Alcor A-2605

Case Report

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October 2013

Alcor A-2605 Case Report Contents:

1. Overview

On March 6, 2013, following pronouncement, we cryopreserved a 91-year old member who wished to keep his name confidential. Referred to by his Alcor ID, A-2605, he chose our neuropreservation option and became Alcor's 116th patient.

Earlier in February, Alcor received a call from the son of one of our members. His father had initially been admitted to a hospital in Chapel Hill, NC for an infection, but his condition worsened to the point that doctors gave him a "failure to thrive" diagnosis". In absence of low quality-of-life interventions, the doctors soon suggested to the family that they move him to a hospice facility for his remaining time.

Expecting that the father possibly had a week or two remaining to live, the son, who was very supportive of his father's wishes, and other family members decided to relocate our member to Scottsdale to enter into hospice. A few days later he was flown by chartered medical jet to Scottsdale.

Our member arrived on Tuesday, February 26, early in the evening and was taken to a hospital in Paradise Valley, AZ, about 7 miles from Alcor. Our equipment and the emergency vehicle were stationed at the hospital, and by the following day, someone was on site at all times during the nine-day standby.

After some ups and downs in the patient's condition, on the morning of Wednesday, March 6, the patient stopped breathing and was officially pronounced at 8:45 am. Five team members participated during the stabilization and transported him to Alcor's operating room, arriving at 9:46 am. Cryoprotective perfusion was concluded at 2:48 pm that afternoon.

2. Personnel

Aaron Drake, Medical Response Director, led response team members Sandra Russell, Joan O'Farrell, LeAnn Cusick and Richard Cremeens during the standby, stabilization and cooldown components of the case. They were supported by Max More, CEO; and Steve Harris, M.D., Chief Medical Advisor.

Personnel at Alcor's surgery suite included José Kanshepolsky, MD, Surgeon; Aaron Drake, NREMT-P, Surgical Assistant; Hugh Hixon, Cryoprotection Perfusionist; Steve Graber, Assistant Cryoprotection Perfusionist; Max More, Ph.D., Scribe; Bonnie Magee, Refractometry; R. Michael Perry, Ph.D., Cooldown Coordinator. Surgical support staff: Sandra Russell, Joan O'Farrell, LeAnn Cusick, Lisa Shock and Jerry Searcy.

3. Pre-Deployment

On February 22, 2013, Alcor received a call late in the afternoon from a member's son, who said that his father was in a hospital in Chapel Hill, NC.

His father had apparently been admitted for a urinary tract infection however a previous problem of normal pressure hydrocephalus became the area of medical focus. Although a shunt had been surgically placed to relieve fluid buildup in his brain, the patient's health continued to deteriorate as indicated by a failed swallow test. Although he remained conscious, he could no longer communicate.

The physician told the family the next procedures would be to insert a feeding tube and place him on a ventilator – however he advised against both as it would lead to a poor quality of life. With a diagnosis of "failure to thrive", the hospital suggested the family move the patient to a hospice facility for his remaining time. This revelation was a surprise to the family as they had no idea he was that sick.

The son was very supportive of his father's cryonics directives, and while not currently a member, he was planning on signing up with Alcor in the future. A family friend who was a nurse predicted that the father maybe had a week or two remaining to live. Given this window of opportunity and level of support, the family decided to relocate to the Scottsdale area so they could enter into a hospice program close to Alcor.

They discussed their plans with Aaron Drake, Alcor's Medical Response Director, to determine how best to transport a wheelchair-bound patient to Scottsdale, who had little strength. The options included a ground ambulance, renting a recreational vehicle or transporting in an air ambulance. The decision would be impacted by when the patient was discharged and his condition at that time. One concern was the standby might have to be performed in Chapel Hill at their home, if they waited too long to depart. Just in case, Alcor alerted Suspended Animation of the situation and said we would deploy them if the family was unable to leave for Scottsdale.

By the next day, Saturday, the hospital had already made plans to discharge the patient to hospice-at-home. The patient's doctors did not believe that he would survive a cross-country drive and that air travel might be his only viable option. This news made the family indecisive about how best to travel to Scottsdale. At first, they intended to drive because the air ambulance price was quite costly but they eventually acknowledged the risks concerning the risks of an across-the-country drive and decided to fly.

Aaron made all the arrangements with Angel Med Flight to fly the family out on Tuesday when unexpectedly, the family changed their mind again, deciding to drive. The air transport plans

were put on hold, given the uncertainty of the situation. Uncertainty gave way to necessity, as at 5 am on Tuesday morning, they urgently called Aaron and said that the patient now appeared extremely bad and flying seemed to be the only remaining option. The family hoped they could keep the originally scheduled flight but Aaron explained that it required a lot of planning to schedule a flight, along with medical crews and pilots, and they would be fortunate just to maintain a Tuesday departure, given the last minute changes. Fortunately, the schedule was not full and they were able to secure the last flight of the day on Tuesday.

The flight, along with the medical crew and patient, departed their location at 12:30 PM (EST) on February 26th, 2013 and arrived the same afternoon at 1:15 pm (MST). There was a fair amount of concern during the flight that the patient might lapse into cardiac arrest from hypotension, so an IV was established and fluids were administered to maintain a stable blood pressure, per their protocols. Upon arrival, an awaiting ambulance drove the patient to a hospital in Paradise Valley that accepts hospice patients on their medical floors.

