Perioperative blood salvage during surgical correction of craniosynostosis in infants

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Surgical correction of craniosynostosis in infants is a very haemorrhagic procedure. The aim of this study was to determine whether the perioperative use of the continuous autotransfusion system (CATS) would reduce homologous transfusion during repair of craniosynostosis. Two groups of patients were studied according to the availability of the CATS in our hospital. The control group had surgery before the system was introduced and the study group had operations subsequently. Use of CATS was associated with a significant decrease in the median (95% confidence interval) volume of homologous blood transfused [413 (250–540) ml in the control group versus 317 (150–410) ml in the CATS group, P=0.02] and in the median (95% confidence interval) number of packed red cell units transfused [2 (1–2) in the control group versus 1 (1–2) in the CATS group, P=0.04] in the perioperative period. Use of CATS is associated with a reduction in homologous transfusion during the surgical correction of craniosynostosis in infants.


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Craniosynostosis is a relatively common disorder, related to premature closure of skull sutures, with an estimated incidence of one per 2000 live births.1–2 Early surgical correction is mandatory, otherwise the deformation of the skull which occurs during rapid growth of the brain in infancy may lead to increased intracranial pressure in children older than 1 yr, particularly if multiple sutures are involved.3 Surgery is aimed at restoring normal anatomy at an early age to achieve the best cosmetic result and to avoid possible cerebral consequences.2,4 Procedures for correction of craniosynostosis are performed in young infants with a small blood volume yet represent major surgery with extensive blood loss.5–7

The risks associated with homologous blood transfusion (HBT) are well known.8 They are particularly relevant in haemorrhagic surgery and have lead to the development of methods for reducing HBT,9 including perioperative autotransfusion and blood salvaging. Perioperative autotransfusion of washed red blood cells is an established method to reduce perioperative transfusion requirements.10 The technique was limited until recently to adults because the processing of less than 300 ml of salvaged blood was considered a contraindication to intraoperative autotransfusion.11 The centrifugation bowls used by such devices were too large compared with the small blood volume of children. This has led to the introduction of new autotransfusion devices12–14 with smaller bowls that can support a smaller blood volume. A new generation of autotransfusion devices (CATS, Fresenius AG, Bad Homburg, Germany), based on the technology of cell separators is also available. The CATS, introduced recently in our hospital, has a washing chamber in the shape of a double spiral, with a capacity of 30 ml, which processes shed blood continuously.15–16

We performed a retrospective, case-controlled study to ascertain the efficiency of perioperative autotransfusion using the CATS in infants scheduled for surgical correction of craniosynostosis. The hypothesis of this study was that the use of the CATS was associated with a reduction in the amount of homologous blood transfused.

Patients and methods
From September 1997 to April 1999, 120 surgical procedures were performed on children for the correction of craniosynostosis in our hospital. During this period, the CATS was introduced into service and subsequently used...
routinely. Exclusion criteria for the study included the use of a postoperative closed-wound drainage autotransfusion system and incomplete data. Two groups of patients were compared. The study group (CATS) included patients who received perioperative autotransfusion using the CATS, and the control group (CONT) included the patients who did not, because they were operated on before the CATS was available.

**Intraoperative management**

All the procedures were performed by the same paediatric neurosurgeon under general anaesthesia without induced hypotension, after skull infiltration with epinephrine 1:200 000 in normal saline. After premedication with oral potassium clorazepate 0.5 mg kg⁻¹, general anaesthesia was induced with 8% sevoflurane and 50% nitrous oxide in oxygen, followed by sufentanil 0.5 μg kg⁻¹ i.v. Neuromuscular block was achieved with vecuronium 0.1 mg kg⁻¹. After orotracheal intubation, general anaesthesia was maintained using a continuous infusion of sufentanil (0.5 μg kg⁻¹ h⁻¹) and controlled ventilation with 1–1.5 MAC sevoflurane and 50% nitrous oxide in oxygen. Monitoring included continuous ECG, invasive arterial and central venous pressures (CVP), core temperature, pulse oximetry, end-tidal carbon dioxide concentration and urine output (vesical catheter) measurements. Intraoperative management was as previously described. Briefly, isovolaemic compensation of blood loss was strictly observed, with fluid replacement based on haemodynamic variables (to maintain mean arterial pressure in the range 45–55 mm Hg and CVP above 2 mm Hg) using colloid and blood transfusion. Transfusion of packed red blood cells, or of salvaged blood when available, was used to maintain an haematocrit (Hct) in the range 0.28–0.35. Fresh frozen plasma was used only in patients requiring transfusion of more than 70% of estimated blood volume.

