

The price of innovation: a primer on high risk, high reward surgery

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Provenance: This is an invited Editorial commissioned by Section Editor of JTD, Jianfei Shen, MD (Department of Cardiothoracic Surgery, Taizhou Hospital of Zhejiang Province, Wenzhou Medical University, Taizhou, China).

Comment on: Ando M, Nagase Y, Hasegawa H, *et al.* External stenting: A reliable technique to relieve airway obstruction in small children. *J Thorac Cardiovasc Surg* 2017;153:1167-77.

Submitted Oct 16, 2017. Accepted for publication Oct 19, 2017.

doi: 10.21037/jtd.2017.10.127

View this article at: <http://dx.doi.org/10.21037/jtd.2017.10.127>

Difficult problems stimulate the development of novel therapies which more often than not are high-risk due to the nature of the disease process. Rare diseases offer few opportunities to refine a technique or protocol. Diseases that leave patients in critical and unstable conditions leave little margin for error. In the face of these apparently insurmountable challenges, surgeons are sometimes left with little choice but to offer novel or untested procedures that may pose a high risk. This is not because they are brash or cavalier, but because with high risk comes high rewards in a setting where inaction is to accept failure. It is out of these situations that the frontiers of medicine and surgery are advanced. Ando and their colleagues' large case series of external airway stenting for airway obstruction in small children is an example of this process at work (1). This group's contribution highlights three important aspects of innovative procedures in high-risk situations: modification of established techniques; acceptance of a learning curve and weathering the complications that arise during the process.

Severe pediatric airway obstruction due to tracheobronchomalacia (TBM) is an example of a situation which is uncommon, often life threatening and without a uniformly standard solution. Patients suffer from "dying spells" of severe hypoxia, collapsing airways are at risk for recurrent obstructive pneumonia and patients can become dependent on mechanical ventilation with confinement to the ICU. Treatment focuses on relieving external compression by surrounding structures or artificially supporting the airway itself. While aortopexy is a standard approach to treatment of TBM, other techniques were

developed out of necessity and under duress. The first internal airway stent used for TBM was performed by Filler in 1988 (2). A Palmaz metallic stent previously used for vascular indications was inserted urgently into a child in "a desperate attempt to save 'their' life." In this situation, an untested indication for airway stenting became a novel treatment of last resort. Filler and other groups have built on this experience and now internal airway stenting is a well-accepted option for treatment of TBM. The external stenting technique reported by Ando is a modification of the external stenting for long segment TBM in children reported in 1997 by Hagl *et al.* (3) The use of separate anterior and posterior rigid prosthesis to support the airway was devised to allow for future growth of the child. The concept and modified technique were independently conceived and published by two other groups in addition to Ando *et al.* (4,5) This highlights the scope of the problem in that current strategies for TBM treatments were lacking which inspired several creative individuals to develop a new solution.

The implantation of a new procedure is often the culmination of significant planning based upon relevant past experience. Despite the diligent preparation, there will be a learning curve associated with executing the plan in a real-world situation. With each success or failure, the procedure becomes more refined. The authors acknowledge the mistakes made early in the experience which led to adjustment to their external stenting technique. Proceeding with a developing therapy with the knowledge that there is a high probability of failure or complication is a difficult ethical issue. Weighing the risks and benefits of such

a proposition is essential, especially when the patient being considered is a child. This reinforces the need for transparency with the patient and family such that all those involved are informed of what is at stake. It should never be forgotten that each individual patient in a developing experience singularly gains or losses by where they happen to be on the learning curve.

One of the strengths of Ando's case series is the granular detail of adverse outcomes. Extensive airway surgery in a small child will expectedly be accompanied by complications. The group is to be commended for their detailed reporting of mortality as well as complications including graft infection, bilateral phrenic nerve palsy, bilateral recurrent laryngeal nerve injury requiring tracheostomy and graft erosion causing aorto-esophageal fistula. These events are not a reflection of surgical skill or judgment, but rather demonstrate the reality of the high-risk situation at hand. In addition, the truthful depiction of complications serves as an internal measure of improvements to be made as well as a guide to other groups who wish to adopt the technique. Finally, an accurate portrayal of possible complications is necessary for both providers and patients to determine if the risk of surgery is worth the potential gains. In the setting of severe TBM in children, the potential for significant complications with external airway stenting is offset by the catastrophic consequences of the disease itself.

Perceiving the opportunity in challenge is a hallmark of all innovators. The history of surgery and medicine is rich with individuals who have endeavored to find novel solutions for their patients when standard treatments have failed. In an era of risk-averse defensive medicine, there should always be a place for the art and practice of surgery

where calculated risks are necessary to achieve rewards thought previously to be unobtainable.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Bribriesco A, Ahmad U, Raja S. The price of innovation: a primer on high risk, high reward surgery. *J Thorac Dis* 2017;9(11):4323-4324. doi: 10.21037/jtd.2017.10.127