



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Questions on Cell Salvage During Cancer Surgery

A hospital transfusion service medical director asked the e-Network for input regarding the use of autologous blood salvage during cancer surgery. Apparently, an anesthesiologist at her hospital requested that she **bleed the practice of reinfusing salvaged autologous blood (using a leukocyte reduction filter), when the blood salvage occurs during cancer surgery, and the possibility exists that the salvaged blood might contain tumor cells.** Apparently another facility in the community is offering this service. Before endorsing such a practice, however, the inquiring medical director wonders what her colleagues in blood banking think about such a practice. The medical director recalls reading articles that report tumor cells are able to **traverse** a leukoreduction filter in an in vitro model. Also, she is curious about the combination of **filtration and irradiation** of the salvaged blood - would this be acceptable/safe? Finally, she wonders if there are **any regulatory considerations** prior to initiating such a practice?

The following input was submitted from members of the e-network;

1. A medical director of a **transfusion service in Virginia** commented that in her experience, it is **not a common practice** to perform blood salvage when there is gross contamination of the surgical field with bacteria or tumor. However, the rate of cancer recurrence following blood salvage where there is a risk of contamination of the salvaged blood by tumor is an unknown. This member states that such a practice currently falls outside of the usual practice in her community, but that it is an interesting question, as is the practice of leukoreduction on salvage blood, in general. The bottom line is that at this member's facility, they do **not** perform blood salvage during cancer resections and the request to offer this service has not been made.
2. The medical director of a **community blood center in Oklahoma** writes that the question of reinfusing intraoperatively salvaged blood from a patient with malignancy (whether the blood is washed and concentrated or not) remains an unanswered question for the last 20 years. This member comments that the use of leukoreduction filtration when reinfusing the salvaged blood may be of some value in acting as a particulate filter, but is highly unlikely to remove all tumor cells if they are present. However, (as was pointed out in reply #1 above), this member comments that there still are no data to support that intraoperative blood salvaged from patients whose surgical field is contaminated by a malignancy is "bad". In order to be on the safe side, **in the few instances where this member's institution has assisted in the intraoperative salvage of blood during cancer surgery, this member's personal recommendation has been to irradiate (using 2500 rads of gamma irradiation)** the intraoperative salvaged blood prior to its reinfusion, so that (in this replying member's opinion) the irradiation would negate any possibility of metastatic issues.
3. A **blood bank physician and 'ethicist' in Pennsylvania** commented that he would **advise against** this practice, but that if it is done, that appropriate **informed consent** be obtained beforehand. He comments that there is enough anecdotal evidence to suggest that tumor cells could be reinfused with the salvaged cells. For example, he states that based on solid organ transplant data, that the potential is there for transmission and possible seeding of tumor cells. However, as is pointed out in the above two replies, there is little safety and efficacy data available. According to this replying member, if the surgeon wants to continue with autologous cell salvage, then at the minimum, some safety and efficacy data should be collected (and monitored) and/or the patients treated as part of an IRB-approved protocol so that they are at least properly informed that the risks associated with autologous cell salvage and transfusion in this setting are unknown. Finally, this member **does not see that irradiation of the salvaged blood would be problematic or harmful, but again, there is little data** that it would be beneficial. Even **pre-operative** autologous donation in cancer patients raises concerns.
4. A **CEO/Medical Director of a donor center in Northern California** commented that leukocyte reduction **filters do not remove sufficient cancer cells** when intraoperative salvage is used in cancer surgery, but **irradiation is an effective way to inactivate** tumor cells in this situation. This member points out an article in TRANSFUSION by Hansen et al. last year on this topic.

Editor's NOTE: An [abstract of this article](#) can be found on Pub Med (Nat'l Library of Medicine). The replying member comments that Hansen has done extensive studies and shown irradiation to be both safe and effective in this situation, and that one of the irradiator manufacturers is seeking European approval for this use of an irradiator. The CEO/Medical Director's facility has written a report supporting this application of an irradiator. **Second Editor's NOTE:** Here is [another article](#) on this subject.

