Albumin-impregnated Polyester Vascular Prosthesis for Abdominal Aortic Surgery: An Improvement?


Department of Cardio-Vascular Surgery and Department of Clinical Immunology, Les Hôpitaux Universitaires de Strasbourg, Strasbourg, France

Aim: To compare the peroperative blood loss and the postoperative systemic inflammatory reaction in patients receiving either a Vasculour II Albumin pre-impregnated prosthesis (VA group, n = 32) or a preclotted Vasculour II prosthesis (V group, n = 33) for elective surgery of the abdominal aorta.

Setting: University Hospital.

Design: Prospective, randomised study.

Methods: Peroperative blood loss was measured over two different periods: Phase I from the beginning of the operation to the completion of the proximal anastomosis, when blood loss cannot be related to the model of prosthesis implanted and phase II after the completion of the proximal anastomosis to the end of the operation. Postoperative blood loss was evaluated by the determination of the retroperitoneal drainage volume over a period of 2 days immediately following the operation. The presence of periprosthetic fluid was measured with echography at days 4, 9, 30 and 60. The postoperative systemic inflammatory reaction was evaluated by measuring the sedimentation rate and the C reactive protein levels daily from day 1 to day 9, and at days 14, 21, 28, 45, and 60, and by measuring the body temperature daily from day 1 to day 9.

Results: No significant differences of peroperative blood loss were observed. The same proportion of patients (35%) in both groups received homologous transfusion. The mean number of units of homologous blood transfused per patient was respectively 0.77 and 0.91 for the VA and the V group. The retroperitoneal drainage volume and the percentage of patients with periprosthetic fluid did not differ significantly. No significant differences in systemic postoperative inflammatory reaction were observed.

Conclusion: There were no benefits in using albumin-impregnated prosthesis as opposed to preclotted prosthesis in terms of peroperative and postoperative blood loss, or by looking at the incidence of homologous blood transfusion. However, the glutaraldehyde cross-linked albumin did not induce any systemic inflammatory reaction.

Key Words: Blood vessel prosthesis; Polyester; Albumin-impregnated; Abdominal aortic surgery; Blood loss; Inflammatory reaction; Randomised controlled trial.

Introduction

Polyester vascular prostheses were designed with a porous textile structure in order to promote infiltration and anchorage by the surrounding tissue after implantation. However, high porosity could be responsible for blood loss through the prosthetic wall after releasing the clamps. Preclotting of the prosthesis is usually with the patient’s blood before systemic injection of heparin. An alternative procedure consists in impregnating and/or coating the prosthesis with a bioerodible matrix at the time of the manufacturing process. This concept was first introduced in the early sixties, and has been commercially available since the early eighties, using albumin, gelatin, or collagen. Impregnated prosthesis have become popular. The main reasons for their use are the reduction of intraoperative blood loss and consequently reduction of homologous transfusions, and the reduction of infection rate by limiting surgical handling during the preclotting stage. However, these theoretical advantages have never been firmly demonstrated. Moreover there may drawbacks such as systemic inflammatory or immunological reactions related to the sealant.

In a previous retrospective clinical study, we demonstrated good clinical results when an albumin-impregnated polyester prosthesis was used for the surgery of the abdominal aorta. The aim of this study was...
randomised clinical study was to compare an albumin-impregnated vascular prosthesis with its preclotted skeleton in order to address two questions:

1) Does the implantation of an impervious albumin-impregnated prosthesis reduce the amount of perioperative blood loss, and consequently the amount of homologous blood transfused, during elective aortoiliac surgery?

2) Does the implantation of glutaraldehyde cross-linked albumin impregnated prosthesis cause a systemic inflammatory reaction?

**Materials and Methods**

**Patients**

This study was conducted from February 1992 to April 1993 in 65 patients. The criteria for inclusion of patients in the study was reconstructive surgery for abdominal aortic aneurysm (AAA) or aortoiliac occlusive disease (AIOD) with an aortoarterial, aortobiliac or aortobifemoral graft. Criteria for exclusion were: reoperation after previous reconstructive surgery of the abdominal aorta, associated renal superior mesenteric artery, or popliteal revascularisation, emergency surgery, known immunological or allergic disease, or coagulopathy. Oral informed consent was obtained from each patient. The patients were randomised at the time of the operation to receive either a preclotted DeBakey Vasculour II prosthesis (Bard USCI, Billerica, MA, U.S.A.) or a De Bakey Vasculour II Albumin (human albumin impregnated) prosthesis, using a random table.

