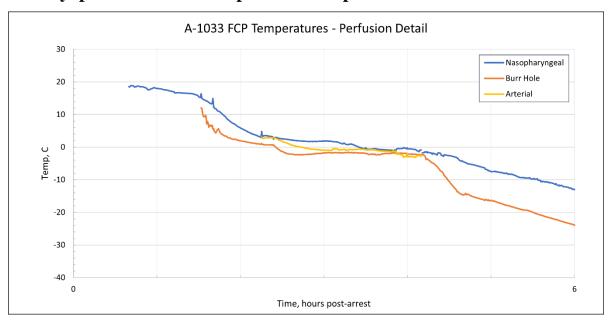


12. Discussion

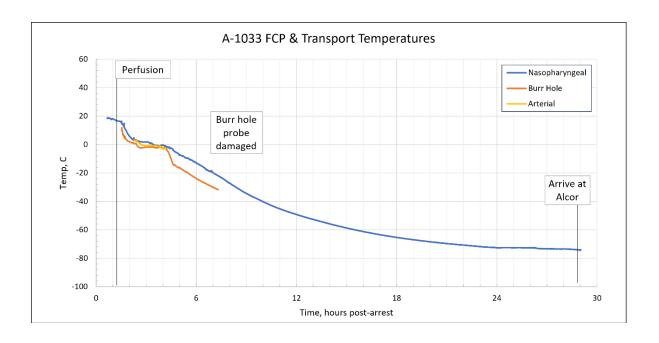
The SAVe ventilator was not functioning off battery. The SA team member had a battery pack and cord, so it was able to be plugged in and ran off this battery.

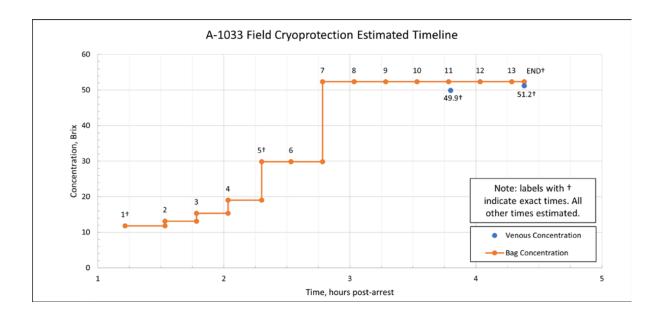
The staff at the funeral home, where surgery and cryoprotection was initially planned to be performed, did not understand that Alcor's mobile recovery vehicle (MRV) would be parked in their parking lot and used to perform those procedures. When the MRV arrived, they were told that they could not park there and do the procedures. Another funeral home, 25 minutes away, was secured and the procedures took place at the second location. This points out the importance of good communications and verification that all parties are clear about Alcor's needs.

