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Clinical Education Presented By:

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The process of autologous blood transfusion is examined using the Boehringer Laboratories AUTOVAC® Intraoperative Autotransfusion System (Model 7904R). A review of clinical applications on the use of shed whole blood across a spectrum of surgical procedures and actual clinical results obtained with the Boehringer AUTOVAC® system are presented. Whole blood autotransfusion when used in appropriate clinical settings has shown to be an effective method to reduce allogeneic exposure with minimal complications. The Autovac system provides whole blood that is appropriate for vascular and trauma procedures.

Materials and Methods

The autotransfusion system described here is the Boehringer Laboratories' AUTOVAC® Intraoperative 7904R. The 7904R has a built-in precision regulator that allows the unit to be attached directly to line vacuum while providing safe, regulated vacuum levels to the surgical field. The 7904R includes a standard Yankauer wand and six feet of suction tubing for blood collection. Each unit can collect up to one liter of whole blood for reinfusion.

In the operating room, suction is available through wall outlets supplied by a central hospital vacuum system. An optimum setup includes a wall outlet meeting NFPA code and unrestricted vacuum line to the 7904R.

The device is setup in the OR using sterile technique. Citrate anticoagulant is aspirated into the device per manufacturer's directions. Ten (10) collections were performed in a clinical setting and samples were extracted for laboratory hematological evaluation.

Results

Ten (10) collections were performed in a clinical setting and laboratory evaluations were performed on the collected blood product. Results are summarized in Table 1. Hematological values are typical of a salvaged blood product indicating mild dilution and some cell lysis. The collected blood was adequately anti-coagulated. Positive blood cultures were detected and are typical of airborne pathogens. Clinical staff found the system simple to assimilate and surgeons readily distinguished between waste suction and suction for salvage.

Discussion

Two basic types of systems are currently available for intraoperative autotransfusion: cell processing systems and whole blood devices. Cell processing systems filter the collected blood and then utilize centrifugation to separate the red blood cells from the other constituents of blood. Whole blood systems collect and filter the blood and then return the blood to the patient, usually in the operating room. The two types of systems are both being used effectively. There are advantages and disadvantages to both types of systems and therefore, they are suited for different clinical applications.

Cell Processing

Presently, many surgeons utilize autotransfusion with a cell processing step (23). Cell processing systems utilize vacuum to aspirate blood from the surgical site to a cardiotomy reservoir. The blood is mixed with heparin or citrate during collection to prevent coagulation. The anticoagulated blood is then mixed with saline solution and centrifuged at about 4800 rpm. This process removes approximately 90% of the supernatant hemoglobin, heparin, citrate, activated complement, as well as proteins like albumin and clotting factors (48). The final washed red blood cell product has a hematocrit of 55 - 60% (18).

The major advantage of cell centrifuging type systems is their ability to remove many contaminants such as urine, amniotic fluid or plasma free hemoglobin (1,12, 48). Therefore, authors recommend that cell processing should be used for orthopedic procedures (19, 25, 38) as well as abdominal and other procedures where contamination is present (19,32). These machines do remove some bacteria, but many of these organisms remain (11, 21).

There are several disadvantages to cell processing autotransfusion systems. A major disadvantage is the inability of these machines to separate contaminants from blood without the removal and discard of blood elements other than the red blood cells (12,35). The beneficial blood elements which are removed include

platelets and proteins, such as the clotting factors and albumin. The removal of these components from blood can be responsible for a dilutional coagulopathy when blood loss is high (35). Most cell centrifuges, because of their high centrifugal forces, are also responsible for the destruction and loss of 10% - 15% of the collected red blood cells. In some systems the loss can be as high as 24% (32). The time required to process the blood is an additional drawback (14). Processing can take from 3-7 minutes when the machine is in the operating room. If the blood has to be taken to a different department to be processed,