Preoperative biological evaluation included determination of hemoglobin level, red blood cell, leukocyte, and platelet counts, sedimentation rate (SR), and C-reactive-protein (CRP). A prothrombotic state which could be responsible for early postoperative graft thrombosis was ruled out by evaluating the S protein, C protein and antithrombin III levels.

**Surgery**

The operations were conducted via a transperitoneal approach. Precollating of the non-impregnated prostheses was performed using 30–40 ml of non-heparinised aortic blood, following a two-step method as previously described. Before arterial clamping, systemic anticoagulation was performed by injection of heparin (1.5 mg/kg). The prostheses were implanted using polypropylene monofilament 4/0 running suture for aortic or iliac anastomoses and 6/0 running suture for femoral anastomoses. After completion of the anastomoses and release of the clamps, heparin was reversed by protamine sulphate. The prosthesis was then covered by the aortic wall of the aneurysm or the retroperitoneal tissues. Redon suction drains (Charriere 9) were placed along the prosthesis, and were taken out at the second postoperative day. Antibiotic prophylaxis was given as systemic intravenous injection of 1.5 g of cefamandol at the time of the operation, followed by four injections of 0.750 g during the first postoperative day.

An intraoperative autotransfusion system (Cell Saver 4, Haemonetics, Braintree, MA, U.S.A.) was systematically used. Blood collected in the reservoir was washed and centrifuged only when the volume exceeded 500 ml. Washed blood cells were then rein fused in the patient during or after the operation. Criteria for per and postoperative homologous transfusion were haemoglobin levels lower than 8 g/100 ml or hematocrit fractions lower than 25%. These thresholds were increased respectively to 10 g/100 ml and 30% when patients suffered significant coronary disease demonstrated at the preoperative coronary angiography performed in case of clinical angina or signs of ischaemia or myocardial infarction at the electrocardiogram, and poor haemodynamic tolerance.

Uneventful postoperative hospitalisation was 9 days. The patients were discharged with coumadin anticoagulant therapy for a 6 week period. Perioperative events within the first month after operation were recorded. We evaluated mortality, morbidity and prosthetic thrombosis and infection. Delayed complications were recorded over 2 months.

**Blood loss**

Blood lost during the operation was continuously collected by the suction tip. The use of sponges was limited to a minimum, and blood collected in sponges was gently squeezed and aspirated by the suction tip. In order to distinguish between prosthesis-related and unrelated blood loss, the collected volume was evaluated over two different phases of the operation:

**Phase I** extended from the abdominal wall incision to the completion of the proximal anastomosis, immediately before releasing the clamps. This phase included the blood lost during the exposure and the control of the vessel segments for anastomoses, and the blood leaking from the clamped vessel and/or from the lumbar arteries.
Phase II extended from the release of the proximal clamps to the completion of the operation. This phase included the blood lost at the level of the anastomoses and through the prosthetic wall after clamp release, and when applicable, the blood taken for the preclotting of the non-impregnated prostheses.

Total blood loss was defined as the sum of phase I and phase II blood loss. Differences in blood loss attributable to differences between preclotted and impregnated prostheses occur in phase II and not in phase I.

The 2-day postoperative retroperitoneal volume drainage was considered an indirect sign of blood loss and recorded. Delayed periprosthetic blood loss was estimated by echography at days 4, 9, 30, and 60. The echographies were performed using a Duplex colour scan (Ultramark 8, Advanced Technology Laboratories, Seattle, WA, U.S.A.), by an examiner blinded to the type of prosthesis. The presence of periprosthetic fluid was scored as moderate or large. The number of units of homologous red cells transfused during and after the operation were noted.

Systemic inflammatory reaction

Systemic inflammatory reaction was evaluated according to three criteria:

The first was body temperature which was recorded four times daily during the first 2 postoperative days, and then twice daily for the following 7 days. The highest value of each day was noted. The two other criteria used were sedimentation rate and C reactive protein levels which were measured daily for the first 9 postoperative days, and then at days 14, 21, 45, and 60.

Haematological parameters

Red blood cell, leukocyte, and platelet counts, as well as haemoglobin and fibrinogen levels were measured at days 2, 4, 6, and 9 after the operation.

Statistical analysis

Student t-test and non parametric mean comparison test in the case of non-normal distribution or non equal variance of the variables, were performed to analyse the continuous variables. Chi-square test was performed for discontinuous variables. A level of significance of 0.05 was chosen and expressed as p for the Student t-test, and z for the non-parametric test. The results were given as mean ± s.d. The statistical analysis was performed with Statgraphics software (vers. 5.00, 1991, STSC Inc.)