**Postoperative management**

At the end of the surgical procedure, all the patients were admitted to the post-anesthesia care unit (PACU) for ~20 h. The CATS blood saver device was used to salvage the blood during the surgical procedure and for the first 6 h in the PACU.

**Measurements**

Preoperative blood samples were drawn for measurement of red blood cell and platelet count (PC), haemoglobin concentration (Hb), Hct, and coagulation screening, including prothrombin time (PT) and activated partial thrombin time (aPTT). Serial blood samples were obtained for measurement of blood-gas tensions and Hct at the beginning of the surgical procedure, at least every 30 min during the operation and as frequently as clinically indicated during the perioperative stay in PACU.

For the two groups the following data were collected: the type of craniosynostosis (Table 1); physical characteristics of the patients (age and body weight at the time of surgery); preoperative clotting status (PT, aPTT, PC); and preoperative Hct (pre Hct), Hct at admission and Hct at discharge from the PACU. In addition, blood loss, the volumes of colloid and crystalloid infused, the volume of homologous and autologous blood transfused, and the number of packed red cell units used were recorded for the intraoperative period, the postoperative period and for the total duration of the study (intra- and postoperative periods).

**Estimation of blood loss**

In an attempt to simplify estimation of blood loss, all estimated volumes referred to red cell volumes (see Appendix). Estimated blood volume (EBV) and red cell volume (ERV) were calculated before surgery. On the basis of a packed red blood cell Hct of 0.75 and a salvaged blood Hct of 0.65, the following variables were calculated for the intraoperative, postoperative, and total period of the study: (i) estimated homologous red cell volume transfused (ERCVth); (ii) estimated autologous red cell volume transfused (ERTCa); (iii) estimated red cell transfusion (ERT); (iv) estimated red cell deficit (ERCD); (v) estimated red cell loss (ERCL); and (vi) the percentage of the patient’s ERV lost (ERV/ERCV). All these variables (except for ERCV) were calculated for the intraoperative, postoperative and perioperative periods of the study.

**Statistical analysis**

The primary endpoint for assessing the efficiency of the CATS was the comparison of intraoperative, postoperative
and perioperative volumes of homologous blood transfusion and the number of homologous packed red blood cell units transfused. The other variables used to ensure a comparability between the two groups were the physical characteristics and factors influencing perioperative bleeding and transfusion.

Data are expressed as mean (SD) in case of normal distribution, or as median (95% confidence interval) in case of non-normal distribution, or as number of cases (%). Statistical analysis used the unpaired Student’s t-test in cases of normal distribution and the Mann–Whitney U-test in cases of non-normal distribution for continuous variables, while the Fisher’s exact test was used for discrete variables. All P values were two-tailed, and a P value of less than 0.05 was required to reject the null hypothesis. Statistical analysis was performed using NCSS 6.0 software (BMDP Company, Los Angeles, CA, USA).

Results

There were 21 patients in the CONT group and 20 patients in the CATS group. All were physical ASA status I or II. There was no difference between groups with regard to physical data, the Hct in the preoperative period, Hct on admission to the PACU and discharge from the PACU, the ERCV or the clotting status (Tables 1 and 2). The volumes of crystalloid and colloid infused were not different between the two groups during the three periods studied, nor were the ERCD, ERCL and ERCL/ERCV (Tables 2 and 3).

We found a reduction in the volume of homologous blood transfused in the CATS group in the postoperative and perioperative period, but not in the intraoperative period. There was also a significant reduction in the number of packed red blood cells units transfused during the perioperative period in the CATS group (Table 4).

Discussion

The results of this study suggest that the use of the CATS autotransfusion device may significantly reduce, but is not able to avoid, homologous blood transfusion during the surgical correction of craniosynostosis in infants.