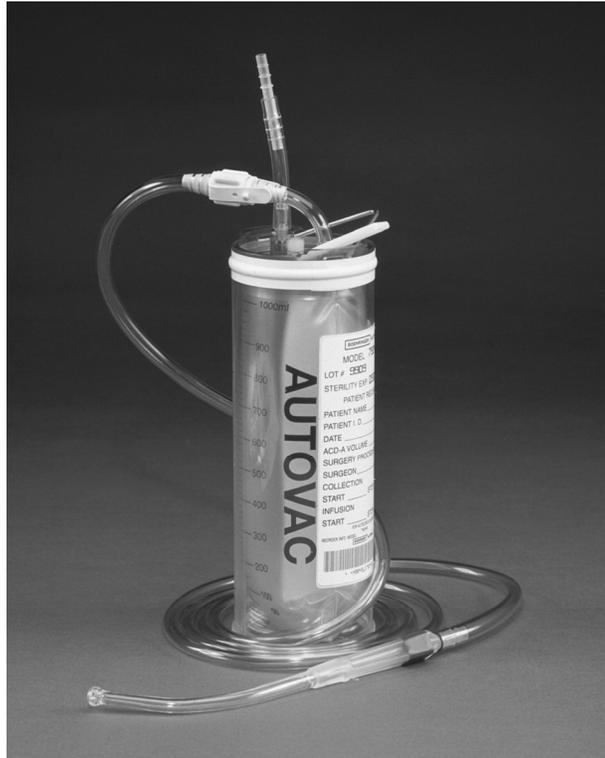
this delay can be considerably longer. Another significant disadvantage to such systems is the cost (3, 28, 35). The hardware required to process the blood is complicated and can cost \$40,000(12) or more. The disposable software is also not inexpensive. Additionally, a trained, dedicated technician is required to run the equipment (38). Maintaining availability of autotransfusion with processing during second and third shift and weekends can be a serious scheduling problem.

These drawbacks have caused a number of doctors to explore alternatives to cell processing. These clinicians point out that the need to centrifuge has not been proven and, when the blood is not contaminated, many consider processing to be a costly and often unnecessary step that removes beneficial elements (3, 12, 28, 35, 37, 50).

Assay	units	Average	Max	Min
Fibrinogen	mg%	53.73	140.00	20.00
Factor VIII	u/ml	1.30	2.00	0.23
Factor V	u/ml	0.19	1.20	0.01
Antithrombin 3	mg/dl	4.71	7.40	2.10
PT	u/ml	0.41	1.05	0.13
APTT	u/ml	0.71	1.80	0.44
WBC	u/ml	1.08	1.64	0.70
RBC	sec	77.95	100.00	15.60
Hemoglobin	sec	100.00	100.00	100.00
Hematocrit	#x10 ³	6.24	17.50	1.80
Platelet	#x10 ⁶	5.683	23.7	0.8
Free Hemoglobin	gm	5.6	7.5	2.6

Whole Blood Devices

Increasingly, hospitals are looking to whole blood devices, as opposed to cell processing systems to meet their intraoperative autotransfusion needs (2, 3, 35). These systems are typically simple canister based systems. Vacuum is used to aspirate uncontaminated blood from the surgical field. In order to reduce cellular destruction, the vacuum level is typically limited to less than 150mmHg(1) and the mixing of air and blood, as well as surface skimming, during aspiration should be minimized(16,46). As the blood is collected, it is filtered to remove any large debris or clots. An anticoagulant, such as citrate or heparin, is often added to the blood as well. The blood is readily available and can be given back to the patient when needed. Upon infusion, the blood is filtered again through a microaggregate filter in order to remove any additional debris which may form or which exists in the surgical field as a result of the surgery.



systems are immediately available and time for setup is minimal. Such clear benefits to the patient and hospitals have created significant recent interest in whole blood autotransfusion (2,3,7,35).

Whole blood systems do not remove the contaminants that cell processors can and they are not recommended for orthopedic procedures (19,25,38), except postoperatively where they have found extensive use. Whole blood devices are also not recommended for procedures where there is contamination, such as amniotic fluid (1) or intestinal contents. In orthopedic procedures, blood loss is typically very slow and excessive air/blood mixing during aspiration can increase the levels of plasma free hemoglobin (19, 47). Some authors argue that free hemoglobin can be nephrotoxic and can result in renal failure from activation of the clotting system (11, 13). Others, however, question this

assessment (12, 20, 35, 39). Coagulopathy from activation of the clotting system is another concern (11, 49). Glover and Broadie have used whole blood autotransfusion extensively in trauma. These investigators have observed that a patient in a state of shock who receives more than 10 liters of replacement fluid of any sort will usually have an alteration in clotting mechanisms. Whether this blood is from the bank or autotransfused has little significance on the clotting alteration (14). Ouriel et. al. studied whole blood autotransfusion in 100 abdominal aortic aneurysm procedures with an average of 1729 ml of blood autotransfused. He measured increased levels of fibrin degradation products and plasma free hemoglobin but found that the laboratory abnormalities had no clinical significance (35). Despite these theoretical concerns, many authors continue to report on the usefulness and cost-effectiveness of the whole

The benefits of whole blood intraoperative autotransfusion are numerous. The patient benefits because platelets and proteins, such as albumin and clotting factors are returned along with the oxygen carrying red blood cells(12,35). There is no delay in returning the blood to the patient due to a time consuming processing step (14, 19). When the patient's blood pressure is dropping rapidly, it may be necessary to return blood immediately. Whole blood autotransfusion offers important benefits to the hospital as well. A major benefit to the hospital is the simplicity and cost-effectiveness of these systems (2, 3, 12). They do not require costly hardware or maintenance, nor do they require a lengthy training program or the presence of a dedicated individual to operate complicated equipment (8, 17, 50). A scheduling system for cell processors is not needed because whole blood

blood autotransfusion method (2, 3, 7, 8, 12, 14, 35, 50).

