The Power of Disruptive Technological Innovation: Transcatheter Aortic Valve Implantation (TAVI)

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Statement of Purpose: Biomaterials and implantable medical devices, including pacemakers, prosthetic heart valves, endovascular stents, total joint replacements, intrauterine contraceptive devices and intraocular lenses, have contributed to advances in health outcomes and the standard of medical care. However, technological progress has also contributed to economic challenges associated with increasingly complex and often very costly procedures and devices. Transcatheter Aortic Valve Implantation (TAVI) is a novel intervention to treat high risk patients with aortic stenosis otherwise inoperable by conventional aortic valve replacement (AVR), in which a self-expandable or balloon dilatable valve prosthesis is inserted into the aortic valve position during an interventional catheterization through the femoral artery. The patient's native aortic valve is pushed aside and compressed against the aortic root. In contrast to s*ustaining innovation*, i.e., improving technology along traditionally accepted performance standards, via iterative, focused modifications that enhance performance patient outcomes and/or utility, *disruptive innovation* (DI) fundamentally shifts performance and utility metrics. We sought to evaluate how the principles of DI, as applied to TAVI, can instruct the generic challenges of developing and implementing technology-intensive health care.

Methods: We considered key characteristics of TAVI, including implantation procedure, device design, cost, and patient population so treated, in the context of the characteristics of DI, as enumerated by Christensen (generically) [1]: 1) simpler, cheaper and lower performing; 2) lower margins, not higher profits; 3) not usable and unwanted by leading firms' most profitable customers; and 4) first commercialized in emerging or insignificant markets.

Results: Central to Christenson's model of disruptive innovation is that the initial market for disruptive technologies is limited to emerging or insignificant markets. However, since TAVI offers its most significant value directly through minimally invasive implantation, TAVI adds a "new" patient population not at the expense of those undergoing traditional AVR. Thus, although TAVI was restricted initially to a limited indication (non-surgical candidates or high-risk patients with unacceptably high risk), this target demographic is not a small or insignificant market. Approximately 85,000 AVRs are done annually in the US, and as many as 30% of patients with severe symptomatic AS are inoperable.[2] Moreover, the design of prosthetic valves used in TAVI, typically a bioprosthetic tissue valve, bovine pericardium, mounted on a compressible metallic stent, is necessarily different than that of conventional substitute heart valves. Two transcatheter aortic-valve devices are currently approved by the FDA for use in the United States, and many other models are in preclinical and clinical developmental stages. Moreover, TAVI has not been lower performing than AVR in the short-term. The PARTNER clinical trial results demonstrate noninferiority of transcatheter valves relative to surgically implanted valves, in the short term, thereby contradicting the "lower performing" tenet of the disruptive innovation framework.[2] Long term complications associated directly with the biomaterials-tissue interactions would be generally expected to be similar to those of bioprosthetic valves implanted surgically[3], but this has not yet been confirmed. A transcatheter aortic valve device is estimated to cost approximately $30,000 while a traditional prosthetic mechanical or tissue valve costs approximately $4,000 +. Thus, TAVI does not meet the "cheaper" characteristic; nevertheless, this evaluation of cost might reach a different conclusion if viewed from the different perspectives of the provider, the hospital or the broader healthcare system, especially with respect to the longitudinal systemic total healthcare costs of a patient. Thus, despite the presently high unit cost of TAVI devices, the procedure is less invasive, done by interventional cardiologists not cardiothoracic surgeons, and treats a "new" patient population distinct from those undergoing classical surgical AVR, yielding a potentially shorter recovery. Should the long-term performance of transcatheter valves ultimately approach that of surgical valves, market dynamics may change and indications for the use of transcatheter technology may expand into lower risk surgical candidates. This expansion of utilization is consistent with the characteristics of DI, which identifies technologies that start in a niche market and, evolve through sustaining technological improvements.

Conclusions: TAVI exemplifies key characteristics of typical DI but clearly extends the paradigm. Moreover, should the long-term performance and durability of transcatheter valves approach that of surgical valves, TAVI may be offered to lower risk surgical candidates, and steadily march into the mainstream. Therefore, transcatheter valves will like represent an increasingly attractive commercial opportunity for manufacturers.

References:

1. Christensen CM. The Innovator's Dilemma. Boston, MA: Harvard Business School Press, 1997.
2. Leon MB, et al. N Engl J Med. 2010; 363; 1597-1607.
3. Schoen F, Levy RJ. J Biomed Mater Res. 1999; 47:439-465.

*This research was completed while DB was a student in HST. It is independent from his current employment with Covidien, Boulder, CO, and does not necessarily represent the views of and should not be attributed to Covidien. It is solely the work of the attributed authors.