

IT'S HEART TO SEE.

an Early Health Technology Assessment of
rendering 3D-images prior to Transcatheter Aortic Valve
Implantation.

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TITLE	ITS HEART TO SEE: AN EARLY HEALTH TECHNOLOGY ASSESSMENT OF RENDERING 3D- IMGAGES PRIOR TO TRANSCATHETER AORTIC VALVE IMPLANTATION
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ABSTRACT

Its HEART to SEE

BACKGROUND:

Patients undergoing heart surgery are preoperatively examined using a combination of imaging modalities. Dependent on the outcome, the type of surgery is determined, risks are estimated and the surgery is planned. New types of technology are able to convert CT, MRI and ultrasound images into a 3-Dimensional object, to look at the image from different angles and get a cross-sectional view of the heart as a whole. The use of 3D-imaging is not yet common for cardiac surgery, since it is unknown whether 3D-imaging is actually beneficial, and if so, where it could be used and what the potential effect could be. A preliminary survey indicated its value may be highest in transcatheter surgery.

METHOD:

The aim of this study is to investigate the potential effect of 3D-imaging on the outcome of TAVI procedures. The potential effect on different outcomes - compared to the costs – is estimated in an early Health Technology Assessment using a Discrete Event Simulation Model. Input data for the model is obtained from individual patient data, and data gaps are filled in with the use of Expert Elicitation. Uncertainty is assessed with the use of both deterministic and probabilistic sensitivity analysis

RESULTS:

Results showed that TAVI costs could potentially be reduced with €686 and the system itself costs €180 per patient (with 50 TAVI procedures a year and payment in 5 years). Therefore, the expected cost savings equal €506 per TAVI procedure when using 3D-imaging, and the corresponding Cost-Benefit Ratio is 3.37. Sensitivity analysis showed that the amount of successful valve implementations has the most influence on cost-savings, and could potentially result in a cost-saving between –€517 up to +€1581. Probabilistic sensitivity analysis showed that the probability of 3D-imaging reducing costs is 74%.

CONCLUSION:

Using 3D-imaging prior to TAVI procedures has a favourable Cost-Benefit Ratio. However, it is still uncertain whether costs would be saved, and if so, how large cost savings would be. Also, the actual use and implementation of 3D-imaging in clinical practice will determine its impact to a large extent. Use of 3D-imaging in patients where conventional imaging results are unsatisfactory, and more preoperative imaging is necessary to safely perform the procedure, could lead to lower costs and higher benefits.

keywords: TAVI; 3D-imaging; 3D-rendering; cost-benefit study; discrete event simulation; early health technology assessment

1. BACKGROUND

CARDIAC SURGERY

Patients undergoing cardiac surgery are preoperatively examined using either CT-scan, MRI-scan, Trans Oesophageal Echo (TEE), Trans Thoracic Echo (TTE), Coronary Arteriography (CAG), or a combination of those scans (1–3). These diagnostic imaging tools give detailed information about the type and seriousness of the abnormality in the heart, after which the treatment and further prognosis is assessed (4). Dependent on the outcome of the examination, the type of surgery is assessed, risks are estimated and the surgery is planned (1, 4).

Most common types of surgery are Coronary Artery Bypass Graft (CABG) and valve replacement surgery (aortic or mitral). Access to the heart can be obtained through either full sternotomy (open heart operation), minimal sternotomy, or with a transcatheter approach (5). The type of surgical approach used is based on patient anatomy and patient risk. Most common are open heart operations, but when these are difficult to perform (e.g.: in reoperations), another approach must be chosen. The transcatheter approach is mostly used in older, high-risk patients, in whom a sternotomy is no longer a safe option. Examination is sometimes difficult due to the complex nature of the cardiac problem. Ageing population, previous cardiac operations and continues progress in cardiovascular medicine makes patients differ in their cardiovascular morphology, making the anatomical structures of the heart difficult to assess preoperatively (6–8).

3-DIMENSIONAL IMAGING IN CARDIAC SURGERY

New types of technologies are able to convert the CT, MRI and ultrasound images into an 3-dimensional object (see list of figures and figure 1), providing the user with the opportunity to look at the image from different angles and get a cross-sectional view of the heart as a whole (9–12). With better insight in the patients morphology, the surgical type and approach can be assessed more correctly before surgery, decreasing the surgical risks for the patient.

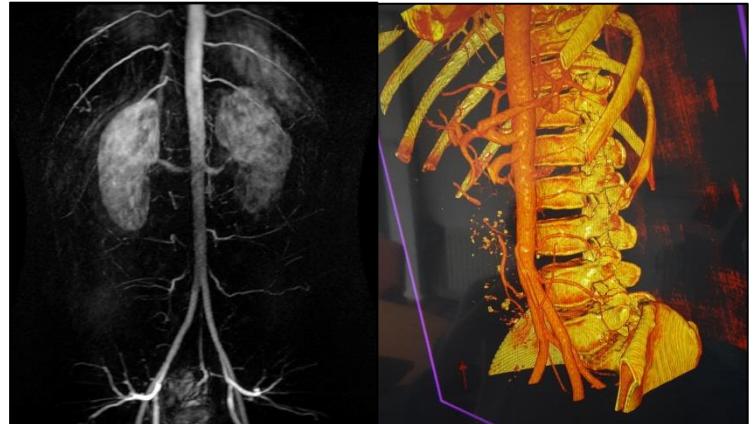


Figure 1: Comparison between conventional and 3D-imaging. Left image shows a contrast CT of the Aorta Abdominalis, where the right image shows a 3D-image.

Besides the 3D-TEE, the uses of 3D-imaging techniques have not yet been standardized for cardiac surgery. The current limitations lay in the poor image quality, the high price of the image-rendering systems and the difficulty of rendering and using 3D-data (13). These limitations are diminishing due to ongoing advances in technology, but it is unknown whether 3D-imaging is actually beneficial, and if so, where it could be used and what the potential effect could be.

EARLY HEALTH TECHNOLOGY ASSESSMENT

Since only single-centre experiences and/or case studies are available concerning 3D-imaging in cardiac surgery (6, 14–17), an early Health Technology Assessment (HTA) can be used to investigate the potential effect of 3D-imaging in cardiac surgery.

With early HTA, assessment of the usefulness and (possible) advantages of a new technology during their development is possible, even when data from clinical trials is lacking (18). By modelling simplified scenarios of real-life, an estimate of the potential impact can be derived (19).

Discrete Event Simulation Modelling (DES) is a modelling technique which simulates 'individual' patients that undergo events. The main advantage of DES, relative to other modelling techniques, is that it can be used to mimic complex environments – like a hospital – by simulating time, probabilities, resources and queues (20, 21). When exploring the effect of using 3D-imaging in

cardiac surgery, the potential effect on surgical outcome is important, as well as the effect on the process and costs. Discrete Event Simulation takes individual patients into account instead of following a cohort of patients, which makes it a valuable modelling technique when looking at the potential benefit of using 3D-imaging in cardiac surgery (21, 22).

PRELIMINARY SURVEY

The expected usability of using 3D-imaging is very broad (23, 24). A preliminary survey is taken under cardiologists (n=4), radiologists (n=2) and thoracic surgeons (n=5) in order to investigate where in the current process 3D-imaging is expected to be beneficial.

Based on the results from the preliminary survey, the impact of 3D-imaging is expected to be linked to the invasiveness of the surgical approach, with 100% of the respondents rating 3D-imaging as least beneficial in open heart operations, while 85,7% rated 3D-imaging as most beneficial in transcatheter operations.

