

Medical Center

In the tradition of the Medical College of Virginia

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RISKS AND BENEFITS OF PROCIT FOR INFANT SKULL SURGERY

Almost all children undergoing skull-remodeling surgery require blood transfusions. Studies have shown that the average amount of blood lost during craniosynostosis repairs can be equal to the child's total blood volume. There are no good studies that tell us the risk of a child not surviving this type of surgery, but a generally accepted estimate is that the risk of not surviving is probably less than 1 in 300 operations. The most common cause of death is because of too much blood loss.

Procrit is a drug, which is given by injection, which stimulates the body to make more red blood cells. It has been used by many surgeons to increase the amount of red blood cells in their patients before any operation that a large amount of blood loss would be expected (even though the drug has not been approved by the FDA for specifically raising blood levels before surgery). After receiving this drug, there are more red blood cells in an infant's body before surgery begins. If two babies have the same operation and lose exactly the same amount of blood, but one baby started out with more red blood cells, then that child would have more at the end of the operation.

In 2002, a study was published by that concluded that those children who received Procrit (human recombinant erythropoietin) before surgery only required blood transfusions about half the time, whereas those children who did not receive Procrit had an almost 100% transfusion rate.¹ Further studies have corroborated this conclusion.²

There are risks associated with giving blood transfusions. Most parents worry about their child getting HIV, or AIDS, from a transfusion. Actually, the risk of this is extremely low (less than 1 in 400,000). The risks of Hepatitis is far greater, being about 1 in 15,000. The most common risk of getting a blood transfusion is having a reaction called Transfusion Related Lung Injury (TRALI). This is estimated to occur in about 1 in 5,000 transfusions (with a death rate of 5-10%). In addition, there are studies that have suggested that the surgical infection risk may be lower in those who do not receive a blood transfusion.

There are risks associated with giving Procrit. One risk is that a child might develop an allergic reaction called Pure Red Cell Aplasia, which results in the body shutting down all red blood cell production. When this happens it is necessary to give blood transfusions every month until the condition gets better.

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Pediatric Plastic Surgery

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To my knowledge, this reaction has never occurred in a young child (but it is possible). Johnson & Johnson estimated the risk of this complication occurring is about 1 in a million doses.

Recently the FDA administered a “black box” warning concerning Procrit (www.fda.gov/cder/drug/InfoSheets/HCP/RHE2007HCP.htm). This was done because studies showed three things of concern. The first concern is in patients with terminal cancer who were no longer candidates for getting chemotherapy. For these patients who received Procrit, their tumors were noted to grow faster. The second is in patients with kidney failure on dialysis. When these patients received Procrit, they had a higher incidence of heart attacks and strokes. The third study looked at adults undergoing spine surgery. In 681 patients about half were given Procrit and the other half were not. The study found that the chance of having a blood clot in the legs was more than twice as high for those who got Procrit. The concern would be could this blood clot break off and go to the lungs, leading to death (no patients died of this in the study, however). Therefore, there is a risk that if an infant receives Procrit, that child would be more likely to develop a blood clot in the legs that could lead to more serious problems. Most physicians agree that the risk of blood clots in the legs of infants, is much less than in adults. In fact it might be that if the blood is more likely to clot in infants getting Procrit, that this could be beneficial during skull surgery by limiting blood loss.

With every decision in medicine and there are risks associated with every treatment, and there are risks of not having that treatment. Doctors need to try to learn as much as possible about both sides, and try to chart the safest course for each patient. At the current time, given all the information that I am aware of, I believe that it is better to give Procrit before infant skull surgery than to not give it. If my child needed this surgery, my child would get Procrit before the operation.

1. Fearon JA, Weinthal J. The use of recombinant erythropoietin in the reduction of blood transfusion rates in craniosynostosis repair in infants and children. *Plast Reconstr Surg.* 2002 Jun ;109(7):2190-6.
2. Krajewski K, Ashley RK, Pung N, Wald S, Lazareff J, Kawamoto HK, et al. Successful blood conservation during craniosynostotic correction with dual therapy using procrit and cell saver. *The Journal of Craniofacial Surgery.* 2008 Jan ;19(1):101-5.

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