Results

At randomisation, the patients were included in the Vasculour II Albumin group (VA group) \((n = 32)\), or the Vasculour II group (V group) \((n = 33)\). These groups were not statistically different in terms of risk factors, indication for surgery and type of prosthesis implanted (straight vs. bifurcated prostheses) (Table 1).

The mean postoperative duration of the hospitalisation for the Vasculour II Albumin group was \(11.0 \pm 12.0\) days (range: 7–30 days). There was no postoperative death. Morbidity consisted of one emergency reoperation for massive bleeding related to the leakage of the proximal anastomosis 2h after the implantation of an aortobifurcated prosthesis for AAA, one delirium tremens, one reoperation at the seventh postoperative day for a subcutaneous groin haematoma, and one \(in situ\) venous femoropopliteal bypass performed on the eighth postoperative day for critical ischaemia. No thrombosis or infection of the graft occurred. One patient died 45 days after surgery. The death was related to cerebral haemorrhage secondary to anticoagulant therapy. No thrombosis or infection of the graft occurred.

The mean postoperative duration of hospitalisation for the Vasculour II group was \(9.9 \pm 4.3\) days (range: 7–25 days). There was no postoperative death. Morbidity consisted of one respiratory insufficiency with prolonged intubation and respiratory assistance, one

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<th>Table 1. Patients characteristics at randomisation</th>
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urinary tract infection, two delayed cutaneous healing at the groin, two pneumonias, one ascitic decompensation, and one paraplegia following the surgery for AAA. No thrombosis or infection of the graft occurred. No death, and no prosthetic thrombosis or infection of the graft occurred.

**Blood loss**

After releasing the clamps the albumin-impregnated prostheses were found to be blood tight. Blood leakage through the preclotted wall of the Vasculour II prostheses was limited and easily stopped by compression with sponges. No prolonged blood leakage was noted. Surgical handling was found to be similar for both prostheses. The blood loss in each phase for VA and V groups is presented in Fig. 1. No significant difference in blood loss was observed between each group and between procedures for AAA and for AIOD in each group (Fig. 2). *Phase I*: Blood loss was 471.9 ± 396.6 ml for the VA group and 463.3 ± 468.7 ml for V group. *Phase II*: Blood loss was 629.2 ± 675.3 ml for the VA group and 655.9 ± 616.3 ml for the V group. **Total preoperative blood loss**: Blood loss was 1101.1 ± 971.6 ml for VA group and 1119.2 ± 797.1 ml for V group.

The postoperative drainage volume values of two patients were excluded from the study. One patient in the VA group had massive postoperative bleeding because of the leaking of the proximal anastomosis. The second patient was in the V group and had postoperative ascitic decompensation with a drainage volume of ascitic liquid larger than 2000 ml. Excluding these two patients, the mean postoperative drainage volume was 530.7 ± 262.4 ml for the VA group and 452.6 ± 162.9 ml for the V group (ns). The percentage of patients with periprosthetic fluids detected by echography at days 4, 9, 30, and 60 were not significantly different between the two groups. Periprosthetic fluids collections were mainly moderate, and large in two cases (1 case per group). 34.4% of the preclotted prosthesis recipients had homologous transfusion as compared to 36.4% for the albumin-impregnated prostheses recipients. The difference was not significant. Mean units of homologous red cells transfused were 0.72 and 0.91 respectively (Table 2).

**Systemic inflammatory reaction**

Mean body temperature and peaks of temperature higher than 38.5°C were not significantly different between both groups (Fig. 3, Table 3). Sedimentation
Table 2. Homologous red cells units transfused (mean ± S.D.)

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<th>Intraoperative transfusions</th>
<th>Postoperative transfusions</th>
<th>Overall operation transfusions</th>
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<tr>
<td>V group</td>
<td>0.24±0.75</td>
<td>0.66±1.38</td>
<td>0.91±1.51</td>
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<tr>
<td>VA group</td>
<td>0.34±0.90</td>
<td>0.37±0.98</td>
<td>0.72±1.22</td>
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rates were similar for both groups, increasing to reach a plateau by day 3, with values near 50 mm. This plateau lasted until day 14 after which time it gradually decreased back to values of 20 mm by day 60. CRP levels were similar in both groups. CRP increased and peaked at day 3 post-surgery with values of 170 mg/l for the V group and 140 mg/l for the VA group. Preoperative values were re-established after day 21 post-surgery (Fig. 4).
Table 3. Patients with postoperative body temperature peaks higher than 38.5°C

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<tr>
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<th>V group</th>
<th>VA group</th>
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<tr>
<td>0 &lt; day &lt; 5</td>
<td>11</td>
<td>7</td>
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<tr>
<td>4 &lt; day &lt; 10</td>
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Haematological parameters