The effect of using 3D-rendering systems is mostly applicable in the diagnostic and pre-surgery planning pathway (88,7% and 77,8% respectively). One of the cardiologist stated that: *"3D-imaging is especially helpful in the diagnostic pathway to fine-tune the diagnosis to determine the optimal treatment. During surgery it is helpful when placing devices."*

The full survey and the remaining results can be found in Appendix I and II.

Based on the results, the potential effect of 3D-imaging is expected most in Transcatheter Aortic Valve Implementations (TAVI). In a TAVI procedure, a deflated aortic valve is implemented transfemoral, transapical or transaortal. The valve is placed in the right spot with the use of a catheter and expanded; pushing the current aortic valve away. TAVI procedures are mostly done in high-risk and older patients, in whom a sternotomy no longer is safe (25). With the transcatheter approach patients can be operated who otherwise could not be operated due to the high risk of mortality.

Prior to TAVI, a TTE or TEE is made to assess the valve morphology and a CT scan is made to determine the right surgical approach. During surgery, TEE is used to assess the valve size and the right placement of the replacement valve. Since there is currently limited data available about 3D-imaging in TAVI procedure, this study aims to investigate the cost-benefit of pre-operatively using 3D-imaging next to conventional imaging in patients undergoing a TAVI procedure.

2. Method

OBJECTIVE OF THE STUDY

The aim of this study will be accomplished by answering the following main question:

"What is the expected cost-benefit of pre-operatively using 3D-imaging next to conventional imaging in patients undergoing a TAVI procedure?"

To answer this question, a Discrete Event Simulation Model is made using a framework from the Good Research Practices in Modelling Task Force, a collaboration between ISPOR and the Society for Medical Decision Making (26). Making and running the model exist of 4 steps:

1. The model itself is made by converting the clinical pathway into a series of events the patient is simulated through. More information can be found under '*Discrete Event Simulation Model*'
2. Input data is obtained from MST patient data. See "*MST patient data*" for more information.
3. Because of lacking data on the outcome of cardiac surgery with 3D-imaging, experts are asked to fill in the data gaps in the model. More information about this can be found under '*Expert Elicitation*'
4. The model is executed and results are gathered. Analysis of the results is done by performing a sensitivity analysis.

Outcome of the study is the expected cost-benefit of using 3D-imaging prior to TAVI procedures.

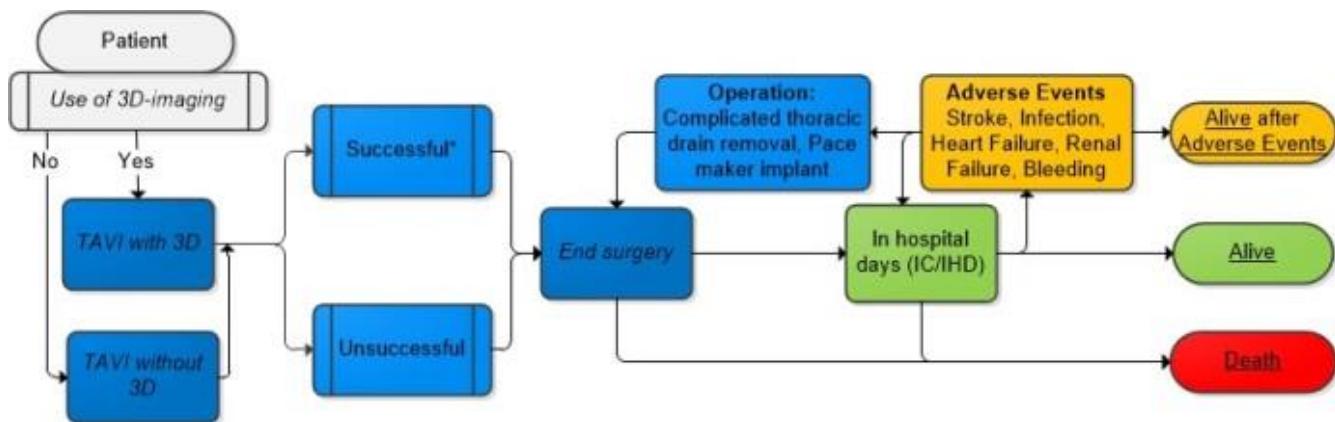


Figure 2: Discrete Event Simulation model. Successful surgery is identified as both successful access and successful implant in the first try. Otherwise the procedure is regarded unsuccessful. TAVI: Transcatheter Aortic Valve Implementation, IC: Intensive Care, IHD: In-Hospital Days

DISCRETE EVENT SIMULATION MODEL

A DES-model is made to simulate the effect of 3D-imaging on the outcome of TAVI surgery. The model is shown in figure 1. Based on the attributes from the patient, probabilities are adjusted within the model. When 3D-imaging is used, corresponding probabilities will be loaded in the rest of the model. The model will simulate a 30-day timeframe, since long-term outcome data is not available and experts are unable to correctly estimate long-term outcomes. The model will simulate 10.000 patients to reach a 95% confidence interval (27). More detailed information about the development of the DES model for this study can be found in Appendix III.

PATIENT DATA MST

To get data for the 'TAVI without 3D'-pathway, patient characteristics and input data for the model are retrospectively obtained from MST patient data. Data from all TAVI procedures in 2015 till March 2016 are being used ($n=71$). For every patient, an intraoperative report and 30-day follow-up must be available, otherwise successful access and successful implantation cannot be assessed. Costs are based on the diagnosis treatment combination from MST.

EXPERT ELICITATION

Data for the 'TAVI with 3D'-pathway of the model is gathered with the use of expert elicitation. Expert elicitation is subjected to bias, so a framework from Haakma et. al. (2014) is used to minimize bias (28, 29).

A sample of 15 experts – either (interventional) cardiologist or thoracic surgeons – is invited to attend a demonstration from Ps-Medtech (Amsterdam, Netherlands), in which their 3D-imaging system will be demonstrated. The aim is to include 15 experts in this study, since it is assumed that the benefit of including more experts starts to decrease after 12 (30). After the demo, experts are asked to estimate the procedural differences and the changes in outcome when using 3D-imaging prior to TAVI procedures. Experts are asked about 'operation approach success', 'operation implant success', 're-operation', 'adverse events' and '30-day mortality'.

The experts are asked to give the most likely value for a parameter (the mode), followed by the lowest and highest likely value, plotted as a Probability Density Function (PDF) by using the Project Evaluation and Review Technique (PERT) approach (31).

As heterogeneity was expected, a calibration method is applied. Experts are given a weight to adjust for expertise, so that the expert with most experience is weighted most. The weighting is based on both TAVI and 3D experience (see table 3), since these are factors that determine the reliability of the answer.

Table 1: Criteria and weights for the calibration of experts

Experience with TAVI procedures	Experience with 3D-imaging
---------------------------------	----------------------------

None	1	None	1
Involved in planning	2	Demo	2
Performs TAVIs	3	Work with 3D-system	3

By using a linear pooling algorithm, the PDFs are combined to an overall probability distribution: $p(\theta) = \sum_{i=1}^n W_i P_i(\theta)$.

Where $P(\theta)$ is the overall probability distribution, W_i is the weight of the expert (summing up to 1) and $P_i(\theta)$ is the distribution probability (32). The overall probability distributions will then be used in the model. Further details can be found in Appendix IV and V.

