Original Article

An In Vitro Evaluation of an Automatic Clamp for Use with Centrifugal Pumps

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ABSTRACT

The risk of air emboli is a concern for all perfusionists. A new clamping device for use with centrifugal pumps is designed to clamp both the arterial and venous lines at the first indication of air or retrograde flow, thereby allowing the perfusionist to evaluate the situation and correct the problem before entraining air into the arterial pump head. After evaluating this device in our lab, we conclude that this new safety device should be added to the heart lung machine by all perfusionists using centrifugal pumps.

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INTRODUCTION

The risk of air emboli during cardiopulmonary bypass (CPB) is well documented and is a primary concern of perfusionists (1,2,3,4). In an effort to prevent this occurrence, safety devices such as level detectors and bubble detectors incorporated into the perfusion system have become the accepted standard of care. Many heart-lung machines today incorporate systems that will slow or stop the arterial pump head (roller) when either alarm is activated. Unfortunately, this is not feasible or desired when using centrifugal pumps. The automatic stopping of a centrifugal pump would allow retrograde flow. There have also been problems interfacing the various manufacturers' equipment to allow for servo regulation based on the level detector.

DESCRIPTION OF THE DEVICE

A new device, Automatic Tubing Clamp (ATC), developed by Rocky Mountain Research, Inc.[a] has received FDA approval and is now commercially available. The device consists of an ultrasonic air detector, an arterial line clamp, a venous line clamp, and a control box (Figure 1).

The ultrasonic bubble detector is designed to trigger the two clamps when a predetermined amount of air is detected. It also is designed to activate the clamps when retrograde flow is detected. The ultrasonic transducers are dry coupled outside the tubing and require no gel or blood interface. The transducer can be preset by the manufacturer to trigger at any bubble size in the range of 0.02 ml to 1 ml.

The clamping devices are pneumatically opened and spring closed. They operate utilizing compressed air which can be from either the hospital gas system or a cylinder. The clamps exert a pressure rated at 32 lbs on the tubing when activated. The clamps are connected to the control box by 4 ft cables.

The control box is 5" x 10" x 11" , weighs 10 lbs, and is designed to be pole mounted on the heart-lung machine. The controls consist of manual open and close for each clamp as well as an automatic mode for use during CPB. Two audible and visual alarms indicate detection of air and retrograde flow.

MATERIALS AND METHODS

The circuit consisted of a hollow fiber membrane oxygenator with integrated hard shell venous reservoir[b] , a centrifugal pump[c] , and a second reservoir (Figure 2). The circuit was primed with normal saline and debubbled. Flow rates were then set at 2, 4, and 6 LPM to test the device. Crystalloid was used as the fluid medium because it is less likely to absorb any bubble and is better in testing such a device. Air was injected in the circuit just distal to the outlet of the venous reservoir proximal to the transducer. Mannitol was added through the filtered inlet and also through the venous inlet via the sampling manifold.

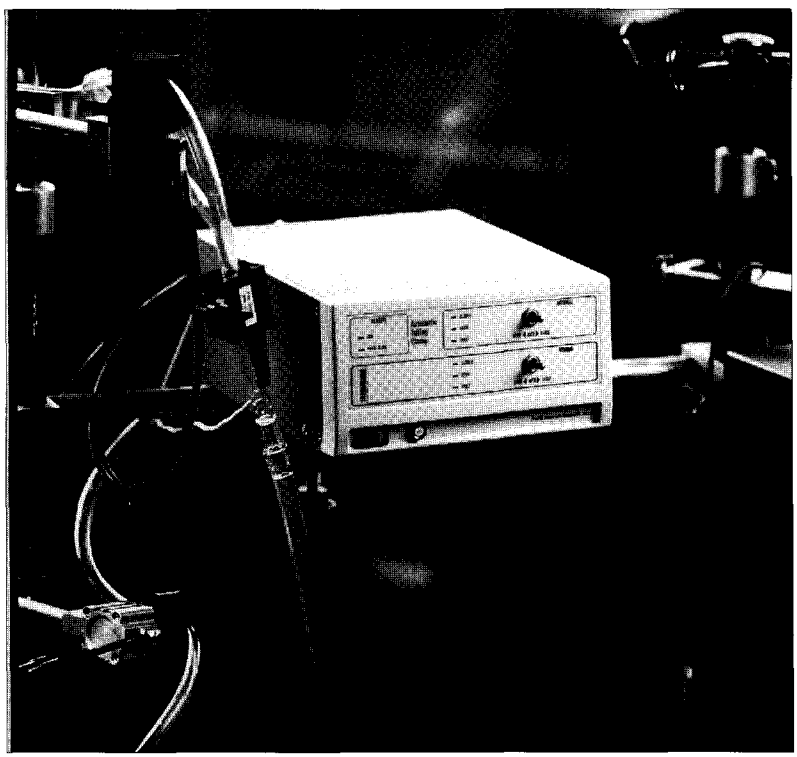
To test the device for effectiveness in detecting and preventing retrograde flow, the centrifugal pump was turned off and the position of the reservoirs allowed for gravity drainage from the "patient reservoir" to the pump head to the oxygenator and venous reservoir. This was checked by clamping the outlet of the "patient reservoir" and filling it, turning the device off, then turning the pump off and observing the patient reservoir empty and the venous reservoir fill. With the outlet of the "patient reservoir" clamped, this would only be possible with retrograde flow.

