HFV: Applied Technology, Saving Both Lives and Costs

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INTRODUCTION

In today's healthcare financing crisis, technology is often cast as a culprit. In the tertiary care ICUs of the US healthcare system, technology and skills have been assembled to save lives, whatever the cost. Some criticize that this money is wasted mostly extending lives rather than saving them. While some argue that this also applies to the neonatal ICU, those most informed appreciate the difference. In fact, the struggling three pound premature infant of 20 years ago who often died, today not only routinely survives, but also often grows up with minimum pulmonary morbidity. Of course, now the envelope is being pushed towards one pound or lower, evoking the same criticism. This is no surprise. Often the heroic measures of one era evolve to become the standards of care of another. In the future healthcare environment, however, standards of care will have to face stricter tests of cost effectiveness. This article examines high frequency ventilation (HFV), one emerging cost effective technology that saves both lives and money. The discussion revolves around the objective and subjective considerations appropriate to the consideration of adding high frequency ventilation technology to one's nursery.

High frequency ventilation was first applied experimentally in the nursery in the early 80s.[1,2,3] It was directed at infants with severe respiratory failure who were failing conventional ventilation. These infants required higher and higher peak pressures to maintain marginal gas exchange. Unfortunately, with each life saving increase in ventilator settings came accelerating respiratory barotrauma and cardiovascular compromise. Dr Robert deLemos and his associates at Wilford Hall Medical Center, as well as other centers around the country, reasoned that with the elimination of high peak inspiratory pressures possible with HFV, this vicious cycle might be broken. It was also natural to speculate that if rescue intervention with HFV could break the cycle of life threatening pulmonary barotrauma, perhaps early application could reduce the development of air leak syndromes, and chronic lung disease. These suppositions were correct, and following FDA approval of three high frequency ventilators (Life Pulse Jet, Infant Star Flow Interruptor, and the 3100 Oscillator) between 1989 and1991, the use of HFV has become common in tertiary care nurseries. Consistent with the original rescue application, the first two devices are approved only for rescue (failing conventional ventilation) of infants with air leaks. In contrast, the 3100 Oscillator (HFOV) is also approved for early intervention with several studies supporting its safety and effectiveness at reducing barotrauma.[4,5] Because many of the potential economic benefits seem to be related to early intervention, we will only discuss the application of the 3100 Oscillator. We, however, do not want to imply that in the future, similar outcomes might not be proven for other HFV approaches.

Deciding whether to offer HFOV as a means of therapy at a specific institution is an individual decision based on many factors. However, standards of practice will dictate whether HFOV treatment is clinically justified based on general cost, risk and potential clinical benefit. Based on established standards of practice, the individual center can then weigh its specific cost (start up and ongoing), willingness to transfer more patients to tertiary centers and issues of timeliness of intervention and technical difficulty of transfer.

HFOV has become standard therapy at many tertiary care nurseries. Two general applications prevail. The first is the rescue of infants, most often referred to tertiary centers, who are failing conventional ventilation therapy. The second involves early intervention in the respiratory distress process, in an effort to reduce pulmonary barotrauma. A recent survey of HFOV users found that approximately two-thirds supported this early intervention concept.[6] More extensive data from the International HFV Registry, however, indicates that the predominant number of patients treated are for rescue.[7] The application of HFOV over a wide continuum of patients is certainly appropriate. Two specific applications, however, have significant potential for cost savings. These are the ECMO candidate and immediate prophylactic application in the low birth weight infant. First we will address cost of providing HFOV and then specific cost savings potential of the two applications.

COST OF HFOV

The cost of providing HFOV therapy is straightforward if you consider the relative cost compared to conventional ventilation.

To do so one needs to consider the increased capital expense, incremental training costs and incremental operating cost. The initial cost of the 3100 is comparable to many adult ventilators, but nearly twice that of some infant ventilators. This increment of about $15,000 however, if amortized over five years, is only $8 per day. Even if you assume the ventilator will only be used a third of the time, this equates to $24 per day of use. The Oscillator does require a special circuit which in routine use should add about $50 per day. Costs for maintenance are comparable to conventional ventilators. Thus, the incremental cost of using the Oscillator may be $74 more per day, as related to a typical daily charge for conventional mechanical ventilation of $500. A recent survey of SensorMedics 3100 users found that the incremental daily charge for HFOV above conventional ventilation ranged between zero and $500 with many charging nothing extra.[6]

Training associated with all new technology must always be considered. In order to accelerate the learning curve in individual nurseries, SensorMedics offers a two and a half day off site training program for one or two team leaders, as well as a four part, four hour video inservice with work book and laboratory experiments for the entire staff. The decision to add HFOV to a nursery requires the support of the whole staff, as with any new device. Dr David Durand of Oakland comments, "The concepts of HFOV and the operation of the 3100 are in some ways simpler than conventional ventilation. However, it is inappropriate to consider its use without thorough training."