4. Deployment

Aaron met the family and the patient when they arrived at the hospital. The hospice intake coordinator took a report from the flight medics and completed the admittance process. After performing an assessment of the patient and evaluating the report from the flight crew, the hospice nurse was quite concerned about the condition of the patient. Given the stress of the cross country flight, the fatigue level of the patient was much greater than expected and although they did not anticipate the patient would pass in the next day or two, the coordinator said he would have difficulty in determining how long the patient might have to live until he settled down from the experience.

Aaron reviewed Alcor's protocols with the hospice coordinator, nursing supervisor and attending physician. They discussed possible scenarios that might develop and one specific area of concern regarding continuous monitoring. As the family was exhausted and planning to retire to a local hotel for rest, there would be no one to monitor the patient. Occasional checks would be performed by floor nurses but this allowed for lapses that could prove problematic. To bridge these gaps, the attending physician authorized the patient to be assigned as a telemetry patient, meaning his cardiac activity would be monitored by specialized staff, 24/7. Alarms would alert telemetry staff if there were any unusual cardiac rhythm activity, giving all of the medical staff advance warning of impending difficulty. While this floor was not set up for telemetry, extra provisions would be made to incorporate this patient into their monitoring system.

Arrangements were also made to secure an unoccupied room adjacent to the patient for Alcor to store their pre-positioned equipment and a place for standby team members to stay, while still

giving the family private time to spend with their loved one. This would later prove to be invaluable given the duration of the standby. Finally, permission was granted to park the Alcor rescue vehicle (RV) directly outside of the hospital's Emergency Department. This would allow the quickest and most direct access to the patient's room while steering clear of the publicly used areas such as lobbies, waiting areas and common elevators.

Once all of these arrangements were made, Aaron spoke with Max and Alcor's Deployment Committee and provided an update on the situation. The group decided that Aaron should stay overnight as a precaution and to re-evaluate the patient's condition the next day to determine when a standby should be initiated. In the meantime, Aaron relocated the rescue vehicle from Alcor to the designated spot at the hospital later that evening and assembled and positioned the equipment to the room adjacent to the patient.

The following morning brought a variety of medical evaluations and an opportunity to establish a baseline of the patient's condition. Through discussions with the deployment committee, it was decided that Alcor should initiate a standby and keep response team members onsite throughout the duration. Aaron and team member, Richard Cremeens, set up at the hospital while Sandra Russell and Joan O'Farrell, both from Critical Care Research in Rancho Cucamonga, CA, drove to Scottsdale to be ready to assist Thursday morning.

These four people created two teams, which started a 12 hour rotation between night and day to staff the standby. A fifth individual from the Terasem Cryonics Response Team in Melbourne, FL, LeAnn Cusick, RN, was also asked to fly out and participate. LeAnn arrived on Friday afternoon and started in on the rotation as well.

The days that followed brought a very slow and controlled decline in the patient's health. He remained mostly unconscious but showed occasional signs of some level of awareness when family was present. Although he was not being given any water, the IV fluids that were administered during the transport were probably sustaining him for a while, given his slow metabolic state. The teams continued to rotate every 12 hours so two people were always awake and on scene at the hospital, while others rested at the nearest available hotel.

On the eighth day of the standby, Tuesday, March 5th, there were some significant changes throughout the day in the patient's condition. His breathing had become very shallow as the hospice doctor had increased the dosages of morphine to ensure he remained comfortable. His skin was now tenting, indicating serious dehydration was setting in. Discolored and mottled skin began to spread throughout his legs and feet as blood circulation slowed. His urine output had almost stopped and was very dark in color. His blood pressure was low but not at a critical level. Oxygen saturation readings were normal, but misleading, as he was receiving humidified O2 via

cannula for comfort. These signs and symptoms, coupled with occasional apneic periods in his breathing, suggested that clinical death should occur sometime in the next 12 hours.

5. Field Stabilization, Cooling & Transportation

On March 6th, 2013, the ninth day of the standby, the patient's breathing changed from regular to very erratic a little after 8:15 in the morning. Aaron spoke with Sandra to see if they could immediately depart the hotel and join him and Richard at the hospital, as he anticipated the patient would not survive long. The portable ice bath (PIB) was brought into the patient's room and placed alongside the patient's bed. Aaron began preparing the stabilization medications while Richard placed a base layer of ice down in the PIB. At 8:45 AM, the patient coded and was immediately pronounced by the attending physician who was on the medical floor.

The patient was rolled on to his side while a Mega Mover blanket was placed under him. A rectal occlusion device was inserted to prevent fecal contamination of the ice water. From there, he was moved from the hospital bed to the PIB. The LUCAS 2 automatic chest compression device was placed over the patient's chest and started to restore blood circulation by compressing the heart within the rib cage.

Aaron used a Bone Injection Gun to insert a 16 gauge trocar needle into the patient's right tibial plateau to gain intraosseous (I/O) access for medication administration. Once obtained, a 3-way stopcock with an extension set was secured to the metal catheter and a 10cc flush of saline confirmed patency. Meanwhile, Richard covered the patient's body with additional ice to increase the cooling process.

Joan, Sandra and LeAnn arrived at 8:48 AM, three minutes after pronouncement. They handed the first of the low-volume medications to Aaron who bolused them through the I/O port. Sandra and LeAnn continued to push the additional medications through the same port. Using a Miller endotracheal blade, Aaron visually inserted a #4 King Airway tube into the patient's esophagus to establish an advanced airway which was then secured with a Thomas tube holder. An impedance threshold device, called a Res-Q-Pod, was placed between the tip of the tube and an Ambu bag valve mask, which roughly doubles the blood flow through the heart and increases the blood flow to the brain by 50%, during ventilations.

