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Discussion

DR. J. ALEX HALLER, JR. (Baltimore, Maryland): First I would like to correct Dr. Walter Merrill retrospectively to his earlier paper because his statement that 43% of Americans will reach 80 years of age is untrue because he apparently is not considering babies under 1 month of age as Americans! If they are included, less than 43% will achieve 80 years of age because those statistics by the various life insurance companies do not include babies under 1 month of age. Thus the other frontier, not old age but newborn, is the one that Dr. Howell and his associates have brought to our attention.

He was kind enough to provide the manuscript to me several weeks ago, which has given me the opportunity to become more nervous about what I might like to say, but more importantly, he has given me a time to have some of our statisticians look at his complicated data.

Our statisticians indicate that his figures are correct.

Dr. Howell's thesis is an important one, that all babies who have a diagnosis of congenital diaphragmatic hernia before or after birth should be managed in neonatal surgical centers where ECMO is available.

Does his data support that thesis? It has a profound impact on many very fine surgeons in this auditorium who can certainly close holes in the diaphragm!

Is there a significant advantage to having such babies in neonatal units where intensive care and other forms of support are routinely available to them?

This technology called extracorporeal membrane oxygenation, has, I believe, been looking for a disease for many years! Whether it has found it yet remains to be seen.

Most of Dr. Howell's patients were being treated for meconium aspiration syndromes. Life-threatening meconium aspiration reflects poor obstetrical care, and therefore, I think an important adjunct to this proposal that there be in the same ECMO centers, excellent obstetrical programs, including continuous medical education to decrease this preventable complication.

How about babies with congenital diaphragmatic hernia? He has shown us that with the use of this ECMO technology, there is better than a 50% survival rate, but just barely better. When Dr. Robert Gross first reported his series in the 1940s from the Boston Children's Hospital, there was a 50% survival rate! Many things have changed since then because many of Dr. Gross' patients survived longer than 24 hours in outlying areas and selected themselves as survivors. Dr. Gross noted that the real challenge was in those babies less than 24 hours of age, the group in which Dr. Howell is using ECMO.

Technically more than one third of Dr. Howell's patients required the use of a prosthetic material in the repair in the hole in the diaphragm, which is more than most of us have in our own experience. What are your indications, Dr. Howell, for the use of prosthetic material?

What would be the outcome of these children in your region who had the repair of their diaphragmatic hernias in outlying hospitals if they did not require referral to you? In other words, you have shown us that those babies who came late or after operative repair have a much higher mortality rate. Do you know how many children at the same time were operated on successfully in those same centers and who were not referred to you? That is a statistic that we did not hear and the one that would convince me that your thesis is correct.

Finally, what are you doing about regional leadership in all aspects of this prenatal and postnatal diagnosis? Do you have in place a regional system that brings the high-risk pregnant mother into your center to make available to them as early as possible these modern forms of technology?

Have you indicated to the various referring hospitals that your team is ready? What do you believe is the responsibility of a neonatal surgeon in such a regional program?

DR. KEITH E. GEORGESON (Birmingham, Alabama): When you consider what Dr. Haller just mentioned that 30 years ago the mortality rate was reported as 50% and more recently that mortality rate has been climbing, it is refreshing to hear a paper describe a technique that is reversing that trend.

The reason that ECMO is successful, I believe, is because oxygen is a potent pulmonary vasodilator and most of our congenital diaphragmatic hernia patients die of persistent pulmonary hypertension.

We have been extremely impressed with the efficacy of ECMO as well, and for the last 2 years have been using a slightly different protocol. Instead of immediate repair of the diaphragmatic hernia, we have delayed repair depending on conventional medical management and ECMO to stabilize the patient. Those patients who stabilize with conventional management are managed with ECMO. Those patients who do not stabilize are placed on ECMO once they meet criteria.

Using this protocol and taking patients who are symptomatic immediately at birth, that is they are cyanotic right at birth, we have taken a mortality rate that was initially 80% and dropped it to 45%.

Do you have exclusion criteria or do you put all patients who have reached your center on ECMO if they meet the criteria? In other words, do you exclude nonresponders from ECMO?

Have you ever repaired any of your patients while on ECMO, and do you think there is any place for this technique?

Wouldn't you prefer to have the patients referred to you before hernia repair? When we were reviewing our own patients, we found that we had lost a number in the operating room or before going to the operating room, just from logistical delays.

What percentage of your patients do you think have such profound pulmonary hypoplasia that they would not respond to ECMO?

DR. CHARLES G. HOWELL (Closing discussion): Dr. Haller, what would be the outcome for a child in our region who was not referred for ECMO who had surgical repair elsewhere, and didn't require ECMO?

We have talked with our referring centers, and that data is as hard to get as you can imagine. The issue that I tried to address with them is that I can't convince them not to operate on the child in their center. What I have tried to do is to convince them that if they do that and the patient does survive, to then refer them without delay. Don't wait to see if they deteriorate. Don't hesitate. Don't procrastinate but go ahead and refer the child at that point in time because the average age of death of the infants in group 4, the pre-ECMO deaths, was 26.8 hours, which is more than adequate time for delivery, stabilization, repair, and a flight to an ECMO center.

The regional management of the State of Georgia, with regard to neonatology, has been established by one of the authors on this paper, William P. Kanto. Bill was in charge of regionalization for the State of Georgia for many years and the care is worked out very well for medical problems, but not for surgical problems. Surgical problems seem to filter to the areas that have a surgeon who does pediatric surgery, and it is that area of regionalization that we have not been able to change.

We were hoping that the work that we are doing as well as other ECMO centers are doing will cause a change, and as Keith suggested in his last question, (Would I prefer to get the patient before surgical repair?) the answer to that is yes. I am unable to mandate referral as is any one else, but I think that in due time this will change.

Dr. Georgeson's question, do you have exclusion criteria for infants besides the basic ones of gestational age and uncorrectable anomalies and parental refusal of therapy? We don't at this time. We too are realistic. We don't have any survivors with a PCO^2 of more than 100, but we do have survivors in Dr. Desmond Bohn's group C, the predicted 100% mortality.

I am hesitant to recommend exclusion numbers, whether it be PO^2, ventilation index, PCO^2, or whatever. Our experience, as well as the Washington group's, has noted survivors in patients who have met previously published criteria for exclusion.

Have we repaired any patients while on ECMO? We have not had the pleasure of doing that yet. We have two infants *in utero* right now, and will certainly consider its use if appropriate.

We have experience with other surgical procedures while on ECMO for other conditions, and it can be associated with more than the usual bleeding.

Wouldn't you rather have patients before ECMO? I certainly would, and I would welcome the opportunity for the people in our referral area to send the infants to us antenatally, if they know, and if not, shortly after birth.

What percentage of our infants have pulmonary hypoplasia so severe that they would not respond to ECMO? We reviewed the autopsies on all nonsurvivors. Of those autopsy cases, we had two infants who died in the delivery room, which I mentioned earlier. One had 5 g total lung tissue, 3 g on right side and 2 g on the left side. The other had 4 g on right side and 2 g on the left side.

I don't think that any significant increase in lung growth would have occurred in 7 to 10 days in those two infants. I don't know how to predict such a severe pulmonary hypoplasia except to say that those two babies were in trouble from the minute they were born, and could not be resuscitated. They didn't even live long enough to be transported to the neonatal ICU to consider ECMO.

When we reviewed the lung weights in the remaining deaths, we noted a range of 30 to 110 g of lung tissue. As Dr. Haller and I have discussed earlier, I don't know how much lung tissue is in the babies that do survive, so I can't compare it to those who died.