BURN PATIENT RESUSCITATION SYSTEM

This application is a continuation application of U.S. patent application Ser. No. 12/977,609, filed on Dec. 23, 2010, which is a divisional application of U.S. patent application Ser. No. 12/076,554, field on Mar. 19, 2008, which claims the benefit of U.S. provisional application Ser. No. 60/895,670, filed on Mar. 19, 2007 entitled Approaches to Improving Treatment of Burn Patients. These applications are hereby incorporated by reference.

The U.S. Government in addition to any other rights it may have through at least one inventor has a paid-up license in this invention and the right in limited circumstances to require the patent owner to license others on reasonable terms as provided for by the terms of award number N00014-03-1-0363 awarded by the Office of Naval Research, Department of Defense.

I. FIELD OF THE INVENTION

This invention relates to a semi-closed loop or closed loop system and method for burn patient resuscitation.

II. BACKGROUND OF THE INVENTION

Effective resuscitation of burn injuries is critical for lowering both the mortality and morbidity rates of burn patients. Both treatment and rehabilitation of burn injuries requires a large economic investment by hospitals in terms of cost and long term intensive care requirements for patients with severe and/or large percentage body burns. It is not uncommon that a normal size adult will receive over 30 liters of fluid while having urinary output (or urine output) totaling less than 2 liters, which results in a gain of about 60 pounds from the fluid retention in the body resulting from, for example, capillary leakage in response to the injury.

Each year approximately 45,000 adults and 15,000 children require hospitalization due to burn injury with 5,000 dying due to the severity or complications resulting from their injuries. For the military population, injury patterns due to current conflicts may include both traumatic and burn injuries that necessitate immediate treatment. Furthermore, recent studies have shown that over resuscitation of burn injury is not uncommon, resulting in significant iatrogenic complications.

Critical to survival are the initial 48 hours of post-burn resuscitation; however, this time period is extended in situations where the patient takes a long time for care and eventual transport such as occurs when brining burned soldiers from the Iraq theater to the U.S. Army Institute of Surgical Research (USAISR) burn unit at Fort Sam Houston, Tex. During this phase, patients require prompt initiation of fluid therapy, and around-the-clock care by experienced burn surgeons and intensivists. However, advanced burn care expertise is not found in most hospitals, and the care outside of burn centers can lead to increase morbidity from infusing too much fluid. This limitation includes receiving centers, whether they are civilian emergency rooms, forward military facilities or ad hoc medical facilities for mass casualty. Because acute burn care is particularly labor intensive, burn injuries sustained in mass casualties can quickly overwhelm even the best hospitals and burn centers. Clearly, there is a need to reduce the workload of advanced burn centers and to impart burn expertise to less specialized medical facilities.

The pathophysiologic response to large thermal injuries (≥30% of total body surface area [TBSA]) is characterized by substantial plasma extravasation and general edema formation, leading to intravascular volume depletion and burn

shock. Delayed or inadequate fluid resuscitation is associated with increased morbidity and mortality. Initial treatment currently consists of isotonic crystalloid infusion based on a regimen that is directed towards volume replenishment to obtain cardiovascular stabilization and maintain adequate renal function. However, such treatment is only partially effective due to an array of circulatory mediators and sustained fluid extravasations into the extravascular space.

a. Current Resuscitation Regimens

Defining the best solutions, infusion rates, and volume requirements for resuscitation of burn injury has been an ongoing research focus for the last 100 years. Several formulas have been developed to guide the care provider with a predicted infusion volume for the first 24 hours and with a specific initial infusion rate based on the size of the burn injury and patient weight. Infusion rates are adjusted hourly, based on the urinary output (UO) of the patient during the last measured period. The most common contemporary infusion formulas are the Brooke formula (2 ml/kg per % TBSA for 24 hours) and the Parkland formula (4 ml/kg per % TBSA for 24 hours). Fluids are periodically adjusted to maintain an adequate urinary output, within a predetermined target range. The rationale for using urinary output as the target endpoint to adjust fluid therapy is that if urinary output is normal then glomerular filtration rate, renal blood flow, and cardiac output are likely to be adequate. Target values are based on ranges determined by age (adult or pediatric), patient weight, and sometimes other factors that contribute to normal renal output. Adult target values are 0.5-1.0 ml/kg per hour or 30-50 ml/hr. Pediatric patients often require larger volumes due to greater insensible losses, and have a formula with a higher target urinary output of 1.0-2.0 ml/kg per hr. Maintaining urinary output targets is expected to normalize renal function, while avoiding excess or inadequate fluid infusion that may lead to an increase in complications or mortality. But recent reviews have suggested that this approach frequently leads to severe over-resuscitation, with many burn units administering mean volumes larger than the Parkland recommendation.

The current standard of care for patients receiving burn resuscitation is paper charts that include a flow sheet similar to that illustrated in FIG. **1**A. In some situations where electronic charting is used, the monitors will provide data to the electronic charting system as illustrated in FIG. **1**B, which is only a slight improvement over the flow sheet since there is no analysis of the data.

To evaluate contemporary methods of burn resuscitation, a meta-analysis of the last 26 years of burn resuscitation was conducted. A search of Medline for all clinical burn studies in which fluid resuscitation was guided by the Brooke or Parkland formula with adjustment in infusion rates to restore and maintain target urinary output was done. Data from 31 studies, which included 40 groups and 1,498 patients was extracted. FIGS. **2**A and **2**B show the total 24-hr volumes infused and the mean urinary outputs, respectively. Mean percentage of total body surface area (% TBSA) was 45±2% and mean fluid intakes were 5.1±1.3 mL/kg per % TBSA, with mean 24-hr urinary outputs of 1.1±0.4 mL/hr per kg. All studies reported mean volume administration exceeding the Brooke formula and 86% of studies reported mean values above the Parkland formula. In general, patients are resuscitated to achieve levels of urinary output that are at or above the high end of target level. However, most of the burn centers infused sufficient lactated Ringer's solution (LR) to induce mean 24-hour urinary outputs exceeding 1.0 mL/kg. The primary conclusions from the meta-analysis are: (1) total volumes infused typically exceed the Parkland formula and