Another Bone Injection Gun was used to establish a second intraosseous access point in the left tibial plateau to allow both vasopressor medications to be administered via a Baxa Dual-Rate infusion pump with microbore extension tubing. This was hung on an IV pole that was mounted on the side of the PIB. An initial bolus of the medications was given manually to initiate efficacy prior to continuing with the automated medication drip.

LeAnn placed two thermocouples into the patient's nasopharynx and secured them using a surgical stapler. These were connected to a DuaLogR to begin recording the temperature descent of the patient. The DuaLogR was placed within a water resistant mini-Pelican case and hung on the IV pole.

As the medium volume medications were being administered, the surface convection cooling device (SCCD) was placed over the ice in the PIB. A large volume of water was added to the ice and the SCCD was activated to begin circulating the ice water, to increase the cooling rate of the patient.

Aaron directed Richard to go downstairs to the parking lot where the Alcor rescue vehicle was positioned just outside the emergency entrance to start the engine, turn on the air conditioning to high and prepare the back area for loading. The patient was then covered with a privacy drape and the team left the room with the PIB in tow.

Using the non-public service elevator, the PIB was rolled through the hallways and out onto the parking lot where the RV awaited. The lift gate was lowered and the PIB was loaded and raised up into the back of the vehicle. The PIB was locked into the anchor positioned in the center of the vehicle and the team closed up the back prior to departing. Within 30 minutes of pronouncement, the patient was heading towards Alcor.

The LUCAS 2 was converted from DC power to AC power to conserve battery life. Five gallons of water was added to the ice bath to support the SCCD water recirculation. This device was placed over the patient to continuously bathe the body with ice-cold water to achieve faster cooler using convective cooling, in addition to the normal conductive cooling from simple ice contact.

The drive took 23 minutes which allowed time for the large-volume medications to be bolused through 60cc syringes. The drive was purposely slow due to the large volume of ice and water within the PIB. Starts, stops and turns can cause the ice water to crest the sides of the PIB and pour out onto the floor of the vehicle. The safety of the personnel in back of the vehicle is also a consideration.

Somewhere while en route, the thermocouples became dislodged from the patient's nasopharynx, possibly giving inaccurate cooling temperatures. The excessive movement of the patient in the PIB during transportation is probably the cause of the dislodging. These were re-secured upon arrival. We also discovered upon arrival that the SCCD battery had failed.

6. Surgery

The Alcor surgical team was ready and waiting when the rescue vehicle pulled up to the rear doors of Alcor at 9:41 am. The LUCAS 2 was switched back from AC to DC to allow chest compressions to continue while the portable ice bath was moved to the operating theatre. The rear of the rescue vehicle was opened; the ice bath was unlocked from its brace and loaded onto the lift gate, which then lowered to the asphalt.

Our normal protocol suggests that we delay the start of surgery until the nasopharynx thermocouple reads 20º C or below, given there are no extenuating circumstances. To accomplish this, the patient remains in the portable ice bath with the LUCAS 2 continuing to circulate blood until we reach our benchmark temperature, when the patient is then moved to the surgical table. This time, it was decided to attempt to establish burr holes and gain vascular access while the patient remained in the ice bath while chest compressions continued. Dr. José Kanshepolsky was skeptical that he could isolate the carotid arteries while the patient was being jostled about, but was willing to attempt the procedure.

The head was shaved by Aaron prior to aseptically prepping the region to be incised. Dr. Kanshepolsky made two vertical incisions with a #10 scalpel to expose the skull. The scalp was parted with Weitlaners and bilateral burr holes were drilled, at 10:04 AM, using a Codman craniotome perforator. The exposed dura mater of the brain was cut through using the #10 scalpel and the remainder was cleaned up with a Sperling-Kerrison rongeur. A thermocouple probe was inserted into the right burr hole and secured to the scalp with 2-0 Silk. A crackphone element was inserted into each of the burr holes and also secured with 2-0 Silk.

During this time, Steve Graber, Alcor's Readiness and Technical Coordinator, had replaced the SCCD battery that had failed with a temporary battery; however this too failed about 10 minutes later.

The patient's face and chest were then draped, leaving only the neck exposed for the surgery. Aaron aseptically prepped the exposed region. Dr. Kanshepolsky then proceeded to make a skin incision with a #10 scalpel blade along the anterior border of the left sternomastoid and divided the loose areolar tissue through dissection using Metzenbaum scissors and DeBakey forceps. Aaron held the surgical field open with two Army-Navy retractors. Once the left common carotid artery was identified and isolated with a right angle Kantrowitz Mixter forcep, a silk tourniquet and a DeBakey bulldog clamp were used to ligate and maintain vascular control. The same procedure was repeated for the right common carotid artery.

Once both of the arteries were isolated, the LUCAS 2 was turned off and CPS was stopped at 10:48 AM. Both the carotid arteries and jugular veins were then severed distal to the clamps

using a #11 scalpel blade. Due to the previously surgically inserted shunt in the patient's right jugular vein, no drainage was expected from the right side.

