



Journal Club

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Challenging authority during a life-threatening crisis: the effect of operating theatre hierarchy. Sydor DT, Bould MD, Naik VN, et al. *Br J Anesth.* 2013;110:463–71.

This fascinating article will introduce you to the concept of the “transfusion authority gradient.” Imagine a second-year general surgery resident on early morning rounds with their attending physician, reviewing the case of a 56-year-old woman post colectomy with an asymptomatic hemoglobin level of 8.5 g/dL day 3 post surgery. The attending physician “orders” the resident to transfuse 2 U of red cells. Most residents would know that the transfusion is unwarranted, but how many of these residents would attempt to challenge their attending physician on rounds? I suspect few would challenge for fear of confrontation and concern regarding a negative end of rotation evaluation. The “authority gradient” or “status asymmetry” between health care providers is just one of the obstacles to appropriate use of blood. Hence, it does not matter if the resident knows when to transfuse if they have no ability to challenge more senior team members about transfusion decisions. Research has shown that the “authority gradient” is a significant contributor to patient morbidity and mortality.

In this trial, 60 anesthesia trainees were randomized (stratified by year of training) into 2 different simulated and video recorded operating room environments: hierarchical or nonhierarchical. Hierarchical environments had this flavor: no introductions, no social conversations, suggestions from residents were not accepted, team members referred to by title, and nurses were submissive. In contrast, the nonhierarchical operating theater setting was much friendlier: introductions were made, friendly demeanor, suggestions from residents accepted, and first names used for all interactions. Before the start of the simulation, trainees were asked to complete a personality questionnaire and were given 3 minutes to read the preoperative assessment of the patient. The scenario was a 60-year-old man undergoing a bowel resection with anemia and risk factors for coronary artery disease. The patient was a practicing Jehovah's Witness who strictly refused blood products. During the case, there is a vascular injury with resultant massive bleeding and a drop in the hemoglobin level to 5 g/dL. The staff anesthetist asks the nurse to call the blood bank for 4 U of uncrossmatched blood. When the blood arrives, the staff anesthetist orders the resident to check and spike the blood. The residents were scored on their ability to challenge their attending anesthetist in attempts to prevent the blood transfusion on a 6-point advocacy inquiry scale: (1) they say nothing; (2) oblique answer “We're transfusing him?”; (3) inquiring directly that the patient did not want blood; (4) repeated attempts of level 3; (5) crisp

advocacy such as “Dr Jones, this patient is a Jehovah's Witness and I am concerned about violating his rights”; (6) takes over the case and calls in a second anesthetist. Obviously the “correct” approach is escalation to a level 6 response if required to block the transfusion.

The results were shocking. Most residents went ahead and checked the blood (92% in the hierarchical vs 76% in the nonhierarchical group, $P = .08$) and then hung the blood (62% in the hierarchical vs 57% in the nonhierarchical group, $P = .72$). There was a huge range in the 6-point advocacy inquiry rating from 1 to 6 in both groups, with a median of 4 in both groups. There was no statistically significant effect of the hierarchical environment on the resident's responses. On a positive note, their scores improved with each year of training: year 2, 3.5; year 3, 3.75; year 4, 4.0; and year 5, 4.5. Although, I would have predicted that, by year 5, they would have reached a level 6 response. Sex and personality traits had no impact on advocacy inquiry scores. The existing literature suggests that these low level challenges are likely to be ineffective. Neither of the 2 participating training programs had any formal curriculum to address the “authority gradient,” and the authors hypothesized that the improvement in scores at higher level of training were likely due to narrowing of the authority gradient, rather than topic specific training.

Medical school and residency training programs need formal curriculum to address the “authority gradient” if we are to improve patient safety. It would be in the best interests of the transfusion community if this “problem” was openly discussed during transfusion lectures and seminars so that residents are aware of this problem and have some guidance about the available strategies to ensure the patient gets the best care. In aviation, a “two-challenge rule” is used by a subordinate, and they are authorized to take over control if responses are nonsensical. We are a long way from the “two-challenge rule” in medicine, but opening this discussion up with trainees is the first step in addressing this transfusion safety problem. (JC)

The Transfusion Alternatives Pre-operatively in Sickle cell disease (TAPS) study: a randomised controlled multicentre clinical trial.

