Anti-platelet therapy in non-cardiac elective surgery

Editor—We were interested to read Mantz and colleagues' multicentre randomized controlled trial of anti-platelet therapy in non-cardiac elective surgery—the STRATAGEM Trial.

Trying to assess the balance of risk between bleeding and thrombosis in patients taking long-term anti-platelet agents is an area of significant clinical importance and variation in practice. The initial trial methodology seems sound and may have added to the body of knowledge regarding the interruption of anti-platelet agents in patients undergoing elective surgery. The researchers hypothesized that maintenance of aspirin was superior to its discontinuation when considering a balance of major thrombotic and bleeding events.

The study design required 1421 patients to be recruited to demonstrate the desired outcome with a significance of 0.05 and 80% power. However, since the trial was stopped with only 291 patients recruited, it was severely underpowered, indeed with <50% power. Thus, the chances of being able to detect a true difference between these populations would appear to be limited. The authors mention this in their discussion: ‘because the trial was stopped early and hence underpowered, we cannot rule out a benefit or a harm of one of these two strategies’ yet still go on to conclude that ‘we did not demonstrate a difference in terms of the occurrence of major thrombotic and bleeding events between preoperative treatment with aspirin and preoperative interruption of anti-platelet therapy’. We suggest that this is overstating their case.

A negative trial outcome can enhance the evidence base regarding a treatment or its discontinuation, yet it must be statistically sound in order for its results to be applied to the entire population. We do not believe that this is the case here. Given that many people only read abstracts, it is of concern that the abstract fails to mention the underpowered nature of the results in its conclusion. Even more worryingly, in the Editor’s key points, no warning is given about this, merely stating: ‘Although a negative study, the data provide useful safety information regarding preoperative aspirin’. In such an underpowered study, we do not believe that this conclusion can be drawn and stating this without qualification gives real risk of providing falsely reassuring data that are not statistically sound. We suggest that this study could be used as a discussion regarding the safety of preoperative aspirin discontinuation or maintenance, but no more.

Declaration of interest

None declared.

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Reply from the authors

Editor—We thank Drs Clevenger and Jaggar for their interest in our study. They state that because our study was underpowered, our conclusion that ‘we did not demonstrate a difference in terms of the occurrence of major thrombotic and bleeding events between preoperative treatment with aspirin and preoperative interruption of anti-platelet therapy’ is overstating our case. We respectfully disagree with them. Indeed, this conclusion is only what the data enable us to say, with no attempt to overinterpret the results. They also caution that care should be used when extrapolating negative results to practice, particularly when studies are underpowered. We agree with this statement, and clearly made the case that our trial was underpowered, which should be taken into consideration in the interpretation of our results.

We believe, however, that the comparison of our results with that of the ongoing large randomized, blinded, multicentre POISE-2 trial, once completed, will be of great interest to improve the efficacy and safety of preoperative aspirin management in surgical patients.

Declaration of interest

None declared.

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Maternal temperature increase

Editor—We were very interested to read the article by de Orange and colleagues on the effects of combined spinal and epidural (CSE) anaesthesia on maternal temperature during vaginal delivery. It comes as no great surprise to us that a CSE would increase maternal temperature, without any major detriment to mother or baby. Maternal temperature in labour is something we have been looking into at...