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PRINCIPAL INVESTIGATOR: Allan L. Bucknell, M.D. AUTHORS: Michael B. Simpson, M.D. Kevin P. Murphy, M.D. Henry G. Chambers, M.D.

CONTRACTING ORGANIZATION:

Brooke Army Medical Center (HSC) Department of Surgery Fort Sam Houston, TX 78234-6200



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Evaluation of Effect of Postoperative Wound Drainage Reinfusion Using The Solcotrans Orthopaedic Drainage/ Reinfusion System in Reducing the Need for Whole Blood Transfusion (HSC) MIPR No. 90MM0513

Allan L. Bucknell, M.D.; Michael B. Simpson, M.D. Kevin P. Murphy, M.D.; Henry G. Chambers, M.D.

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Brooke Army Medical Center (HSC) Department of Surgery Fort Sam Houston, TX 78234-6200

U.S. Army Medical Research & Development Command Fort Detrick Frederick, Maryland 21702-5012

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A prospective randomized study was conducted using the Solcotrans Orthopaedic Drainage Reinfusion System for postoperative blood salvage in total joint arthroplasty. Twenty four patients comprised the study. The amount of postoperative autologous blood salvage average 946 milliliters. Only twenty-five persent of the study group required postoperative transfusions, compared to eighty-three percent of the study group. In total knee arthroplasties, only 11 percent of the study group required transfusions, compared to seventy-eight of the control group. These differences were significant with P values less than 0.01. There were no transfusions reactions, infectious complications, or coagulopathies.

Postoperative blood salvage is a safe, reliable, and effective source of autologous blood.

Blood Loss; Arthroplasty; Knee; Hip; RAII; Human Subjects

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Introduction

The utilization of autologous blood is highly recommended for patients undergoing total joint arthroplasty. Several techniques are now available to limit the need for homologous transfusions in these patients. These include the preoperative collection of autologous blood, various anesthetic techniques designed to limit blood loss, and intraoperative salvage of autologous blood. Recently, several reports have discussed the role of postoperative blood salvage in total joint arthroplasty. However, these reports have been based on use of automated cell saver devices that require experienced technicians for their operation. This has limited their use to the recovery room setting.

The Solcotrans Orthopaedic Drainage Reinfusion System is a simple closed canister system that allows for the collection, and subsequent reinfusion, of postoperative wound drainage. This system provides a source for fresh autotransfusion in patients who experience substantial postoperative blood loss. The system has been in clinical use by orthopaedists for several years, but to date, there are no reports in the literature regarding the effectiveness of the device.

We conducted a prospective, randomized study in patients undergoing elective total joint arthroplasty to determine the effectiveness of the Solcotrans Orthopaedic Drainage Reinfusion System. We were primarily interested in whether postoperative blood salvage would decrease the need for postoperative blood transfusions in these patients. We monitored closely for any complications resulting from the use of the device.

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Materials and Methods

The patient population was chosen from consecutive patients scheduled to undergo elective primary total joint arthroplasty. Participation in the study was voluntary. Patients were randomly assigned to either the control or study group. All patients were enrolled to the preoperative autologous blood program.

All patients received the same prooperative and postoperative care. The decision whether or not to cement components was made by the senior author without prior knowledge of the patients status in the study. Anesthetic techniques were determined by the attending anesthesiologists who were unaware of the study. Hypotensive anesthesia was not in use at this institution during the study. Patients received identical postoperative prophylaxis for deep venous thromboses (TED compression stockings, preoperative mini-dose heparin, postoperative minidose heparin until postoperative day three, and then low dose aspirin).

Patients enrolled in the study group had a 1/4" Solcotrans drain inserted in the operating room under the deep layer of the wound closure. Once closure was complete, the drain was connected to the collection unit and placed under continuous suction at 20 cm H₂O pressure. Forty milliliters of ACD-A anticoagulant was added to the first collection unit. Collection continued for five and a half hours or until the unit was full. At that time, the amount of drainage was noted. If greater than 350 ml, the drainage was reinfused and a new Solcotrans unit connected. If the drainage was greater than 150 ml but less than 350 ml, the drainage was reinfused but a standard Hemovac closed intermittent suction canister was connected. If the drainage was less than 150 ml, the drainage was not reinfused but collection continued until the attending surgeon elected to pull the drain. This sequence was repeated for each Solcotrans unit placed. For each Solcotrans unit reinfused, an aliquot of blood was obtained and sent for complete blood count and aerobic and anaerobic cultures. Patients in the study group had a Hemovac 1/4" drain inserted in the operating room. Postoperative wound drainage was carefully monitored and recorded for all patients.

