LETTERS TO THE EDITOR

September 5, 1986

To the Editor:

In the Spring 1986 issue of The Journal of Extra­Corporeal Technology, the article entitled “Right Ventricular Assist with Conventional Cardiopulmonary Bypass Equipment” discussed the use of a Sams roller pump in an application for which it is not indicated in the product labeling. We have not evaluated the application and thus cannot comment on its safety or efficacy. We therefore do not and cannot recommend the use of our product in the manner described.

Sincerely,

Samslnc/3M
C. Marshall Smith, P.E.
Quality Assurance and Regulatory Affairs Manager

September 16, 1986

To the Editor:

We appreciate the comments of C. Marshall Smith and Sams Inc/3M. We recognize the shortcomings of using an occlusive pump for long-term assist and, therefore, understand the apprehension of Sams Inc/3M concerning product labeling.

Due to the lack of a centrifugal pump, our group pursued the use of a roller pump for ventricular assist in those very difficult patients with possible reversible failure. After testing with animal models, we found that the roller pump could be used safely for ventricular assist when the proper protocol was followed. This procedure, however, was changed when a centrifugal pump was acquired by our group. The non-occlusive properties make the centrifugal pump the superior choice for long-term assist.

Sincerely,

Michael Corrigan, Paul DiGregorio, Alan Markowitz, Jose Soto, and Gary Freeman

MEMORANDUM

TO: Michael L. Houliston, Esquire
FROM: Jeff Riley, Editor, Journal of Extra­Corporeal Technology
DATE: September 22, 1986
SUBJECT: Smith (Sams/3M) Letter to the Editor, September 8, 1986

Mr. Houliston, please find attached: 1) a Letter to the Editor from Mr. Marshall Smith disclaiming the application of the Sams roller pump reported by Mr. Michael Corrigan in the previous issue of JECT, 2) my letter to Mr. Corrigan, 3) Mr. Corrigan’s reply letter to Mr. Smith of Sams, and 4) a copy of the article from JECT to which Mr. Smith refers.

If appropriate for you to do so, I would like you to comment on this unique situation. A multitude of Open Heart Centers around the world are employing roller pumps for ventricular assist and respiratory assist just as Mr. Corrigan has reported. Mr. Smith points out that if a problem occurs while these roller pumps are being employed, the user is all alone and quite responsible for misapplication. Interestingly, Mr. Smith is opening the market for the centrifugal type pumps which have FDA approval for “long-term” assist (greater than eight hours). Mr. Smith is saying: use the centrifugal pump; and Mr. Smith is putting all of the perfusionists in the world on notice that to employ the roller pump in long-term situations is negligent.

My question is: “Does an institution’s non-availability of a centrifugal pump free the perfusionist from the liability exposure to employing a “custom device” setup that incorporates a roller pump when a patient needs the circuit to sustain life?”

If possible, I would like to publish your response to this question or at least quote you in my own letter of explanation. This is a complex, timely issue and I would like for us to be able to provide an answer and, perhaps, some guidance.

Thank you for your help.

October 2, 1986

Dear Jeff:

I have done some preliminary research regarding the question raised in your 9/22/86 memo. Before I respond to you, I would appreciate the following information:

a. What are the indications that right ventricular assist is necessary or advisable?

b. Would the surgeon or the perfusionist make the judgment and order the RV assist?

c. If ordered, when does the RV assist occur—i.e., pre-op, op, or post-operatively—and for how long?

d. Assuming that a centrifugal pump is not available, what means have been employed in the past to achieve RV assist (excluding the roller pump technique in question)?

e. Am I correct that the technique described by Corrigan et al., involves a modification of the usual roller pump set-up?

f. Is, as I gather from your memorandum, the use of a roller pump for long-term RV assist widespread? If so, is the “Corrigan Technique” used?

g. Is the need for long-term RV assist widespread in terms of frequency of cases?
h. What is the cost comparison between the roller and centrifugal pump?

i. In lay terms, what is the essential difference between a roller and centrifugal pump that makes the centrifugal pump more adaptable or satisfactory for long-term RV assist?