The Boehringer AUTOVAC® System

Boehringer AUTOVAC® Intraoperative Autotransfusion System is a whole blood canister type system. Vacuum is used to aspirate blood from the surgical site via a wand and flexible tubing into the collection canister, which incorporates a standard blood bag sealed to a rigid cap. The cap provides a vacuum regulator which automatically limits vacuum to safe levels, and allows for attachment directly to wall vacuum. An ACD-A port, for the administration of ACD-A (Acid Citrate Dextrose Solution A) into the system, is provided as well. Within the blood bag, a clot filter (170 micron) removes large particulate and clots that may be aspirated into the system, while minimizing pressure drops which impose shearing forces on blood cells.

Use of the system is simple and straightforward. Wall vacuum is attached to the vacuum connector. With the optional integral regulator, vacuum within the canister is automatically limited to safe levels. Therefore, a wall regulator is not required. Next, ACD-A is either aspirated into the system through the wand or, alternately, injected through the ACD-A port. At this point, collection begins. During collection, care is used to collect from pooled sources to minimize mixing of air and blood so as not to damage the cellular constituents of the blood. Once the unit is full, the filter shut off will automatically stop collection. If the unit is full, or if blood is required, the bag may be removed from the canister after detaching vacuum. Residual air in the system is removed by squeezing the bag. At this point, a 40 micron filter and standard infusion set are attached to the spike port of the bag. The blood may then be administered either by gravity or with an external pressure cuff.

The Boehringer AUTOVAC® Intraoperative System offers numerous advantages to the user. The simple design allows for quick setup and immediate availability. When it is important to maintain intra vascular volume, this may be a significant advantage. Because operation of the system is simple and limited to a few steps, no dedicated operator or extensive hardware is required and

training time is reduced. The Boehringer AUTOVAC® System incorporates a number of design features which make the system much simpler than any competitive counterpart or cell processing systems.

Anticoagulation

When using the Boehringer AUTOVAC® System, an anticoagulant is desirable to prevent the blood from clotting in the system. Two anticoagulants commonly used during autotransfusion are heparin and ACD-A (Acid Citrate Dextrose Solution A). Heparin acts as an anticoagulant by forming complexes with antithrombin III and thereby accelerating the rate at which antithrombin III inactivates various enzymes of the coagulation cascade(34). The citrate in ACD-A prevents coagulation by chelating plasma calcium and inhibiting several critical calcium dependent steps in the coagulation cascade (48). ACD-A is the recommended anticoagulant for use with the Boehringer AUTOVAC® System because it does not alter the coagulation system as dramatically as heparin(2) and because the citrate is rapidly metabolized by the liver.

Some patients undergoing procedures involving autotransfusion are systemically heparinized; therefore, this blood is less prone to clotting. When collecting heparinized blood in the Boehringer AUTOVAC® System 40 ml of ACD-A is used for each 460 ml of blood collected. The first 40 ml of ACD-A should be added prior to collection to allow mixing of blood and ACD-A in the canister. If the patient is not heparinized, 40 ml of ACD-A may be used for each 300 ml of collected blood.

Vascular Surgery

Whole Blood Autotransfusion has been used extensively during vascular procedures and has been shown to significantly reduce exposure to allogeneic blood (3, 8, 35). Vascular procedures are well suited to autotransfusion with the Boehringer AUTOVAC® System because blood loss is of predictably high volume and rapid flow. It is not uncommon for blood loss to exceed one liter during an elective abdominal aortic aneurysm repair (7, 35).

Whole blood intraoperative autotransfusion has been used in numerous vascular procedures. These include abdominal aortic aneurysm repair (7, 35), aortoiliac/aortofemoral bypass surgery, endarterectomies, peripheral vascular surgery (30), and venous thrombectomy(3). During aortic surgery Ouriel et. al. transfused an average of 1729 ml of intraoperatively salvaged whole blood to 100 patients (35). During venous thrombectomy Bartels et. al. provided an average of 1056 ml of intraoperatively salvaged whole blood to 100 patients (3). Both studies demonstrated an average of over 65 % reduction in allogeneic transfusions, compared to controls.