Using scalpels, the remaining tissue around the neck was severed, leaving only the spinal column intact. At 11:09 AM, the cephalon was separated using an osteotome and mallet, taking 9 minutes. At 11:20 AM, the cephalon was moved from the PIB to the neuro box and mounted in the cephalon ring.

Both carotid arteries were cannulated with 18 Fr. red robinson catheters and secured in place with a surgical basket stitch. After an initial flow of perfusate, the vertebral arteries were identified with mouse tooth forceps and secured with Diethrich micro bulldog clamps. The ramp was started at 11:25 AM and perfusion began.

7. Perfusion

The cryoprotection process ended when the effluent refractive index from the left jugular was over 50.35 Brix for at least 30 minutes. The right hemisphere of the brain was substantially retracted but it was difficult to determine retraction on the left side. The amount of cryoprotection fluid used was only about 5 liters of M22x1.25; substantially less than normal.

The patient had been hydrocephalic and had a ventricular shunt installed in the right jugular. As a result, the right carotid was considerably reduced in size and there was no venous return from the right jugular. Conversely, the left carotid was substantially enlarged to accommodate the impairment of the right carotid, and the regular 18Fr cannula used was a bit undersized in consequence.

The burr holes, cannulation, and separation were all carried out in the transport ice bath, and washout begun in the ice bath using a flying line with return circulation, after which the cephalon was moved to the cooldown box.

It was noted that forty-five crackphone events were observed, several on both channels, and beginning at ~-130 ºC. No analysis has been attempted at the time of this report.

8. Timelines

March 6, 2013, 8:45 AM, MST

Stabilization

8:45 Patient pronounced
Permission to begin procedures given
8:46 Patient rolled on to Mega Mover

Rectal Occlusion Device inserted
Patient moved to PIB
8:47 Chest compressions started using LUCAS 2
Patient covered with additional ice
8:48 1st intraosseous access site established
Remainder of team arrives to patient room
8:50 100,000 U Heparin administered
80mg Gentamicin administered
90ml THAM administered
8:52 Advanced airway secured
8:53 2nd intraosseous access site established
8:56 300mg Acetylsalicylic Acid in 10ml THAM administered
8:57 Bolus of 1mg Epinephrine and 20 IU Vasopressin administered
Baxa infusion pump started with 29mg Epinephrine and 180 IU Vasopressin
9:00 250,000 U Streptokinase administered
9:01 SCCD placed around patient
9:02 Water recirculation started
Patient covered with additional ice
9:04 200mg Propofol administered
500cc Hetastarch administered
9:06 400mg SMT (S-methyl-isothiourea) in 25ml Sodium Citrate administered
9:10 Patient covered with privacy drape
Departed room for elevator
9:13 Patient and team in elevator
15mg Ketorolac administered
9:16 Loaded patient in to Alcor rescue vehicle
9:18 Departed for Alcor Central
9:21 2.0g Ni-Ky in 25ml Sodium Citrate administered
9:23 400cc Vital Oxy administered
9:24 Patient covered with additional ice
9:26 250ml Maalox administered
9:29 Tip of microbore tubing broke off syringe
Epinephrine and Vasopressin administered manually
9:31 250cc Maalox administered through King airway
500cc Mannitol administered
9:35 Continued administration of large volume medications
9:41 Arrived at Alcor facility

Surgical

09:46 Moved to operating theatre
10:03 Repositioned patient to start burr holes causing an incorrect 8 ºC temperature reading
10:04 Started burr holes
10:10 Temp 15.8 ºC
10:19 17.4 ºC

10:20 Fixed the SQQD with temporary battery
10:22 17.6 ºC
10:28 Failure on thermocouple on center line of arterial line; replaced
10:30 18.3 ºC
10:32 Battery failure again on SCCD
10:33 19.1 ºC
10:34 22.1 ºC
10:35 22.4/19.9 ºC
10:36 Stopped CPS to reposition; started again in seconds
10:38 17.8/20.0 ºC
10:39 18.1 ºC; one of two nasopharyngeal temp probes came out indicating probable incorrect temperature on one
10:40 19.9 ºC; cardiopulmonary support (CPS) ongoing using LUCAS 2
10:45 Dr. Kanshepolsky began the surgical procedure while CPS continued in the ice bath
10:47 Dr. Kanshepolsky noted that the exposed carotid was an unusual color
10:48 Carotids isolated; removed LUCAS 2 for cannulation
10:51 22.6/20.2 ºC; when CPS stopped, the B1 started freezing in the heat exchanger. The heat exchanger was warmed up to clear the ice blockage
10:57 Pump restarted using new chiller
11:00 22.3/20.5 ºC
11:05 20.7/20.0 ºC
11:03 No jugular access on right due to shunt explaining no drainage from that side
11:04 Began washout
11:05 Initiating pump; bringing speed up
11:07 Initiating ramp; 18.9/19.5 ºC
11:09 18.0/19.3 ºC
11:10 Burr hole: 16.6 ºC
11:12 Burr hole: 15.9 ºC
11:15 Burr hole: 14.6 ºC; nasopharyngeal: 16.5/18.2 ºC
11:17 Burr hole: 13.4 ºC; nasopharyngeal: 15.4/18.1 ºC
11:18 Cephalon isolated; burr hole: 12.2 ºC; nasopharyngeal: 12.9/17.2 ºC
11:20 Transfer cephalon to perfusion box; burr hole: 11.1 ºC; nasopharyngeal: 15.6/15.6 ºC
11:22 Burr hole: 9.0 ºC
11:25 Burr hole: 9.0 ºC; ramp started; pressure is good: 135, pump speed: 24
11:32 Burr hole: 6.6 ºC; nasopharyngeal: 4.8 ºC
11:34 Burr hole: 5.9 ºC; nasopharyngeal: 4.0 ºC
11:37 Burr hole: 4.6 ºC; nasopharyngeal: 3.2 ºC
10:38 Started box temp control
11:48 Burr hole: 2.7 ºC; nasopharyngeal: 1.4 ºC
12:38 Ramp paused at 30 Brix, drop temperature to -3 ºC
12:55 Resumed ramp
14:48 End cryoprotection
15:21 Began cooldown
16:30 End cryoprotection of A-2605 and moved to cooldown; cleanup commenced.

