Using Cadaver Simulation to Improve Communication and Economy of Movement as Evidence of Progress with the Trans-catheter Aortic Valve Implantation (TAVI) Learning Curve

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Abstract
Trans-catheter Aortic Valve Implantation (TAVI) is an endovascular treatment for critical aortic stenosis. An early “learning curve” is important drawback of TAVI that can dramatically alter patient safety and hospital costs. There is paucity of data regarding the quantification of learning experience associated with the technique. The aim of this study was to assess learning curve in clinical staff involved in the implementation of TAVI. We hypothesize that training sessions will improve economy of movement (EoM) as characterized by measuring jerkiness of trunk movement in medial-lateral direction. Using wearable technology based on tri-axial accelerometer, the EoM of a scrub technician, who was naive to TAVI procedure, was assessed during 6 consecutive TAVI procedures, including 4 cadaver TAVI simulations and 2 clinical cases. In addition, communication errors between the surgery team were monitored. During the cadaver simulation training, the communication error was reduced by 46.2%. Similarly, the EoM was enhanced by 17.3% (p=0.04) with a non-significant reduction rate of 4.99±4.26% per practice. Interestingly, both communication errors and EoM were reduced during real cases compared to the first simulated case, suggesting that cadaver simulation translated into real cases. This proof of concept study suggests that EoM could be used as an alternative method to objectively evaluate the learning curve during surgical procedures. Results should be confirmed in a larger sample size in both physicians and support staff assisting with TAVI procedure.

1. INTRODUCTION
Trans-catheter Aortic Valve Implantation (TAVI) is a minimally invasive endovascular procedure for the treatment of critical aortic stenosis [1]. It has gained acceptance in the treatment of patients who are ineligible for conventional surgical aortic valve replacement [2]. Patients who undergo TAVI benefit from superior survival and symptomatic outcomes versus patient who carry medical palliation [3, 4]. To date, more than 10000 TAVI procedures have been completed [5] and a recent study by Osnabrugge et al. reported nearly 18000 and 9200 new TAVI candidates in Europe and North America each year, respectively [6].

TAVI is a complex procedure requiring a dedicated team of cardiac surgeons, interventional cardiologists, echocardiographers and anesthesiologists [1, 7]. A careful training of TAVI team and a close collaboration between them seem to play a major role in having a successful TAVI program [1, 8].

1.1. Current training procedures and their challenges
Advanced training and experience are an important factor for success of TAVI [9]. Current TAVI training starts with theoretic procedural preparation during lecture and laboratory-based education followed by live case observation [10-12]. In addition, other tools have been used to improve skills such as surgery on simulators, cadavers/animal and “dry runs”. Simulators are used to gain familiarity the catheter system [1] and surgery on cadaver/animal is used to rehearse the required techniques for the transfemoral or transapical aortic valve implantation [13]. "Dry run” training provides an opportunity to improve communication and familiarity with new tasks [14], thereby improving team choreography [1]. Despite these potential benefits, the best metrics to assess benefit of such trainings and how they are translated to actual cases have not been validated.

Admittedly, simulations cannot replicate all aspects of an actual TAVI case, particularly many of the complications that happen in real cases such as sudden bleeding or change
in patient blood pressure. After the training phase, a number of proctored cases should be completed. Frank, open debriefings about difficult cases have proved valuable [12].

1.2. Quantification of learning during training/practices and their benefit

For evaluation of learning during TAVI training, performance measures need to be defined. Plotting performance versus experience (e.g. number of completed cases) creates a learning curve [15] and it is expected that with more experience, the performance tends to improve [16]. TAVI learning curve involves the improvement in multidisciplinary teamwork to execute a complex intervention. An early “learning curve” is an important drawback of TAVI that can dramatically alter patient safety and hospital costs [16]. Communication failures among cardiology, CT surgery and cardiac anesthesia and uncertainty about roles among support staff are common triggers for adverse events during the TAVI learning curve. In an article published recently, Block talked about the importance of learning curve in TAVI procedure [7]. The effect of training and learning curve in TAVI procedure has been evaluated in different studies [16-20]. In general, we could classify the learning curve in TAVI to two groups that try to 1) evaluate patient’s outcome [18-20] and/or 2) evaluate the TAVI procedure itself [16, 17, 20].