Alterations in clotting and other hematologic mechanisms increase as the amount of blood (autologous or allogeneic) transfused increases. As there is less experience with large volume whole blood autotransfusion, more caution should be exercised when infusing more than 2 liters of blood. Several authors have reported on high blood loss in vascular type procedures. Davies et. al. reported on the use of whole blood autotransfusion in 25 patients undergoing aortic surgery; 8500 ml of blood was autotransfused in one patient. Davies found that autotransfusion significantly reduced the use of allogeneic blood (8). McKenzie et. al. studied whole blood autotransfusion in 62 patients undergoing vascular procedures. Four patients in the group received an average of 9,487 ml of autotransfused blood. Comparison with the remaining 58 patients who received an average of 1,866 ml of autotransfused blood demonstrated no significant hematologic differences between the two groups and no complications attributed to autotransfusion in either group (31).

Donayre et. al. employed the AUTOVAC[®] intraoperative autotransfusion device in patients undergoing endoluminal repair of abdominal aortic aneurysm. Fifty patients were divided into four groups based on blood loss. Overall blood loss was 834 cc with a 75% recovery rate. Hematuria was associated with blood loss greater than 1000 cc, but there was no affect on renal function. Only one patient in the series required an allogeneic transfusion and the authors considered the AUTOVAC[®] to be a safe alternative to bank blood for patients undergoing endoluminal AAA repair(10).

Trauma

Whole blood autotransfusion is an important technique for the management of trauma (20,27,37,51). The Boehringer AUTOVAC[®] System is ideal for trauma cases because it can be set up in less than a minute by emergency room or surgical staff. Immediate needs for blood can be met quickly without the delays inherent to typing and cross matching of allogeneic blood. Prompt return of blood to trauma victims can be important for patients who are hypotensive and have experienced large volume intravascular blood loss by the time they reach the hospital (14).

Numerous authors have reported on the use of whole blood intraoperative autotransfusion in trauma applications. Plaiser et. al. used whole blood autotransfusion on patients with penetrating injuries from gunshot or stab wounds. Autotransfusion was utilized on patients with blunt trauma as well. Injured organs included liver, spleen and stomach. Blood loss was reported to exceed 10 liters in some cases (37). Strom and colleagues reported on the successful use of whole blood autotransfusion during repair of ruptured aneurysms (44) and Linker et. al. successfully utilized the technique during traumatic aortocaval fistula(27).

A concern with the use of autotransfusion in trauma cases is the presence of bacterial contamination. Blood pooled in a body cavity from an old wound can be a culture medium for potentially contaminating organisms. Two specific body fluids which can contaminate blood are bile and pancreatic juice. Intestinal contents and urine are potential contaminants that can be encountered in patients with abdominal trauma, particularly penetrating injuries (20, 51). Infusion of blood suspected of containing these contaminants is contraindicated.

There are several important guidelines that should be followed in order to deal with contamination in trauma. Blood should not be collected for autotransfusion if it is more than six hours old (41). The six hour time limit minimizes the risk of bacterial contamination from an old wound. In all cases, two suction systems should be used: one for waste and one for autotransfusion. If contamination is suspected, and if circumstances permit, blood should be collected and held for infusion until the nature of the contamination is

determined. Once the nature and extent of contamination has been assessed the collected blood can be infused or discarded. This is the decision of the transfusionist; the risk of contamination must be weighed against the benefits of autologous blood. Blood contaminated with liver, bile and pancreatic fluid has been infused clinically by Glover (15) and Jacobs(20). Some investigators believe that autotransfusion can be used if the stomach or small bowel is injured, but not in cases of large bowel trauma. In general if the likelihood of gross contamination is high, autotransfusion should not be used. Finally, if contamination of autotransfused blood is suspected, administration of appropriate antibiotics may decrease the risks of sepsis (42,46,51)

Anticoagulation During Trauma Surgery

The requirement for anticoagulation during trauma surgery can be quite different than that for other procedures. Heparinization is generally not desirable, as this may lead to further hemorrhage in an already bleeding patient (51); therefore, use of ACD-A is indicated in the Boehringer AUTOVAC® System.

In many trauma patients, blood which has pooled in the pleural, mediastinal or peritoneal cavities may not clot. This blood has undergone a process of defibrination and is incoagulable and, therefore, addition of an anticoagulant may be unnecessary (6). When the trauma to the patient involves damage to larger blood vessels, bleeding can be brisk and the blood can then be coagulable(52). Under circumstances of rapid blood loss, ACD-A is indicated in a ratio of 40 ml for every 300 to 460 ml of blood collected.

