

WHITE PAPER

ECONOMIC BENEFITS OF THE BELMONT[®] RAPID INFUSER

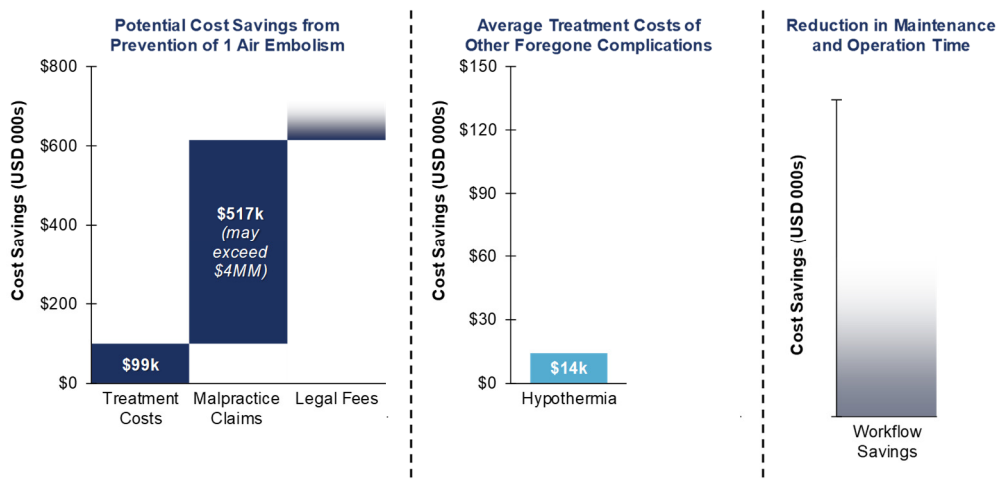
UPDATED: June 12th, 2020

By: Jeff Bessen[†] Ph.D., Andrew Millar[†], Darcy Krzynowek[†], Mark Speers[†]

ABSTRACT

Rapid infusion of fluids provides significant, often lifesaving, clinical benefits for patients experiencing severe blood loss. However, rapid fluid infusion carries risks including venous air embolism (VAE), hypothermia, and water bath-based infuser related bloodstream infection.

The Belmont Rapid Infuser is a medical device with advanced features designed to infuse fluids at a wide range of flow rates while reducing the clinical risk of complications and minimizing the economic burden of massive transfusions. The Belmont is easy to operate and uses electromagnetic induction to provide instantaneous dry heating. Other infusers rely on water bath technology and take significantly longer to warm up. The rapid heating mechanism of The Belmont ensures fast treatment in situations where each minute of delay is associated with a 5% increase in mortality. Safety features include air bubble detection with ultrasonic sensors and automatic air removal from infusion fluids to prevent VAE, and instant and precise heating to prevent cold fluid-induced hypothermia. Prevention of these conditions has the potential to improve patient outcomes while eliminating complications with high per-event average treatment costs, including VAE (\$98,900) and hypothermia (\$14,100). In addition to the savings from avoided complications, the features of The Belmont also mitigate potential litigation costs, with median closed claims for air embolism patients valued at \$517,000 per event, not including legal fees.



The Belmont Rapid Infuser has additional safety and convenience advantages for providers, which may be especially valued in settings that infrequently perform rapid infusions such as lower patient volume rural or community hospitals. The Belmont's dry heating technology requires minimal maintenance, especially compared to water bath-based fluid warmers that require monthly cleaning. Disposables are pre-assembled, color-coded, and do not require calibration for variable flow rates, allowing for rapid setup and deployment, even by infrequent users. A touchscreen display provides on-screen setup instructions, key datapoints during infusion, and operational alarms with instructions for corrective measures.

In summary, The Belmont Rapid Infuser offers optimal clinical performance for patients in addition to economic benefits to providers. The Belmont Rapid Infuser delivers significant clinical and economic value over other systems used in massive transfusions such as the

Smiths Level 1 H-1200 due to faster time to treatment, avoided costs of treating complications of infusions, improved litigation risk management, and reduced staff time requirements for operation and maintenance.