Fluoroscopy time, valvuloplasty to valve deployment time, radiation exposure and contrast volume studied by Alli et al. during performing TAVI procedure on 44 consecutive patients [16]. Their results show that procedural time, radiation, and contrast volumes significantly decreased with increase in experience. Also, existence of plateau after the first 30 cases in their research proposed that it takes 30 cases to attain proficiency. The same parameter as Alli et al. study has been evaluated in another research on 500 consecutive high-risk patients [17]. The results of this study also confirm that operating time and radiation exposure reduced with experience. Gurvitch et al. studied the effect of learning curve based on a total of 270 patients who underwent TAVI [18]. They conclude that TAVI outcomes improve with experience. In a study done by Wendler et al., reduction in incidence of technical intra procedural complications have also been reported which reflects the learning curve but 30-day mortality remained unchanged [20]. Learning curve studied by Pasie et al. did not show any significant change in 30-day mortality [19].

Besides the above mentioned parameters, error in performing a technical task (e.g. improper placement of surgical device), economy of movement in navigating the required tools (e.g. path length and proportion the distance of the tool tip exceeds the optimum distance), and blood loss have also been used as learning curve in other minimally invasive surgery such as laparoscopic surgery. Furthermore, good communication and debriefing after surgery were a factor that caused a quick learning curve in minimally invasive cardiac surgery as studied by Leonard et al. [21].

In this study, we hypothesized that training and enhancing between team communications, can improve the economy of movement (EoM) in clinical staff during TAVI procedure. As a case study, we explored body motion using a wearable sensor on one clinical staff who participated in 6 consecutive cases including four training sessions and two clinical cases. Since the jerkiness of motion is an indicator of economy of motion and may be used as an indicator for the performance of human motion, it stands to reason that assessing the jerkiness of motion may be an indicator of learning effect after practices.

2. METHODS AND MATERIALS

After approval of this study by the institutional review board (IRB) in University of Arizona, physicians (two interventional cardiologists, two cardiac surgeons, cardiac anesthesiologist, and a non-invasive cardiologist) and support staff (three catheterization lab nurses and three CT surgery nurses) were recruited to participate in four cadaver TAVI simulations over a four month period followed by two clinical cases.

Each simulation and clinical case involved videotaped performance in the hybrid operating room, and a debriefing session to review case highlights. Two raters independent of the TAVI team reviewed videos for major communication errors.

Economy of movement of one clinical staff (scrub technician), who assisted in the TAVI procedure, was measured using a wearable sensor (PAMSys™, Biosensics LLC, MA, USA) inserted in a tank top shirt to assess trunk acceleration with sample frequency of 50Hz. One of the nurses (scrub technician), who was naive to TAVI procedures was asked to wear the shirt for the entire procedure. To identify the start and end of procedure, an observer logged the beginning and termination of each procedure, and the data was analyzed only during TAVI procedure.

The wearable sensor allows measuring trunk acceleration in all three-body planes (e.g. sagittal, frontal and transverse). An algorithm was designed to quantify the jerkiness of body movement during TAVI procedure. In summary, the medial-lateral movement of body in frontal plane was measured by the average variation in acceleration (estimated from standard deviation of acceleration) continuously monitored by a 3 minute moving window. To remove the aberrant data,
the 5th and 95th percentiles of the measured jerkiness per trial were excluded.

Since the duration of each TAVI practice was different, except a simple real case only first 50 minutes of captured data for each trial was considered for final data analysis and between trials comparison.

Repeated measures ANOVA test was used to examine significant change in jerkiness of movement as a function of TAVI cadaver simulated practices. In addition, Student–Newman–Keuls correction was used as the post-hoc to assess pairwise comparisons between the first and the last cadaver simulated jerkiness of movement.

To characterize the early learning curve during cadaver simulations, an exponential curve \( Y = a \times \exp(-X/\tau) + b \), where 'a', 'b', and 'τ' are constant values and X is number of practice, was fitted to the averaged jerkiness values measured during each simulated cases. The gain and time constant resulted from simulated cases were mapped to the results obtained during real cases to explore whether the gained benefit is translated from simulated cases to real cases. In addition, to identify the magnitude of practice benefit, the jerkiness of movement in medial-lateral direction in subsequent trials were compared to the first training case experience, assuming the first case as baseline with value of 100%. Thus, a reduction in percentage of movement jerkiness is considered an enhancement in economy of motion or learning effect during TAVI procedure.

