

THEMISEAL IN ORTHOPAEDIC SURGERY

SUMMARY

60 consecutive patients undergoing major orthopaedic surgery were divided into two equal groups at random. Just before closure of the operative wound 10 ml, 50 ml or 100 ml of feracrylum a new locally active haemostatic agent or saline as a control was instilled in the wound and left in place for two minutes. The collection in the vacuum suction drain was monitored at 1, 6, 12, 24 and 48 hrs. post operatively.

The trial group had an average of 23.4% less post operative collection at the end of 24 hrs. A dose of 50 ml was found to be most effective.

This study involves a new locally acting haemostatic agent, Feracrylum. We present the method and results of a controlled trial carried out in 60 patients undergoing major orthopaedic surgery where Feracrylum was used against control, where normal saline was used.

Haemostasis has a very important place in any surgical procedure. At every stage, from incision, proper haemostasis can lead to a clean field of exposure, low blood loss and minimum post operative infection due to less collection in the wound. In fact, in a medically advanced nation like France, major orthopaedic surgery is accompanied by half an hour spent in obtaining and maintaining meticulous haemostasis.

A brief recapitulation of the pharmacology of this new locally acting haemostatic agent is in order. Feracrylum is an incomplete iron salt of poyacrylic acid. Within a pH range of 2.9 – 4, it forms water-insoluble complexes with proteins of various origins, including those contained in blood plasma. It is available as 1% aqueous solution which is a transparent, pinkish, odourless liquid with a sour taste. It can be sterilized at 120 degrees and 1.5 atm. And is stable in storage in this form for 2 years and more. It has been found to be extremely safe in animal studies and the only contra-indication for its use is in a patient receiving S-Amino-Caproic Acid. It is safe in children and can be used in patients with blood clotting disorders such anaemia, afibri-nogenaemia and haemophilia. Due to its high molecular weight it is not absorbed into the systemic circulation and hence does not affect the functioning of any organ such as liver or kidney. Most importantly, it does not display any rebound bleeding or effect the healing process.

To measure the efficacy of a 1% solution of Feracrylum we devised this study. Post-operative drainage in a vacuum suction bottle provides a fair gauge of the capillary and venous ooze which remains after all major spurters and bleeders are ligated or cauterized. Most wounds continue to drain for 48 hours after major surgery. A study of the collection in the vacuum suction drainage bottle at 24 hours after wound closure where a 1% solution of feracrylum was instilled for 2 to 3 minutes in the wound just prior to closure in alternate patients and an equivalent amount of normal saline was instilled in the wound for the same period in the other half. This study was carried out on 60 consecutive patients undergoing major orthopaedic surgery. Three different dosages of the haemostatic agent 10 ml, 50 ml and 100 ml were used in order to find which is most effective whether there are any adverse effects with high doses.

This series had 60 patients, 30 trial patients and 30 controls. The age distribution was 11 years to 65 years in the trial patients with an average of 39 years. The control patients ranged from 13 years to 80 years with an average age of 42 years. The sex ratio was 19 males to 11 females in the trial cases as compared to 17 males and 13 females in control cases. Out of the 60 major procedures, 12 were on the spine, 3 on the pelvis (mainly iliac bone grafting), 20 in the upper extremity and 25 in the lower extremity.

The results were analyzed in three categories where different doses of Feracrylum had been used as compared to the three categories where an equivalent amount of normal saline had been used. The maximum, minimum and average values in each group were compared at each specified time interval.

In cases where 10 ml of Feracrylum was used the average collection was 11.54% less at 24 hours as compared to the control group. 50 ml produced a 23.4% decrease in the average collection while 100 ml had only a marginal change as the average collection was 25.15% less in the trial group as compared to the control group at 24 hours. There were no adverse effects seen, even when 100 ml was used in a child of 14 years.

In conclusion, we observed that Feracrylum has a significant role to play in major orthopaedic surgery as it decreases the overall post operative collection in the wound. A dose of 50 ml kept in contact with the wound for 2-3 minutes is the most effective. Although the haemostatic properties were used only at the conclusion of the surgical process, we can safely infer that its use throughout the procedure, whenever any difficult ooze is encountered, will lead to a cleaner field without the use of electro-cautery or other systemically acting chemical haemostatic agents.