Transcatheter aortic valve implantation: from fantasy to reality

Kasra Shaikhrezai1*, Billy McWilliams2, Edward T Brackenbury3, Sai Prasad3, Tristan D Yan4, Renzo Pessotto3, Vipin Zamvar3 and Geoffrey Berg1

Abstract
Increased life expectancy has led to the presentation of more complicated patients in old age for the replacement of the aortic valve. The emergence of Transcatheter Aortic Valve Implantation (TAVI) was considered as a significant breakthrough in the management of symptomatic, moribund patients suffering from aortic valve stenosis who had been rejected for surgical intervention. A novel technology often has a long journey from the point at which it is created to its every-day-use. It is now obvious that TAVI practice in multiple institutes around the world has gone beyond the evidence. Serious concerns have been raised questioning the current TAVI practice. Analysis of future TAVI use may assist clinicians and healthcare managers to understand and deploy this technology in accordance with the evidence.

Keywords: Transcatheter Aortic Valve Implantation (TAVI), Technology, Evidence-based practice

Background
In the spring of 2002 Alain Cribier deployed the first transcatheter valve implantation in a moribund patient who had been rejected for surgery [1]. In January 2004 Edward Lifesciences (Inc. Irvine, CA, USA) began mass production of catheters over which an expandable valve can be driven into the aorta up to its anatomical position at the aortic root [2].

Traditionally a new technology in medicine is evaluated on the basis of its safety, efficacy and effectiveness. In addition Markov model can be used for economical evaluations [3]. We did not examine the TAVI technology according to the aforementioned criteria and tools while our main focus was to analyse the TAVI trends by using the Gartner Hyper curve [4].

The literature was searched via Medline using the OVID interface and where appropriate the level of evidence is mentioned according to the Oxford Centre for Evidence-based Medicine (OCEBM) [5] classification.

TAI gartner hype curve
In 1995 the Gartner Company (Inc., Stamford, CT, USA), an information technology research and development corporation introduced a new tool called “Hype” cycle to analyse the behaviour of any emerging technology and assist organisations and investors to predict the technology trends [3]. As TAVI has been certified and recognised as a technology [6] (level 5), it is appropriate to analyse its behaviour since creation using the Hype cycle phases (Figure 1).

Phase 1: technology trigger
TAVI did not reach the stage of product launch until Edward Lifesciences (Inc., Irvine, CA, USA) produced SAPIEN® valves; closely followed by the Medtronic CoreValve® (Medtronic Inc, MN, USA). The product launch was disseminated by Leon et al. [7] (level 1B), who first published the results of a randomised controlled trial comparing TAVI vs. medical therapy/valvuloplasty vs. Aortic Valve Replacement (AVR). The results of PARTNER studies [7-10] (level 1B) have been widely used for of the promotion of TAVI programmes and significantly influenced the management of high-risk patients [11] (level 5). These studies demonstrated that in selected high risk patients suffering from aortic stenosis the survival in 1-year was similar in TAVI and AVR. It
Currently, there are no clear guidelines available to assist the surgeons in determining which patients would best be treated by TAVI or AVR. In 2012 a group of independent researchers [6] claimed that more than 40,000 TAVI procedures which have been performed throughout the world cannot be justified from both a clinical and cost-effectiveness point of view. The analysis criticises the clinicians who have manipulated the indications to beyond the evidence in TAVI practice.

Neil Moat, the principle investigator of the first major UK TAVI registry [17], says “We have enough experience with TAVI now that we have to accept that the devices are different and they do have different advantages and disadvantages, and I think it’s excellent that we are starting to discuss the type of patients that would benefit from one device or another” [13]. This statement also confirms that the TAVI technology is currently at its peak of inflated expectations moving towards the “Trough of disillusionment” phase.

Phase 3: trough of disillusionment

This phase has not yet arrived for TAVI. In this sequence the use of the technology visibly diminishes indicating that it has just become unfashionable. In this stage the rate of publication of TAVI-related articles topics reduces significantly.

Phase 4: slope of enlightenment

The Scottish Government report on TAVI [18] (level 5) confirms that: “There is no consensus on what constitutes high surgical risk, no reliable method to identify elderly patients are most likely to benefit from AVR and no standard criteria by which to select patients for TAVI.” Although the report confirmed that TAVI must be only used in patients who are considered as inoperable it concluded: “There is a lack of standardisation of the definitions of “inoperable” and “high risk” as they are primarily based on clinical judgement.” The report also revealed that the minimum cost of the procedure is £21,059 whereas for AVR is much less. The report concluded that TAVI for inoperable patients is more expensive yet, at the same time, more effective than medical therapy. However there is a paucity of evidence with regards to economic burden of TAVI.

