Questions and Answers session – 8th October, 2020

Please note that the following text is not an accurate reproduction of the minutes of the online session. They have been extensively edited to make it more informative and useful to readers.

What error is this study prone to? Is it a type 1 or 2 error?

It would be prone to a type 2 error. This is when you do not collate enough evidence to reject the null hypothesis. This usually happens in studies which are under-powered therefore a difference which exists cannot be shown.

What constitutes high risk of bleeding in a splenic injury patient?

According to previous literature, this would be a poor splenic preservation rate at 6 months.

You mentioned a couple times that the radiologists were blinded, at what stage of the trial were the radiologists blinded and why would you blind the radiologists because they do not make the decision for prophylactic embolization?

The outcome is splenic embolization rate and this is defined radiologically as 50% or more vascularised spleen and the absence of splenectomy. The secondary outcome is the splenectomy rate (which would be decided by the surgeon). Not all forms of embolization may be visible on CT, but they would be able to see the infarction.

How can you call this a blinded study if you haven't blinded the patient or the clinician who is making the decision?

That's a very good point. It all has to do with the wording of the primary outcome because it is radiologically defined. It would be difficult to blind the medical team looking after them.

How was the random sequence generated? Was allocation concealment ensured and why is this important?

They are not overly clear. It seems like they have done block randomisation based on centre. They don't specify what they use to generate the sequence. It is not clear if they took any sort of precaution in ensuring that allocation concealment was maintained.