Abdominal, Cardiac, and Obstetric Procedures

In addition to vascular and trauma procedures, the Boehringer AUTOVAC® System may be utilized in other applications. Abdominal surgery where significant blood loss is expected is an excellent opportunity for the use of the Boehringer AUTOVAC® System. Wilson et. al. found whole blood autotransfusion to be a valuable technique for patients undergoing nephrectomy, hepatic lobectomy and splenectomy (50). A number of other authors have reported on autotransfusion of significant quantities of blood during surgical

procedures involving the spleen (9, 43, 44). Most patients undergoing procedures involving abdominal organs will not be heparinized; therefore, 40 ml of ACD-A should be used in the Boehringer AUTOVAC® System for every 300 ml of collected blood.

The Boehringer AUTOVAC® System may also be used during cardiac surgery. Popovsky et. al. has successfully used whole blood autotransfusion in 314 patients undergoing coronary artery bypass grafting or routine valvular surgery. No patient in this series had complications attributable to the autotransfusion procedure (38). Ovrum reported on use of autotransfusion in 500 coronary artery bypass operations and was able to avoid infusion of allogeneic red blood cells in 98.6% of the patients (36). The Boehringer AUTOVAC® System can be used to collect blood shed intraoperatively and can be used to collect and infuse blood left in the pump circuit after bypass is complete. Patients undergoing cardiac surgery are usually heparinized; therefore, 40 ml of ACD-A is indicated for each 460 ml of collected blood.

Whole blood autotransfusion is a valuable technique for obstetric and gynecologic procedures. Merrill utilized this technique in 39 patients with ruptured ectopic pregnancy. An average of 1300 ml of blood was autotransfused per patient and the technique was found to be safe and effective in reducing allogeneic blood usage (33). Grimes reported on the successful use of autotransfusion during hysterectomy and salpingo-oophorectomy (17).

An important concern with obstetric procedures is the infusion of amniotic fluid. Because the catastrophic effects of amniotic fluid embolism are well known, blood containing amniotic fluid should be not be autotransfused under any circumstances (1). Care should be taken to avoid mixing of the child's and mother's blood as this mixture, could produce an adverse reaction if infused.

Cancer Surgery

Cancer surgery is an important opportunity for use of the Boehringer AUTOVAC® System. Intraoperative autotransfusion in cancer patients can eliminate allogeneic transfusions which have reported immunosuppressive effects in cancer patients (4,26). Historically some users of

intraoperative autotransfusion have hypothesized that tumor cells collected during intraoperative autotransfusion would promote metastatic disease. Several authors have studied this issue. There has been no direct evidence of this occurrence (1). Karczewski et. al. demonstrated that a whole blood autotransfusion system with a 150 micron and a 20 micron filter removed 50 -68% of the tumor cells collected during autotransfusion(50). Dale demonstrated that centrifugation does not remove cancer cells from red blood cells in the case of cell processing(2).

There are numerous citations in the literature of doctors who have utilized autotransfusion during cancer surgery. Zulim et. al. (52) used intraoperative auto transfusion in 39 patients undergoing liver resection for malignant disease. They found that overall survival and risk of recurrence in this series was comparable to those patients in whom intraoperative autotransfusion was not used. Klimberg has us intraoperative autotransfusion in over 500 cane patients. He studied 19 patients undergoing surgical resection of urologic malignancies. Klimberg et. al. studied 51 additional patients undergoing radical cystectomy for carcinoma of the bladder and found that none of the patients developed diffuse metastatic disease compatible with intravascular dissemination of tumor. He concludes that intraoperative autotransfusion, can be safely used in patients undergoing surgery for urologic malignancies (24). Nevertheless, this remains a controversial autotransfusion issue.

Conclusion

The Boehringer AUTOVAC® Whole Blood Intraoperative Autotransfusion System is ideal for the collection and infusion of intraoperatively shed blood. Quick setup and ease of use make the system an excellent choice for patients whose red cell needs pose challenging cross matching problems.

The high quality blood provided by Boehringer AUTOVAC® System can reduce exposure to allogeneic blood in patients undergoing vascular, abdominal and obstetric surgeries. The system is suited to procedures where blood can be collected from a pooled source, significant blood loss is

anticipated, blood products are normally ordered and a transfusion is indicated. Intraoperative autotransfusion with the Boehringer AUTOVAC® System can be an important part of a hospital's blood management program.

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