3. RESULTS
The cadaver simulated trials durations ranged from 55min to 87min with an average duration of 75.5±14.0 minutes. After completing the cadaver cases, two real cases were performed, one included a simple case with duration of 25 minutes and the second one was a complex case with duration of 400 minutes.

The first simulations were characterized by high incidence of major communication errors, largely related to misunderstanding of individual duties with improvements noted in the later simulations (13,13,12,7 errors/case) and translating into the first clinical TAVI cases (2,1 errors/case). Specifically, there was a 70% increase in the use of closed loop communication over the course of the simulations and clinical cases.

Figure 1 illustrates the jerkiness of truck movement in medial-lateral direction for all simulated and real cases. Figure 2 illustrates the changes in jerkiness of movement during simulated and real cases. The average value of jerkiness of trunk movement for the scrub tech for the first cadaver simulation was 0.098±0.021 g, which was significantly higher than the 4th cadaver simulated training

Figure 1: Jerkiness of movement for TAVI cadaver simulations and real cases.

Figure 2: Jerkiness of movement is significantly reduced as a function of cadaver simulated practices in exponential fashion.
(17.3%, p=0.04, 95%CI=[0.000, 0.0352]g) as well as the first real case (27.5%, p=0.019, 95%CI=[0.005,0.049]). The magnitude of jerkiness of movement was reduced by an average rate of 4.99±4.26% per practice. However, the reduction trend was not statistical significant in our sample (p=0.23). In the first real-live TAVI case (case #1 with duration of 25 minutes), the average jerkiness of movement was 0.073±0.080 g, which indicates a further reduction of 12.6% compared to last simulated trial. While, the second TAVI real case (case #2 with duration of 400 minutes), the jerkiness of movement was 0.086±0.025g, which indicates a moderate increase of 2.81% compared to last simulated case but was 12.0% lower than the first simulated case.

An exponential fit describing the learning curve as function of practice was Y=0.014exp(-X/1.506)+0.082 in which X denotes the trial number (assuming the first case is equal to ‘0’), with a time constant of τ=1.506 (goodness of fit: r-square=0.93, RMSE=0.0026). According to this model, the estimated jerkiness movement for the first real case is projected to be 0.083g, which is in range of the observed values for the first two real cases including simple TAVI case with operation duration of 25min and average jerkiness of movement of 0.073g and the complex TAVI case with operation duration of 400min and average jerkiness of movement of 0.086g. This indicates that similar to improvements in communication, improved economy of motion during simulation did translate into the first two clinical cases.

4. DISCUSSION

This study found that a simple and low cost wearable technology based on a tri-axial accelerometer is useful to characterize how economy of motion evolves in a key technician during the early phase of the TAVI learning curve. Conventional methods for body motion analysis include electromagnetic systems, and optical motion analysis systems (video-based tracking). The electromagnetic systems are susceptible to noise within a metallic environment (e.g. operation room) [22, 23] and camera-based systems can have field of view blocking problem, which is the case in actual operation rooms [23]. Moreover, it should be noted that video-based tracking system requires placement of reflective marker on joints and segmental landmarks, which is obtrusive to the surgeon, and is a time-consuming task. One of the key advantages of the proposed system is that it can unobtrusively capture body movement and it is not sensitive to electromagnetic interferences in operation room and to blocking problem as well. Also, in comparison to time required for installations of markers in video-based systems, attaching this wearable sensor is quick.

Although in this study we focused on economy of movement, the wearable technology can be enhanced to measure physiological parameters such as heart rate, respiration rate, and skin temperature, which could be used to assess individual stress as described in our previous study[24]. Combination of physiological measurement and economy of movement could be enhanced to further characterize early progress with the learning curve during TAVI procedure. Clear metrics of training progress provide feedback to the clinical staff that is critical to be able to reduce the risk of adverse events during the early implementation of TAVI.

Previous studies have demonstrated the benefit of body motion and posture assessment of clinical staff during surgical procedures. For example, van Veelen and colleagues[25] by assessing problems encountered during 12 endoscopic operations and surveying involved medical staff, revealed the association between postural discomfort and the problems that occur during minimally invasive surgery. Measuring body posture during surgery/training can also be useful in evaluation of the physical demands during a long operation [26]. Furthermore, maintaining proper postural stability is very important for surgeons performing minimally invasive surgery as they may strategically change their body posture for better surgical outcomes [27]. Several studies have analyzed upper-body postures [22, 27-31] for purpose of defining the optimal surgical postures, however none have addressed the effect of training on economy of movement (EoM) of upper body.