SENSITIVITY ANALYSIS

To assess parameter uncertainty and the effect of different parameters on the outcome of the model, both Deterministic Sensitivity Analysis (DSA) and Probabilistic Sensitivity Analysis (PSA) will be executed, since, according to the NICE Technology Appraisal Committee, they should be used both to fully address uncertainty (33).

In DSA, all input parameters are independently changed within the parameter distributions – also known as univariate sensitivity analysis -, and the

change in outcome compared to the mean benefit (33). In PSA, probability distributions are applied to the ranges of input parameters. By randomly drawing from those distributions (Monte Carlo simulation), different outcomes are estimated. These outcomes are used to calculate the parameter uncertainty surrounding the cost-benefit (34).

3. Results

PATIENT DATA

Data from 71 TAVIs performed between January 2015 and March 2016 was obtained. Of those 71, 1 patient was still in the hospital at the time of this study. No outcome data was available, so the patient was excluded. Baseline characteristics, procedural outcomes and clinical outcomes are shown in table 1. Mean age was 81.4 ± 5.6 years and males were in slight minority. The mean Logistic EuroSCORE II was $4.13 \pm 4.2\%$.

The transaortal, transfemoral and transapical approach was used in 46%, 50% and 4% respectively.

Table 2: MST Patient data

MST patient data	Total (n=70)			
Baseline Characteristics				
Male	34 (48,6)			
Age	81.5 ± 5.6			
Logistic EuroSCORE I	15,6 ± 7,9			
Logistic EuroSCORE II	4,13 ± 4,2			
Procedural data				
Operation approach success	69/70 (98,6)	Transaortal (n=32)	Transfemoral (n=35)	Transapical (n=3)
Valve implant success	67/70 (95,7)	31/32 (96,88)	35/35 (100,00)	3/3 (100)
Operation time	101 ± 38	31/32 (96,88)	32/35 (94,29)	3/3 (100)
Costs valve	€ 19.880,00	110 ± 47	91 ± 23	125 ± 7
Intensive Care days	$1,91 \pm 1,85$	1,88	1,74	4,00
Nursery ward days	$2,60 \pm 2,60$	3,79	1,37	4,33
In hospital mortality	2/70 (2,86)	1/32 (3,1)	1/35 (2,9)	0/3 (0,0)
Clinical outcomes				
re-operation	8/68 (11,7)			
PM implant	6	1/31 (3,1)	5/34 (14,7)	0/3 (0)
Drain removal	2	2/31 (6,5)	0/34 (0)	0/3 (0)
Adverse events	21/68 (30,9)			
No readmission	10	5/31 (16,1)	4/34 (11,8)	1/3 (33,3)
readmission	9	4/31 (12,9)	4/34 (11,8)	1/3 (33,3)
Mortality	2	2/31 (6,5)	0/34 (0)	0/3 (0)

Values are given in Mean (%), Mean ± SD or n/N (%). PM: Pacemaker

In one operation, the TAVI procedure was converted to a normal AVR, which took 340 minutes to complete. The valve was not correctly implemented the first time in three cases. Costs of the valve is €19,880,- (35). In-hospital mortality appeared in 2 cases, with pneumonia as the leading cause. Re-operation was necessary for 8 patients, of which 6 needed a pacemaker and 2 needed their thorax-drain surgically removed.

Adverse events appeared in 21 cases, most of which were decompensatio cordis and infection. Eight patients were readmitted and 2 patients died of adverse events (both due to decompensatio cordis), making the total 30-day mortality rate 5,7% (4 out of 70 patients).

OUTCOME EXPERT ELICITATION

From the 15 respondents asked to participate in the elicitation, 10 (66%) actually answered and returned the questionnaire. Respondents are shown in table 3. From the 10 respondents, 2 were excluded because they were unable to elicit the changes in outcome when using 3D-imaging, for which they stated that every patient is different and therefore generalizing outcomes is too difficult. Of the eight experts, one interventional cardiologist stated that he expected no added value from the 3D-system, while the others expected the system to improve TAVI outcomes.

Table 3: Respondents and their weighting

No.	Specialism	TAVI score	3D score	Weight
1	Thoracic surgeon	3	2	0,147
2	Interventional cardiologist	3	2	0,147
3	Cardiologist	1	2	0,088
4	Cardiologist	1	2	0,088
5	Cardiologist	2	2	0,118
6	Thoracic surgeon	3	2	0,147
7	Interventional cardiologist	3	2	0,147
8	Interventional cardiologist	3	1	0,118
9	Thoracic surgeon	3	2	-
10	Cardiologist	1	2	-

Weight is calculated by dividing individual score by total (34). 'No score' is given when the respondent was unable to fill in the form

The pooled data is shown in figure 3 as a probability density function. Appendix VI shows the individual elicitations per variable, in which the heterogeneity between the individuals is visible.

Estimated prevalence

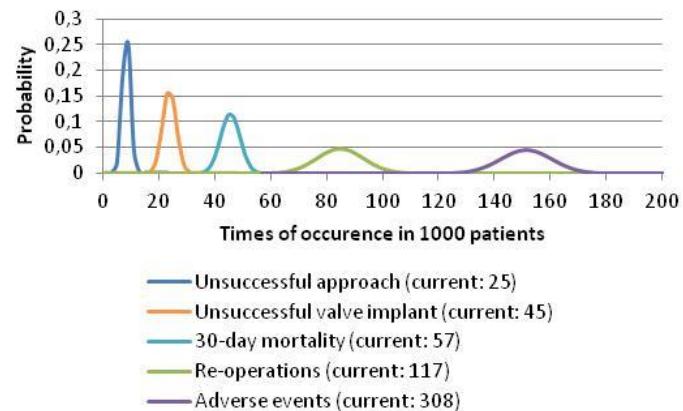


Figure 3: Estimated prevalence in 1000 patients. Pooled data from 8 experts.

Successful approach was most homogeneous between experts, with a mean estimated prevalence of 8,3 ($\pm 1,38$). Valve implant and mortality were estimated at 23,8 ($\pm 2,43$) and 45,6 ($\pm 3,48$) respectively. Re-operations (84,8 $\pm 8,3$) and adverse events (151,4 $\pm 9,2$) were proven to be the most difficult to estimate, and severe heterogeneity between experts was displayed.

OUTCOME OF THE DES MODEL

The DES model is completed with patient data from MST (table 2) and results from the expert elicitation (figure 3). Input for the DES model is shown in table 5.

The mean results in table 4 show that, on average, a TAVI patient costs around €36.334,- and this could potentially be lowered to €35.648,- when using 3D-imaging. Making the benefit €686,-. Most benefit is gained by less unnecessary valve implementations. Due to the high price of the valve, this could save up to €428,- on average.

Table 4: mean results from the DES model

Mean results:	Valve costs	Operation costs	In-hospital costs	Re-operation costs	Re-admittance costs	Total
Conventional imaging	€22.879	€8.838	€4.190	€144	€283	€36.334
3D-imaging	€22.451	€8.772	€4.181	€68	€176	€35.648
Cost-saving per TAVI	€428	€66	€9	€76	€107	€686

Cost of TAVI procedure with and without 3D-imaging. Not accounted for the costs of the 3D-imaging system. Conventional imaging is based on patient data from MST. 3D-imaging is based on the outcome from the expert elicitation.