In 2011 Hartzell Schaff in the editorial section of the New England Journal of Medicine [19] (level 5) raised his concerns regarding the large risk of stroke in TAVI patients which can be up to 8.3% in 1 year [8]. He also noted that TAVI does not remove the disease therefore the diseased valve may create an irregular zone which makes the patient vulnerable to thromboembolic events. Alain Cribier has also expressed concerns regarding the extensive deployment of this technology without a sufficient follow-up on the durability. He says: “I have to...
continually fight against a tendency to treat patients who are good surgical candidates with TAVI. The issue is that, the long-term durability of the TAVI valve is unknown, but the surgical technique lasts for 20 years” [2].

In this phase the true understating of TAVI technology needs to be achieved. This includes the TAVI capability with transparent advantages and disadvantages.

Phase 5: plateau of productivity
In the guideline published by the National Institute for Health and Clinical Excellence [20] it was emphasised that there is sufficient evidence of serious complications of TAVI. Although the NICE guideline clearly states that TAVI is the treatment of choice for patients not suitable for surgery, it does not clarify the definite contraindications to conventional surgery. It is sometimes the case that a surgeon’s decision to deny a patient conventional surgery, has been altered by another surgeon who subsequently operated upon the same patient with satisfactory outcomes. It has been previously demonstrated that AVR rejection constitutes a high degree of subjectivity [21] (level 4).

At this stage a consensus on the actual use of TAVI in daily practice needs to be achieved in order to minimise the bias and subjectivity of decision making process. Both latter phases would be achieved when a standardised protocol is available by which the high risk patients can be precisely rejected for surgery.

Conclusion
When Percutaneous Coronary Intervention (PCI) took over the Coronary Artery Bypass Graft (CABG) practice in a large number of patients it was not predictable that coronary stenting will soon go beyond the evidence and even reach to malpractice [22]. The warning given by Van Brabandt et al. [6] is important to avoid the mistakes of PCI practice and adhere to the evidence in promoting the TAVI programme. Hype cycle can be used as a road map to facilitate the progress of TAVI as an adjunct to AVR to treat moribund inoperable patients and aid healthcare planning.

Multidisciplinary approach is the foundation of TAVI practice and the “heart team” comprising the cardiologists, surgeons and anaesthetists must be the core of the practice for all referred patients.

Abbreviations
AVR: Aortic valve replacement; CABG: Coronary Artery Bypass Graft; ESC: European Society of Cardiology; EACTS: European Association for Cardio-Thoracic Surgery; FDA: United States Food and Drug Administration; GARY: German Aortic Valve Registry; NICE: National Institute for Health and Clinical Excellence; OCEBM: Oxford Centre for Evidence-based Medicine; PARTNER: Placement of aortic transcatheter valves; PCI: Percutaneous coronary implantation; TAVI: Transcatheter aortic valve replacement.

Competing interests
The authors declare that they have no competing interests.

Authors’ contributions
KS conducted the literature search and wrote the manuscript; BM supervised the project and revised the manuscript; ETB revised the manuscript and recommended papers; SP revised the manuscript and recommended papers; TF revised the manuscript and recommended papers; VZ revised the manuscript and recommended papers; GB supervised the project, revised the manuscript and recommended papers. All authors read and approved the final manuscript.

Acknowledgements
Except for the authors there was no person who substantially contributed towards the study or the manuscript. There is no source of funding.

Author details
1Department of Cardiothoracic Surgery, Golden Jubilee National Hospital, Glasgow, Clydebank G81 4DY, UK. 2Department of Anaesthesitics, Intensive Care & Pain Management, Cardiff University, Cardiff, UK. 3Department of Cardiothoracic Surgery, Royal infirmary of Edinburgh, Edinburgh, UK. 4Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, Sydney, Australia.

