

Flow Awareness as a New Safety Device for Cardiopulmonary Bypass

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Abstract: Safety devices such as bubble detectors and level detectors have been in use for more than 40 years and initially reduced the risks associated with gaseous emboli during cardiopulmonary bypass; however, the risks have not been eliminated. This research explored a new safety device designed to further reduce these risks: Flow Awareness Technology. This device visually alerts the perfusionist when the ratio of venous return does not equal the amount of arterial flow. To determine the efficacy of this device, 33 participants with no perfusion background were randomly assigned to Group A (flow awareness only), Group B (level detector only), or Group C (control). These participants were instructed to turn off the arterial pump when they noticed that the fluid in the venous reservoir had begun to drop or if their assigned safety device was triggered. The venous line was fully occluded at times unknown to the participants.

These times coincided with before, during, or after times that the participants were expected to paper-chart known values. Each participant's amount of fluid lost (in milliliters) from the reservoir and reaction time (in seconds) to shut off the arterial roller pump were measured. Group A lost an average of 80.8 mL, Group B lost an average of 173.6 mL, and Group C lost an average of 140.3 mL. Average measured time for each group is as follows: Group A took 2.16 seconds, Group B took 4.31 seconds, and Group C took 4.09 seconds to shut off the arterial pump. Statistics support the hypothesis that Flow Awareness Technology significantly reduces the reaction time to an adverse event such as a sudden occlusion of the venous line, thus reducing the amount of fluid lost during such an event. **Keywords:** cardiopulmonary bypass, CPB, equipment, patient safety, perfusion. *J Extra Corpor Technol. 2019;51: 20-5*

Gaseous emboli (GE) used to be one of the top three causes of major accidents during cardiopulmonary bypass (CPB) (1-3). Perfusion technology has made an effort to attenuate this issue. With the invention of bubble detectors and level detectors more than 40 years ago, these occurrences have lessened; however, they remain a cause for concern (2). It has been shown that there is a linear relationship between the number of intravascular microemboli detected during CPB and the incidence of cerebral injury (4). Further advancements need to be made to protect patients from GE incidents.

Flow Awareness Technology is a safety device that alerts the operator of reduced venous drainage, which could help lessen the occurrence of GE incidents. In its current state, this technology consists of one turbine flow probe in the venous line and one in the arterial line which measure the flow

passing by them. The probes are connected to an analog-to-digital converter which then communicates with a table in Microsoft Excel (Microsoft Corporation, Redmond, WA). It compares the ratio of flow between the two points and alerts the user if the flow ratio differs from a one-to-one ratio.

Perfusionists have many responsibilities contributing to patient safety. Maintaining blood gases, hemodynamic status, and appropriate flow rates comprises just a few. "...the primary responsibility of the perfusionist...is...to maintain a safe operating level in the oxygenator at all times" (5). The biggest contributing factor to maintaining a safe operating level is a fast reaction time. "The most common cause of arterial air embolization is inattention to the venous reservoir level with subsequent loss of a safe operating level to the point where either vortexing occurs or the reservoir itself is totally or intermittently empty and gas is pumped through the arterial line" (5). A faster reaction time means less chance of draining the venous reservoir and, therefore, less chance of pumping air to the patient.

The purpose of this study was to determine whether Flow Awareness Technology, as compared with the use of a level detector or no safety device, reduces a perfusionist's

Received for publication June 6, 2018; accepted January 4, 2019.
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The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

reaction time during sudden loss of venous return, thus reducing the amount of fluid lost from the venous reservoir.

In 2000, Mejak et al. (2) conducted an 80-question survey of cardiac surgeons regarding perfusion incidents and the use of safety devices. This covered the period from July 1996 to 1998 and had a 54% response rate. Massive gas embolism was reported 23 times, leading to six deaths. Venous reservoir level detectors were used in 70.4% of cases. These findings were compared with other perfusion safety articles in 2005 by Palanzo (3). Also discussed in the latter article were studies carried out in 1980, 1981, 1982, 1986, and 1997. Mejak identified current safety device usage. Knowing whether perfusionists are willing to use safety devices is imperative for research concerning the development of new safety devices. Palanzo compared many perfusion safety and incident studies showing the downward trend of incidents due to the rise in safety device usage. It also showed that GE has been an ongoing problem that has not yet been eradicated.