INTRODUCTION

Rapid infusion improves survival and clinical outcomes in severely injured patients¹. “Rapid infusion” is typically defined as infusion of ten units of blood over a 24-hour period² or three units of blood in a one-hour period³. The clinical need for rapid infusion can arise during severe trauma, post-partum hemorrhage (PPH), and liver or other organ transplants².

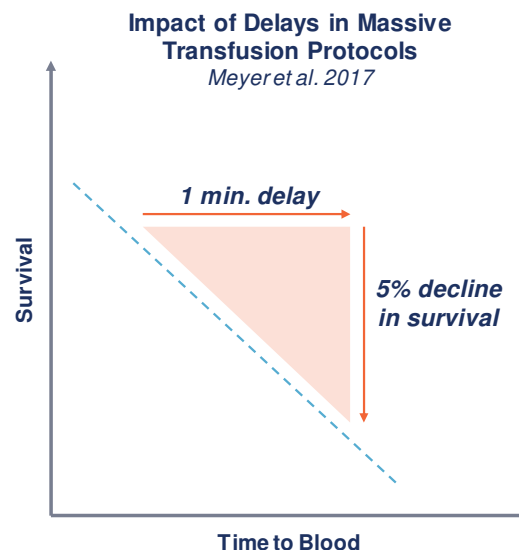
Hospitals and trauma societies such as the American College of Surgeons are increasingly developing specific massive transfusion protocols (MTPs) to mitigate the risks to severely bleeding patients⁴⁻⁶. These risks include venous air embolism⁷, perioperative hypothermia⁸, and water bath-based infuser related bloodstream infection. The negative consequences associated with sub-optimal rapid transfusions translate into worse clinical outcomes^{7,10} and increased medical costs^{11,12}. In rural facilities or settings where trauma patients are encountered less frequently, there are even greater risks when performing massive transfusions, possibly because staff rarely perform the procedures or utilize infusion equipment without advanced safety features¹³. As a result of these and other factors, trauma patients in rural settings experience higher mortality rates than those in urban settings^{14,15}.

In order to prevent infusion complications, MTP guidelines call for warmed fluids^{6,16} and monitoring for air emboli¹⁷. Among the several devices available to hospitals for facilitating MTPs, only The Belmont Rapid Infuser has a suite of advanced safety and efficiency features that deliver superior clinical performance while offering economic benefits to providers.

LIFESAVING POTENTIAL OF THE BELMONT RAPID INFUSER

The need for massive transfusions may arise at any time in any care setting. The aforementioned clinical situations in which massive transfusions may be required (severe trauma, PPH, and organ transplants) are widespread in the US. According to the National Trauma Data Bank, there were nearly 140,000 incidents of patients with severe or very severe trauma in US hospitals in 2016, resulting in almost 25,000 deaths¹⁸. The rate of PPH in the United States has been growing¹⁹, and in 2017, an estimated 2.9% of women who give birth in the US experienced excessive bleeding²⁰. Additionally, there were over 15,000 liver, heart, and lung transplants in the US in 2019²¹.

During massive transfusions, quicker response times translate into saving additional lives and improving patient outcomes^{22,23}. One study of MTPs concluded that each minute of delay in delivering blood to patients was associated with a 5% increase in mortality²⁴. The Belmont contains advanced time-saving features that ensure transfusions can begin quickly and be carried out optimally every time. The Belmont’s dry



electromagnetic induction-based heating technology requires just seconds to warm fluids, e.g. near-frozen blood stored at 4°C, to the proper normothermic temperature (37.5°C)²⁵, even at very high flow rates. In contrast, water bath-based infusers take significantly longer to warm up. For comparison, a water bath-based rapid infuser, the Level 1 H-1000, required up to 8 minutes to achieve the proper temperature²⁶. Even infusers that utilize other dry heating mechanisms, such as conductive plate warming, can take minutes to heat up²⁶. The Belmont is the only rapid infuser with an intuitive touchscreen interface that provides visual and descriptive alarms if set-up errors are detected. When errors are detected, the touchscreen provides instructions to implement corrective measures. Finally, The Belmont disposables are color-coded and preassembled (with the reservoir, patient line, and heat exchanger already connected for easy installation), further accelerating patient time to treatment.