For all study and control patients, blood samples were obtained preoperatively, in the recovery room, and on the first second and third postoperative days. These were sent for complete blood counts, prothrombin time, and partial thromboplastin time.

Postoperative transfusions were ordered for any patient whose hemoglobin level was lower than ten grams per deciliter or whose hematocrit was less than thirty. We chose to transfuse based on laboratory values in order to avoid observer bias in ordering transfusions. The decision regarding the need for transfusion for any patient should be made on the entire clinical setting, not merely the laboratory values.

Statistical analysis was performed using the chi-square technique.

Results

Each group consisted of twelve patients. Each group contained nine total knee patients and three total hip patients. The groups were very similar in all respects. There was no significant difference in the preoperative laboratory values of the two groups. The demographics and preoperative laboratory values for each group is depicted in Table 1.

The average intraoperative blood loss was somewhat lower in the study group, twohundred-fifty milliliters compared to three-hundred-sixty milliliters. This difference was not significant, and both groups had similar recovery room hemoglobins and hematocrits. However,

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the study group had a much higher average postoperative blood loss. Thus, the total blood loss was higher in the study group. Coagulation studies remained similar between the two groups. There was no evidence of coagulopathy in any of the patients. This data is depicted in Table 2.

The twelve study patients received a total of twenty-four Solcotrans units, ranging from one to four units per patient. This represented an average postoperative blood salvage of ninehundred-forty-six milliliters. The collection time per unit increased with the increasing number of the unit. The hematocrit of the salvaged blood averaged 34.6 percent. This percent of red cell mass did not decrease as the sequence of the unit increased. All aerobic and anaerobic cultures of the salvaged blood were negative for bacterial growth. See Table 3.

A total of sixteen patients require transfusions during the study. Three of these patients (four total units) were transfused intraoperatively at the discretion of the anesthesiologist. These transfusions were not considered in the remainder of the analysis. Postoperatively, only three of the twelve study patients (25%) required transfusions compared to ten of the control patients (83%). Looking at only patients undergoing total knee arthroplasty, only one patient in the study group (11%) needed a postoperative transfusion, compared with eight of nine (78%) in the control group. These difference were both statistically significant by the chi square method with P values less than 0.01. The study group required a total of six units of blood compared to nineteen units in the control group. This data is seen in Table 4.

Discussion

Numerous authors have reported methods for the utilization of autologous blood in elective total joint arthroplasty, the common goal having been a desire to limit the exposure to

homologous blood products.^{1,2,3,4,6,7,8,9,10} While the use of autologous blood is now standard practice in orthopaedics, the techniques for providing autologous blood are still evolving.

The preoperative collection of autologous blood is a proven means of decreasing the subsequent exposure to homologous blood products.^{2,3,4} This technique is widely available and can be utilized at smaller community hospitals. However, there is the potential for donor morbidity, especially in elderly patients with cardiopulmonary compromise. Goodnough has shown that nearly seventeen percent of orthopaedic patients were unable to donate the amount of autologous blood requested by the attending orthopaedist.⁵ Invariably, some patients will not succeed in donating the amount of autologous blood that they will require.

Intraoperative blood salvage has now emerged as another source of autologous blood for certain orthopaedic procedures. Most studies have shown intraoperative blood salvage to further decrease the need for homologous transfusions.^{6,7,8} This technique requires the use of a sophisticated automated cell saver device. This adds additional expense to the procedure in the form of equipment and technician support. Because of the cost of the equipment, not all hospitals may have the technology available to their patients.

Postoperative blood salvage is still in the developmental stage. Several recent reports have documented the efficacy of postoperative salvage using a cell saver device in the recovery room for the immediate postoperative phase.^{9,10} Again, this method remains expensive, labor intensive and not universally available.

The Solcotrans Orthopaedic Drainage Reinfusion System is closed loop system that allows for the collection of postoperative wound drainage and its subsequent reinfusion. The system id simple to use and requires no special equipment. The wound drainage is filtered through a large volume in-line 260 micron pre-filter before reaching the storage unit. The blood is then reinfused through a 20-40 micron microaggregate filter. Use of the system requires no special training. The system allows for the collection of multiple units depending on the amount of drainage without changing drainage tubes. To date, no clinical studies have been published that determine the efficacy of the Solcotrans in orthopaedic patients.