Disruptions occur in every situation, and the operating room is not an exception. Wiegmann et al. (6) found that not only do disruptions to surgical flow occur in the operating room, but they are also directly related with surgical errors. They observed 31 cardiac surgeries and found that teamwork and communication failures were the highest predictors of surgical errors. Other disruptions cited were mechanical failures, resource inaccessibility, and training of new staff. This article shows that whereas some distractions are avoidable, some are not. New safety devices that help eliminate distractions will improve overall patient safety.

Distracted driving has some implications that apply to perfusion safety. Seppa (7) uses the term “inattentive blindness” to describe people looking at something without seeing it. This article was aimed at cell phone use while driving. A driver is four times as likely to get into a crash while talking on a cell phone because people do not multitask; they toggle between tasks. This toggling makes drivers focus more narrowly on the road and reduces the amount of peripheral scanning they are able to do.

Perfusionists must constantly scan their reservoir, pressures, temperatures, and the operating field. While scanning other necessary parameters, the reservoir remains in the peripheral vision and is susceptible to not being seen. Some distractions cannot be avoided in the operating room, which makes Seppa’s article pertinent to this research.

Seppa’s article is similar to findings by Carlson and Tinker (8). They studied reaction time to stimuli in various fields of vision. Their subjects had to move a lever in the correct direction corresponding to which field of vision they saw the stimuli. Subjects had more latency in response to stimuli presented in their peripheral vision. Similar results were found for stimuli placed in the lower quadrants of vision.

These findings are pertinent to this research because those two parameters (lower and peripheral) describe the perfect position for a venous reservoir, especially when only gravity drainage is being used. The position of the reservoir cannot be changed in many situations, but combating the slower reaction time caused by reservoir location is possible.

Noticing that a reservoir level is dropping requires a perfusionist to notice a change in motion. Barbur et al. (9) found that it takes 7 ms longer to notice a change in motion than a change in color. They studied the pupil’s involuntary reaction to stimuli, including color changes, structure changes, and motion. They found that larger stimuli are associated with shorter reaction times. J. J. (2) also found that a warning shortened a person’s reaction time. In this study, subjects were warned with a flash of light that their stimulus was about to appear. Once the stimulus appeared, they were to respond appropriately. Subjects who received the warning had shorter reaction times than those who received no warning. The time between the warning and the stimulus was called the “expectation time.”

These two studies relate to this research because they have identified flaws in the common operating room setup. The venous reservoir is in a position to provide the slowest reaction time, and the perfusionist receives no warning that the reservoir level is going to drop.

Currently, bubble detectors are included in the *American Society of ExtraCorporeal Technology’s* standard guidelines (11). Level sensors are included when a hard-shell reservoir is being used. Knowing that the use of these safety devices is expected is necessary as this research explores the possible addition of further safety device use.

This literature review brings together seemingly unrelated topics. Gaseous emboli occurrences during CPB, once a widespread problem, have improved as safety devices have been manufactured. Because GE has not been eradicated, new advancements must be made. These advancements must take into account human capabilities. Perfusionists can be distracted, and distraction leads to “inattentive blindness,” which can have fatal consequences on the road or in the OR. The human eye responds to larger, centrally located stimuli more quickly than it does to smaller, peripherally located stimuli. It also responds more quickly to changes in color than to changes in motion. These parameters must all be accounted for in the next step of perfusion safety.

