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ORIGINAL PAPER

Calvarial remodelling for sagittal synostosis: does fibrin glue (Tisseel™) reduce post-operative blood transfusion requirements?

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Abstract
Introduction Calvarial remodelling for sagittal synostosis is extensive surgery and is associated with potential risks; the most significant of these is blood loss.
Materials and methods We studied 16 patients undergoing calvarial remodelling by the same surgical team over a 12-month period to determine whether scalp closure with fibrin glue (Tisseel™) could decrease post-operative bleeding and the need for blood transfusion. In the last 5 months of the period studied, fibrin glue (Tisseel™) was used and six out of the 16 patients had their wound closure assisted by this means. Data was prospectively collected on age at surgery, the estimated peri-operative blood loss, the volume of blood transfused intra-operatively, the volume drained in the first 8 h post-operatively, the total post-operative drainage and the volume of any post-operative blood transfusion required.
Results and discussion The two groups were comparable with a similar mean age at surgery, estimated peri-operative blood loss and intra-operative blood transfusion requirements. The volume drained in the first 8 h post-operatively was 172 ml in the treated group compared to 246 ml in the untreated group ($p<0.02$) and the total post-operative drain volume was 301 ml compared to 441 ml ($p<0.01$). None out of the six patients treated with fibrin glue required post-operative transfusion compared to two out of ten in the untreated group. The use of fibrin glue has enabled us to reduce post-operative bleeding and the need for post-operative blood transfusion.

Keywords Blood conservation · Fibrin glue · Calvarial remodelling · Sagittal synostosis · Craniosynostosis · Craniofacial surgery

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Introduction

Sagittal synostosis is the most common form of craniosynostois with an incidence of one in 4,000 live births [1]. It has been our practice to treat sagittal synostosis by total calvarial remodelling since 2003 [2]. During this period, we have performed approximately 100 procedures. Surgery is performed early, ideally before 6 months of age to provide the best possible cosmetic appearance and prevent the risk of raised intracranial pressure [3]. Calvarial remodelling is extensive surgery performed on young children and, as with all surgery for craniosynostosis, is associated with potential risks. The most significant of these is blood loss [4, 5]. Many techniques and surgical refinements have been described to conserve blood loss including the use of pre-operative recombinant erythropoietin, peri-operative autologous blood transfusion and post-operative re-infusion of drained blood [6–8].

The use of fibrin glue in craniofacial surgery was first described in 1990 [9]. Since then, it has been used to aid the repair of dural defects, skull base fractures and calvarial bone gaps [10–12]. Fibrin glue has been used extensively in other surgery fields, such as liver resection and upper

gastro-intestinal tract endoscopy as a mechanism of controlling blood loss and improving haemostasis [13, 14]. To reduce the post-operative bleeding in our patients undergoing calvarial remodelling for sagittal synostosis, we introduced the use of fibrin glue (Tisseel™) as an aid to scalp closure. Using the post-operative drainage volume, post-operative drop in haemoglobin levels and the need for further blood transfusion as outcome measures we compared these patients with previous patients with whom fibrin glue had not been used.

Materials and methods

A prospective study was undertaken of all patients treated surgically by calvarial remodelling, over a 1-year period from October 2007 to September 2008 by the same surgical team. We excluded patients who were undergoing surgery by other surgeons, had calvarial remodelling for conditions other than single suture sagittal synostosis (such as pan-synostosis) or had a documented dural tear during surgery as this increases the post-operative drain volume. The use of fibrin glue was introduced from April 2008 onwards. The following data set was collected: the age at surgery, the estimated peri-operative blood loss, the volume of blood transfused during surgery, the post-operative drain volume (divided into the first 8 h, drainage after the first 8 h and total drainage) and whether blood was transfused post-operatively.

The following patient pathway was followed. The procedure was carried out through a bi-coronal zig-zag incision with separate subgaleal and pericranial flaps. Calvarial remodelling was performed using a technique similar to those described elsewhere [15, 16]. We favour an extensive remodelling with anterior and posterior barrel staving, resection of the pteryon and double barrel stave osteotomies of the elevated lateral bone panels. This is associated with a higher blood loss than other techniques such as strip craniectomy. Five millilitres of Tisseel™ (Baxter Healthcare, Newbury, UK) was used during closure. Half of the Tisseel was used to cover the exposed calvarium and dura, the remodelled bone was then replaced and periosteal flaps were closed with polyglactin sutures. A single-size 12-gauge gravity drain was placed and the remaining 2.5 ml of Tissel were sprayed over the pericranial flaps and the under surface of the subgaleal scalp flap. The incision was closed with polyglactin sutures. A post-operative haemoglobin level measurement was performed on the morning of the first and second day after surgery. The surgical drain was removed on the morning of the second post-operative day. Patients were transfused post-operatively, according to a fixed protocol, if they had a haemoglobin of <8.0 g/dl or were symptomatically hypovolaemic and not responding to a crystalloid bolus.