Although new technology and clinical approaches require the support of the staff, HFOV training is not extraordinary. With the typical cost of treatment of a premature infant in the NICU ranging between $75,000 and $300,000, adding HFOV is not a budget breaker. Nevertheless, HFOV is still inappropriate if it does not improve outcomes in a cost- effective manner.

ECMO CANDIDATES

It has become standard practice to consider extracorporeal membrane oxygenation as the intervention of last resort in near term infants with severe respiratory failure triggered by a range of etiologies. There is a broad base of experience supporting ECMO's appropriateness. Most accept that ECMO intervention achieves a survival rate of 80% in a population of children with a likely survival of 20%.[8] This improvement in mortality, however, comes with significant morbidity, the most common being neurological, with seizures and/or infarctions in over an eighth of the patients.[8] In addition, costs associated with ECMO are extraordinary. The total hospital charges for an ECMO patient typically range between $60,000 and $100,000. While the total number of patients requiring ECMO are only about 1,200, the total cost approaches a billion dollars per year, nationwide. Dr Durand underscores this issue. "Although we are a regional tertiary care nursery with a large ECMO program, we are aggressive about avoiding its use."

To consider pre-ECMO HFOV rescue as a standard of practice, three questions must be addressed. Does HFOV reduce the need for ECMO? If HFOV is more broadly applied and reduces the use of ECMO, will this reduce morbidity or mortality? More to the point of this discussion, how will costs be impacted? The answer to the first question appears to be a resounding yes. HFOV seems to reduce the need for ECMO.[9,10] As most are aware, the effectiveness of HFOV varies depending on the disease etiology as well as the center's experience. One analysis of a large data base of HFOV experience at Wilford Hall Medical Center projected a likely success of 85% for diffuse respiratory failure and 50% in meconium aspiration syndrome and hypoplastic lung.[11] Wilford Hall and others have recently reported success rates for MAS and hypoplastic lung as high as those for diffuse respiratory disease, when HFOV is used as a more primary, rather than rescue, intervention.[10,12,13] Based on a typical mix of diagnoses, this should be reflected in a 50% or higher reduction of ECMO at the typical center. This seems consistent with the experience of ECMO centers and their referring sites as well as a recent controlled trial.[10] Dr Steve Minton of Provo echoes this. "Since we have started using HFOV aggressively, we have dramatically cut our ECMO referrals," he says. "In fact, we have not referred a patient for ECMO in four years. Several other tertiary centers in our area have had similar experience when they started using HFOV." Dr Reese Clark of Atlanta adds, "Our recent controlled trial certainly supports the ability of HFOV to reduce the need for ECMO. We saw no statistically significant differences in length of stay, death or morbidity between patients subjected to ECMO and those rescued. However, I feel the risk of significant long term morbidity and cost of treatment is much higher with ECMO than with HFOV."

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The potential for cost savings are significant. The typical charges for ECMO treatment alone range between $15,000 and $35,000, depending on the length of the treatment, concomitant complications and outcome. Thus, an ECMO Center doing 20 patients per year could reduce ECMO charges by approximately a quarter million dollars annually (10 patients at $25,000 each) with HFOV. Other factors also come into play. Some of the costs associated with being an ECMO center are fixed and must be amortized over a large number of patients. In addition, the logistics of offering HFOV trials to ECMO candidates while they are still treatable may at times create some inefficiency and potential risk. While this is a simplistic cost savings model, the order of magnitude of the potential savings, coupled with the perceived reduction in risk seems compelling. For these reasons an HFOV trial for the ECMO candidates is quickly becom-

ing a standard of care at ECMO Centers. Dr Clark adds, "There is no doubt that this is happening; in fact in our area it has gone a step further as referring centers respond to our success by adding Oscillators to their nurseries."