The surgical correction of craniosynostosis is usually performed in children under 6 months with a small blood volume. Relatively small blood losses can therefore have significant clinical consequences. A review of the literature shows that blood losses vary from 20% EBV to as high as 500% EBV. 17–19 The majority of studies report losses between 50 and 100% EBV. 5.6 20–22 Transfusion rates of homologous blood parallel the amount of blood loss. Thus,

| Table 2 | Volumes of crystalloid and colloid infused, and hematocrit (Hct) in the post-anaesthesia care unit (PACU) in the control group (CONT) and in the study group (CATS). Data shown are median (95% confidence interval). The results presented for the perioperative period are the median values (95% confidence interval) of the data obtained during the intraoperative and postoperative periods. There was no significant difference between the two groups. |
|---------------------------------|-----------------|-----------------|-----------------|
|                                | Crystalloid     | Colloid         | Hct in PACU     |
|                                | infused (ml)    | infused (ml)    | on arrival (%)  |
|                                |                 |                 | at discharge (%)|
| Intraoperative period          |                 |                 |                 |
| CONT group                     | 120 (70–210)    | 150 (100–250)   | 37 (31–39)      |
| CATS group                     | 140 (85–160)    | 190 (150–300)   | 36 (34–38)      |
| Postoperative period           |                 |                 |                 |
| CONT group                     | 675 (630–840)   | 50 (0–100)      | 37 (30–41)      |
| CATS group                     | 660 (550–800)   | 0 (0–100)       | 35 (32–37)      |
| Perioperative period           |                 |                 |                 |
| CONT group                     | 960 (720–1055)  | 250 (180–400)   |                 |
| CATS group                     | 770 (680–940)   | 250 (150–350)   |                 |

| Table 3 | Blood loss during the three periods studied in the control group (CONT) and in the study group (CATS). Data shown are median (95% confidence interval). The results presented for the perioperative period are the median values (95% confidence interval) of the data obtained during the intraoperative and postoperative periods. ERCT, estimated red cell transfused; ERCD, estimated red cell deficit; ERCV, estimated red cell volume; ERCL, estimated red cell lost; % of patient’s ERCV lost, ERCL/ERCV. There was no significant difference between the two groups. *A negative value indicates an overcompensation of blood loss |
|-----------------|-----------------|-----------------|-----------------|
|                  | ERCT (ml)       | ERCD (ml)       | ERCL (ml)       | ERCL/ERCV (%) |
| Intraoperative period |                 |                 |                 |                |
| CONT group       | 181 (116–287)   | –1 (–10 to 11)* | 176 (117–318)   | 84 (55–114)    |
| CATS group       | 210 (112–300)   | –3 (–14 to 15)* | 217 (134–337)   | 99 (45–143)    |
| Postoperative period |                 |                 |                 |                |
| CONT group       | 165 (90–187)    | –3 (–12 to 9)*  | 159 (87–187)    | 78 (36–89)     |
| CATS group       | 91 (59–162)     | –4 (–10 to 14)* | 86 (48–177)     | 43 (17–70)     |
| Perioperative period |                 |                 |                 |                |
| CONT group       | 323 (187–405)   | 2 (–9 to 5)     | 324 (174–417)   | 127 (78–173)   |
| CATS group       | 325 (213–478)   | 0 (–6 to 8)     | 342 (214–458)   | 120 (63–217)   |

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the blood losses observed in the present study are comparable to those that we have reported previously and are also in the range reported by the majority of authors. The introduction of CATS for blood salvage is considered a major advance in HBT reduction. This device can support, through its centrifugation bowl of 30 ml, very small volumes of blood loss. In addition, it can continuously treat blood loss, which minimizes the time required for obtaining autologous packed red cells ready for transfusion. Moreover, this device has been shown, in a recent experimental study comparing three autotransfusion devices (CATS, Haemonetics Cell Saver 5 and DIDEKO Compact-A & Advanced), to be the autotransfusion device most adaptable to paediatric use. In fact, continuous operation of the CATS guarantees a Hct level > 60%, independent of the amount of shed blood to be processed, with a recovery rate near 100% of the processed blood.

We were not able to show a reduction in HBT during the intraoperative period. This may be related to the low EBV of infants and the sudden intraoperative blood loss that cannot be salvaged by the device, due to an inevitable delay in use. The small volumes of autologous blood transfused in the intraoperative period (Table 4) support this assumption. This finding is in contrast to the results of Jimenez and Barone. Surprisingly, these authors showed efficient blood salvage for the majority of their patients during the intraoperative period using the Haemonetics Cell Saver III (centrifugation bowl of 125 ml) with a relatively low blood loss. However, the results of this study have been the subject of controversy. On the other hand, the results of our study, regarding the efficiency of the blood salvaging technique, are in accordance with the results of others. It should be noted that except for the study by Jimenez and Barone which focused on paediatric neurosurgery, the other studies were orthopaedic, in particular scoliosis surgery. In this particular type of surgery the patients are usually older and have a higher blood volume which can be more easily maintained by intraoperative autotransfusion.

