

Original Article

Centrifugal Pump Failures

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ABSTRACT

Centrifugal pumps will not pass gross quantities of gaseous emboli due to the nonocclusive nature of the pump. However, retrograde flow can occur under circumstances that include: product malfunctions, low flows, and human errors. Negative pressure created by falling arterial perfusate can draw air into the cannula. Food and Drug Administration (FDA) records about centrifugal pump malfunctions were obtained. Out of 350,000 cases completed with centrifugal pumps over a 23 month period, the FDA received reports of 68 malfunctions, 22 electrical burning smells, and three speed surges, yielding a failure rate of 1 in 3,763 cases. FDA records revealed five death reports and three serious injury reports. A survey was sent to 2,424 Society of Thoracic Surgeons' members to obtain more information; 285 who use centrifugal pumps responded. Sixty surgeons (21%) reported 108 malfunctions, including 46 complete pump failures. Fifty-one of 243 surgeons (21%) who use centrifugal pumps for bypass reported that perfusionists have forgotten to clamp the pump line, resulting in backflow. We conclude centrifugal pumps are generally safe, but malfunctions, low flows, and human errors can lead to retrograde flow and occasionally air embolization. There are valves that can be added to the bypass circuitry to prevent this risk.

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INTRODUCTION

Air embolism in cardiac surgery can produce serious complications, including death (1). One study found that from 1972 through 1977, 92 deaths and 61 permanent injuries were attributed to arterial line embolism from roller pumps (1). Newer perfusion systems with rotating impellers use centrifugal force to impart kinetic and potential energy to circulate the blood (2). When air enters the pump head of a centrifugal device, there is a reduced tendency for gas embolization due to the nonocclusive nature of the pumping mechanism. However, because centrifugal pumps are nonocclusive, retrograde flow can commence whenever the pump malfunctions, the pump stops, or when the pump slows and the pressure produced by the pump is less than the pressure needed to sustain forward flow (3-4).

Retrograde flow can create a hemodynamic siphon that can exsanguinate the patient and can draw air into the arterial line at the cannulation site (2-3). In vitro testing shows that retrograde flow can commence 540 msec after power to the pump is shut off. The reverse flow occurs even though the rotor is still spinning. This flow rate can rise to 2.5 l/min after another 470 msec (3).

Reed reports that there have been six separate instances of centrifugal pumps that passed air into the arterial line (4). The first failure of a centrifugal pump leading to air embolism from retrograde flow was reported in 1990 (2). In 1993, another perfusion system exhibited an increased incidence of unexplained stops. The company, which attributed the malfunctions to electrical noise, static discharge, and power fluctuations, later issued a safety alert related to these incidents, estimating the overall occurrence rate of unexplained stops at 0.4% (5).

Curtis reports three mechanical pump failures when using centrifugal pumps as univentricular or biventricular assist devices in 27 patients who could not be weaned from bypass. The most significant incident was a friction seal failure and electromagnetic decoupling of the motor drive that caused the device to stop. In the other two cases, there were problems with the flow sensor, which made it impossible to measure output (6). Finally, in 1991, another manufacturer recalled centrifugal pumps from Florida, Texas, and China after reworked units had a failure of the magnet polls which caused the motor rotors to stop (7).

A Freedom of Information Act request was filed with the Food and Drug Administration (FDA) to determine the incidence of centrifugal pump failures, which should be reported to FDA under the Safe Medical Devices Act of 1990. Surveys were sent to 2,424 Society of Thoracic Surgeons' (STS) members to obtain additional information. The purpose of this project was to determine the overall safety of the pumps and to ascertain how many injuries and deaths were associated with malfunctions.

MATERIALS AND METHODS

A pump malfunction was defined as any event that occurred

just before or during bypass that may have affected the patient's outcome. Some of the incidents listed in the FDA files included: pumps that stopped, vibrating noises, console lights flickering with intermittent motor speed, broken wires that prevented perfusionists from reading the console RPM, and loss of AC power. Other reports dealt with electrical burning smells, decoupling of the electromagnetic fields between the magnets of the centrifugal pumps and pump heads, grinding noises that forced perfusionists to turn off the centrifugal pump to regain control, and speed surges. A speed surge was defined as a sudden, unexpected increase in the rotational speed of the pump.

The authors of this paper simply tabulated the occurrence of these incidents as the information was described in the FDA files. The survey tool is depicted in Figure 1. The survey was designed and distributed by the authors. An applied research laboratory tabulated the data. The authors excluded contradictory responses.

RESULTS

FDA records indicate that 93 medical device reports were received for centrifugal pumps from November 1991 through October 12, 1993. Sixty-eight of these reports were malfunctions, 22 were electrical burning smells, and three were speed surges. There were approximately 350,000 open-heart procedures using centrifugal pumps during this period, which yields a failure rate of 1 in 3,763 cases. There are five death reports and three serious injury reports in the FDA records. Because of the limited information provided under the Freedom of Information Act, it is unclear what role, if any, the centrifugal pumps played in these deaths and injuries.