In this study, patients who underwent postoperative blood salvage with the Solcotrans Orthopaedic Drainage Reinfusion System experienced greater postoperative blood loss compared to the control group. Berman *et al* has shown that continuous suction drains provide greater overall wound drainage than intermittent spring-loaded suction drains.¹¹ This difference was seen despite the fact that continuous suction drains had less serous and serosanguineous drainage. Our results are in agreement with their findings. Despite greater overall blood loss, the hematocrit of the wound drainage obtained under continuous suction was quite constant, allowing for prolonged postoperative blood salvage.

We chose to transfuse all patients for hemoglobins less than ten or hematocrits less than thirty. While we acknowledge that this is an arbitrary cut-off, it did allow for an unbiased determination of transfusion needs. We felt this was necessary in order to determine if the postoperative salvage of blood helped to maintain red cell mass and thereby decrease the need for transfusions. Despite this higher postoperative blood loss, the study group had consistently higher postoperative hemoglobins and hematocrits than the control patients. They also required significantly fewer transfusions than did the control group. We feel that postoperative blood salvage is particularly effective in uncemented total knee arthroplasty, where intraoperative blood loss is minimal, and postoperative blood loss can be significant.

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Conclusions

The Solcotrans Orthopaedic Drainage/Reinfusion System provided a safe, effective means of postoperative blood salvage. Our patients received an average of 946 ml's of salvaged postoperative blood. The hematocrit of the salvaged blood averaged 34.6 percent. Patients receiving postoperative blood salvage required significantly fewer transfusions than the control group. They also had higher postoperative blood losses, which is most likely due to the continuous suction nature of the salvage technique used in the study.

Postoperative blood salvage is an effective means of limiting postoperative transfusions in elective total joint arthroplasty. However, we feel that preoperative collection of autologous blood should be utilized for all patients scheduled for total joint arthroplasty. Effective postoperative salvage may decrease the amount of blood that needs to be procured from patients preoperatively.

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Table 1 Study and Control Group Characteristics

	Study Group	Control Group
Number	12	12
Age Range (years)	53-76	41-76
Average Age (years)	64.7	59.6
Male:Female	5:7	5:7
Procedures	3 Uncemented THA	3 Uncemented THA
	3 Cemented TKA	3 Cemented TKA
	1 Hybrid TKA	3 Hybrid TKA
	5 Uncemented TKA	3 Uncemented TKA
Preoperative Hemoglobin (g/dl)	12.7	12.5
Preoperative Hematocrit (%)	37.5	37.5
Preoperative PT	11.5	11.8
Preoperative PTT	28.2	27.3

Table 1

Patient characteristics for the study and control groups. Hybrid TKA's consisted of a cemented tibial component, an uncemented femoral component, and either a cemented or uncemented patellar component.

Table 2

Average Blood Loss (in ml's) and Laboratory Study Results

	Study Group	Control Group
Operative Blood Loss	250 (50-750)	360 (75-750)
Postoperative Blood Loss	1087 (490-2284)	551 (190-850)
Total Blood Loss	1337	911
Postop Hemoglobin (g/dl)	10.8	10.7
Postop Hematocrit (%)	32.9	31.3
Postop PT	11.8	11.9
Postop PTT	30.4	29.6

Table 2

The average operative and postoperative blood losses in the two patient groups. The postoperative hemoglobin and hematocrits are recovery room values. The postoperative PT and PTT values are based on four postoperative values: recovery room and the first, second, and third postoperative days.

Table 3

Characteristics of Postoperative Blood Salvage Based on Order of Collection

Sequence	First	Second	Third	Fourth
Number	12	7	4	1
Average Volume (ml)	49()	468	426	500
Average Collection Time (Hrs)	3.8	4.5	4.9	5.5
Average Hematocrit (%)	32.7	38.3	32.9	39.2

Table 3

The chart shows the trends encountered during the collection of multiple units for blood salvage. Even with increasing number of postoperative units salvaged, the salvage blood continued to be an effective source of red cell mass as evidenced by the high hematocrits.

Table 4

Incidence of Postoperative Transfusions

	Study (Postop Salvage)	Control (No Salvage)
Number of Patients	12	12
Patients Requiring Transfusions	3	10
Percentage of Group	25%†	83%†
Total Number of Units Transfused	6	10
Number of TKA Patients	9	9
Number of TKA Patients Transfused	1	7
Percentage of TKA Group	11%†	78%†
Total Number of Units Transfused	2	14

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†Statistically significant difference with P < 0.01.

Table 4

Postoperative blood salvage resulted in a significant decrease in the number of patients requiring

postoperative transfusions. These differences were statistically significant.