MATERIALS AND METHODS

Participants were recruited via e-mails to local university organizations and posters hung on the University of Nebraska Medical Center (UNMC) and University of Nebraska Omaha campuses. Twenty-seven participants

were needed for this study to hold 90% power; 33 participants were recruited. Participants were excluded if they had prior experience operating a heart–lung machine (HLM) or if they were aged less than 19 years. UNMC Institutional Review Board (IRB) approval was granted before any recruitment or testing (IRB #354-17-EX). Participants were randomly assigned to a group and subgroup as they volunteered, and each subject participated in three back-to-back trials. All trials were conducted in the same location, with the same operating room background noises being played (12), and using the same equipment primed with red fluid, resulting in 1 L in the reservoir. Informed consent was obtained and the appropriate script was read. The script informed the subjects that they were to remain seated on a stool in front of the HLM for the duration of the three trials, chart a line of data every 30 seconds (pump flow rate and two temperatures), and stop the arterial roller head by turning off the knob when they noticed the venous reservoir volume dropping or if their assigned alarm was triggered. Participant questions were answered before beginning the first trial. Further explanation was provided between trials, if needed.

One investigator set the flow rate at an appropriate flow (approximately 4.2 L/min) to maintain a steady 1,000-mL level in the reservoir while using gravity drainage. The other investigator stood behind a drape, ready to clamp the venous line at times unknown to the subject. These times were 1:00, 1:20, or 2:40 minutes, which coincided with times during, before, or after when the participant was supposed to chart a line of data. This was carried out to ensure that the subjects would not be able to use the charting time as a way to prepare for the next event. The order of these times was randomized between subjects. Once the arterial roller head was turned off, the elapsed time and the amount of fluid lost from the reservoir were recorded by the second investigator, and the reservoir fluid level, timer, and background noise were reset for the next trial.

Once the line was clamped, the investigator who did the clamping measured the time lapsed by watching the timer. The other investigator (seated next to the venous reservoir) observed the amount of fluid lost from the reservoir. The two data points were recorded, the timer was reset, and the flow rate was reestablished to attain and maintain a level of 1,000 mL in the reservoir.

Instrumentation

A Sorin S3 HLM with a Terumo FX-15 oxygenator and reservoir (Terumo Medical Corporation, Somerset, NJ) was used along with two temperature probes. A 5-gallon bucket acted as the patient and was filled with red fluid and placed on an operating table. A surgical drape was used to conceal the investigator from view of the subject. A laptop was used to display a timer (in seconds) for both investigators and subjects to see (Figure 1). The turbine

probes for the Flow Awareness Technology and the level detector sensors were left in place for all three groups but were only used for the appropriate group (Figure 2). All other equipment was reused for each trial.

The Flow Awareness Technology raised an alarm by changing the color of the computer monitor: Green meant the arterial and venous flows were equal. When the venous line was clamped, the screen would turn red, indicating that the venous flow was less than the arterial flow.

The level detector raised an alarm with an audible beeping when the volume in the reservoir fell below the level of the detector. In this study, the level detector was placed at 800 mL.

Pilot Testing

One trial was carried out with a perfusion student before formal testing. Through this pilot test, it was concluded that one investigator would closely watch the level in the reservoir by sitting next to it because the level would slightly rise/fall over the 1–2 minutes the pump was running. If the level had risen to 1,050 mL or fallen to 950 mL before the venous occlusion event, the investigator would mentally note this and make appropriate adjustments to the final volume lost. It was also determined that the investigator behind the drape and performing the venous line clamping was more easily able to time each trial.

RESULTS

The amount of elapsed time (in seconds) and fluid lost from the reservoir (in milliliters) were recorded as separate data points for each trial. With 33 subjects each conducting three trials, 99 data points were collected. Of these 99 data points, five were deleted, resulting in a total of 94 data points.

A one-way analysis of variance (ANOVA) study was used to analyze the data. Twenty-seven subjects were needed for this study to have 90% power to detect differences among the means between the three groups. The total number of participants was 33, yielding >90% power. *p*-values of .05 or less are statistically significant.