No significant difference in haemoglobin levels were observed. Preoperative values were between 13 and 14 g/100 ml. They decreased at the second postoperative day to near 10 g/100 ml and remained at this level for at least 7 more days. Leukocyte counts demonstrated fluctuations with time with higher values for the V group than for the VA group. Significant differences were noted at days 0 (z < 0.05) and 6 (z < 0.01). Leukocyte counts increased 2 days after surgery and returned to preoperative levels by 9 days after surgery. No specific reaction could be noted by differential counting in all patients. No significant differences related to platelet count were observed between the VA and the V group. The mean preoperative was 250 000/mm³. The minimal level was attained at day 2, and gradually increased to reach values between 350 000 and 400 000/mm³ by day 9. Post-surgery fibrinogen levels increased in both groups to peak by day 4 and only slightly decreased over the subsequent 5 days. Fibrinogen level was significantly higher at day 6 for the V group than for the VA group (z < 0.05).

Discussion

Since the introduction of polyester vascular prostheses, many improvements have been made to give them long term mechanical stability and optimal tissue encapsulation. The impregnation of the porous textile structure by a bioerodible matrix was first proposed as a way of keeping the wall impervious at the time of the implantation. Different techniques have been used to preclot prostheses for more than twenty years.12-13

Studies on the effect of impregnated polyester vascular prostheses on blood loss during aortic surgery have already been performed. The first studies were retrospective or prospective, but were not randomised.14-17 They concluded that the use of such prosthesis reduced intraoperative blood loss and consequently the amount of homologous blood transfusions. Three previous randomised studies on the effect of impregnation of a polyester prosthesis on intraoperative blood loss have been published.18-20 Harris et al.18 did not demonstrate any differences in intraoperative blood loss when the prosthesis implanted for AIOD surgery was collagen-impregnated (950.3 ± 567.5 ml) or preclotted (933.3 ± 567.5 ml). On the other hand, De Mol van Otterlo et al.19 demonstrated a significant overall difference in intraoperative blood loss between their collagen-impregnated (2425 ml) and preclotted (1907 ml) prosthesis recipients groups. They measured the intraoperative blood loss during three periods of

Fig. 4. Postoperative C reactive protein in procedures with albumin-impregnated and preclotted prostheses. (#: z < 0.05). (●) VA groups; (○) V group.
the operation in order to differentiate between prosthesis and non-prosthesis related blood loss. During their phase III, which characterised blood loss through the interstices of the prosthesis, no significant difference was observed. Becquemin et al.\textsuperscript{20} also failed to demonstrate any difference in intraoperative blood loss with the implantation of either an impregnated or a preclotted prosthesis.

In our randomised study, the operative procedure was divided in two distinct phases in order to differentiate between prosthesis-related and non-prosthesis-related intraoperative blood loss. In our hands, the use of albumin-impregnated prosthesis did not significantly reduce intraoperative blood loss. Distribution of blood loss values during each phase and during the overall operation demonstrated a high variability in both groups. This high variability indicated that intraoperative blood loss is mainly related to factors other than the prosthesis such as surgical difficulties.

The 2 day postoperative periprosthetic drainage, which was considered an indirect estimation of delayed blood leakage through the wall of the prosthesis, showed no significant difference. The evaluation of the presence of prostatic fluid over 2 months after the implantation of the prostheses was undertaken on the basis that blood oozing through the prostatic wall could occur at the time of the fibrinolytic reaction in the case of preclotted prostheses, or during bioresorption of the cross-linked albumin of the impregnated prostheses. There was no significant difference between the proportion of patients with periprosthetic fluids in each group.

On the basis of SR and CRP, we failed to demonstrate any difference in systemic inflammatory reaction between the two prostheses. The Vasculour II Albumin prosthesis is impregnated with glutaraldehyde cross-linked human albumin which could avoid immunological reactions. However, previous experimental studies also found good biocompatibility of immunological reactions. However, previous experimental studies also found good biocompatibility of immunological reactions.

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In conclusion, the use of an albumin-impregnated prosthesis for the reconstruction of the abdominal aorta is safe since no increased inflammatory reaction was observed when compared to a preclotted prosthesis. However, the use of such a prosthesis failed to reduce the intraoperative blood loss and consequently the amount of homologous blood transfused. The albumin-impregnated prosthesis is more convenient when a blood-tight prosthesis is necessary, as for heparinised patients or for ruptured abdominal aneurysms or emergency abdominal aortic surgery.

Acknowledgements

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References


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