Howard J, Malfroy M, Llewelyn C, et al. *Lancet.* 2013;381:930–8.

The preoperative management of adults and children with sickle cell disease often includes red cell transfusion. However, the exact need for red cell transfusion has been debated for a number of years. The Transfusion Alternatives Pre-operatively in Sickle cell disease multicenter trial was designed to answer the question of whether prophylactic preoperative red cell transfusion is necessary in patients with sickle cell disease undergoing low- or medium-risk surgery. Patients with hemoglobin concentrations greater than 6.5 g/dL and

oxygen saturations more than 90% were randomized to 2 groups, one group to receive a transfusion before their operation and the other to remain untransfused. Otherwise, their care was determined by the attending hematologist and anesthesiologist. Children and adults with sickle cell anemia or other subtypes of sickle–thalassemias—were eligible for recruitment.

The trial was stopped early because of a clear difference in the number of serious adverse events (SAEs) reported between the 2 groups (30% in the no transfusion group vs 3% in the preoperative transfusion group). At this stage, rates of recruitment had been low, such that of 343 patients screened, only 70 were randomized. These SAEs were almost all acute chest syndromes. Alloimmunization was seen in 1 patient (it should be noted that extended red cell matching commonly includes full-Rhesus and K1 antigen phenotyping in the UK). Patients receiving a preoperative transfusion had significantly fewer SAEs and fewer transfusions during or after their operations than those who did not receive a preoperative transfusion.

The data from the trial suggest a benefit from preoperative red cell transfusion in this group of patients for these procedures. It was concluded that patients with sickle cell disease undergoing low- to medium-risk surgery should be offered a preoperative transfusion. The authors and the accompanying editorial highlight a number of research questions not addressed by this trial, including the management of patients with higher hemoglobin concentrations or those undergoing low-risk surgery, as the numbers in these subgroups were smaller, but, at least in this clinical setting of medium-risk surgery in sickle cell disease, red cell transfusions have clear benefit. (SJS)

Effects of fibrinogen concentrate as first-line therapy during major aortic replacement surgery. Rahe-Meyer N, Solomon C, Hanke A, et al. *Anesthesiology*. 2013;118:40–50.

There would be several advantages if surgical bleeding could be treated using specific factor concentrates as opposed to plasma or cryoprecipitate. With concentrates, there is minimal risk of transfusion-transmitted disease or reactions, and the exact amount of each needed factor could be given as opposed to rough estimates. In this context, Rahe-Meyer et al present findings of a randomized controlled trial involving fibrinogen concentrate.

The authors randomized patients undergoing aortic arch repair. Before bypass, a ROTEM measure was taken on each subject. After removal from bypass and heparin reversal, patients with “microvascular” bleeding were given fibrinogen concentrate at a dose based on the ROTEM results or placebo. Opaque syringes helped ensure blinding. The presence of “microvascular” bleeding was determined through weighing of surgical cloths that had been applied to the field for 5 minutes. Based on prior studies, cloth weight greater than 60 g but less than 250 g was considered evidence of microvascular bleeding (>250 g was considered “macrovascular”). Five minutes after medication administration, bleeding mass was again measured. If the result was again in the microvascular range, patients received either 2 bags of apheresis platelets (if platelet count <100,000/ μ L) or 4 U of fresh frozen plasma (FFP) (if platelet count >100,000/ μ L). After 5 minutes, bleeding mass was again determined, and if still in the microvascular range, the component not previously given was transfused. Bleeding mass was then determined every 5 minutes with administration of 1 bag of apheresis platelets and 2 U of FFP if continued microvascular bleeding. Patients were also given red cells to maintain a hemoglobin level of 8.5 g/dL. The primary outcome was total blood component usage during the 24 hours after study medication administration. The study was powered to detect a 50% difference in blood component usage assuming a mean baseline usage of 8.5 products.