Group A (flow awareness) had an average reaction time of 2.15 seconds, which resulted in an average fluid loss of 79.61 mL. Group B (level detector) had an average reaction time of 4.34 seconds with an average fluid loss of 173.18 mL. Finally, Group C (no safety device) had an average reaction time of 4.07 seconds, with an average fluid loss of 138.83 mL (Figure 3). Based on the amount of fluid lost and the last data point for flow recorded by the subject, the reaction time for each trial was also calculated (Figure 4).

The analysis showed statistical significance between all three measured parameters between Groups A and B

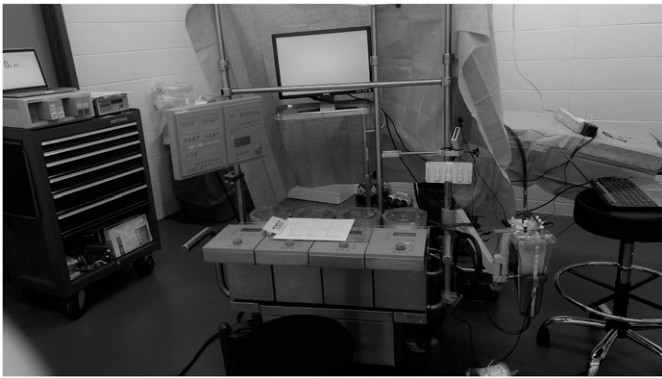


Figure 1. Flow awareness experiment setup.

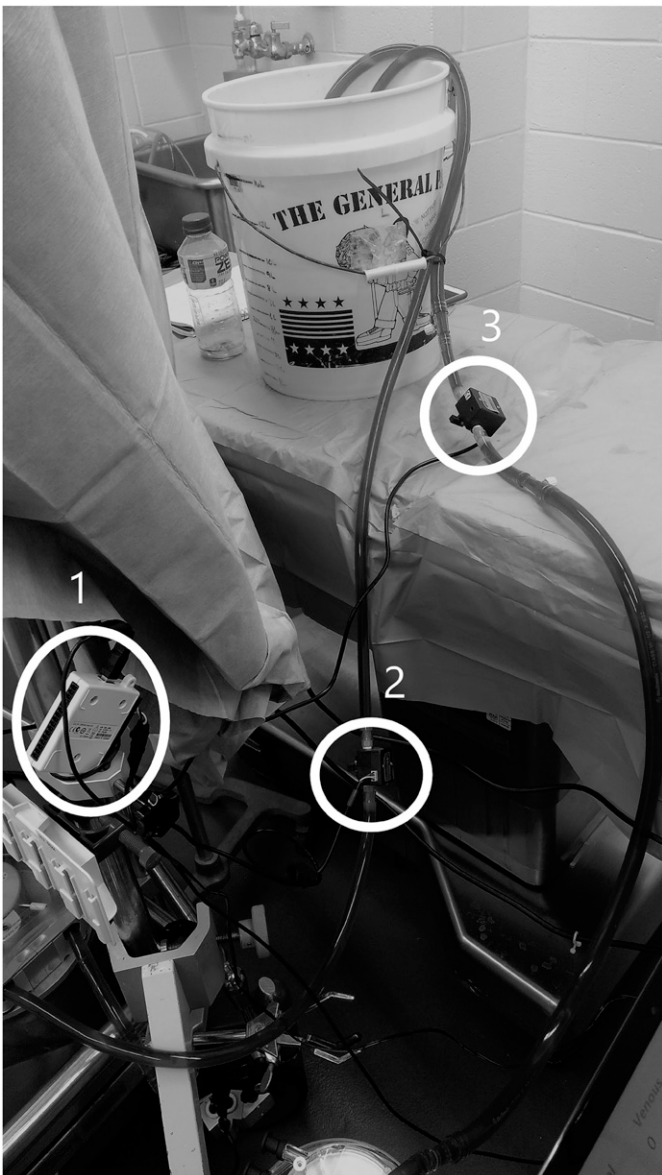


Figure 2. Flow Awareness Technology inline. 1. Analog-to-digital converter. 2. Arterial line turbine. 3. Venous line turbine.

