acrobat

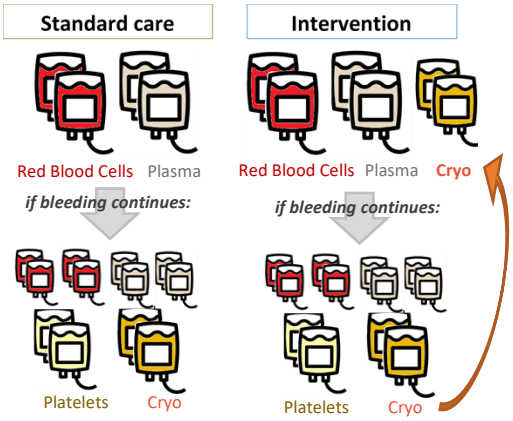
administering cryoprecipitate in obstetric bleeding at an earlier time

Participant Newsletter
January 2022

Background

Severe bleeding is one of the more common complications in childbirth. In about 1 out of 50 women, this bleeding can be so severe that blood transfusions are needed. There are different blood products that can be given, and doctors normally give red blood cells and plasma first; only if this is not successful are other products given. One of these products, **cryoprecipitate (or "cryo"),** is a blood product that contains a lot of fibrinogen, a protein which can act as a kind of glue to help stop the bleeding. Cryo is a frozen blood product and needs to be thawed before being given to patients.

By giving cryo earlier, it might be possible to stop the bleeding faster and avoid complications. In order to prove this, we would need to perform a large, complex and expensive research trial. We conducted this pilot ("test") study to find out if such a large trial would be feasible and to find out:



- whether hospitals are able to deliver the intervention, and what barriers there might be;
- whether women and healthcare staff are happy to take part in the study and what their views are;
- whether early cryo is safe and what we should measure in a future trial.

Who ran the ACROBAT study?

The study was organised by researchers of the Barts Research Centre for Women's Health (BARC) at Queen Mary University of London, and funded by Barts Charity.

BARTS CHARITY

Queen Mary University of London

BARC
BARTS RESEARCH CENTRE FOR WOMEN'S HEALTH

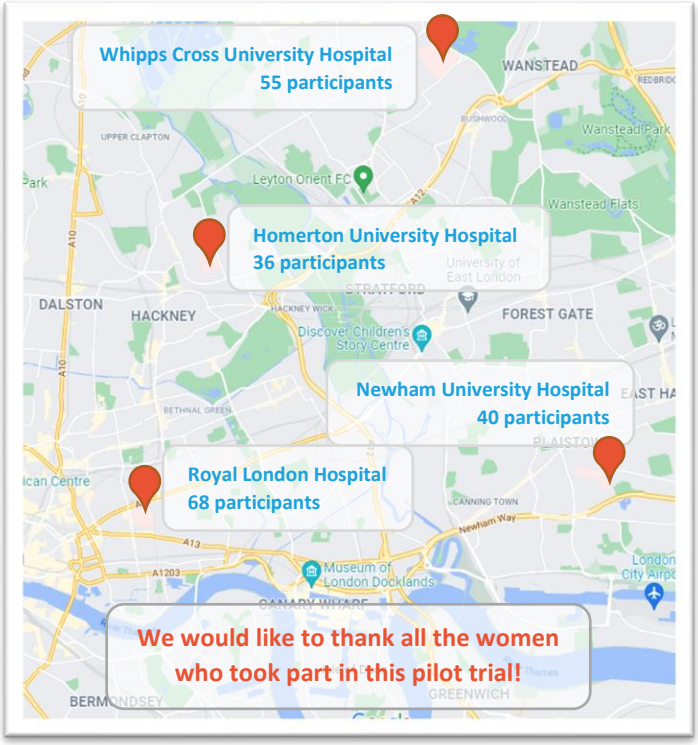
Who took part in the ACROBAT study?

Between March 2019 and January 2020, 199 women who experienced severe bleeding in childbirth were included in the ACROBAT study in four different hospitals in London (see map). Two of the hospitals were randomly allocated to the control group and the other two to the intervention.