ADDING HFOV

This brings us to a discussion of when it is appropriate to add HFOV rescue of ECMO candidates at a nursery without ECMO. Dr Keith Meredith of Colorado Springs says, "If the nursery has many ECMO referrals, the alternative of local HFOV pre-ECMO trials is compelling." Clearly, all level three and most level two nurseries would like to retain the local family-infant relationship as well as avoid the $2,000 to $4,000 cost associated with a transport. In addition, earlier, more measured intervention has a higher probability of success than late stage pre-ECMO salvage.[7,10,12] Dr Minton comments on his recently reported experience with congenital diaphragmatic hernia, "We intervene immediately at birth and the child remains on HFOV for surgery and post-op recovery. Our survival is over 90% with infrequent need for ECMO." Dr Meredith adds, "In a near term baby with RDS, we try to intervene with HFOV before air leak and extended oxygen exposure has occurred. This approach not only reduces the need for ECMO, but also should reduce the pulmonary morbidity in those patients who ultimately require ECMO." Dr Clark warns, "I think that pre-ECMO rescue is an appropriate trend. But without a primed ECMO system at bedside, the trial must be careful and not prolonged." Individual guidelines must be developed which take into account transport time, individual HFOV experience, as well as disease process and severity.

For these reasons, level three and many aggressive level II nurseries are adding HFOV capabilities. Eventually standards of practice will probably dictate that a fair trial of HFOV be conducted before ECMO eligibility. Smaller nurseries will then face a decision. They must either add HFOV capability or be prepared to transfer near term infants when they develop severe RDS, rather than waiting for them to meet ECMO criteria.

As pre-ECMO HFOV trials become a standard of care, one can predict several trends, some of which are already underway. First, there will be a reversal in the growth of ECMO centers. Whether or not the number dramatically reduces will depend on issues of safety of long transport and inter-hospital competition tempered by economic issues. Second, the type of patients ultimately requiring ECMO will change dramatically towards those with severe cardiovascular compromise. Finally, many nurseries without ECMO will add HFOV capability. This will demand new clinical guidelines to identify those patients on whom a HFOV trial can be safely attempted and those that ought to be transferred immediately. The net outcome of this transition ought to be comparable mortality and reduced morbidity with reduced hospital charges and cost.

EARLY APPLICATION - PREMATURE INFANTS

While the survival of premature infants has improved steadily over the last decade, chronic pulmonary morbidity remains a major problem. Exogenous surfactant treatment was once hoped to be a "silver bullet." Its effectiveness is supported by numerous extensive randomized trials and its use is widespread. No one should question its significant clinical impact or cost effectiveness. Nevertheless, respiratory distress syndrome and its resulting mortality and chronic pulmonary morbidity are still major problems, in spite of aggressive surfactant therapy.[14,15,16,17] Leaders in high frequency research long ago speculated, and later supported with clinical studies, that early (ie, nonrescue) intervention with HFOV would reduce barotrauma and chronic lung disease.[4,5] Importantly, recent animal studies and experience in the nursery indicate that HFOV and surfactant have a synergistic effect.[18,19,20] This effect is consistent with hypotheses that HFOV establishes better, more uniform lung inflation, thus facilitating more extensive distribution of surfactant and secondly, that HFOV eliminates damaging tidal breaths in surfactant compromised lung units.[21] Dr Clark comments on his randomized trial of low birth weight infants, "While limited to only 83 infants, we showed a drop in chronic lung disease of about half and also a trend towards cutting ventilator days in half." Dr Meredith adds, "Our retrospective comparison of 87 slightly bigger babies also showed ventilator days being nearly cut in half and an even bigger reduction in the need for rescue doses of surfactant."

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Two randomized multicenter studies are well underway to try and confirm these benefits. Both studies apply HFOV early in the first hours of life, at first signs of respiratory distress. The most important projected economic outcomes are a reduction in the length of mechanical ventilation, and reduced need for rescue doses of surfactant. A reduction in the incidence of chronic lung disease is also expected. Each offers the potential of significant cost impact if realized. While nearly twenty centers are participating in these studies, others find the current information sufficient to proceed with early application of HFOV. Dr Meredith comments, "We feel the point is important enough to prove, but two of my past colleagues chose to not participate in the studies. Instead they implemented early intervention as a standard practice in their nurseries." Dr Minton adds, "When we instituted randomization, after a period of early intervention in all infants with RDS, we had lots of resistance from the nurses and respiratory therapists. They had seen enough to believe that early application makes a big difference."

The typical total charges for infants on mechanical ventilation are well over $3,000 per day. Therefore any significant

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