Twenty-nine patients received fibrinogen concentrate, and 32 received placebo. Both groups were well matched in regard to perioperative and operative characteristics. The average dose of fibrinogen concentrate was 8 g. Patients receiving fibrinogen

concentrate had a median of 2 transfusions, whereas those receiving placebo received a median of 13 ($P < .001$). The placebo group received a median of 2, 8, and 4 red cell, plasma, and platelet products, respectively, whereas for the fibrinogen group, these values were all zero. Forty-five percent of fibrinogen concentrate patients did not receive any transfusions compared with none of the placebo group. There was no significant difference in hemoglobin level at the time of last suture or 1 day after surgery. Fibrinogen levels were approximately 155 mg/dL in both groups after the removal from bypass and were 260 mg/dL in the fibrinogen concentrate group and 189 mg/dL in the placebo group at the time of the last suture ($P < .001$). One day after surgery, levels in both groups returned to approximately 340 mg/dL. The authors do not report blood loss during surgery. There were no adverse events that were thought to be due to study medication administration.

Rahe-Meyer et al present intriguing results. In this phase II trial, there is evidence for benefit from fibrinogen concentrate in patients with moderate levels of bleeding during aortic replacement surgery. One major caveat is that the difference in blood product use was primarily driven by FFP and platelets. Given the study's very aggressive transfusion protocol (large amounts of plasma and platelets and high hemoglobin threshold) as well as the atypical method of determining bleeding, it is not clear if these results would translate to standard practice. Still, the findings are worthy of further investigation in larger multicenter trials. (RH)

Impact of fibrinogen levels on outcomes after acute injury in patients requiring massive transfusion. Inaba K, Karamanos E, Lustenberger T, et al. *J Am Coll Surg*. 2013;216:290–7.

We are completely in the dark when it comes to where we should be targeting the fibrinogen level in massively bleeding patients. The optimal target is probably somewhere between 0.8 and 3.0 g/L during active hemorrhage. Due to the lack of data from prospective randomized trials to guide our fibrinogen replacement decisions, clinicians are divided on this topic. Some believe that the level should be maintained over 2.0 g/L, and others believe that a level of 1.0 g/L is more than adequate for hemostasis. Like me, you will be hopeful that this report regarding fibrinogen levels in adult trauma patients will clarify this issue further, but unfortunately, you will be disappointed. All it tells us is that patients with low fibrinogen levels have much worse outcomes (but, of course, you knew that—you see this everyday in your massively bleeding patients). What it does tell us is that the average “trauma team,” even at this prestigious trauma hospital, is a bit in the dark about the importance of monitoring the patient's fibrinogen level during the period of active hemorrhage. Only 34% of a cohort of massively transfused patients had their fibrinogen measured on arrival to the intensive care unit at this academic center. In addition, patients with very low fibrinogen levels had received a lot less cryoprecipitate, plasma, and platelets than patients with “better” fibrinogen levels. So at the end of reading this report, you will be left wondering whether the bad outcomes were due to inferior care or whether patients with low fibrinogen levels had more severe injuries and hence destined for worse outcomes.

This retrospective study reviewed the fibrinogen levels, coagulation test results, transfusion data, baseline characteristics, and outcomes of patients massively transfused over the first 24 hours at a single center. To be eligible to be included in their analysis, they had to have survived long enough to be admitted to the intensive care and had a fibrinogen level measured on arrival. Over a 12-year period, 758 trauma patients were massively transfused, but only 260 (34%) had had a fibrinogen level measured and were included in the analysis. I wondered if the other 498 patients had fibrinogen measurements performed in the trauma room and operating room but were excluded from this report. The authors note that there was no difference between patients with fibrinogen measurements and those without,

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