On April 26th 2013, A-2605 was placed in a neurocontainer for permanent storage.

9. Issues and Actions

Issue: The SQQD had low battery problems.

Action: Additional car-starting battery packs have been purchased.

Issue: The craniotome motor seized up and a battery-powered electric drill was substituted. This solution was not very satisfactory as it didn't seem to have the needed power.

Action: The craniotome was later coaxed back in to operation and has been used subsequently without a problem. A stronger battery powered electric drill was purchased as backup.

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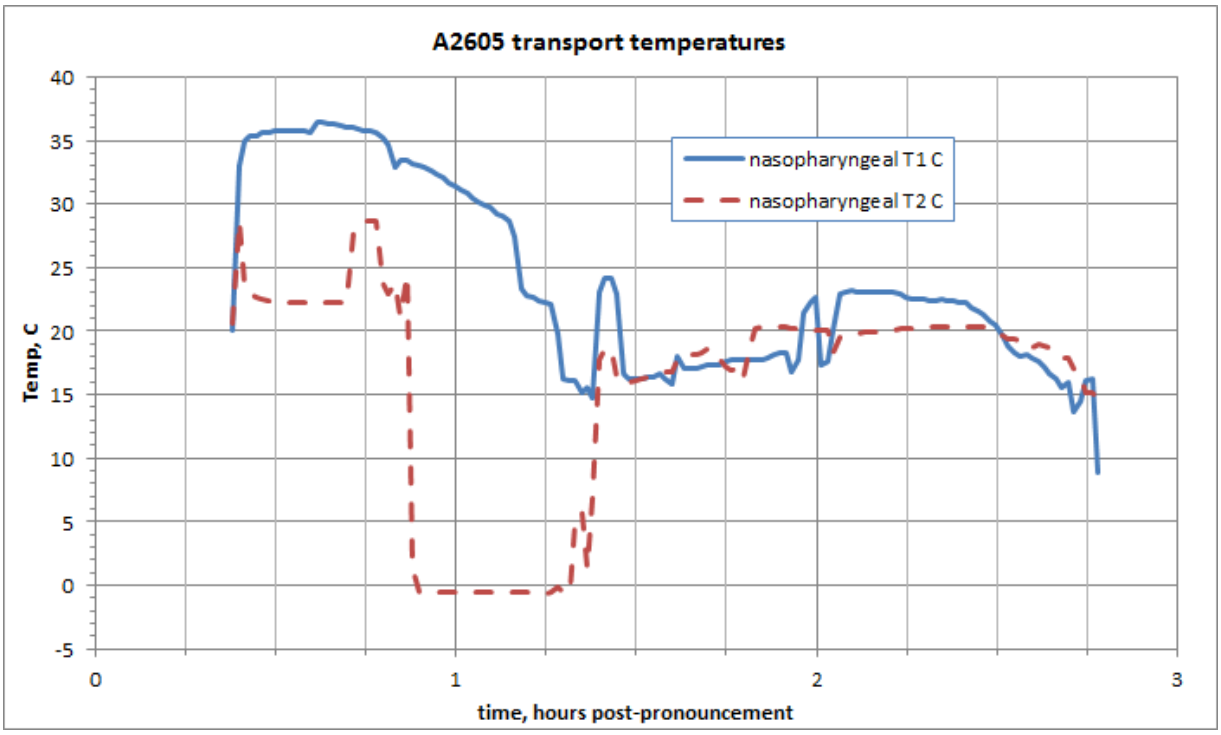
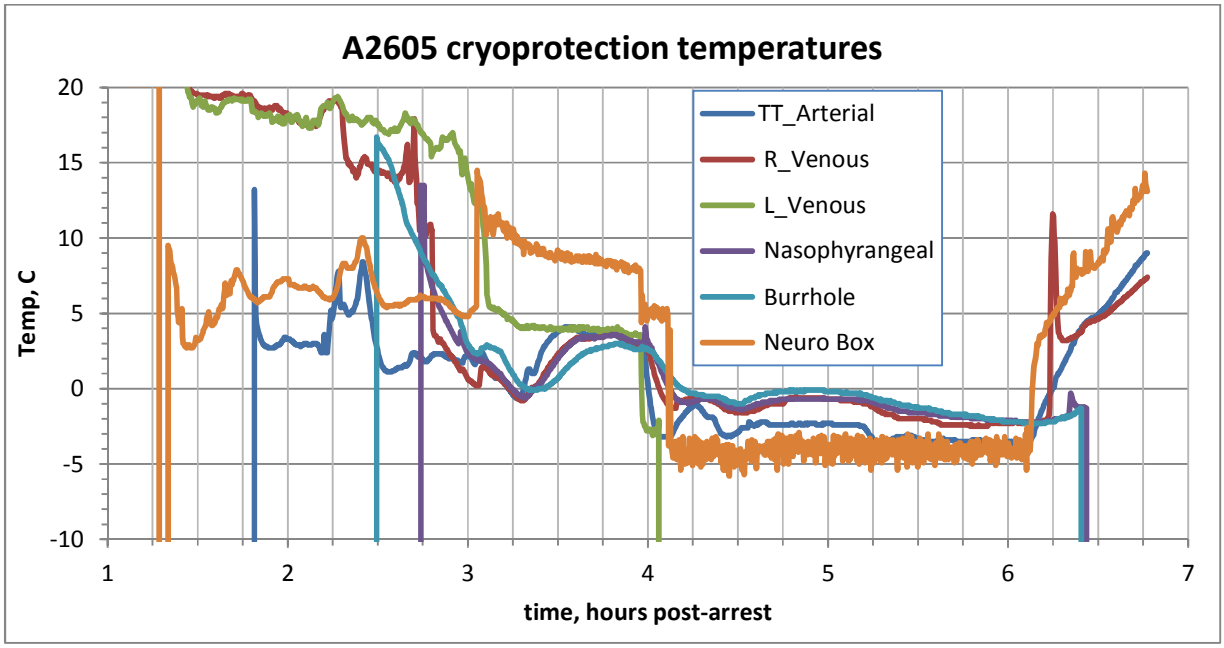
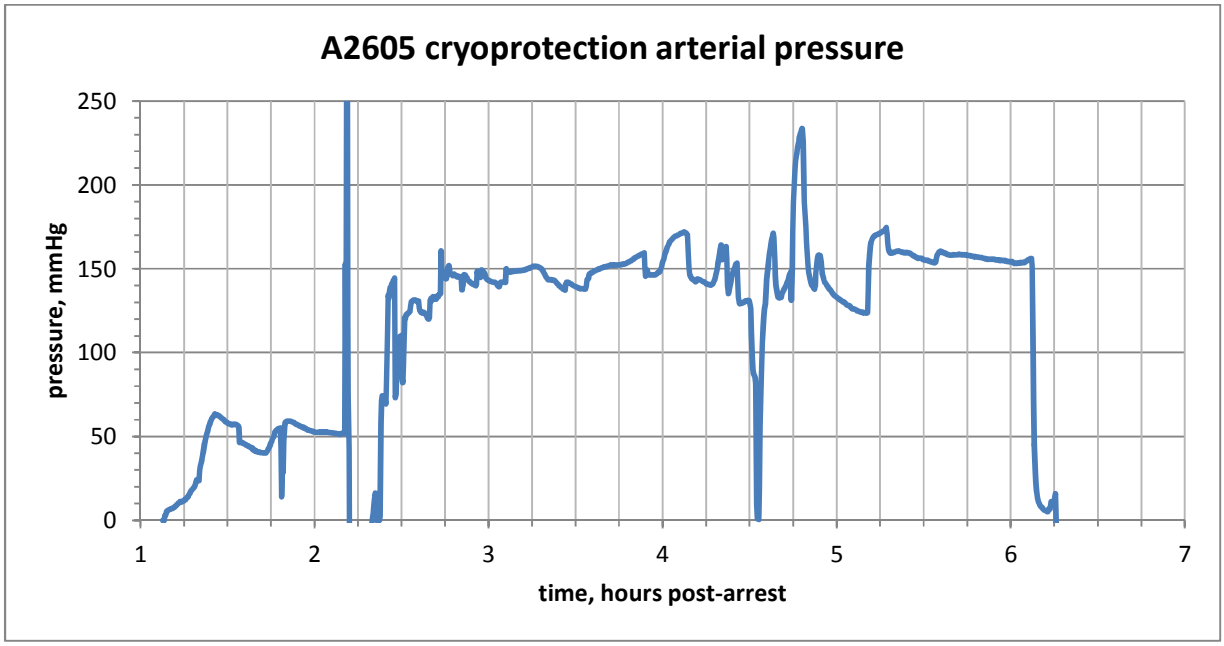
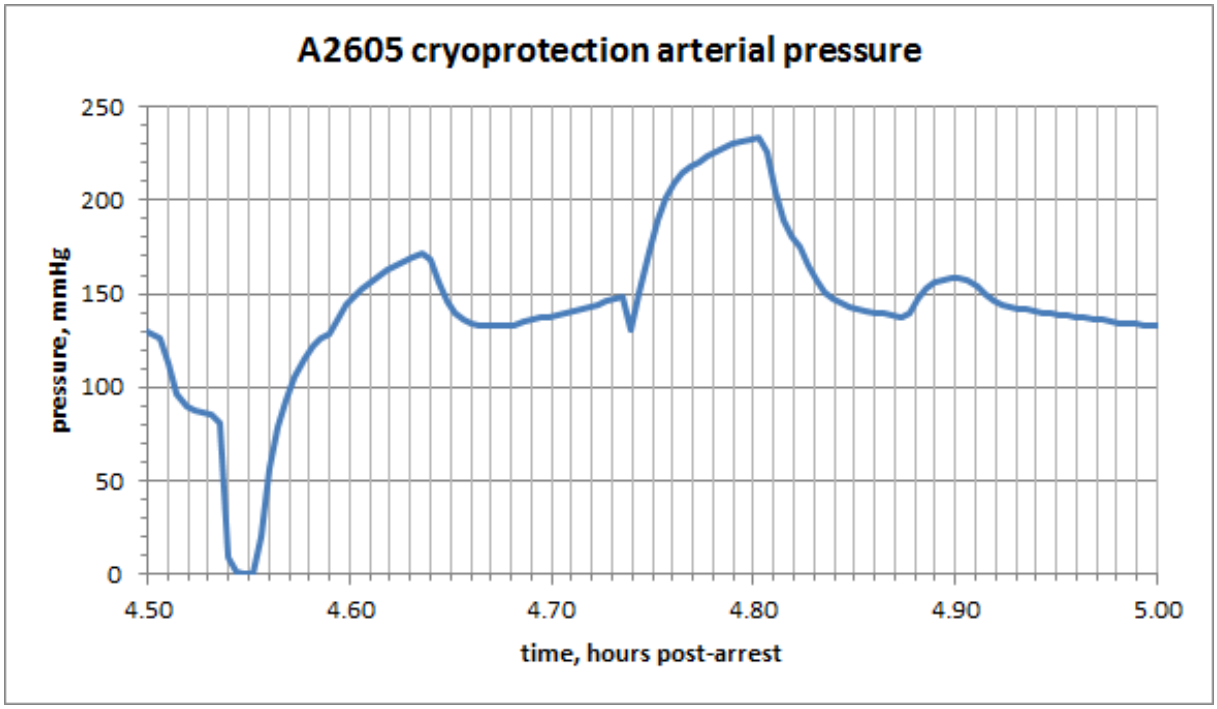
10. Graphs