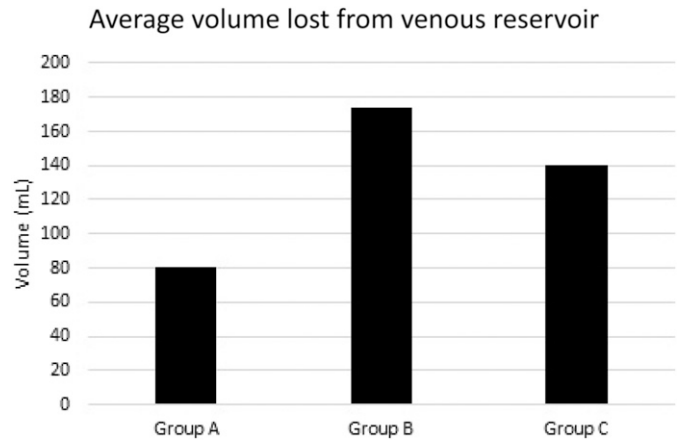


Figure 3. Average volume lost from the venous reservoir. Group A: flow awareness group; Group B: level detector group; Group C: control group.

and Groups A and C. There was no statistical significance between Groups B and C for any of the parameters (Table 1).

The timing of each trial was designed to happen either before, during, or after a 30-second mark when the subjects were instructed to chart a line of data. For all three groups combined, each trial that was conducted at 1:20 minutes (before being expected to chart) had an average reaction time of 2.85 seconds with 97.1 mL of fluid loss. Each trial conducted at 1:00 minute (during charting) had an average reaction time of 3.92 seconds with 152.4 mL of fluid loss. Finally, each trial conducted at 2:40 minutes (after charting) had an average reaction time of 3.79 seconds with 145.2 mL of fluid loss.

The analysis showed statistical significance for all three parameters when comparing “during” charting and “before” charting. Statistical significance was also shown when comparing “before” charting and “after” charting. There was no significance when comparing “during” charting and “after” charting (Table 2).

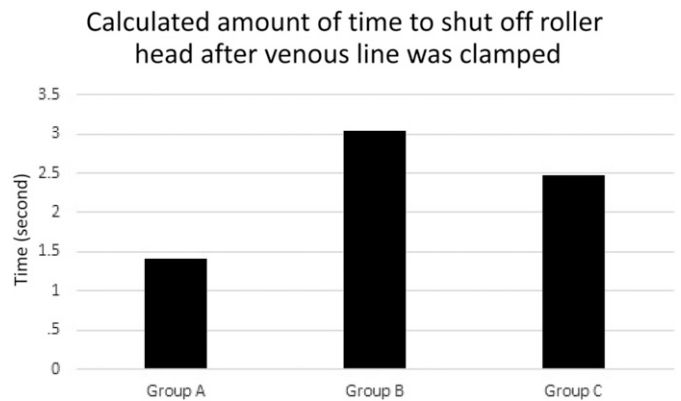


Figure 4. Calculated amount of time to shut off the roller head once venous line was clamped. Group A: flow awareness group; Group B: level detector group; Group C: control group.

Table 1. Raw data and statistical analysis of flow awareness experiment.

	A	B	C	A vs. B (<i>p</i> -Value)	A vs. C (<i>p</i> -Value)	B vs. C (<i>p</i> -Value)
Measure volume lost (mL)	80.8	173.6	140.3	−92.8 (.001)	−59.5 (.023)	33.3 (.188)
Calculated time elapsed (s)	1.41	3.05	2.47	−1.64 (.001)	−1.06 (.002)	.58 (.191)

Group A: flow awareness group; Group B: level detector group; Group C: control group.

DISCUSSION

One factor that must be taken into account is that the experiment was not conducted in an actual operating room. There are many different types of distraction in the operating room in addition to the charting that we used, such as communication with other staff, manipulating oxygen/CO₂ parameters, and giving drugs on pump to name but a few. Another limitation to this experiment was that the subjects were expecting an event to occur. Although they were not aware of exactly when, they were still somewhat prepared for a major change to happen. It is important to always be prepared for this, but we rarely expect adverse events to occur.