Table 5: Input data for the DES model

	Value	Range	Distribution
<i>General</i>			
IC days	1,91	1,74-2,33	Poisson
Nursery ward days	2,60	2,39-2,78	Poisson
Hospital days after AE	5	1,12-9,17	Poisson
Costs TAVI procedure	€7.656,-	-	
Costs TAVI valve	€19.880,-	-	
Cost IC day	€1.329,-	-	
Cost nursery ward day	€597,-	-	
Cost PM implant	€390,-	-	
Cost drain removal	€70,-	-	
<i>Probabilities</i>			
Conventional imaging			
Approach success	98,60%	95,8%-100%	Normal
Implant success	95,70%	90,9%-100%	
Re-operation	11,70%	4%-19%	
Adverse events	30,90%	9%-28%	
Mortality	5,70%	0%-11%	
3D-imaging			
Approach success	99,17%	98,7%-99,6%	Beta
Implant success	97,61	96,8%-98,4%	
Re-operation	8,48%	7,1%-9,9%	
Adverse events	15,15%	13,3%-17,1%	
Mortality	4,56%	3,5%-5,7%	

Cost of the 3D-system is estimated €30.000,- in purchase costs and €3.000,- a year for a service contract. Assuming that the system will be fully payed in 5 years (which is the standard), and for 50 TAVIs a year (minimum amount in MST) the costs for 3D-imaging will be: $\frac{(\frac{30.000}{5} + 3.000)}{50} = €180$ per TAVI patient; making the mean cost-savings €686 - €180 = €506,-.

The following equation gives the Cost-Benefit Ratio (CBR):

$$CBR = \frac{\text{Benefits}}{\text{Costs}} = \frac{€606,-}{€180,-} = 3.37$$

Cost-benefit ratio is used to show the value of an investment. A ratio of 3.37 means that for every €1,- invested, €3,37 will be gained.

Tornado graph

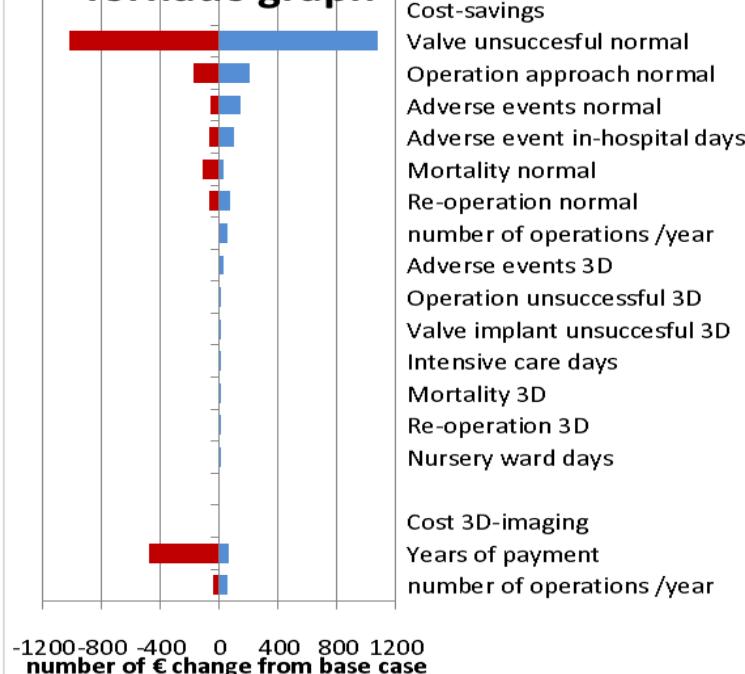


Figure 4: Tornado graph. Results from the deterministic sensitivity analysis. Change in € from mean average (table 4) is shown.

Cost-saving acceptability curve

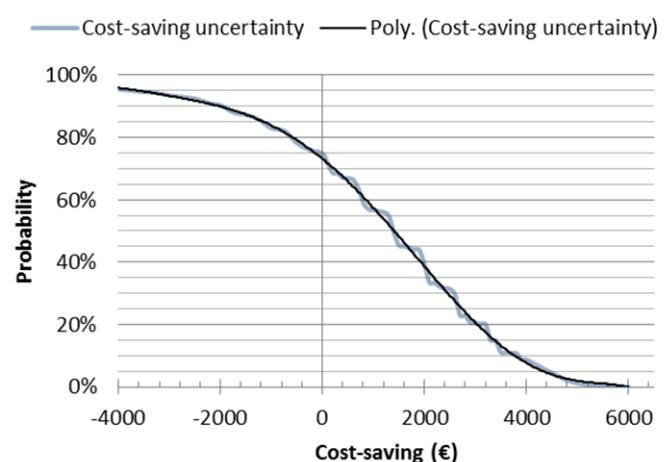


Figure 5: Cost-saving acceptability curve. Cumulative probability is shown for every minimal amount of cost-saving

OUTCOME OF THE SENSITIVITY ANALYSIS

Both deterministic and probabilistic sensitivity analysis is performed to assess the parameter uncertainty. The result of the deterministic sensitivity analysis is shown in figure 4. Uncertainty of the model is mostly based on the MST data, since the relatively low sample size ($n=70$) results in substantial uncertainty. The successful valve implementation when using conventional imaging was estimated to lie between 90,9% and 100%, and in the mean results this was 95,7%.

The sensitivity analysis showed that, depending on this parameter estimation, cost-savings of TAVI procedures could lay between -€517,- up to +€1581,-. Operation success could change the cost-saving between €325 and €713, and adverse events showed a cost-saving between €440 and €652. Cost of 3D-imaging could result in negative cost-savings (-€154), but only when the system would be fully paid off in 1 year.

The probabilistic sensitivity analysis is performed to assess the parameter uncertainty in the model itself. Figure 5 shows the cost-saving acceptability curve, visualizing the uncertainty surrounding the cost-savings. For every cost-saving the surrounding uncertainty is calculated. The cumulative probability for a cost-saving of at least €0 when using 3D-imaging is 74%. The higher the cost-savings, the lower the probability of it occurring.

4. Discussion

This study aimed to provide insight in the potential effect of using 3D-imaging prior to TAVI procedures. Since there is a lack of randomized studies, this effect is not yet known. Using a Discrete Event Simulation it was found that using 3D-imaging prior to TAVI procedures could potentially improve both procedural success and clinical outcome. Results from expert elicitation indicated an increase in operational success and a decrease in 30-day mortality. Mean outcome showed that TAVI costs could be reduced with €686,- per patient, whereas the system itself costs €180 per patient, resulting in cost savings of

€506,- when using 3D-imaging, and a Cost-Benefit Ratio of 3.37.

However, as mathematician George E.P. Box once said: "*Essentially, all models are wrong, but some are useful.*" (36). Implying that models give useful information, but will always be a simplification of the real world. Parameter uncertainty was assessed to find out how big this deviation with the real world could be and where this would come from. Sensitivity analysis showed that the amount of successful valve implementations is the most important factor for the cost savings, and this could potentially result in a cost-saving between -€517 and +€1581. Probabilistic sensitivity analysis showed that the probability of 3D-imaging resulting in cost-savings equals 74%.