EVALUATION OF THE DEVICE

The ATC is designed to clamp both the arterial and venous lines when air or retrograde flow is detected at the transducer. During operation, the circuit drives one ultrasonic transducer

a Rocky Mountain Research, Inc. Salt Lake City, UT
b Avecor Cardiovascular, Minneapolis, MN
c Medtronic Biomedicus, Eden Prairie, MN

Figure 1: Automatic Tubing Clamp



which projects ultrasonic energy of a fixed frequency (2.5 MHz) across the tubing and its contents. The second transducer acts as a receiver, sensitive to the ultrasonic energy and frequency transmitted across the fluid path. When a bubble passes through the transmitter pathway, the path of acoustic energy is disrupted. If enough of the transmitted energy is blocked (due to losses from the liquid-gas interface), this low input will signal that air is detected.

To determine the direction of blood flow, the phase of the signal is the discriminator. The phase of the received signal changes with the speed and direction of the fluid flow past the transducer.

When air or reversed flow is detected, the audio alarm is activated, the AIR light or FLOW light is illuminated, and the clamps, if in the automatic mode, are activated and the tubing clamped. The alarm will continue until both clamps are manually opened (presumably after the elimination of air or correction of flow problem). If for some reason the clamps are unable to automatically close, the fault light will illuminate on the control box as the alarm sounds.

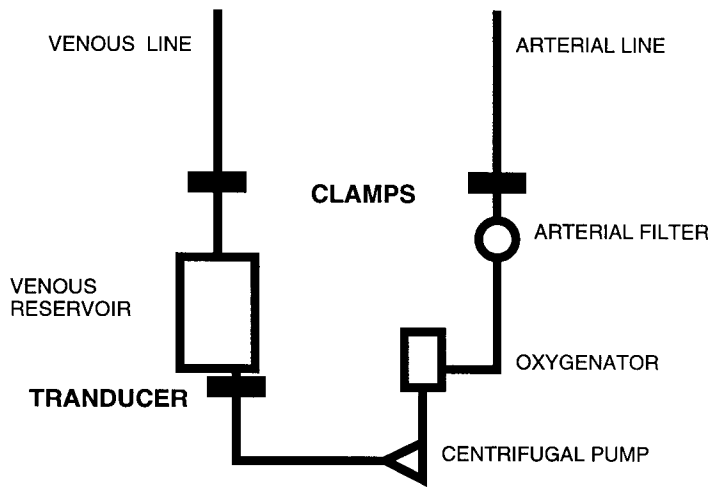
Each clamp is operated by an individual switch which has three positions: open, closed, and automatic. In the automatic mode, the clamps are in the open position and the device is activated and will close the clamps if air or retrograde flow is detected. In the open position, the clamps will remain open if air or reverse flow is detected, although the alarms will still function. In the closed position, the clamps remain closed.

In our lab, we found that by placing the arterial line clamp distal to the arterial filter and placing the transducer just below the outlet of the venous reservoir (Figure 2), we were able not only to prevent pumping air beyond the CPB circuit, but also to prevent air from entering the centrifugal pump head. In examining various positions to place both the transducer and the arterial line clamp, we found this combination to produce the maximum benefit.

The device we tested was set to trigger when a .035 ml bubble was detected. We found that the unit operated properly with over 100 tests of injecting a .3 ml bolus of air in the stopcock located just proximal to the transducer. The device functioned properly at all three flow rates. We found that if we injected the air slowly as to imitate "micro" air, the unit did not trigger, thus avoiding false alarms. We also found that the unit was not activated with the addition of colloids such as mannitol; this was a concern, as we often experience "noise" with our air detector when adding drugs.

In testing for the effectiveness of retrograde flow we found the device to be reliable. The clamps were closed as soon as retrograde flow was detected which occurred at various pump speeds dependent on the volume in the "patient reservoir" as well as the height of the "patient reservoir" in relation to the venous reservoir.

Figure 2: Clamp and transducer placement



DISCUSSION

In a previous report on a prototype of this device, it was suggested that the transducer be placed distal to the arterial filter (5). The manufacturer instructions state that the transducer "should be positioned on the arterial tubing at least four feet proximal to the patient" (6). It is our feeling that air should be detected as early as possible in the circuit to prevent entrainment into the pump head, oxygenator, or arterial filter. In our evaluation, we chose .3 ml of air to simulate a bubble that might prove detrimental to a patient. Our "slow" injection was an attempt to simulate "micro air" which we felt would be handled by the oxygenator and the arterial filter and for which we would not desire the ATC to trigger. As previously stated, the device can be preset by the manufacturer to trigger at a predetermined bubble size from .02 ml to 1 ml.

From our laboratory experience we feel the ATC is a reliable system which will offer the perfusionist the added margin of safety that previously has only been available with a roller pump; i.e., the ability to immediately cease blood flow at the first detection of air. In our lab, the system proved reliable, repeatedly functioned properly, and did not false alarm. For those centers using centrifugal pumps in the arterial position, this device should be an integral component of the perfusion system when utilizing a centrifugal pump.

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