



Device clinical trials: the importance of “repurposing” technology

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Comment on: Goudie E, Oliveira RL, Thiffault V, et al. Phase 1 Trial Evaluating Safety of Pulmonary Artery Sealing With Ultrasonic Energy in VATS Lobectomy. *Ann Thorac Surg* 2018;105:214-20.

Received: 18 March 2018; Accepted: 30 March 2018; Published: 10 April 2018.

doi: 10.21037/vats.2018.03.05

View this article at: <http://dx.doi.org/10.21037/vats.2018.03.05>

As we all know, the US is facing a cost crisis in healthcare. As a share of the nation's gross domestic product, healthcare accounted for 17.9% in 2016 as reported in the National Health Expenditure Data from the Centers for Medicare and Medicaid Services (1). Health care economists project that this will continue to increase on an annual basis. Cost containment is essential; but what is really driving these expenditures?

We are witnessing the aging of our population, suffer from system inefficiencies and there has been an evolution in public demand for healthcare. Technology and medical devices too have been deemed key drivers of the ever rising healthcare costs.

The relationship between medical devices and expenditure, however, is a complex one.

Technological advances are driven by a number of factors including the desire of medical professionals to find better ways to diagnose and treat patients. Some technologies have global applications; electronic health records for example can be applied in all systems and were created with the goal of simplifying coding and documentation to allow physicians to focus more on patient care. In essence you spend money to save money. In contrast, some devices are created to meet the needs of a very specialized patient population. With the average cost of development for high-risk medical devices reported at 94 million dollars, some of this expense is ultimately shifted onto patients, hospital systems, and insurance payers (2,3).

Cost containment demands that medical devices be adopted with value in mind—i.e., does the intervention provide superior quantity and quality of life and does it justify the cost. In addition to price transparency and a competitive marketplace, capturing the worth of a medical device also demands that we maximize usage across

applications and specialties.

Perhaps this is why Dr. Goudie and co-authors' study is so timely and important: the authors made use of a readily available technology rather than require the creation of a new one.

In their pilot study entitled “Phase 1 Trial Evaluating Safety of Pulmonary Artery Sealing With Ultrasonic Energy in VATS Lobectomy”, the authors sought to demonstrate a technique to improve the ease and safety of taking small pulmonary arterial (PA) branches during lobectomy. Twenty patients undergoing lobectomy had a minimum of one branch (≤ 7 mm) of the PA sealed with an ultrasonic energy vessel-sealing device. Feasibility and preliminary safety were established with no patient experiencing a complication related to this method of sealing PA branches.

Congratulations to Dr. Goudie and authors on their study and I will look forward to a future pivotal trial to truly establish efficacy and safety.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned and reviewed by the Section Editor Dr. Monisha Sudarshan (Mayo Clinic Rochester, Minnesota, USA).

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/vats.2018.03.05>). The author has no conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/vats.2018.03.05

Cite this article as: Gillaspie EA. Device clinical trials: the importance of “repurposing” technology. *Video-assist Thorac Surg* 2018;3:12.