5. **A blood banker in New York** comments that he thinks **the jury is still out** on the advisability of doing this practice. He certainly would get informed consent in writing from the patient explaining the possible advantages and disadvantages. He thinks the combination of **filtration and irradiation or irradiation alone would be a good idea** given the uncertainties.
6. **A director of transplantation and transfusion medicine services at a university in North Carolina** is of the opinion that because of the theoretical concern that malignant cells recovered and reinfused during cancer surgery may seed distant sites, the literature on this subject contains statements regarding cancer surgery as an absolute or relative contraindication for intraoperative blood salvage. However, there are **no studies that demonstrate an increased risk for metastasis** with intraoperative blood salvage, while **there are studies that suggest little risk of metastatic seeding** of tumor cells. For example, **Hart** and colleagues at the University of Florida have studied patients undergoing radical cystectomy for carcinoma of the bladder. Of 54 patients who received intraoperatively salvaged blood, **none** developed diffuse metastatic disease. [reference: Hart OJ, Lkimberg LW, Wajsman z., et al. Intraoperative autotransfusion in radical cystectomy for bladder cancer. Surg Gynecol Obstet 1989;168:302-6] The reality is that intraoperative blood recovery is frequently employed if a tumor is thought to be well encapsulated. The use of a **leukocyte reduction filter** has been suggested as a means of minimizing the potential tumor cell contamination. **Perseghin** et al studied 16 patients with lung cancer and the use of a 3rd-generation polyester filter. In 9 out of 16 cases (56%), neoplastic cells were detected in prefiltration samples, but **none were found in postfiltration** cytopspins. They concluded that intraoperative blood salvage combined with appropriate filtration could be a very useful and safe tool in reducing allogeneic blood transfusion in cancer patients. [reference: Perseghin P. Vigano M. Rocco G. Della Pona C. Buscemi A. Rizzi A. Effectiveness of leukocyte filters in reducing tumor cell contamination after intraoperative blood salvage in lung cancer patients. Vox Sanguinis. 72(4):221-4, 1997]. Similarly, **Kongsgaard** et al studied the removal of malignant cell lines (breast cancer PM1 and MCF7) that had been seeded into blood and then filtered through a RC400TE leukocyte reduction filter. Detection of malignant cells was performed with immunomagnetic beads and clonogenic assays. and **no viable tumor cells were found after filtration** with the leucocyte depletion filter. They concluded that the use of a leukocyte filter after intra-operative blood salvage may make autotransfusion safe even in tumor surgery. [reference: Kongsgaard UE. Wang MY. Kvalheim G. Leucocyte depletion filter removes cancer cells in human blood. Acta Anaesthesiologica Scandinavica. 40(1):118-20, 1996 Jan]. In regard to the question of **irradiation** of units, some centers have advocated the use of gamma irradiation to minimize the risk of malignant cell proliferation. Hansen et al (as cited above in reply #4) studied the radiosensitivity of tumor cells by blood irradiation was studied in vitro with cells from 10 cell lines and from 14 tumor preparations after their addition to red cells in high numbers, or with blood shed during cancer surgery. **After irradiation of tumor cell contaminated blood with 50 Gy, no cell colony formation was observed**, which indicates a reduction rate exceeding 10 log. Irradiated cancer cells showed viability, but no residual DNA metabolism. They concluded that a 50-Gy dose far exceeds that needed to inactivate the number of proliferating tumor cells observed or expected in wound blood and that these results provided the experimental basis for the clinical application of blood irradiation for intraoperative blood salvage in cancer surgery. Note, **this level of irradiation is twice that used to normally irradiate blood products**.
7. Some years ago, when this replying member was Chairman of **AABB's Committee on Autologous Blood**, that committee addressed this issue. At that time, no member of the Committee was aware of a single case of dissemination of cancer via intraoperative salvage of blood in a surgical field involving a malignant tumor. This replying member states that he has not heard of a case since. At that time, the committee **did not use language to prohibit intraoperative salvage** in such cases, because the committee members could **envision an exceptional situation where it might be the only source of a life-saving transfusion**. For example this member says that he would use such a transfusion in an O-negative very elderly person with multiple antibodies, rather than create a severe shortage for others, or deny the patient a procedure. Otherwise, the procedure has risks that have not been adequately evaluated to justify the practice in surgical fields with malignant tumors, with or without leukocyte filters. Of course, a study with one specific tumor that "caught" 100% of malignant cells would prove nothing for a different tumor.
8. **A transfusion service medical director in Michigan** writes that it has been a few years since he last reviewed this subject. He states that there is no question that the risk of collection and transfusion of neoplastic cells is significant when a cell saver is used during resection of tumor and the literature has been consistent in reporting that it is possible to recover circulating neoplastic cells from blood even from routine preoperative autologous collections in patients with malignancies.

Since the cells are already circulating, the significance of reinfusing them is unclear. After extensive discussion at his hospital, it was **decided to not use the cell saver** during resection of neoplasias. This member continues to state that while it is very controversial, he thinks the risk of transfusing allogeneic blood may be greater than using autologous blood which has been salvaged from a cancer surgery. The member is of the opinion that if one were to chose to go ahead with this practice, he would **agree with the combination of leukocyte reduction and irradiation** of these products. **If the autologous blood from the cell saver comes into the blood bank**, the whole process becomes a blood bank process and would have to **meet regulatory scrutiny** from our friends at the FDA and our colleagues at AABB. The member realizes that the regulatory concerns raised by these manufacturing steps are complex for leukocyte reduction because, if the blood bank does the filtration, it must be demonstrated that the reduction worked. This means establishing a testing protocol and the appropriate process controls and quality assurance monitoring. If one is already performing irradiation, this step can be treated like any other in your current process. The replying member cautions that if intraoperative red cell recovery is not currently a blood bank process, think very carefully before you bring this "under your wing." This is a very interesting subject and should elicit some strong opinions and good debate.

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Addenda:

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