Statistical analysis was performed using an unpaired *t*-test with Microsoft Excel 2003; significance was originally taken at $p<0.05$ and corrected to $p<0.0125$ using Bonferroni's method ($n=4$: age, peri-operative blood loss, the volume of blood transfused during surgery and the post-operative drain volume).

Results

Sixteen patients who underwent calvarial remodelling during the study period met the inclusion criteria. Six of these had their wound closure assisted by the use fibrin glue. The results are summarised in Table 1. There was no significant difference between the mean age of the two groups ($p=0.15$), the estimated peri-operative blood loss ($p=0.44$) and intra-operative transfusion requirements ($p=0.56$). There were no episodes of wound breakdown, infection or other complications in either group of patients.

There was a significant difference in the total post-operative drain volume between the two groups of patients ($p=0.01$), this was accounted for mainly by the difference in drain volume in the first 8 h after surgery ($p=0.02$) rather than the volume drained after the first 8 h ($p=0.06$). Two of

Table 1 Comparison of blood loss, drain volume and transfusion requirements in patients undergoing calvarial remodelling with or without the use of fibrin glue to aid scalp closure

	Fibrin glue ($n=6$)	No fibrin glue ($n=10$)
Mean age in months	11 (range 8 to 18)	8 (range 4 to 14)
Mean peri-operative estimated % total blood volume lost	87% (62%–156%)	102% (66–186%)
Mean volume intra-operative blood transfusion (ml)	349 (200–590)	307 (200–660)
Mean post-operative drain volume in first 8 h (ml)	172 (110–250)	246 (180–325)
Mean post-operative drain volume after first 8 h (ml)	129 (50–200)	195 (110–280)
Mean total post-operative drain volume (ml)	301* (200–425)	441 (300–600)
Number of patients requiring post-operative blood transfusion	0	2

*$p<0.0125$

the patients with whom fibrin glue was not used required further post-operative blood transfusions, whereas none of the patients with whom fibrin glue was used required additional transfusion.

Discussion

Calvarial remodelling for sagittal synostosis can lead to substantial blood loss and clinicians have a responsibility to minimise this during a patients' treatment. Fibrin glue has been proposed as a good haemostatic agent in several different surgical fields [17] and following its introduction into our craniofacial practice we measured its effect using post-operative transfusion as our main outcome criteria.

For this study to be of value, the group of patients treated with fibrin glue had to be comparable to the untreated group. This prospective study consisted of two consecutive series of patients, the first of ten patients and the second of six patients over a 12-month period. There was no element of randomisation between the two groups. We only included those patients with non-syndromic single suture sagittal synostosis. The mean ages were similar, as it has been shown that a younger age at operation is a predictor of increased blood loss during craniofacial surgery [5], this is confirmed by the similar peri-operative total estimated blood volume lost. It is also accepted that having a consistent team of the same surgeons and other operating theatre staff prevents unnecessary blood loss [4].

Our two key findings were that post-operative drainage was decreased, particularly in the first 8 h after surgery and that there was no requirement for further post-operative blood transfusion in the group treated with Tisseel™. The decrease in post-operative drainage was a statistical significant objective finding; however, the decreased requirement for transfusion can only be regarded as an observation due to the limited numbers studied. We propose that this is due to two separate mechanisms of action. Firstly, the fibrin glue seals off any capillary bleeding from the dura and the cut bone edges. In addition, it also closes a potential dead space between the calvarial bone and the scalp flap into which blood might collect post-operatively. In addition to this, the haematocrit of the drain fluid during the first 8 h is higher than in the following period, hence, red cell mass is conserved.

We accept that even though we have encouraging results, this is a relatively small study and to obtain a higher level of evidence for the use of fibrin glue during calvarial remodelling for sagittal synostosis a formal prospective randomised trial would need to be performed with a greater number of patients, rather than the consecutive series presented in this paper. However, in our practice, the use of fibrin glue has enabled us to reduce our post-operative blood transfusion requirements and is a useful adjuvant to craniofacial surgery without any complications related to its use.

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