Overall, 371 surgeons (15%), including two of the paper's authors, responded to the survey. Two hundred and eighty-five of the respondents use centrifugal pumps for ventricular assistance or routine cardiopulmonary bypass. Sixty surgeons reported 108 centrifugal pump malfunctions, including 46 complete pump failures. There were 21 electrical burning smells and 26 speed surges.

These malfunctions, burning smells, and speed surges were postmarked from groups in 52 different cities. Of the surgeons with pump failures, electrical burning smells, and speed surges, 13 said the information was reported to the FDA, 22 said it was not, and 36 were unsure. (Eleven surgeons reported electrical burning smells or speed surges but did not consider these to be malfunctions. For this reason, 60 surgeons responded that they had experienced a malfunction of a centrifugal pump. However, 71 surgeons answered question 11, "If you have had a pump failure or malfunction, was the information reported to the FDA?")

Fifty-eight surgeons reported observing a malfunction, electrical burning smell, or speed surge with the Biopump^a, 21 for

a Medtronic Cardiopulmonary, Eden Prairie, MN

the Delphin^b, and three for the Lifestream^c. This information is summarized in Tables 1 and 2. These tables include the responses of the 11 surgeons who noted electrical burning smells or speed surges but who did not consider these to be malfunctions. Some surgeons experienced failures with multiple types of centrifu-

gal pumps. The higher number of pump failures for Bio-Medicus pumps just indicates their greater usage. There are no data to suggest that the Bio-Medicus pumps are more incident prone.

When asked did the pump failure cause patient injury, three said yes, 61 said no, and five were not sure. When asked did the

pump failure contribute to a patient's death, two said yes, 64 said no, and three were not sure. Nine of the 11 surgeons who reported burning smells or speed surges but who did not consider these to be malfunctions answered these questions. Their answers were included. Of the eight respondents reporting an injury or death, two were postmarked from the same city, an indication of one possible duplicative report.

Fifty-one of the 243 thoracic surgeons (21%) who use centrifugal pumps for routine cardiopulmonary bypass reported that their perfusionists have forgotten to clamp the centrifugal pump line, which resulted in backflow. The survey did not ask if there was any morbidity or mortality associated with these incidents.

DISCUSSION

There are several limitations to this study. The survey did not ask respondents to list the number of cases they had performed with centrifugal pumps. This denominator would have allowed us to estimate the failure rate for centrifugal pumps. Furthermore, it is possible that surgeons with pump failures may have been more likely to respond than surgeons without pump failures, possibly skewing some results. Finally, because it was an anonymous survey, it was impossible to mail a second survey to nonresponders to improve the response rate of 15%. However, we believe the survey complements the FDA files and provides the first good data on centrifugal pump safety.

Our concern is with the nonocclusive design of centrifugal pumps

Figure 1: Centrifugal Pump Failure Survey

Centrifugal Pump Failure Survey

1. Do you use centrifugal pumps for routine cardiopulmonary bypass?

a. Yes b. No

2. Do you use centrifugal pumps for ventricular assistance?

a. Yes b. No

3. Do you only use roller pumps for cardiopulmonary bypass?

a. Yes b. No

If you answered yes to question number three, please return the survey. You do not need to answer the rest of the questions. However, if you do use centrifugal pumps, would you please answer the following questions?

4. We know that your perfusionist is good, but has he or she ever forgotten to clamp the centrifugal pump line, which resulted in backflow?

a. Yes b. No

5. Have you ever experienced a malfunction of a centrifugal pump?

a. Yes b. No

6. How many malfunctions have you experienced?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5 g. other (list) _____

7. How many times have you observed an *electrical burning smell* with a centrifugal pump?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5 g. other (list) _____

8. How many times have you experienced *speed surges* of the centrifugal pump?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5 g. other (list) _____

9. How many times have you experienced a *complete centrifugal pump failure*?

a. 0 b. 1 c. 2 d. 3 e. 4 f. 5 g. other (list) _____

10. Does your institution have an individual who reports medical device failure to the FDA?

a. Yes b. No c. Not sure

11. If you have had a pump failure or malfunction, was the information reported to the FDA?

a. Yes b. No c. Not sure

12. Please circle the following pumps with which you have observed a malfunction or a failure?

a. Biopump b. Delphin c. Lifestream

13. Did the pump failure cause patient injury?

a. Yes b. No c. Not sure

14. Did the pump failure contribute to a patient's death?

a. Yes b. No c. Not sure

15. If you answered yes to questions 13 or 14, do you have any additional information to report?

b Sarns 3M Healthcare, Ann Arbor, MI
c St. Jude Medical, St. Paul, MN

Table 1: Society of Thoracic Surgeons' Reports of Pump Failures

Pump Type	Manufacturer	# of Surgeons Observing Malfunction/Failure*
Biopump	Medtronic	58**
Delphin	Sarns 3M Healthcare	21
Lifestream	St. Jude Medical	3

* This column includes the number of surgeons who reported at least one failure with that type of centrifugal pump. Some surgeons reported malfunctions/failures with multiple types of centrifugal pumps.