“Every effort should be made to decrease the time to recognition of the need for MTP and the time to administration of the first blood product.” – Meyer et al. 2017

PREVENTION OF AIR EMBOLI WITH THE BELMONT RAPID INFUSER

Venous air embolism (VAE) is caused by introduction of air bubbles into the bloodstream, often resulting in organ or neurological damage, or death²⁷. Air can be introduced via rapid transfusion during insertion or removal of the catheter, through failure to remove air from blood or fluid bags⁷, through outgassing of warmed fluids²⁸, or if line disconnection occurs²⁹. The incidence of symptomatic VAE may be as high as 2%²⁸, and estimates of mortality rates range from 23-50%^{29,30}. Non-fatal complications of VAE include hemodynamic instability, neurologic damage, and end-organ damage³¹. Treatment of these complications typically requires longer hospitalizations, ranging from 3 additional days in the ICU to 9 added days in the hospital overall^{32,33}.

The Belmont Rapid Infuser eliminates the risk of air emboli by detecting and automatically removing air bubbles without affecting fluid resuscitation. In a head-to-head comparison, the air removal performance of The Belmont Rapid Infuser was shown to be superior to that of other rapid infusers such as the Level 1 Rapid Infuser²⁵. In one such study, the Belmont Rapid Infuser successfully removed a life-threatening bolus of air (10 mL), while much of the air remained in the tubing of the Level 1²⁵.

The prevention of air emboli using The Belmont Rapid Infuser results in significant economic benefits. One study calculated that in 2008, average costs associated with inpatient air emboli totaled an average of \$72,222 per patient¹¹ (\$98,900 in 2019 dollars). Major components of this added cost include diagnostic imaging, supportive therapy, and extended hospitalization.

\$98,900
AVG. TREATMENT COST SAVINGS
FROM PREVENTING ONE AIR
EMBOLISM

\$4MM+
MAXIMUM PAYOUT FOR CLOSED
LITIGATION CLAIMS REGARDING AIR
EMBOLISM

Significantly, in 2007, CMS announced that it would no longer reimburse the cost of treating complications of preventable medical errors including VAE³⁴, a policy which other payers have subsequently advocated³⁵. Finally, VAE may result in costly litigation, with reports of median closed claims ranging from \$325,000 to \$517,000 and maximum payouts exceeding \$4MM^{36,37}.

In summary, prevention of a single air embolism event with The Belmont could save a patient's life and provide substantial economic value to the hospital.

REDUCING HYPOTHERMIA WITH THE BELMONT RAPID INFUSER

Hypothermia is typically defined as a core body temperature less than 36°C, which may impair the clotting ability of blood and result in worse patient outcomes³⁸. Massive transfusions can lead to inadvertent hypothermia if fluids are not properly warmed prior to infusion⁸. For example, infusion of one unit of refrigerated blood, or one liter of room-temperature fluid, has the potential to decrease core body temperature by 0.25°C^{39,40}. Hypothermia occurs frequently in severe trauma patients, with rates as high as 50%⁴¹. Indeed, hypothermia as well as acidosis and coagulopathy comprise the “lethal triad” of abnormalities which can exacerbate each other in cases of traumatic hemorrhage, and which may result in death⁵. Studies have shown that patients displaying hypothermia require increased volumes of blood transfusions^{42,43}, which is a negative predictor of outcomes including infection and mortality^{5,44}. Additionally, the infusion of cold fluid itself can lead to increased risk of cardiac events⁴⁵ or infection⁴⁶ and extended hospitalization⁴⁷.