In the hospitals allocated to the intervention, all women who had severe bleeding in childbirth were to be treated with early cryo. Unlike other products, such as red blood cells, cryo needs to be ordered from labs and thawed, and the intervention hospitals were instructed to try and give it within 90 minutes.

The other two hospitals (the control group) continued with standard care as usual, meaning that women who had severe bleeding in these hospitals usually only received cryo later if needed, or not at all (although doctors were still allowed to give cryo sooner if they felt the woman really needed it).

Because the treatment for severe bleeding in childbirth is so urgent and hard to predict, the ethics committee gave us permission to deliver the intervention first, without the women's prior knowledge about the study. Once the women had recovered, the research team approached them to ask for consent to collect data and blood samples for this study.



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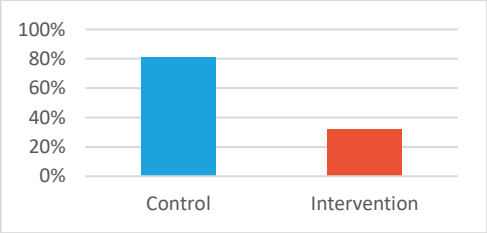
What did we find out?

In terms of whether hospitals were able to deliver the intervention, the hospitals in the control group did better, with 81% of women treated as planned (meaning that they all received standard care, and only a small proportion got earlier cryo on top of that). In the intervention group, 32% of women were treated as planned (meaning they received cryo within 90 minutes); everyone still received at least the usual standard care, but the intervention hospitals struggled to deliver cryo early.



There were several reasons for the issues with the intervention:

- Severe bleeding is managed by a large team of different staff, and sometimes it was not clear who would take responsibility for ordering the early cryo.
- There was a high staff turnover, and it was difficult to make sure that everyone was always aware of the change in treatment.
- Sometimes there were delays because the hospitals had a large distance between the laboratory that kept the cryo and the labour ward. In these hospitals, staff could get the initial blood packs of the other products from a local "blood fridge" instead, and may easily forget to call the laboratory for cryo.

However, we did see that 60% of women in the intervention group did get *some* cryo, almost twice as many as in the control group – though some of this was given later than 90 minutes.

Is it safe?

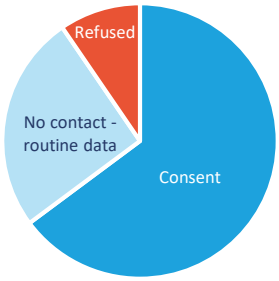
Yes – we did not find any difference in side effects between the two groups, and most importantly we saw no increase in blood clots with early cryo.

Does early cryo work?

As our study was just a pilot study for a potential larger trial, it was not designed to answer that question. We did see that in the intervention group, women needed slightly less surgery, transfusions, or intensive care, but we would need to measure these in a large trial to confirm that this was not just due to chance.

What did women think?

The rate of consent to the study was very high: only about 10% of women refused to have any data collected. In about 25% of cases, we didn't manage to speak to the women about the study before they were discharged, and didn't manage to contact them afterwards. In these cases, we had permission to collect routine anonymised data for these women in order to still get reliable study data.



We interviewed some of the participating women, as well as the staff who recruited them, and we learnt that:

- Women who were interviewed found the intervention acceptable, and did not mind that they were only told about it afterwards, as the intervention was low-risk.
- Staff tried hard to find the right moment to approach women before they were discharged from hospital, and this was often a bit of a balancing act – between the requirements of the study and the needs of the woman who is still recovering.
- Women said they had a lot going on just after childbirth, and this sometimes affected their ability to process and remember study information.

What does this mean?

We think it is possible to continue with a larger trial, but we would need to make some changes in how the intervention is done – for instance, we would need to make sure that staff have clear lines of communication for ordering early cryo. New technology making cryo available more quickly might also help a future trial.

Want to find out more?

Go to **barc-research.org/acrobat** for links to the full publication and other updates.