As indicated on CPB disposables, many venous reservoirs range from having 150–200 mL as the minimum operating level before the manufacturer warns of possible vortexing. These trials began with a level of 1,000 mL, so by placing the level sensor at 800 mL it mimicked those lower level thresholds while trying to avoid the risk of de-priming the circuit. This level would also yield a maximum reaction time for subjects while reading the level as specifically as possible.

Of the 99 data points collected, five had to be deleted. During one trial, the subject turned the knob the wrong way, which increased the roller head flow and caused more fluid to be lost than expected. For two separate subjects, their first trial was deleted because of confusion. They each noticed the level dropping but seemed hesitant and did not move to turn off the pump. The investigator let the level drop to 200–300 mL before turning off the flow to avoid de-priming the circuit. In another two studies, there were equipment malfunctions that led to testing errors.

The time it took for a subject to shut off the roller head was recorded during each trial. This timing was performed by the investigator who clamped the venous line at a specified time. After doing so, she continued to watch the timer until she heard the pump stop. As the study moved forward, it was decided that this was not the most accurate

way to measure time, but consistency was maintained. Once the trials concluded, the investigators calculated the reaction time using the amount of fluid lost from each trial and the last recorded flow for the same trial. Both the observed and the calculated reaction time measurements were used in the analysis and yielded statistical significance.

There is evidence that the flow awareness group had significantly faster reaction times than both the level detector and the control groups. The flow awareness group also lost less fluid from the venous reservoir than the level detector and control groups. The level detector and control groups had mean values for both measured data points that decreased over the course of the trials, meaning that the subjects got better with practice, but these changes were not significant. These statistics show that using Flow Awareness Technology is safer for subjects with no prior perfusion experience; a clinical perfusionist would have more experience. Thus, further research needs to be conducted with practicing clinicians to determine if this hypothesis would hold true for that subject group.

It is interesting to note that the control group had a faster average reaction time than the level detector group. It is possible that subjects in the level detector group believed they had to wait for the level detector alarm to sound before reacting. It is also possible that they had a sense of security knowing that they had an alarm to alert them, whereas the control group knew they had no safety net.

All groups performed significantly better, meaning faster reaction time and less volume lost, before having to chart than during or after a scheduled charting time. There were no significant differences between “during” and “after”. This shows that the act of charting is significantly distracting. Further research is needed in this area to determine if there is a difference between the distractions caused by paper charting (which was used in this study) and electronic charting, which is becoming more popular in the perfusion world.

Further research should be conducted to determine what size of alarm screen is necessary to hold these results.

Table 2. Raw data and statistical analysis of flow awareness experiment by timing.

	Before Charting (1:20)	During Charting (1:00)	After Charting (2:40)	Before vs. During (<i>p</i> -Value)	Before vs. After (<i>p</i> -Value)	During vs. After (<i>p</i> -Value)
Measured volume lost (mL)	97.1	152.4	145.2	−55.3 (.002)	−48.1 (.007)	7.2 (.716)
Calculated time elapsed (s)	1.71	2.68	2.55	−.97 (.002)	−.84 (.007)	.12 (.722)

Group A: flow awareness group; Group B: level detector group; Group C: control group.

This study used a standard computer monitor screen, but this would be cumbersome in a clinical setting. Determining if a smaller screen, a series of light emitting diode (LED) lights, or an audible alarm (to name a few possibilities) could also provide similar results would be more appealing to practicing perfusionists.

Another area for future development is determining how to make this technology compatible with purposeful changes in flow (i.e., filling the heart), or known venous drainage issues (i.e., sucker bypass or plentiful vent return). Finally, further advancements can be made to the current technology. Using external flow probes rather than internal turbine probes would be safer for the patient, but they need to be tested for their own efficacy.

ACKNOWLEDGMENTS

We would like to thank our subjects for traveling to us to conduct this research without compensation and Harlan Sayles, our statistician, for helping us to understand our objectives and our results.

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