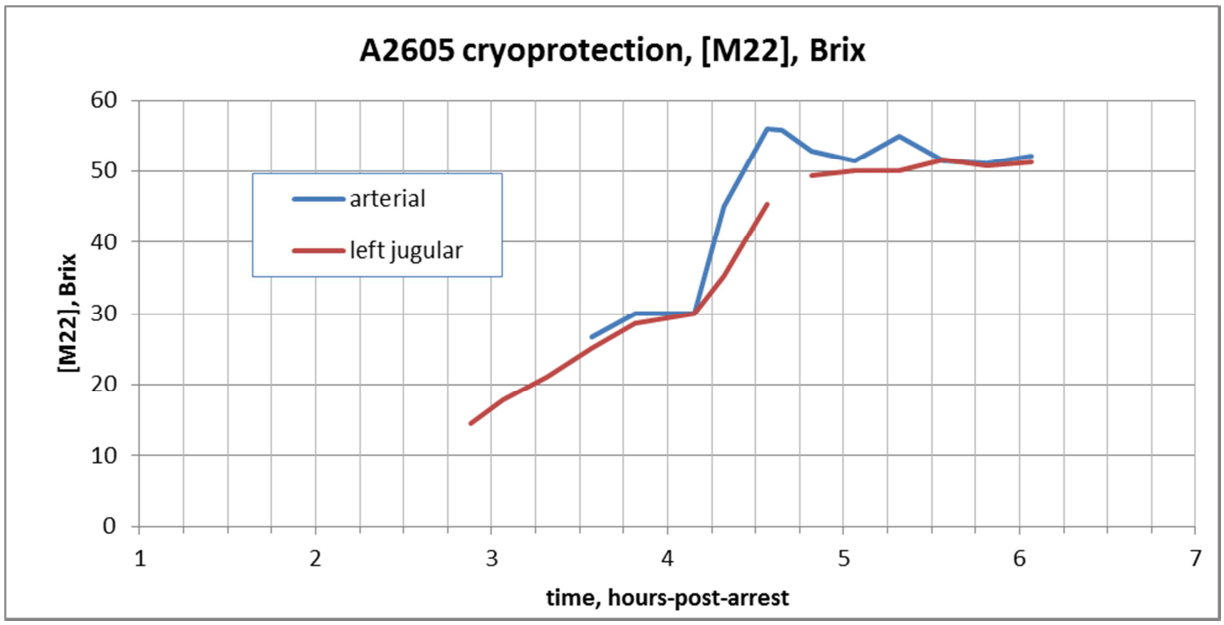


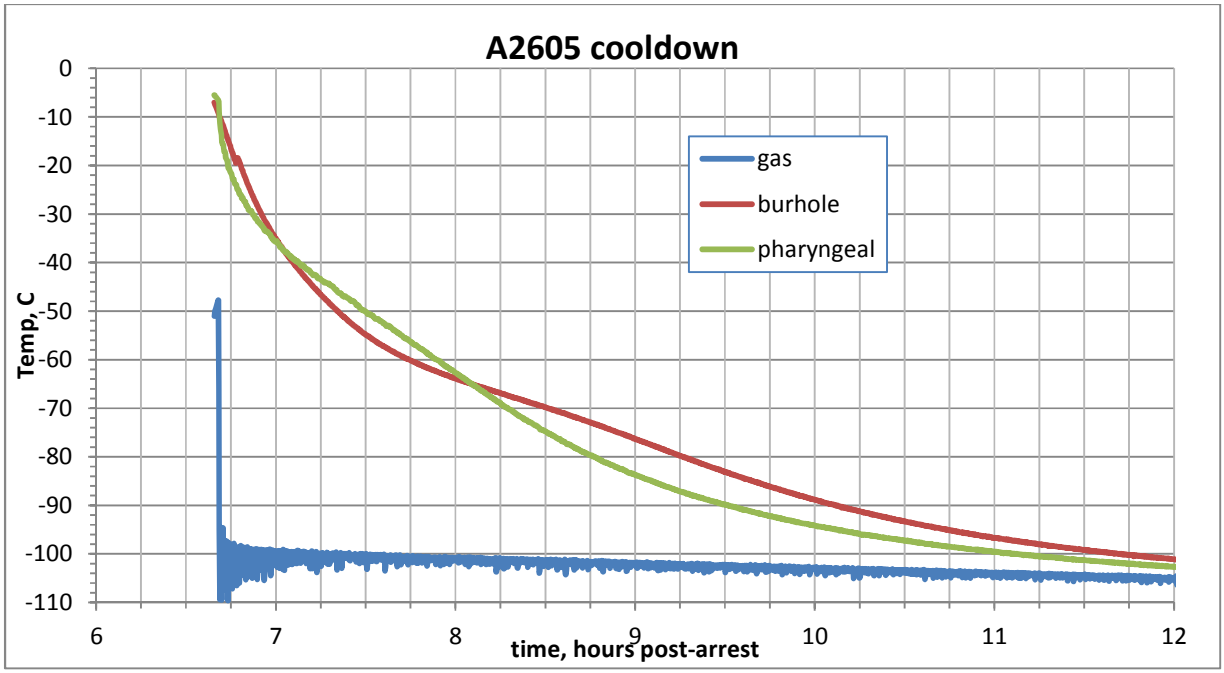
At 4.54 hours post-arrest (15:14), the ramp and main pumps were stopped to rezero the pressure sensor in the data acquisition system, then restarted. This was during the ramp step to terminal concentration. The pressure climbed as a result of the increasing viscosity of the cryoprotectant, and the pump speed was adjusted down to compensate. The viscosity and pressure continued to increase, but was not compensated again. This is the peak. At the 1/4 hour refractive index determination, the arterial concentration was well over the endpoint and the ramp was stopped. The pressure came back down as the cryoprotectant was diluted in the system and the viscosity dropped in response.

