2026 Coagulation (Protamine)

Permission to print:	No
Category	Coagulation
Category 2	Drug / Medication
Severity	Good Catch No Harm Incident
Duration of incident:	minutes
Procedure acuity:	Elective
Description:	63 year old female with carcinoid heart syndrome “for elective tricuspid & pulmonic valve replacements. 59 Kg with BSA 1.6. Anticipating IABP or VA ECMO weaning off CPB. A notable concern was the avoidance of B-agonists that could stimulate a pathological neuroendocrine secretion of vasoactive mediators. Our standard extracorporeal circuit consisting of phosphorylcholine coated tubing, softshell venous reservoir (SSVR), external cardiotomy, Balance coated hollow fibre membrane oxygenator. Primed with 1300mL crystalloid and 500mL Albumex. Patient was fully anticoagulated with heparin (ACTs 500 - 700 sec). This included a loading dose of 30K with 10K in the prime plus an additional 5K given during CPB. Weaning off CPB was associated with right heart failure and surgical bleeding. Bypass time 3½ hours. Cellsaver (sic) and extracorporeal circuit cardiotomy circuits returning significant operative field blood loss. The surgeon requesting a test dose of protamine [approximately 1 mL; 10 mg] considering the right heart failure. Cardiotomy and cellsaving suctioning continuing. Transit time in cardiotomy noted to increase; bubble sensor in outlet of SSVR activated despite sufficient fluid in reservoir. Cellsaver collection reservoir clotted. Alerted surgeon that circuit has a probable thrombus in outlet of SSVR and was not safe for returning to bypass. Surgeon was vacillating on whether needed to go back on CPB as was hoping to resolve surgical bleeding; however, when suggested, requested a new CPB circuit. Second perfusionist primed the pump room located assembled heart lung machine. In the interim, the original circuit was still able to be used to infuse the patient. The replacement heart-lung machine/primed circuit was positioned to left of original system (heart-lung machine positioned parallel to patient on patient's right side) and connected to power, gas and water. The new primed circuit lines were handed to surgeon to be connected to in-situ cannula. Appropriate re-heparinisation undertaken then back onto bypass. Old circuit removed from operative field with heart-lung machine taken out of theatre. A further 1.5 hours of bypass was needed to resolve the surgical bleeding from a hole in the SVC before coming off relatively uneventfully. Significant blood transfusions including clotting factors, platelets and packed cells with a notable volume of processed cellsaver blood returned. The patient had an uneventful post op recovery: 6 hrs post op was rousable and obeying commands. Extubated day 3 post-surgery. Discharged 11 days post op. Presumed that the SSVR bubble detector was activated by the cavitation effect of an obstruction in the outlet. It would be logical to assume that thrombus was the cause – even if not seen – due to sequence of events: test dose protamine, bleeding from SVC, continuing suctioning to HLM and cellsavers, clotting of cellsaver reservoir, increased transit time of external cardiotomy drainage, activation of SSVR outlet bubble sensor.
GOOD CATCH - what went well	Observation of compromised circuit Second cellsaver suction line Preparation and application of replacement circuit Good communication and goodwill amongst all parties involved

What could we do better	All steps were in accordance with our current protocols including turning off suckers when 20% of protamine has been infused.
Preventive actions	It is almost universally appreciated amongst perfusionists, backed by clinical experience and international Standards, that suckers should be turned off immediately upon protamine infusion. However, convincing this necessity to all parties involved poses an ongoing challenge.
Type of incident:	Human Factors
Timing of incident:	PostCPB
Discussed with team:	Yes
Hospital incident filed	No
Ext Authority Advised	No
Supplies Issue	No
Knowledge issue	No
Protocol issue	No
Rule issue	Yes
Skill issue	No
Team Issue	Yes
Violation	Yes
Patient outcome variance f	Nil
Commentary	PIRS2 continues to receive reports of coagulation in the CPB circuit following continued cardiotomy suction after initiation of protamine, this report requiring a new circuit emergently setup to recommence CPB. The reporter importantly points out that despite international standards (including Australia and New Zealand) requiring cessation of cardiotomy suction, “convincing this necessity to all parties involved poses an ongoing challenge” The requirement to discontinue cardiotomy suction at the commencement of protamine administration is specifically addressed in international perfusion standards, including those of the ANZCP (1) and AmSECT (2). Nevertheless, the reported difficulty in convincing all members of the clinical team of the necessity for this practice suggests that continued suction may, in some institutions, represent an established and accepted departure from these standards – a so called normalisation of deviance (3). Reason (1990) describes a routine violation (4) as a deliberate deviation from established safe operating practices that has become customary or normalised. The circumstances described in this report are consistent with the organisational normalisation of a practice that departs from an established safety standard. While this does not establish the intention of individual practitioners, it raises questions about how such a departure can become accepted within routine clinical practice. The issue also highlights the potential influence of professional hierarchy within the operating theatre. Although the clinical perfusionist has professional responsibility for the safety of the extracorporeal circulation, the ability to insist on compliance with an established safety requirement may be constrained by the surgeon-perfusionist relationship. This raises a broader organisational question. Where a recognised safety standard is not consistently followed, is the responsibility for correcting the practice being placed on the individual perfusionist, rather than being addressed through agreed multidisciplinary

protocols and institutional governance – and what role should the surgical profession, through its professional organisations, have in supporting compliance with established patient-safety standards?
Compliance with established standards should not depend on an individual perfusionist having to persuade other members of the clinical team on a case-by-case basis. The cessation of cardiotomy suction at the commencement of protamine administration should be an agreed and consistently applied multidisciplinary practice.
-PIRS2 Editors

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1 ANZCP. Standards and Guidelines. 2022. Standard 8.6.
2 AmSECT. Standards and Guidelines for Perfusion Practice. 2023. Standard 12.1.
3 Vaughan D. The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA. University of Chicago Press; 1996.
4 Reason J. Understanding adverse events: human factors. BMJ Quality & Safety. 1995;4:80–89.