Limitations

Uncertainty originates from limitations in either the model or the data used. Patient data from MST is based on a small patient group ($n=70$). This caused some patient data to differ from literature data. The EuroSCORE I is 15,6 ($\pm 7,9$) in MST against 20,4 ($\pm 12,4$) in the SOURCE XT registry and 30,0 ($\pm 13,7$) in the PARTNER trial, with 2,688 and 130 patient respectively (37, 38). Patients are classified as high-risk with a EuroSCORE I above 15% (39). With less high-risks patients, better procedural and clinical outcomes are expected. This is shown in a better procedural (98,6% vs 95,5%) and device success (95,7% vs 88,5%) (MST vs SOURCE XT). However, the amount of rehospitalizations (14,7%) is more than double the amount of the rehospitalizations in the SOURCE XT registry (6,4%) (37), but MST had no valve-related rehospitalizations. The type of valve used is also an important factor. Newer valves have been produced which are safer (40), and since implant success is an important factor whether or not 3D-imaging is cost-beneficial, this should be accounted for.

Heterogeneity of the elicitation from the experts differs per variable. Successful approach and 30-day mortality show the least heterogeneity between estimations. In the 'valve-

implementation' parameter, a clear distinction is visible between 2 groups, as shown in figure 6: four experts estimate the prevalence to be around 10 per 1000 patients, while three others estimated it to be around 40. Adverse events and re-operations were even less homogeneous, with estimated prevalence between 0,5% to 30% and between 1% to 20% respectively. A bigger sample group would give more insight in the overall estimation and the outliers.

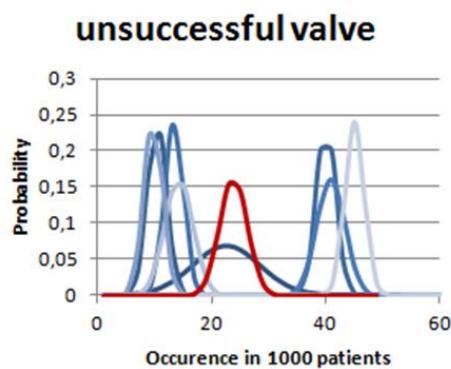


Figure 6: Expert estimations. Occurrence of unsuccessful valve implementation

The linear pooling method was used to combine the experts' answers into an overall probability distribution function (PDF). The red line in figure 6 shows this overall, pooled PDF, but with a mean of 23,8 and standard deviation of 2,4, most estimations done by experts do not fall under the pooled PDF. Perhaps other pooling methods are more efficient, in which all experts estimations are individually used in the model, and the weight could assign the times one expert is used (i.e.: an expert with a weight of 0.3 will be used twice as much as one with a weight of 0.15)

A calibration method was applied, but the weights chosen are arbitrary; there is probably a connection between TAVI performance, experience with 3D-imaging and the ability to correctly estimate procedural and clinical outcomes, but whether - and to what extent - is unclear. Shifting the scores of the weight and assessing the changes in heterogeneity could provide more insight into the calibration method used in this study.

From the 10 experts included in the expert elicitation, 2 stated that they were unable to make estimations. TAVI procedures should be

assessed individually, and they could not generalize the advantage over 1000 TAVI patients. How certain the other experts are with their answers is unclear. To provide more certainty, an alternative behavioural approach where experts will come together and try to achieve consensus about the effect, instead of expert estimating individually, could be used. By consulting with other experts, this approach could potentially lead to less difficulty in estimating the parameters and more confidence in the answers.

The DES model used for this study is a simplification of reality. The expert elicitation was only used to estimate the prevalence of multiple parameters, but it did not look at every possible outcome. The MST data was used to assess current outcomes, but with 70 patients, not every possible outcomes was prevalent. Aortic dissection, cardiac tamponade and coronary occlusion were not included in the model, even though these are important adverse events (36).

Practical implications

Even though results from this cost-benefit study implicates that using 3D-imaging prior to TAVI procedures could lead to a decrease in procedural costs, there are numerical factors which could affect this outcome.

3D-systems are not yet used within MST. System errors and usability are not yet assessed. When these are too bothersome, adequate implementation of the system will not start and the system will not be (fully) used. Furthermore, the system is unlikely to be used solely for TAVI procedures, since the versatility of the system is such that it could easily be used before other difficult operations; both in cardio-thoracic and other surgery types, decreasing the overall costs of the system. Retrospective studies have shown that having better images of the patient could improve preoperative choices made in difficult cases (15, 41, 42). Therefore, the deployment of the system will probably be most beneficial in cases where the conventional imaging is unsatisfactory and more information is needed to safely perform surgery. Isolating the

use of 3D-imaging towards those cases is an important step towards using the 3D-imaging system as efficiently as possible, both in TAVI procedures as well as in other operation types.

Besides surgical planning, the system could be used for educational purposes. Radiologists are able to ‘read’ 2D-images, but for the untrained these images are difficult to interpret. Students and professionals from all kind of specialisms, or even patients, can use 3D-images of anatomical structures/pathologies to improve knowledge about the inside of the human body. Special cases can be explained to patients and made more understandable in case reports, which is something currently done with 3D-prints (43).

Limitations of the 3D-imaging system are the learning curve and the time it takes to adjust the 3D-images so the specialist sees what is of actual interest in. These are limitations that could lead to specialists not using the system, and should be accounted for when deploying the system.

Recommendations

As summarized by Fineberg: “The ultimate value of the diagnostic test is that difference in health outcome resulting from the test: in what ways, to what extent, with what frequency, in which patients is health outcome improved because of this test?” (44). This study looked at the expected cost-savings when using 3D-imaging in general TAVI patients, and with Fineberg in mind, this study could be used as a starting point to more specifically address the advantages of using 3D-imaging in terms of health outcomes.

Uncertainty surrounding the model inputs show that, for 3D-imaging in TAVI procedures, the estimated cost-benefit is not conclusively greater than 1. It should therefore be used as an indication of cost-benefit and as a starting point for further research. When more data is available, these could be used to assess the external validity of this study and to get a more accurate model outcome (45). Further studies could also focus on the use of 3D-imaging in specific cases; when conventional imaging is unsatisfactory and more pre-operative imaging is necessary. For the most

accurate results, these studies must be done with access to a 3D-system, to compare conventional imaging with 3D-imaging, and study the changes in preoperative planning, procedural success and clinical outcomes.

As for the clinical use, a solid implementation plan must be made when deploying the 3D-imaging system. Grol and Wensing (2004) looked at the different incentives and barriers when trying to achieve change (46). Their ten-step model – in combination with the results of this study – could be followed to make sure that there is a platform for using 3D-imaging to its full capacity and that no practical implications will limit the use or benefits of 3D-imaging.

5. Conclusion

When using 3D-imaging prior to TAVI procedures, the conclusion is that 3D-imaging has a favourable Cost-Benefit ratio. Deployment of the 3D-systems in patients where conventional images is unsatisfactory, and where more preoperative imaging is necessary to safely perform the procedure, could lead to larger cost savings as estimated in this study.

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8. Appendix

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Example 3D-imaging system



Appendix I
Preliminary survey

3D-Beeldvorming bij cardio-thoracale ingrepen

Inleiding

UNIVERSITEIT TWENTE.



Geachte Heer/Mevrouw,

Mijn naam is Max Analbers, master student Health Sciences aan de Universiteit Twente. Op dit moment ben ik bezig met mijn masterthesis, waarbij ik onderzoek of het gebruik van 3D-beeldvorming bijdraagt aan beter uitkomsten voor patiënten van cardio-thoracale operaties en wat de kosteneffectiviteit van deze techniek is. Dit onderzoek vindt plaats binnen Thorax Centrum Twente.

