Trial of Prophylaxis vs. No-Prophylaxis Platelet Transfusions in Patients with Haematological Malignancies (TOPPS)

The Research Question:
Is a No-Prophylaxis policy for platelet transfusions for patients with haematological malignancies not worse than (Non-Inferior to) a prophylaxis policy triggered at a level of 10 X 10^9/L, as judged by WHO Grade 2,3,4 bleeding up to 30 days after randomisation?

Background
- Platelet demand is rising
- Maintaining supply is challenging.
- Haematology patients are the highest users, with platelets given to manage bleeding in thrombocytopenia.
- Treatment can be either therapeutic or prophylactic
- >60% platelets are used for prophylaxis

Primary Outcome: Proportion of patients with WHO grade 2 or above bleeding

Methods: eligible patients were randomised to receive either prophylactic transfusions, or to no-prophylaxis with transfusions given only after documented signs & symptoms of bleeding.

Intervention: therapeutic platelet transfusions when signs or symptoms of bleeding

Control: platelet transfusions when platelet count < 10 x 10^9/L

300 patients

298 patients

Results

This study did not demonstrate that a no-prophylaxis approach is non-inferior.
- WHO grade 2-4 bleed occurred in 50% of patients in the no-prophylaxis group compared to 43% in the prophylaxis group.
- Patients in the no-prophylaxis group had more days with bleeding, and a shorter time to first bleed.
- Platelet usage was markedly reduced in the no-prophylaxis group (59% vs. 89%)
- No differences in length of stay or SAEs were seen between groups.

Conclusions from TOPPS
- The results support the continuing use of prophylaxis in patients with thrombocytopenia
- The proportion of patients with Grade 2-4 bleeding was reduced by 7% with prophylactic platelet transfusions
- There is still a high burden of bleeding in many patients, despite prophylaxis.
- The benefit of prophylactic platelet transfusions in the sub-group of patients undergoing low-risk autografts was less clear.

What Next?
- Investigate role of prophylactic transfusions in sub-groups, such as autograft patients
- New studies to improve our understanding of the risk factors for major bleeding
- Investigate alternative strategies to manage the high burden of bleeding that exists despite prophylaxis
- Compare and contrast findings with other recently published platelet trials.