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How does blood loss relate to the extent of surgical wound excision?☆

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ABSTRACT

Purpose: We investigated a novel system that uses image-processing algorithms to accurately measure the hemoglobin content of discarded surgical sponges to determine how blood loss relates to the excised area when current methods to minimize bleeding are employed. The system was used during 130 procedures in adult patients having wound excisions ≥1% BSA (study group). An historic group of 105 similar cases in whom visually estimated blood was determined was also evaluated.

Results: Surgical blood loss was less than previous estimates. The correlation between blood loss and the excised area in the study group was poor (R^2=0.3988 for all patients and R^2=0.1439 for excisions ≥10% BSA). Moreover, the visual estimates of blood loss in the historic group were more closely related to excised area than the accurate measurements in the study group (R^2=0.6017 (historic), R^2=0.3988 (study), $p<0.001$ for both). The mean absolute unstandardized residuals were 140.18±158.52 (historic) vs. 307.99±317.03 (study), $p<0.001$.

Conclusions: As demonstrated in the historic group, visual estimates of blood loss tend to be more related to the size of excision than the amount of bleeding. The actual blood loss is not well correlated with the extent of excision. Clinicians should not rely on traditional blood loss estimates. Accurate measurement is needed to inform transfusion decisions and guide care.

1. Introduction

Quantification of intraoperative blood loss based on visual estimates, gravimetric methods (weighing sponges) or measurement of hemoglobin concentrations is known to be inaccurate [1–3]. While hemoglobin values can help quantify blood loss in normovolemic patients, these values can be confounded by changes in blood volume during and after surgical procedures. Anesthetic agents, fluid administration, insensible losses, temperature and other factors affect the blood volume and consequently the ability of the hemoglobin concentration to reflect the extent of surgical blood loss [4,5]. This can result in inappropriate transfusion decisions.

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During burn and other wound excisions, adequate back bleeding is used to establish a healthy wound bed. This leads to substantial blood loss that has traditionally been thought to be related to the size of the excision. One previous study that used the change in hemoglobin level to determine blood loss estimated blood loss as 387 ml/1% body surface area (BSA) excised [6]. Other studies that also used calculated blood loss based on hemoglobin changes estimated blood loss at 117 ml, 123 ml and 77 ml/% BSA excised [7–9]. A study in pediatric burn patients showed that 2.8% of circulating volume was lost as a percentage of total body surface area (TBSA) excised, whereas 1.8% of circulating volume was lost as a percentage of TBSA grafted [10]. Although estimating blood loss based on excised surface area would be useful if correct, this concept has not been validated using accurate measurement of actual blood loss.

The Triton system (Gauss Surgical, Inc., Los Altos, CA) is a novel FDA-cleared mobile application on a tablet computer (iPad) that uses the enabled tablet camera to capture images of surgical sponges. It performs colorimetric image correction and analysis, and uses cloud-based machine-learning models to quantify hemoglobin mass on surgical sponges in real time. This measured amount of hemoglobin loss per sponge is converted to a volumetric measure using the patient's pre-procedure hemoglobin value. The technology can also be used to measure the hemoglobin content of fluid collected in suction canisters during surgery and is accurate despite dilution with irrigants or other fluids. The performance of the device has been validated in bench-top and clinical settings [11–13].

This study was conducted to determine if there was a meaningful clinical relationship between the extent of wound excision and accurately measured surgical blood loss using the novel system. While the total blood loss is expected to increase as the area of excised wound increases, we hypothesized that the amount of blood loss per unit of area of excision would remain relatively unchanged. We also looked at the relationship between the size of the wound excision and visually estimated blood loss in an historic control group to better understand how blood loss is estimated in the absence of an accurate measure of blood loss.

2. Methods

The investigational protocol was approved by the IRB at the University of California Irvine School of Medicine (HS#: 2015-2418, 2/3/2016). The requirement for written consent was waived since data was de-identified and reviewed retrospectively.

Investigators followed their usual standard of care throughout both phases of the study. In these patients almost all of the blood loss was able to be captured on the sponges with only a small amounts amassing on surgical drapes since attempts were made to use sponges to absorb that blood. Surgical technique was similar throughout the study. Sponges were soaked in epinephrine (1 mg/ml) at a concentration of 30 ml per liter of saline and QuickClot® Trauma pads were used to assist in hemostasis once an adequate wound bed was achieved. No additional hemostatic agents were implemented during the study period and surgical suction was minimal in both groups. Excisions were typically full thickness and tourniquets were not used.

In the device group, all procedural surgical sponges were collected and scanned using the novel system as they were removed from the operative field and a cumulative estimated blood loss was recorded at the end of the case. Surgical suction was not used for these procedures so scanning of and estimation of blood loss in surgical canisters was not performed.

Using the novel system, measured blood loss was related to the size of the excised wound for 130 procedures in adult (age $\geq$18 years) patients having wound excisions $\geq$1% BSA between November 2014 and January, 2016 (study group). The results were compared with visually estimated rather than measured blood loss determined in 105 similar cases between January, 2014 and November, 2014 (historic group).

In the historic group, a visual estimate of blood loss was determined by consensus between the attending surgeon and anesthesiologist. The control group was studied in order to determine how blood loss is traditionally estimated in wound excision patients. Ideally, these estimates should be based on an individualized assessment of bleeding rather than the size of the excised area.

We chose to use an historical control group rather than comparing the blood loss measured by the system with surgeon and anesthesiologist's visual estimation of blood loss during each procedure because we had confidence in the device measurements from a small preliminary study and wished to use the data from the device to support intra-operative and postoperative decision making.

Retrospective collection of de-identified data for both groups included date of surgery, patient age (years), BSA (m^2), total size of burn or wound (% BSA), size of wound excised (cm^2), and hemoglobin concentrations (g/dl) preoperatively, immediately following surgery and on postoperative days one, two and three when performed. Measurements of blood loss (ml) on surgical sponges was recorded from the novel system in the study group. In the historic group, visually estimated blood loss (ml) as recorded in the operative record was documented.

Both measured surgical blood loss in the study group and visually estimated blood loss in the historic group were evaluated in relation to both % BSA excised and cm^2 excised to allow a more accurate comparison between the groups.

2.1. *Statistical analysis*

Continuous variables are expressed as mean$\pm$standard deviation (SD). To study the relationship between excised area and blood loss, the amount of blood loss per area of excision expressed as percentage of BSA was calculated in subgroups of patients with excised areas ranging from 1 to 3.99% of BSA, 4 to 9.99% of BSA, and $\geq$10% BSA. Additionally, the amount of blood loss per area of excision based on the absolute size of the excision (cm^2) was calculated in subgroups of patients with excised areas ranging from $<$1000 cm^2, 1000 to 2499 cm^2 and $\geq$2500 cm^2. Comparisons were made using t-test between cohorts for each subgroup. Linear correlation between the blood loss and the excised area was evaluated

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