De techniek die onderzocht wordt maakt gebruik van 2D beelden gemaakt via CT, MRI en echografie, waarbij de data automatisch omgezet wordt naar een 3D weergave, zodat deze data direct te beoordelen is. Het voordeel van dit systeem is dat meerdere soorten data omgezet kunnen worden naar 3D, en dat deze allemaal via 1 systeem te bekijken en te beoordelen zijn.

Voordat mijn praktijk onderzoek begint wil ik het huidige proces in kaart brengen, onderzoeken welke mogelijkheden er voor dit systeem liggen en welke voordelen het invoeren van 3-D beeldvorming kan hebben. Daarom wil ik u vragen om deel te nemen aan deze enquête.

De enquête bestaat uit 3 onderdelen:

- 1) Huidige beeldvormende technieken en beperkingen
- 2) Het gebruik van automatische 3D-weergave beeldvorming
- 3) Het effect van het gebruik van automatische 3D-weergave beeldvorming en het effect hiervan op de uitkomst van verschillende operaties

Het invullen van de enquête zal ongeveer 5 tot 10 minuten duren. Indien u geen ervaring heeft met 3D-beeldvorming vraag ik u onderstaand filmpje te bekijken (1 minuut). Op deze wijze kunt u een idee krijgen over het systeem en de mogelijkheden.

[URL youtube: <https://www.youtube.com/watch?v=RulkoN-JPjw>]

Mocht u interesse hebben in de uitkomsten van ons onderzoek dan kunt u dit angeven en zal ik u het eindrapport te zijner tijd toesturen. Voor vragen kunt u altijd mailen naar m.analbers@mst.nl.

De enquête begint op de volgende pagina. Alvast hartelijk dank voor uw hulp!

3D-Beeldvorming bij cardio-thoracale ingrepen

Basisvragen

1. Wat is uw naam?

2. Wat is uw beroep?

- Cardioloog
- Thoraxchirurg
- Radioloog
- Overige (geef nadere toelichting)

3. Hoeveel ervaring heeft u met 3D-beeldvorming vanuit CT of MRI beelden?

- Geen ervaring (nog nooit gebruikt)
- Weinig ervaring (enkele malen gebruikt)
- Redelijke ervaring (regelmatig gebruik)
- Veel ervaring (bijna dagelijks gebruik)

3D-Beeldvorming bij cardio-thoracale ingrepen

Deel 1: Huidige beeldvorming technieken:

4. Welke beeldvorming technieken worden er gebruikt bij de diagnosestelling/planning van operaties?

meerdere antwoorden zijn mogelijk.

	CABG	PVI	AVR	MVR	TAVI
CT	<input type="checkbox"/>				
MRI	<input type="checkbox"/>				
TTE	<input type="checkbox"/>				
TEE	<input type="checkbox"/>				
CAG	<input type="checkbox"/>				

Overige (geef toelichting indien nodig)

5. Waarin liggen beperkingen van de verschillende typen beeldvorming?

Meerdere antwoorden zijn mogelijk

	Interpretatie van beelden	Sensitiviteit	Specificiteit	Veiligheid/comfort van de patiënt	Inzetbaarheid
CT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MRI	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TTE	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Interpretatie van beelden	Sensitiviteit	Specificiteit	Veiligheid/comfort van de patiënt	Inzetbaarheid
TEE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CAG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overige (Geef toelichting indien nodig)	<input type="text"/>				

6. Wat is de invloed van de beperkingen van de beeldvorming technieken:

In het diagnostische proces?

Bij het pre-operatief plannen van operaties?

Tijdens het uitvoeren van de operatie?

Bij het postoperatief proces?

3D-Beeldvorming bij cardio-thoracale ingrepen

Deel 2: Het gebruik van automatische 3D-beeldvorming systemen

7. Waar in het proces kan automatische 3D-beeldvorming toegevoegde waarde hebben?

Meerdere antwoorden zijn mogelijk

- In het diagnostische proces
- Bij het pre-operatief plannen en voorbereiden van operaties
- Bij het uitvoeren van de operatie
- In het postoperatief proces
- Overige (geef nadere toelichting)

8. Bij welke operatiertypen zal automatische 3D-beeldvorming het meest effectief zijn?

Antwoorden kunnen worden gesleept met de muis of een getal kan toegekend worden. Het type bovenaan (nummer 1) is het meest effectief, het type onderaan (nummer 4) is het minst effectief.

CABG

PVI

AVR

MVR

9. Bij welke operatie-aanpak zal automatische 3D-beeldvorming toegevoegde waarde hebben?

Antwoorden kunnen worden gesleept met de muis of een getal kan toegekend worden. Het type bovenaan (nummer 1) heeft de meest toegevoegde waarde, het type onderaan (nummer 7) heeft de minst toegevoegde waarde.

Bij open hart operatie met hart-long machine

Bij open hart operatie zonder hart-long machine

Bij min. Invasieve operatie met hart-long machine

Bij min. invasieve operatie zonder hart-long mach.

Bij transfemorale operatie

Bij transapicale operatie

Bij transaortale operatie

3D-Beeldvorming bij cardio-thoracale ingrepen

Deel 3: Het effect van automatische 3D-beeldvorming

10. Wat zal het effect van het gebruik van automatische 3D-beelden zijn op de volgende uitkomsten?

	Veel meer/langer 1:	2:	Geen effect 3:	4:	Veel minder/korter 5:
Mortaliteit tijdens ziekenhuisopname	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beroerte	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Acuut nierfalen na operatie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Infectie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Operatietijd	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intensive Care ligdagen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Verpleegafdeling ligdagen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lengte hartteambesprekingen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heropname <1 jaar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Her-operatie <1 jaar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bloedverlies tijdens operatie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Juiste keuze operatietype (1: slechtere keuzes / 5: betere keuzes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Juiste keuze operatie aanpak (1: slechtere keuzes / 5: betere keuzes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Juiste keuze grootte klepimplantaat (1: slechtere keuzes / 5: betere keuzes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Appendix II*Results survey*Question 1:**Wat is uw naam?**

Answered: 7

Skipped: 4

Question 2:**Wat is uw beroep?**

Answered: 11

Skipped: 0

Antwoordkeuzen	Reacties	
Cardioloog	36,36%	4
Thoraxchirurg	45,45%	5
Radioloog	18,18%	2
Overige (geef nadere toelichting)	0,00%	0
totaal	100%	11

Question 3:**Hoeveel ervaring heeft u met 3D-beeldvorming vanuit CT of MRI beelden?**

Answered: 11

Skipped: 0

Antwoordkeuzen	Reacties	
Geen ervaring (nog nooit gebruikt)	9,09%	1
Weinig ervaring (enkele malen gebruikt)	27,27%	3
Redelijke ervaring (regelmatig gebruik)	36,36%	4
Veel ervaring (bijna dagelijks gebruik)	27,27%	3
totaal	100%	11

Question 4:**Welke beeldvorming technieken worden er gebruikt bij de diagnosestelling/planning van operaties? Meerdere antwoorden zijn mogelijk.**

Answered: 10

Skipped: 1

	CABG	PVI	AVR	MVR	TAVI	Totaal resp.
CT	20%	80%	20%	0%	100%	10
MRI	50%	25%	50%	50%	0%	4
TTE	89%	44%	89%	100%	89%	9
TEE	22%	56%	44%	100%	67%	9
CAG	100%	44%	78%	78%	67%	9

Opmerkingen: "Ik doe niet alle vormen zelf; geen volledig inzicht.", "Indien noodzakelijk ook andere modaliteiten

Question 5:**Waarin liggen beperkingen van de verschillende typen beeldvorming? Meerdere antwoorden zijn mogelijk**

Answered: 10

Skipped: 1

	Interpretatie van beelden	Sensitiviteit	specificiteit	Veiligheid/comfort patient	Inzetbaarheid	Totaal resp.
CT	33%	33%	11%	44%	33%	9
MRI	50%	20%	20%	50%	70%	10
TTE	33%	83%	50%	0%	0%	6
TEE	14%	0%	0%	86%	14%	7
CAG	0%	0%	0%	100%	60%	5

Opmerkingen: "TTE, TEE en CAG behoren niet tot mijn vakgebied, dus ik kan daar geen uitspraken over doen.", "Mbt sensitiviteit en specificiteit hang inzet sterk af van ervaring. Voor meeste complexe pathologien zijn TTE soms al voldoende, bij minder ervaring of twijfel zal een TEE moeten gebeuren. Verder zijn verschillende modaliteiten complementair."