Please feel free to call at your convenience.

Very truly yours,

Michael L. Houliston

October 22, 1986

Dear Mr. Houliston:

Following are the answers to your question of October 2, 1986.

a. Cardiopulmonary bypass patients that cannot be separated from the heart-lung machine because their right ventricle and atrium are not able to carry the work load of pumping systemic blood through the lungs, are often supported with right ventricular assist devices (RVAD). Signs and indications for the implementation of RVAD include right ventricular distention, rising right atrial and systemic venous pressures and inadequate pulmonary artery pressure.

b. The surgeon with the help of the anesthesiologist (and maybe the perfusionist) would order the use of the RVAD in any surgical candidate.

c. RVAD usually occurs after cardiopulmonary bypass when the patient cannot be separated and the left ventricle is functioning normally.

d. Some surgeons have attempted to employ intra-aortic balloon pumping (IABP) in the pulmonary artery. The IABP was designed for use in left ventricular assist (LVAD) and the aortic balloon does not fit well in the pulmonary artery. Other than the vortex pump and, for years, the roller pump, there are no other direct assist devices available for RVAD.

e. No, the technique described by Corrigan, et al. does not modify the hardware of the roller pump. Their technique is only to use it when RVAD is indicated in the absence of the availability of the vortex pump (centrifugal pump).

f. It is hard to estimate how many times roller pumps and vortex pumps are employed for RVAD. RVAD necessity is a low occurring post bypass complication. For years, prior to the vortex pump availability, roller pumps were used sometimes for RVAD and much more commonly for LVAD. Only in the recent years (5) has the vortex pump become commonly used for LVAD and/or RVAD. When ventricles are assisted separately, we call it BiVAD. The roller pump has been used for decades for short-term cardiac assist and replacement and less frequently for long-term cardiac assist and replacement. Now Sarns/3M is warning that the roller pump is not indicated for long-term ventricular assist of any type.

g. I do not know the incidence of RVAD necessity. If I were to guess, perhaps 1 or 2 patients out of 500 open heart patients suffer severe right heart failure to indicate a RVAD.

h. The centrifugal pump is much more expensive. The hardware for the centrifugal pump is about $18,000 and the roller pump, about $7,000 and the disposables are about $350 for the centrifugal pump and the cost of a foot of tubing for the roller pump. This fact is the most obvious reason for desiring to be able to do long-term assist with the roller pump. Additionally, the manufacturer of the centrifugal pump could not meet all the need in the market in recent years.

i. The centrifugal pump is purported to be a gentler blood handling device and the manufacturer has received FDA approval for the use of the device in LVAD and RVAD as well as long-term respiratory assist which is similar to RVAD. The roller pump is thought to be more destructive to blood components in the long term than the centrifugal pump. However, this hypothesis has not been proven in the scientific literature. Many authors have testified that they have been successful in using both type pumps for long-term cardiac assist.

It is hoped that you can see the dilemma here in that the manufacturer is putting our profession on notice that its roller pump is not to be used in this custom circuit for long-term use. However, most clinicians will contend that if a patient needs RVAD and a vortex pump is not available, then they will use a roller pump; it worked in the last decade for LVAD and partial cardiac assist for long periods. Now, all of a sudden, we cannot use Sarns' pumps for over eight hour perfusions or cardiac support.

Your questions are appropriate and I appreciate your time to help sort out the perfusionists' position in this dilemma.

Sincerely,

Jeffrey B. Riley, Editor

November 18, 1986

Dear Mr. Riley:

Thank you for your comprehensive answers to the questions I raised in my letter of October 2, 1986.

As I understand it, the doctor would usually make the decision to order long term RVAD for a particular patient. A perfusionist would not normally be held liable for adverse sequela providing the doctor's orders "...were not so obviously negligent or erroneous as would lead any responsible person to anticipate that substantial injury would result..."