The transfusion risks associated with allogenic blood are well known. Transfusion-related morbidity includes haemolysis, transfusion-related acute lung injury, bacterial contamination, post-transfusion hepatitis, graft versus host disease, haemolytic transfusion reactions, allergic reactions, leucocyte-platelet allo-immunization, acquired immunodeficiency syndrome and complications associated with massive transfusion. The residual risk (per million donations) of viral transmission by seroconverting donors has been estimated to range from 1.56 for HTLV to 15.83 for HBV. Serious or fatal transfusion-transmitted disease will occur in three out of 10 000 single-unit transfusions given. Attempts to decrease these rates have resulted in the development of many techniques, including intraoperative blood salvage.

Our finding leads us to assume that reduction in the volume of homologous blood transfused could reduce the risk of viral transmission. However, more studies are needed to confirm such an hypothesis. There are, however, risks of perioperative blood salvage. Some reports have described complications related to the use of this device, such as transfusion of haemolysed blood, acute haemolytic reactions related to inadvertently giving autologous packed red cells to the wrong patients, and bacterial contamination. The epidemiology of these complications is unknown: more studies on the safety of blood salvaging methods should be undertaken before confirming their safety.

The economic issues of blood transfusion are also of interest. Autologous blood donation has been proven to be more cost effective than homologous blood transfusion, due to the relatively low price of the blood salvage kit and the potential reduction of complications related to homologous blood transfusion. But, some studies have found no cost effectiveness of intraoperative blood salvage, although these have considered only the intraoperative period and the costs of long-term complications. Autotransfusion therapy may be more attractive if used both during the intraoperative and postoperative periods. In our study, autotransfusion was associated with a reduction of homologous blood transfused in the postoperative but not the intraoperative period.

Interpretation of the results must take into account the major limitations of this study, namely that it was retrospective and non-randomized. However, there was no significant difference between the two groups regarding the

<table>
<thead>
<tr>
<th></th>
<th>Homologous transfusion (ml)</th>
<th>Autologous transfusion (ml)</th>
<th>Units of packed red cells (n)</th>
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<tbody>
<tr>
<td><strong>Intraoperative</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CONT group</td>
<td>242 (155–383)</td>
<td>0</td>
<td>1 (1–2)</td>
</tr>
<tr>
<td>CATS group</td>
<td>289 (140–400)</td>
<td>52 (0–145)</td>
<td>1 (1–2)</td>
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<td><strong>Postoperative</strong></td>
<td></td>
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</tr>
<tr>
<td>CONT group</td>
<td>150 (0–230)**</td>
<td>0</td>
<td>1 (1–2)</td>
</tr>
<tr>
<td>CATS group</td>
<td>0 (0–95)</td>
<td>112 (40–160)</td>
<td>1 (0–1)</td>
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<tr>
<td><strong>Perioperative</strong></td>
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</tr>
<tr>
<td>CONT group</td>
<td>413 (250–540)**</td>
<td>0</td>
<td>2 (1–2)†</td>
</tr>
<tr>
<td>CATS group</td>
<td>317 (150–410)</td>
<td>137 (50–195)</td>
<td>1 (1–2)</td>
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preoperative data (Table 1) or the factors affecting blood loss and transfusion (Tables 3 and 4). Equally, Hct in the preoperative period, on admission to the PACU and at discharge from the PACU, the clotting status, and volumes of colloid and crystalloid infused were not significantly different between the two groups. There was also no difference in blood loss between groups (Table 3). Moreover, the study was performed over a relatively short period of time (20 months) and all the patients were operated on by the same paediatric neurosurgeon, using the same surgical procedures. It is therefore unlikely that there is a methodological bias related to the study design.

In summary, we conclude that there is strong evidence for the efficiency of blood salvage in surgical correction of craniosynostosis when used intraoperatively and for the first 6 h in the PACU.

Appendix

In an attempt to simplify estimation of blood loss, all estimated volumes referred to red cell volumes.
Estimated blood volume (EBV)=80 ml kg⁻¹.
Estimated red cell volume (ERCV)=EBV × pre Hct.
Estimated homologous red cell volume transfused (ERCTh)=0.75 × volume of homologous packed red cells.
Estimated autologous red cell volume transfused (ERCTa)=0.65 × volume of autologous salvaged blood.
Estimated red cell transfused (ERCT)=ERCTh + ERCTa.
Estimated red cell deficit (ERCD)=ERCV × difference in Hct.
Estimated red cell lost (ERCL)=ERCD + ERCT.
Percentage of patient’s ERCV lost=ERCL/ERCV.

References

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