This study takes a step forward from previous research studies and explores the effect of training on management of body movement and in effect the improvement in EoM during surgery. Furthermore, the current study is the proof of concept for using single body-worn sensors for capturing and quantifying body movement in an actual operating room.

This study however suffers from several shortcomings that should be addressed in subsequent studies. This is a pilot case study and the results need to be confirmed in larger samples. In addition, this study was not powered to examine association between gained benefit from cadaver simulated practices and procedural proficiency and learning. Another study should explore whether the learning effect during simulated cases can be translated to real-cases via comparison to a control group without simulated practices.

Despite these limitations, this study demonstrates the proof of concept of assessing economy of movement during surgical procedure using a comfortable and practical wearable sensor. In addition it suggests an innovative metric value to assess learning effect of surgical practices during both simulated and real cases, which could be used as an alternative or complementary to traditional metrics.
parameters such as operation time and communication error [16].

5. CONCLUSION

The TAVI learning curve involves multidisciplinary teamwork to execute a complex intervention. Cadaver training provides an opportunity to improve communication and familiarity with new tasks. This pilot study proposed an innovative method to objectively evaluate progress with the learning curve during TAVI simulations and clinical cases. Results suggest that measuring communication errors among physicians and economy of movement in support staff provides valid and practical metrics of team learning. Whether improved communication during simulation as well as improved economy of movement is more likely to translate into initial clinical cases warrants further investigation.

6. REFERENCES


**Biography**

**Saman Parvaneh, PhD:** is currently a postdoctoral research associate in the Department of Surgery, University of Arizona (2012-present). He is also a scientific member of Arizona Center on Aging (ACOA), University of Arizona. Dr. Parvaneh received his Bachelors in electrical engineering in 2003 followed by MSc and PhD degree in biomedical engineering in 2005 and 2011 respectively. During his PhD, his primary focus was on algorithm development and bio-signal processing to predict spontaneous termination of atrial fibrillation. Dr Parvaneh’s current research of interest includes developing novel algorithm for wearable sensor applications to continuously monitor physiological and mental stress in different population including surgeons during robotic surgery as well as patients during clinical visits.

**Sugam Bhatnagar, MPH, MBBS:** is an Associate Research Scientist and Lab Manager of the Cardiac Robotic Surgery Lab at University of Arizona. He received his medical degree (MBBS) from Government Medical College, Nagpur in 2009 and earned an MPH in 2010 from Harvard School of Public Health. His research interest includes outcomes evaluation during robotic surgery, TAVI surgery, and cadaver simulated surgery.

**Robert Poston, MD:** has obtained his bachelor degree in biology from University of Texas at Austin, and went on to complete medical school at Johns Hopkins Medical School in Baltimore, MD. He completed his residency at the University of California at San Francisco and his fellowship at Stanford University School of Medicine in Palo Alto, California. He is nationally known for using robotics for
minimally invasive coronary bypass surgery, is a professor in the Division of Cardiovascular and Thoracic Surgery in the UA Department of Surgery. Dr. Poston’s expertise in robot-assisted minimally invasive coronary artery bypass surgery is unique in Arizona. His research interests include application of high-resolution imaging for heart surgery and investigating the ability of robotic surgery to accelerate the return of exercise tolerance compared to traditional surgical techniques.

Bijan Najafi, PhD: is currently serving with the University of Arizona, Department of Surgery, Department of Medicine, and Department of Biomedical Engineering (Tucson, USA) since April 2012. He serves as Associate Professor of Surgery and the Director of interdisciplinary Consortium on Advanced Motion Performance (iCAMP), member of Southern Arizona Limb Salvage Alliance (SALSA), member of Arizona Center on Aging, Associate Member of Arizona Cancer Center, and scientific advisory board member of Arizona Arthritis Center. He received a Ph.D. degree in Bioengineering followed by a Postdoctoral Fellowship in Applied Biomechanics at the Swiss Federal Institute of Tech (Lausanne, Switzerland), and in Neuroscience at Harvard University. His unique expertise is the translation of wearable sensors for more accurate movement assessment of patients in their natural environment where they're the most comfortable and active. His goal, which he shares with his iCAMP colleagues, is to better understand how people move through their environment. In this way, he believes we may be able to fundamentally change the way we objectively measure quality of life for people across disciplines.