To answer your question as to whether or not the non-availability of a centrifugal pump might subject the perfusionist to liability in the event of injury to a patient, we must address the issue of whether or not the care provided to the patient fell below the standard of care.

The standard of care is the use of the degree of skill and diligence in the care and treatment of a patient that a reasonably prudent (doctor) in the same field of practice or specialty would have used in the same circumstances.
From the information you have provided to me, the following facts are relevant in determining whether or not the treatment (i.e., the use of a roller pump for long-term RVAD) fell below the standard of care:

1. The incidence of cases where RVAD is indicated is low and in those cases,
2. Serious consequences would follow if RVAD was not implemented;
3. A centrifugal pump is not available and,
4. Roller pumps have been successfully used in RVAD for many years.

In my opinion, based upon the above, the standard of care has been met. It certainly would not be negligent to implement available life saving measures. These measures must, of course, be implemented in the proper manner.

In his letter of September 5, 1986, Mr. Smith, on behalf of Sarns Inc/3M, indicates that his company has not evaluated the roller pump vis-a-vis RVAD and it follows that they would not recommend the roller pump’s use in RVAD.

While Sarns’ disclaimer is disquieting, I do not feel it would be determinative on the issue of negligence in a trial involving unsuccessful RVAD using a roller pump. I believe the standard of care, i.e., 10 years successful use of roller pumps could be established.

Very truly yours,
Michael L. Houliston

To the Editor:

In the article by R.C. Spahr, “Extracorporeal Membrane several informations in Acute Respiratory Insufficiency in Neonates,” now at a time when many medical teams are searching for ways to improve the outlook for patients with respiratory distress syndrome. The reader will agree with the conclusions R.C. Spahr has drawn from the clinical results in the neonate. But he may, however, question the argument which leads the author to limit the use of ECMO to the newborn.

This author bases his reserve on the results of the National Institutes of Health multicentric program in 1975. At that time, the study stated the futility of using ECMO in the treatment of adult respiratory insufficiencies. We must not, however, forget that this same study confirmed the failure rate of mechanical ventilation (i.e., the conventional method of treating these patients) even if the hyperoxic and the hyperpulmonary inflation were better controlled and restricted. Thus, in the “Additional Data Collection” of this program, it is noted that more than 67 percent of the 686 patients with acute respiratory insufficiency, died. On the other hand, the survival probability rate of the group of 90 patients entered into the randomized study is less than 10 percent. If the very strict solution criteria for entry into this study is justified on deontological grounds, it is probable that a bias was introduced into this study. To what extent can the pulmonary parenchyma lesions in these patients demonstrate a significant degree of reversibility to appraise the qualities of the different respiratory support methods?

Finally, the possibility given to nine collaborating clinical teams to apply a mechanical ventilation associated with ECMO has had an influence on the final results = putting the lung “at rest” appears to be a factor which improves the possibilities of functional and anatomical recovery of the injured parenchyma. The latter has become especially important since the Gattinoni’s clinical results.

In recent years some intensive care teams have resorted to the use of ECMO in exceptionally serious situations. Such reflections should serve to prompt these teams to publish their observations and to break a certain “code of silence” which would be imposed by the 10-year-old NIH study.

A respiratory support method which requires an extracorporeal circulation will only really be possible when it can be applied with the same ease as a hemodialysis. It is now up to the research groups to innovate and come up with some proposals.

J.P. Gille, M.D.
France

References


To the Editor:

Dr. Gille’s comments are certainly thought provoking. The purpose of our article was to review some of the published information regarding the use of ECMO in the care of the neonate with advanced respiratory failure. Dr. Gille admonishes us to consider the results of the NIH study in a proper historical perspective and in the light of the technological advances that have occurred since the publication of that report. The practitioners of intensive care for patients who are beyond the neonatal period will want to consider these comments carefully as they review their approaches to patients with acute respiratory insufficiency.

Sincerely,
Robert C. Spahr, M.D.
Director
Department of Neonatology
Geisinger Medical Center
Danville, PA