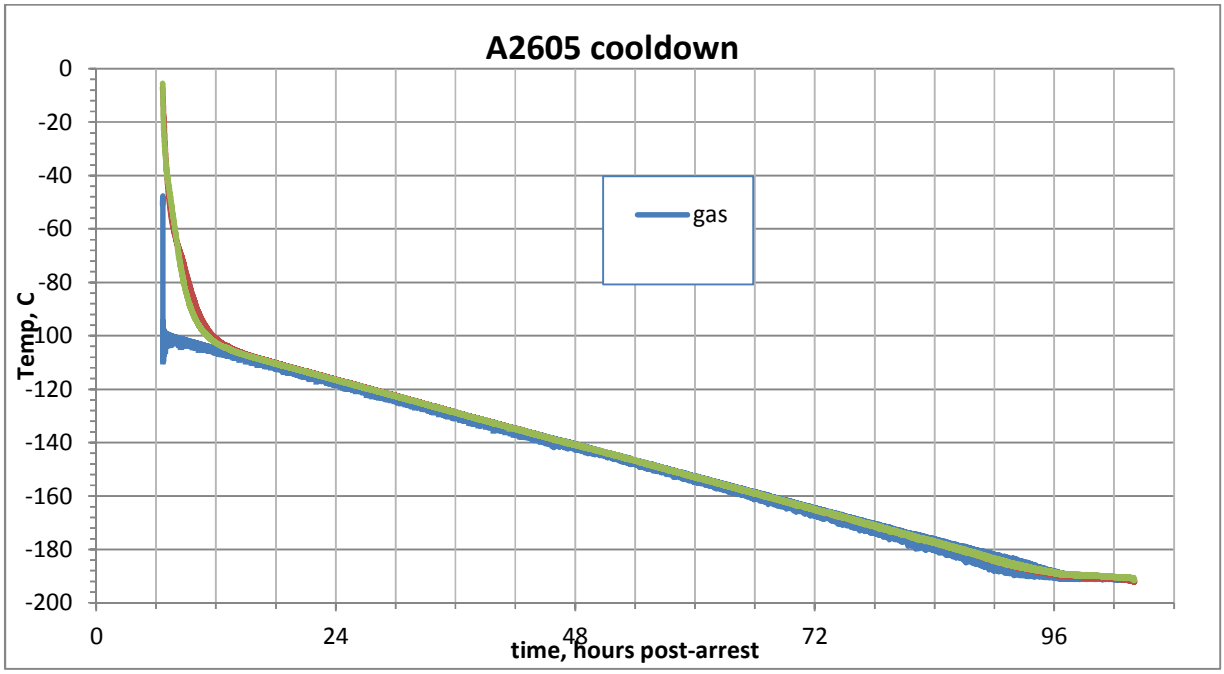


After ~ 5 minutes, the arterial concentration had dropped to the point where the ramp was resumed for a minute or so, and then again after another ~45 minutes, as the effluent concentration made its approach to equilibrium at the desired concentration. Pump speed adjustments were made several times during that time to maintain the perfusion pressure

The "blip" was a downward step of the temperature and indicates that the thermocouple was probably not in sufficient contact with the tissues. It might also indicate that once the patient's head was positioned to establish burr holes, blood flow to the head essentially stopped.







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