** The higher number of pump failures for Bio-Medicus pumps just indicates their greater usage. There is no data to suggest that the Bio-Medicus pumps are more incident prone. The overall usage of each pump was unavailable.

Table 2: Food and Drug Administration Reports of Pump Failures

Pump Type	Manufacturer	FDA Reports of Malfunction*
Biopump	Medtronic	75**
Delphin	Sarns 3M Healthcare	14
Lifestream	St. Jude Medical	4

* This column includes malfunctions/failures, electrical burning smells, and speed surges from November 1991 through October 12, 1993.

** The higher number of pump failures for Bio-Medicus pumps just indicates their greater usage. There is no data to suggest that the Bio-Medicus pumps are more incident prone. The overall usage of each pump was unavailable.

(2-3). With this design, the only way to prevent retrograde flow through these pumps is for the perfusionist to clamp the arterial line when the pump slows or stops, which can occur unexpectedly (8). The nonocclusive design also forces perfusionists to clamp the arterial line when low flows are requested or when patients are weaned from bypass (2). However, 51 thoracic surgeons reported that their perfusionists have "forgotten to clamp the centrifugal pump line, which resulted in backflow." This human error could be disastrous. Kurusz points out that human errors are cited as the factor believed to be responsible for 73.3% of perfusion accidents, compared with 19.5% for device malfunctions or failures (9). The combination of the nonocclusivity characteristic, device failures, and human error raise our concern about patient safety. Furthermore, as in vitro testing has shown, retrograde flow can commence 540 msec after power to the pump is shut off. It is unlikely that even the most conscientious perfusionist could react fast enough to prevent retrograde flow.

The inaccuracy of flow meters at low flows is another safety issue. Other research indicates that the flowmeters on centrifugal pumps are inaccurate and can miscalculate blood flow as

much as 1 l/min at low flows (10). Noon concludes, "Because the flow meter is the only indicator of flow, it should be very reliable to prevent adverse effects to the patient. The manufacturers claim accuracy to within $\pm 10\%$ of the actual flow; however, our findings do not support this..."(10).

The inaccuracy of the flow meter can lead the perfusionist and surgeon to believe blood is flowing to the patient when, in fact, blood is flowing from the patient. One company estimates that 1,500 RPM are needed just to prevent backflow. Below this speed, the rotor does not transfer sufficient energy to overcome the back pressure and reverse flow, forced by the arterial pressure and the same hydrostatic head relied on for venous drainage, will begin (5). The patient's arterial pressure, the hydrostatic difference between the patient and the pump, and the resistance of the tubing and cannula to the blood flow contribute to the RPM needed to sustain forward flow (2).

We have eliminated concern over pump malfunctions, human errors, and the inaccuracy of the flow meters by incorporating a one-way valve into the arterial line for all open-heart procedures. Other research documents that the valve does not significantly affect hemodynamics or hematologic values (3). Because the device is intended only for use in anticoagulated blood, there are no additional thromboembolic concerns (3).

Moreover, we recently weaned more than 150 patients off bypass without arterial line clamping, which is unnecessary with a one-way valve in-line (11). Our perfusionists discontinue bypass by dropping RPM to decrease the flow as indicated by the flow meter. When bypass is stopped, the pump is turned off and the valve automatically occludes the arterial line unidirectionally. There have been no complications from this technique.

With roller pumps, venous blood level detectors back up the busy perfusionist and shut off the pump automatically at low reservoir levels. However, with centrifugal pumps in the circuit, this shut-off feature cannot be used because arterial flow will reverse through the nonocclusive pump head. If a one-way arterial line valve is utilized by the open-heart team, the venous level detector can be used. We urge the centrifugal pump manufacturers to encourage the use of venous blood level detectors to automatically shut off the centrifugal pump. This is the safest thing to do, but only when a one-way arterial line valve is used. The combination of a venous level detector, the shut-off switch, and the one-way valve would provide a simple safety system that would reduce the patient risk during malfunctions, human errors, and a host of other misadventures that can occur in the operating room.

We conclude that centrifugal pumps are generally safe and the overwhelming majority of open-heart operations are completed without incident. However, perfusionists and cardiothoracic surgeons should be aware that patients are at risk because

of pump malfunctions and human errors. These failures and errors can lead to air entering the arterial line. There are currently inexpensive valves on the market to protect against retrograde flow and the potential of air entering the arterial line. We urge perfusionists and cardiothoracic surgeons to consider such valves to avoid a potentially catastrophic incident and to make the heart-lung bypass circuit as safe as possible.

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