Question 6:

Wat is de invloed van de beperkingen van de beeldvorming technieken:

Answered: 10

Skipped: 1

In het diagnostisch proces? Reacties: 100%

- Echo beelden onvoldoende interpreteerbaar door beperkte acoustic window; meerdere onderzoeken nodig
- Kosten en discomfort vs. Opbrengst
- Shared decision nodig
- Wachttijd
- Wachttijd, onzekerheid interpretatie, niet iedereen kan alle vormen (MRI bij pacemaker, ct bij slechte NIFU etc)
- Bepert gebruik van de mogelijkheden
- Vaak de patient (nierfunctie, claustrofobie, lengte onderzoek)
- Vetraging voor CT/MRI
- Ontbreken van de juiste diagnose/gegevens
- De inzetbaarheid: voor functioneel analyse is TTE, TEE en MRI het beste. Ook hartcatherisatie kan hemodynamische data meten. CT weer goed in anatomie, ook bij (klep) endocarditis, terwijl CT kleppen in overige gevallen vrijwel onbeoordeelbaar laat.

In het pre-operatief plannen van operaties? Reacties: 80%

- Soms lastig precies de aard van de ingreep te plannen (geldt mn voor MV chirurgie)
- Idem
- Weet niet
- Wachttijd
- Idem
- Resolutie CT onvoldoende voor AVP
- Tijdsplanning
- TTE en TTEE hebben beperkt field of view. Dus voor preoperatieve doeleinden is CT vaak obligaat. De functionele gegevens en indicatie worden gegeven door CAG, TTE en TEE, evt. MRI

Tijdens het uitvoeren van de operatie? Reacties: 90%

- Idem als preop proces
- Aleen TEE bruikbaar
- Weet niet
- Geen
- Idem
- Beperking van beelschermen, interactief te bedienen
- 3D beeld (TEE) van matige kwaliteit (resolutie)
- Hogere kans op complicaties/aanpassen operatie
- Daar is vooralsnog enkel routinematiq TTE en TEE vorhanden. En op cathkamer of hybride OK CAG

Bij het postoperatief proces? Reacties: 90%

- Idem als preop proces, maar in mindere mate als beeldvorming goed is/was
- Op Ic alleen TTE en TEE bruikbaar, anders transport patient
- Weet niet
- Geen
- Idem
- Patient
- Geen

- -
- Alle technieken zijn inzetbaar, terwijl direct postoperatief echocardiografie wordt gebruikt.

Question 7:

Waar in het proces kan automatische 3D-beeldvorming toegevoegde waarde hebben? Meerder antwoorden zijn mogelijk

Answered: 9

Skipped: 2

Antwoordkeuzen	Reacties	
In het diagnostisch proces	89%	8
Bij het pre-operatief plannen en voorbereiden van operaties	78%	7
Bij het uitvoeren van de operatie	67%	6
In het postoperatief proces	22%	2
Overige (geef nadere toelichting)	22%	2
totaal	100%	11

Opmerkingen: "In het diagnostisch traject m.i. beperkt.", "3D-imaging heeft vooral nut in het diagnostisch proces bij het fine-tunen van de diagnose om te bepalen welke behandeling optimaal is. Tijdens het uitvoeren is het van nut bij plaatsing van devices. Postoperatief veel minder, maar zou bv een residuele lekkage exact kunnen worden gelokaliseerd voor nieuwe behandelopties."

Question 8:

Bij welke operatietypen zal automatische 3D-beeldvorming het meest effectief zijn?

Answered: 9

Skipped: 2

	1	2	3	4	totaal	Score
CABG	14%	0%	14%	71%	7	1,57
PVI	50%	38%	13%	0%	8	3,38
AVR	13%	38%	50%	0%	8	2,63
MVR	17%	17%	33%	33%	6	2,17

Question 9:

Bij welke operatie-aanpak zal automatische 3D-beeldvorming toegevoegde waarde hebben?

Answered: 8

Skipped: 3

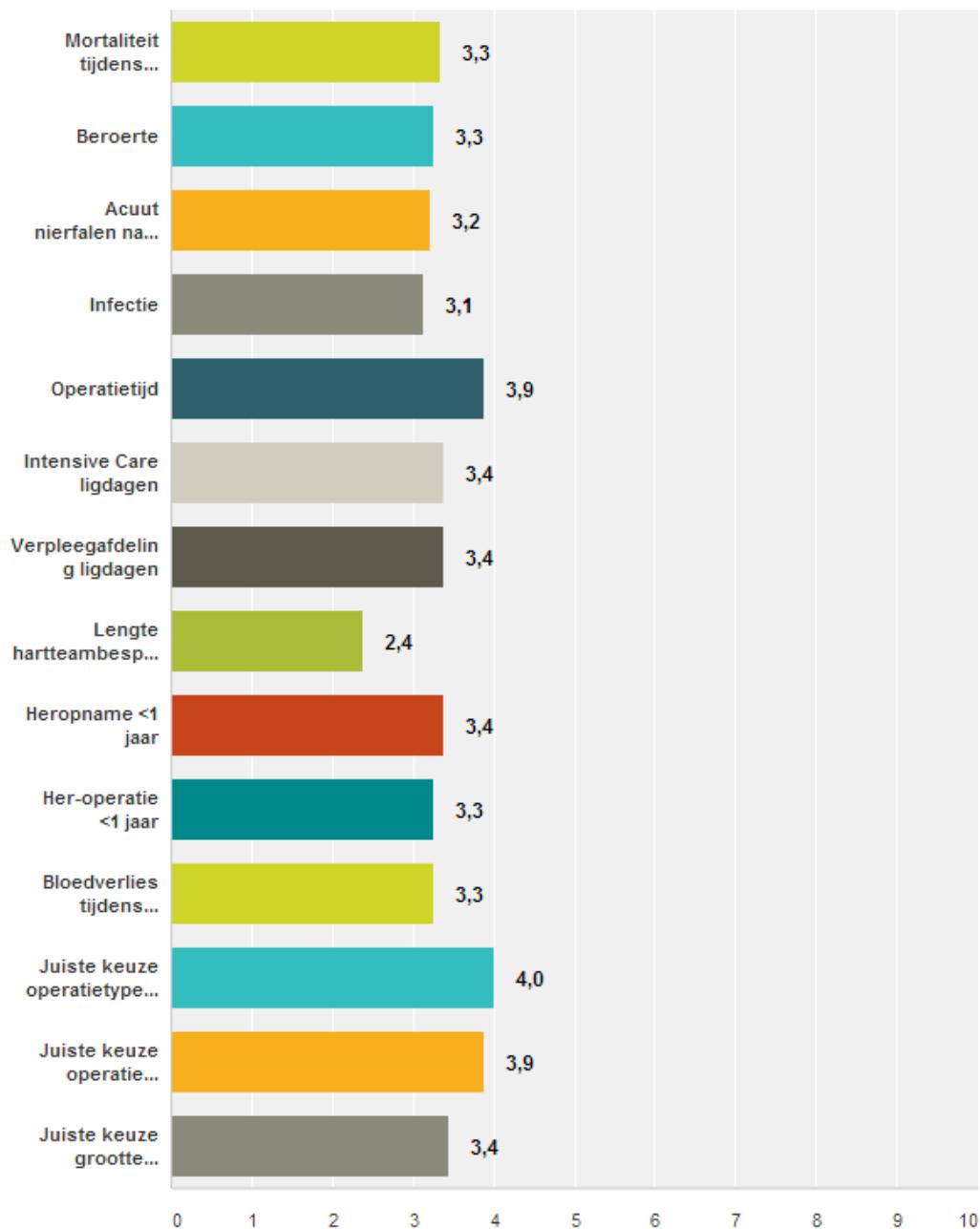
	1	2	3	4	5	6	7	totaal	score
OHO met CPB	0%	0%	0%	0%	0%	67%	33%	6	1,67
OHO zonder CPB	0%	0%	0%	0%	0%	33%	67%	6	1,33
Min. invasief met CPB	14%	0%	29%	14%	43%	0%	0%	7	4,29
Min. invasief zonder CPB	0%	29%	0%	43%	14%	0%		7	4,00
Transfemoraal	43%	14%	42%	0%	0%	0%	0%	7	6,00
Transapicaal	17%	33%	27%	33%	0%	0%	0%	6	5,33
Transaortaal	29%	14%	14%	0%	29%	0%	14%	7	4,57