The Belmont Rapid Infuser minimizes the risk of inadvertent hypothermia by instantly and precisely heating fluids using dry electromagnetic induction technology. The fluid warming capability of induction-based warmers such as The Belmont Rapid Infuser have been shown to be superior to that of other infusers^{25,26,48}. For example, at a flow rate of 500 mL of packed red blood cells (PRBCs) per minute, The Belmont Rapid Infuser maintained a physiological temperature; in contrast, the Level 1 infusate temperature declined over time by 3°C²⁵. The Belmont temperature probe directly measures the temperature of the infusate, while other systems such as the Level I measure the temperature of the bath that is used to heat the infusate. Even infusers that use other dry heating mechanisms, such as conductive plate warming, have been found to warm the infusate to sub-normothermic temperatures^{49,50}.

Mitigation of perioperative hypothermia using

The Belmont Rapid Infuser may yield significant economic value and savings. On average, patients presenting with hypothermia require an increase of 1.3 units of PRBCs transfused⁴². Researchers have found total transfusion costs can reach \$1,180 per

PRBC unit⁵¹ (\$1,675 in 2019), potentially resulting in extra costs for hypothermic patients of \$2,000 or more from increased blood-usage alone. In total, complications stemming from hypothermia of 1.5°C below normal were found to cost an average of \$7,074 per patient⁵² (\$14,100 in 2019). For those patients that suffer cardiac complications of hypothermia- including unstable angina, cardiac arrest, or myocardial infarction – costs may be even higher, with estimates ranging up to \$25,000⁵³ (\$29,300 in 2019). Finally, hypothermic patients require increased hospitalization averaging 3 additional days⁴⁷, at costs ranging from \$1,850 to \$3,780 per patient per day⁵⁴ (\$2,000 and \$4,000 in 2019).

\$14,100
AVG. TREATMENT COST SAVINGS
FROM ONE NORMOTHERMIC
TRANSFUSION

Taken together, the cost savings from normothermic transfusion with The Belmont Rapid Infuser may range from decreased blood usage (\$2,000+) to decreased complications and hospitalization (tens of thousands of dollars).

MINIMIZING THE RISK OF WATER BORNE RELATED BLOODSTREAM INFECTION WITH DRY HEATING

Hospital-acquired bloodstream infections, which are typically considered to be preventable⁵⁵, have been linked to the use of water bath-based fluid warmers⁵⁶. Rapid infusers that use water

baths for warming, such as the Level 1 Rapid Infuser, may therefore pose additional risks of infection, as the warm water can serve as a reservoir for pathogens^{9,57,58} which can come into contact with the infusate. The risks associated with water baths have been highlighted in AABB guidelines for blood warming devices⁵⁹. Indeed, there have been reports of infusers with water baths failing, resulting in water bath fluid being infused into the patient⁶⁰⁻⁶². In at least one instance, physicians concluded that a surgical patient contracted a bloodstream infection due to mechanical failure of a Level 1 Rapid Infuser⁹, with the patient requiring 51 days of hospitalization. Indeed, patients that develop hospital-acquired infections require additional treatment and commonly experience extended hospitalization⁶³. Trauma patients in particular are at an elevated risk of mortality, longer hospitalization, and increased costs resulting from hospital-acquired infections⁶⁴.

Water baths have been linked to potential fluid contamination and bloodstream infections. The dry heating source of The Belmont Rapid Infuser eliminates the need for a water bath heat source, mitigating the risk of fluid contamination from the water bath. Hospital-acquired bloodstream

\$113,300
AVG. TREATMENT COST SAVINGS
FROM PREVENTING A
BLOODSTREAM INFECTION

infections are thought to result in 150 excess deaths for every 1,000 cases¹². Estimates place attributable costs of hospital-acquired bloodstream infections to be \$82,730 (\$113,300 in 2019) on average, depending on the hospital setting^{63,65}. In addition, Medicare has instituted a hospital-acquired condition reduction program, which may result in reduced reimbursement overall for hospitals that fail to reduce hospital-acquired infections⁶⁶. The Belmont Rapid Infuser utilizes dry, instant electromagnetic heating and does not use a water bath.

