Diagnostic and therapeutic medical devices for safer blood management in cardiac surgery: systematic reviews, observational studies and randomised controlled trials

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Plain English summary

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Plain English summary

Background

There is uncertainty as to the value of medical devices that are commonly used in the diagnosis and treatment of anaemia and coagulopathy.

Aim

To assess the clinical benefits and cost-effectiveness of devices in common use for the diagnosis and treatment of cardiac surgery patients with anaemia and coagulopathy.

Methods and results

We demonstrated that bedside (near-patient) diagnostic tests for coagulopathy in common clinical use, or a panel of specific laboratory diagnostic tests, were not superior to using clinical data available at baseline to predict severe bleeding. Further analyses showed that these tests did not improve clinical outcomes and were not cost-effective.

In a multicentre trial we demonstrated that the use of near-infrared spectroscopy as a patient-specific indicator of the need for transfusion was no better than standard care (no near-infrared spectroscopy measurement) and was not cost-effective. A review of all of the existing trials of this technology in cardiac surgery yielded similar results.

In a multicentre trial we failed to demonstrate any benefit of mechanical washing of red cells, a technique that is thought to remove harmful substances known to accumulate in blood when it is stored in the blood bank.

Conclusions

Our programme of work did not support the use of medical devices in clinical use for the diagnosis and treatment of anaemia and coagulopathy. This work highlights the importance of the careful evaluation of devices in clinical trials prior to marketing and supports calls for the revision of regulatory processes for device approval.

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