Received: 18 December 2013 Accepted: 4 March 2014 Published: 7 March 2014

References
1. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, Derumeaux G, Anselme F, Labode F, Lefevre MB. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation 2002, 106:3006–3008.
2. Gruentzig A: An odyssey in transcather aortic implantation. http://www. escardio.org/congresses/esc-2010/congress-news/Pages/tavi.aspx.
3. Briggs A, Sculpture M: An introduction to Markov modelling for economic evaluation. Pharmacoeconomics 1996, 13(4):397–409.
4. Fenn J: When to leap on the hype cycle. https://www.gartner.com/doc/ 484408.
5. OCEBM Levels of Evidence Working Group. “The Oxford levels of evidence 2”. Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index. aspx?o=5653.
6. Van Brabandt H, Neyt M, Huijsten F: Transcatheter aortic valve implantation (TAVI): risky and costly. BMJ 2012, 345:e710.
7. Leon MB, Smith CR, Mack JM, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AD, Bavaria JE, Herrmann HC, Douglas PS, Petersen JL, Akin JJ, Anderson WN, Wang D, Pocock S, PARTNER Trial Investigators: Transcatheter Aortic-Valve Implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010, 363(17):1597–1607.
8. Smith CR, Leon MB, Mack JM, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Williams M, Dewey T, Kapadia S, Babalario V, Touran VI, Corso P, Pichard AD, Bavaria JE, Herrmann HC, Akin JJ, Anderson WN, Wang D, Pocock S, PARTNER Trial Investigators: Transcatheter versus surgical aortic valve replacement in high-risk patients. N Engl J Med 2011, 364(23):2187–2198.
9. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, Fontana GP, Dewey TM, Touran VI, Pichard AD, Fischbein M, Szeeto WY, Lim S, Greason KL, Teinstein PS, Maslair SC, Douglas PS, Hahn RT, Whisenant B, Zajarias A, Wang D, Akin JJ, Anderson WN, Leon MB, PARTNER Trial Investigators: Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012, 366(18):1686–1695.
10. Makkar RR, Fontana GP, Jilaihawi H, Kapadia S, Pichard AD, Douglas PS, Touran VI, Babalario VC, Webb JG, Herrmann HC, Bavaria JE, Kodali S, Brown DL, Bowers B, Dewey TM, Svensson LG, Tuzcu M, Moses JW, Williams MR, Siegel RJ, Akin JJ, Anderson WN, Pocock S, Smith CR, Leon MB, PARTNER Trial Investigators: Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med 2012, 366(18):1696–1704.
11. Van TD, Bannon PG: Transapical aortic valve implantation – A paradigm for innovation and collaboration in modern cardiac surgery. Ann Cardiothorac Surg 2012, 1(2):114.
12. Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Quirós G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Lancellotti P, Pierard L, Price S, Schafers HJ, Schuler G, Stehlniska J,
Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M: Guidelines on the management of valvular heart disease (version 2012). Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2012, 33(19):2451–2496.

13. Nainggolan L: Germany Tops TAVI Table, But Room for Growth Remains. [http://www.medscape.com/viewarticle/752780]

14. Beckmann A, Hamm C, Figulla HR, Cremer J, Kuck KH, Lange R, Zahn R, Sack S, Schuler GC, Walther T, Beyersdorf F, Böhm M, Heusch G, Funkat AK, Meintz T, Neumann T, Papoutsis K, Schneider S, Welz A, Mohr FW, GARY Executive Board: The German Aortic Valve Registry (GARY): a nationwide registry for patients undergoing invasive therapy for severe aortic valve stenosis. *Thorac Cardiovasc Surg* 2012, 60(5):319–325.

15. Dewey TM, Brown DL, Das TS, Ryan WH, Fowler JE, Hoffman SD, Prince SL, Herbert MA, Culica D, Mack MJ: High-risk patients referred for transcatheter aortic valve implantation: management and outcomes. *Ann Thorac Surg* 2008, 86(5):1450–1456.

16. Subramanian SJ, Rastan AJ, Hötzhey DJ, Haensig M, Kempfert J, Borger MA, Walther T, Mohr FW: Conventional aortic valve replacement in transcatheter aortic valve implantation candidates: a 5-year experience. *Ann Thorac Surg* 2012, 94(3):726–729.

17. Moat NE, Ludman P, de Belder MA, Bridgewater B, Cunningham AD, Young CP, Thomas M, Kovac J, Spyt T, MacCarthy PA, Wendler O, Hildick-Smith D, Davies SW, Trivedi U, Blackman DJ, Levy RD, Brecker SJ, Baumbach A, Daniel T, Gray H, Mullen MJ: Long-term outcomes after Transcatheter Aortic Valve Implantation in high-Risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. *J Am Coll Cardiol* 2011, 58(20):2130–2138.

18. Scottish Government: Final report of the TAVI review group – national planning forum subgroup. 2010. [http://www.scotland.gov.uk/Resource/0039/00392167.pdf](http://www.scotland.gov.uk/Resource/0039/00392167.pdf).

19. Schaff HV: Transcatheter aortic-valve implantation–at what price? *N Engl J Med* 2011, 364(23):2256–2258.

20. National Institute for Health and Clinical Excellence: Transcatheter Aortic Valve Implantation for Aortic Stenosis. [IPG 421](http://www.nice.org.uk/ips/421) London: National Institute for Health and Clinical Excellence; 2012.

21. Iung B, Cachier A, Baron G, Messika-Zeitoun D, Delahaye F, Tornos P, Gohlike-Barwolff C, Boersma E, Ravaud P, Vahanian A: Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? *Eur Heart J* 2005, 26(24):2714–2720.

22. Devi S: US physicians urge end to unnecessary stent operations. *Lancet* 2011, 378:651–652.

doi:10.1186/1749-8090-9-43
Cite this article as: Shaikhrezai et al.: Transcatheter aortic valve implantation: from fantasy to reality. *Journal of Cardiothoracic Surgery* 2014 9:43.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at www.biomedcentral.com/submit