ADDITIONAL BENEFITS OF THE BELMONT RAPID INFUSER

The Belmont includes numerous additional safety and convenience features to optimize infusion at a wide range of flow rates for healthcare providers. These features – including color-coded disposables, a descriptive touchscreen interface, automatic air removal, battery operation, and a low-maintenance heating source – may appeal particularly to settings that infrequently perform rapid infusions¹³. The Belmont uses the same disposable set regardless of the desired flow rate⁶⁷, simplifying operations. The Belmont has numerous integrated alarms with visual on-screen cues including over- and under-temperature, problems with disposables, and high pressure⁶⁷, potentially saving time in emergency scenarios. The automatic air detection and removal system enables a single operator to oversee the transfusion, reducing the burden on hospital staff. In addition, the reduced staffing required to operate The Belmont may result in fewer distractions in the ED or OR. Indeed, multiple studies have shown interruptions and distractions in healthcare settings to be associated with increased rates of medical errors and complications such as patient hemorrhage^{68,69}. Finally, The Belmont’s dry heat source requires minimal maintenance, a convenience feature that is noted in AABB guidelines⁵⁹. In contrast, rapid infusers that employ water baths require maintenance every 30 days⁷⁰, a guideline which some hospitals may not follow⁹. There are also reports of water bath-based warming devices leaking or causing electrical shocks to healthcare providers⁶².

In summary, the ease-of-use features of The Belmont may lead to faster infusion of blood, improved workflow, and time savings for hospital staff, even for inexperienced users.

DISCUSSION

The Belmont offers numerous clinical and economic benefits for all hospitals. Foremost, it saves lives by ensuring rapid and safe delivery of fluids to patients in the most critical of situations. It offers improved clinical performance for patients by preventing complications associated with infusion, such as VAE, inadvertent hypothermia, and water bath-based infuser related bloodstream infection . By reducing complications and the associated treatments, excess hospitalization, and potential litigation, use of The Belmont could result in substantial economic benefits for providers. Altogether, The Belmont's advanced features can assist hospitals in optimizing their MTP, resulting in improved efficiency and response times, better clinical performance, and superior health economic benefits relative to other infusion devices.

METHODOLOGY

A targeted literature search was conducted to better understand the clinical benefits and cost-savings associated with use of rapid infusion devices, including The Belmont Rapid Infuser, for intravenous fluid delivery. Key words included: rapid infusion, infusion device, transfusion, massive transfusion protocol, resuscitation, air embolism, air elimination, infusion-related air embolism, microbubble, blood-liquid warmer, fluid warming, fluid warmer, prehospital hypothermia, perioperative hypothermia, dry heat source, water bath, water reservoir, hospital-acquired infection, catheter infection, postpartum hemorrhage, trauma, pressure bags, Belmont, Belmont Rapid Infuser, Belmont Rapid Infuser RI-2, FMS2000, Smiths Level 1, Hotline, Fluido, Ranger, Thermacor, Warmflo, and Gaymar. Searches also included closely related phrases and alternate spellings. The above key words were combined with economic terms such as costs, budget impact, price, and cost-effectiveness, to identify literature with relevant economic components.

For ease of comparison, cost estimates were adjusted to 2019 levels based on the US Bureau of Labor Statistics medical care price index. Between 2000 and 2019, inflation for medical care increased by an average of 3.5% annually, with a high of 4.7% and a low of 2.0%.

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Authors Information

† Employees of Health Advances, LLC, Newton, Massachusetts.

This article was sponsored by Belmont Medical Technologies.