13. Cryoprotection and Temperature Graphs

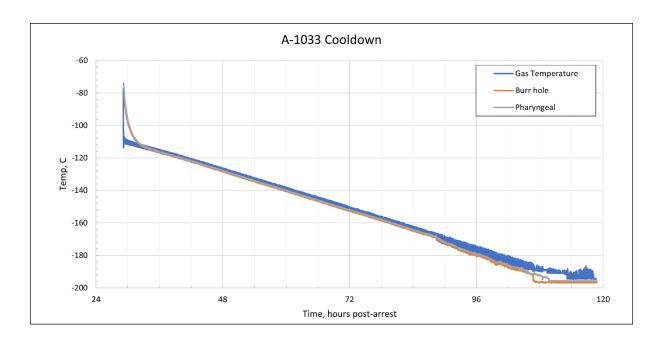


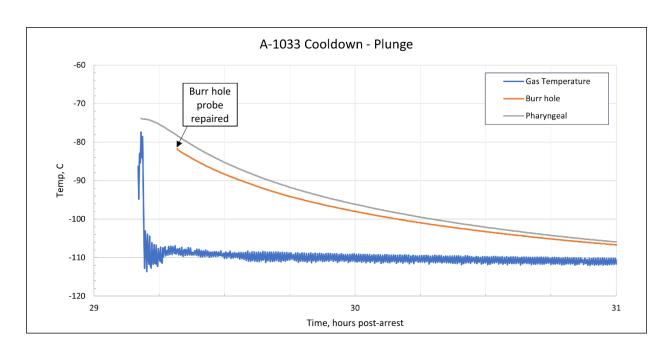














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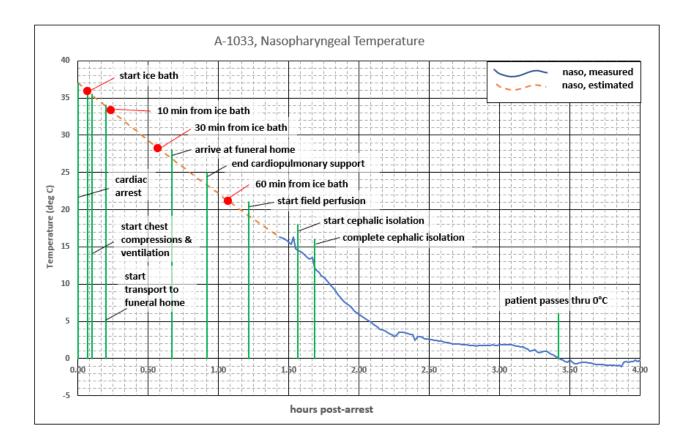
14. S-MIX

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 0°C is 03:25. As shown below, and due to lowering of the body temperature, S-MIX duration is shorter, at 00:44.

		-						
	seg-	days	time (MST)	post-	Tnaso	CPS w/	washout	S-MIX
event	ment#	(T+X)	duration	arrest	(deg C)	ventil.	oxygen.	(hh:mm)
Time of cardiac arrest		T-0	06:33	00:00	37.0			
	seg 1		00:04	00:04	-1.1	no	no	00:04
Start of ice bath & place King airway		T-0	06:37	00:04	35.9			
	seg 2		00:02	00:02	-0.5	no	no	00:02
Start of chest compressions and ventilation		T-0	06:39	00:06	35.4			
	seg 3		00:06	00:06	-1.6	yes	no	00:03
Start transport of patient to funeral home		T-0	06:45	00:12	33.9			
	seg 4		00:28	00:28	-7.0	yes	no	00:09
Arrive at funeral home		T-0	07:13	00:40	26.9			
	seg 5		00:15	00:15	-3.6	yes	no	00:03
End cardiopulmonary support		T-0	07:28	00:55	23.3			
	seg 6		00:18	00:18	-4.1	no	no	00:06
Start of field cryoprotect and perfusion (FCP)		T-0	07:46	01:13	19.2			
	seg 7		00:21	00:21	-4.7	no	no	00:05
Start of cephalic isolation		T-0	08:07	01:34	14.5			
	seg 8		00:07	00:07	-2.4	no	no	00:01
Complete cephalic isolation		T-0	08:14	01:41	12.2			
	seg 9		01:44	01:44	-12.1	no	no	00:10
Patient passes thru 0°C		T-0	09:58	03:25	0.1			
totale			03:25	03:25	-36.9			00:44
	seg 9		08:14 01:44	01:41 01:44	12.2 -12.1			



The below plot shows 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.

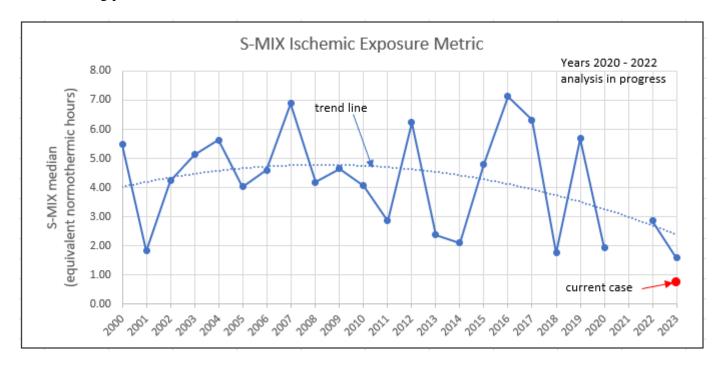


The below table provides cooling data for 10, 30, and 60 minutes after the team first applies water ice.

Patient Coolin	(patient weight 45.2 kg; 99.6 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)	35.9	33.3	28.3	21.2
Temperature drop (°C) from t = 0	0.0	-2.6	-7.6	-14.7
Cooling rate (°C/min) from t = 0	N/A	-0.26	-0.25	-0.25



The following plot shows the trend of S-MIX achieved since 2020.



15. CT Scans

Cryoprotectant Distribution (Post-cryopreservation CT scan)

When the in-house scanner is functional and patients are again being scanned, additional information will be added to this report.

