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 SALVO

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 The SALVO Newsletter

 Study to assess cell-salvage in obstetrics

What's the background?

Caesarean sections are on the increase. Women delivering by caesarean section can bleed quite heavily, and sometimes this can have life-threatening consequences.

The standard treatment in case of heavy bleeding is **blood transfusion.** However, this is done sparingly, as blood is a precious resource, and occasionally there may be transfusion reactions. In recent years, **cell salvage** has been introduced in childbirth.

What is cell salvage?

This is a process by which the blood that a patient loses at surgery is collected by a machine, cleaned and returned to them. It's been used in other types of surgery for decades. We used to be reluctant to use cell salvage in childbirth, because of the risk of amniotic fluid entering the mother's bloodstream (which could lead to amniotic fluid embolism, a serious complication). However, cell salvage cleans the blood thoroughly, so this should not be an issue.

Cell salvage is now increasingly used in caesarean sections, especially where there is a high risk of bleeding. However, we needed more evidence that it is really effective if used routinely.

What did the SALVO study set out to do?

The SALVO study sought to find out if routine use of cell salvage reduces the need for blood transfusions, as well as complications, fatigue and anaemia. It also generated data on the safety and the cost of this treatment. To do this, we decided to conduct a **Randomised Controlled Trial**, which means that participating women were randomly

allocated to receive either cell salvage, or routine care (which includes blood transfusion if needed). We included all women with an increased risk of bleeding – that means everyone who had a caesarean section, except those women who had a section either through choice, or because of a breech baby.

Where and when was the SALVO study done?

The study ran between June 2013 and April 2016 at 26 UK hospitals. In total, **3028 women** were included and randomly allocated to receive either cell salvage or standard care (without routine cell salvage).

Of these women, 1672 women had an emergency caesarean section and 1356 women had an elective (=planned) caesarean section.

We would like to thank all the women and their families who took part in this important trial!



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What did we find out?

Among women who were in the standard care group, **3.5%** needed a blood transfusion.

Among women who were in the cell salvage group, **2.5%** still needed a blood transfusion.

Transfusion rates:



That's a reduction of 1 percentage point – or put another way: For 100 women who were treated with cell salvage, 1 woman avoided a blood transfusion. This difference might be down to chance and doesn't support routine use of cell salvage.

We did not see any difference in the level of women's fatigue or anaemia between the groups.

So that does this mean?

Should we stop using cell salvage in caesarean section? Not quite.

- There are women who refuse donor blood, or who have rare blood groups – for them, cell salvage is very useful.
- Among women who needed emergency caesareans, we did see a clear reduction in blood transfusions when cell salvage was used. Our study was not designed to give a definitive answer here, so more research would be needed to prove this.

Is it safe?

Among all the women who were treated with cell salvage, there wasn't a single case of amniotic fluid embolism – which is what had previously concerned doctors.

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We also did not see any difference in complications between the two groups. This means that cell salvage can be seen as generally safe.

The one thing we did see was a difference in a phenomenon called **fetomaternal haemorrhage.** This is when a woman with a Rhesus-negative blood group has a baby with a Rhesus-positive blood group, and some of the baby's blood enters the mother's bloodstream. If this happens, the mother's immune system can create antibodies – which can then become a problem in a *future* pregnancy.

In the SALVO study, we saw that 21 Rhesus-negative women in the cell salvage group were exposed to fetal blood cells – compared to 9 women in the standard care group. This difference is too large to be down to chance.

However, we were only able to analyse a small proportion of cases, due to the way the data was collected. We also don't know whether women who have fetal blood cells detected necessarily go on to create antibodies. We do think it would be worth doing further research in this group of women.

Want to find out more? E-mail <u>salvo@qmul.ac.uk</u>.

Want to read the full report? Go to: www.journalslibrary.nihr.ac.uk/programmes/hta/105732#

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