Question 10:

Wat zal het effect van het gebruik van automatische 3D-beelden zijn op de volgende uitkomsten?

Answered: 9

Skipped: 2



Appendix III

Making the DES model

The framework for the DES model in this study is based on a report from the ISPOR-SMDM Modeling Good Research Practices Task Force-41). The model itself will be made in R (R version 3.2.3 (2015-12-10)) with the use of R-Studio. Data about how such a model can be made in R-Studio is obtained from a support document from NICE: Cost-Effectiveness Modelling Using Patient-Level Simulation²⁾.

The making of the model exists of different stages in the modeling process: (1) the structural development of the model, (2) the parameter estimation, (3) the model implementation, (4) the model analysis and lastly, (5) representation and reporting.

Introduction

Discrete Event Simulation can be used to simulate an environment or a system, like a hospital environment or a particular disease in a defined population. All DES have six different ‘core concepts’, which are entities, attributes, events, resources, queues, and time.

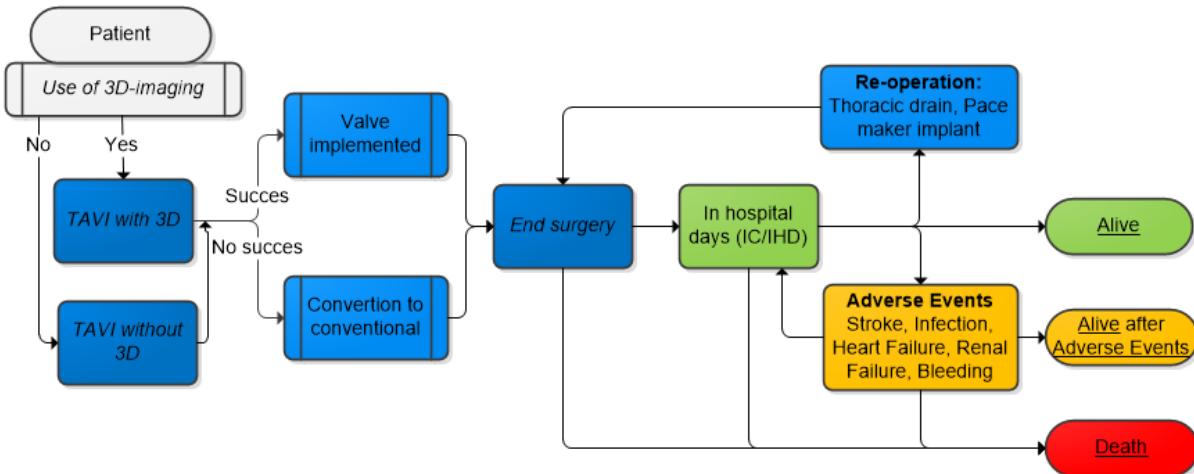
Entities are objects that run through the model. In patient-level simulation, this will most likely be the patient. The patient can experience events, use resources and enter queues, all over time. Attributes, like gender or age, are given to each entity. These attributes can be used to assess how an entity reacts to certain events. If, for instance, a patient is female, it could have a higher risk of mortality after surgery. Events are, very broadly, things that can happen to the entity. It could be the occurrence of adverse events after surgery, or something simple like having an appointment with a specialist. When events occur, resources can be assigned to certain events. A resource is an object that provides a service to an entity (a specialist or an operation room). This may require time, and when a resource is not available, a queue is formed. Time itself is an important component of DES. Since DES is not time-based, but event-based, the model itself keeps track of when certain events happen and how long these events take. By using the time, it is possible to keep track of time periods like operation time, length of stay or survival.

1. The structural development of the model

The first step in making the model is converting the clinical pathway into a series of sequential events. Not all events in this pathway must change the health status of a patient, they can also change the probability of occurrence from other outcomes. The model should identify where decisions are made (i.e.: where is the decision made which surgical approach is most fitting), and consider whether alternative decisions should be represented. The flowchart below shows the events. At first, the patient and their attributes are created. After that, the first step of the patient in the model is the operation. The operation exists of two parts: the part where they access the heart and the part where they implant the inflatable heart valve. After the operation, the patient will recover in the IC and the nursery ward. From there, the patient can either stay alive, get re-operated or develop adverse events (in which they can either stay alive, die or get re-admitted). After running the model, the patient can either be ‘alive’, ‘alive after adverse events’ or ‘death’.

¹⁾: Karon J, Stahl J, Brennan A, Caro JJ, Mar J, Müller J. Modeling using discrete event simulation: A report of the ISPOR-SMDM modeling good research practices task force-4. Value Heal. 2012;15(6):821–7.

²⁾: Davis S, Stevenson M, Tappenden P, Wailoo AJ. Technical Support Document 15: Cost-Effectiveness modelling using patient-level simulation. NICE DSU. 2014.



Attributes are patient specific variables, like their state or history. Global variables are not specific for patients, but remain the same for all entities (like the costs of a TAVI-procedure). Events are used to update both patient attributes and global variables.

Patients attributes are:

- Right choice of surgical approach
- Right implementation of valve
- Surgery time
- In hospital days
- State

Global variables are:

- Valve costs
- Surgical costs
- In-hospital costs
 - Costs per Intensive Care day
 - Cost per nursery ward day
- Re-operation costs
- Re-admittance costs
- Total costs

The events in the model are all set before the model will be run. When the simulation starts, patients attributes are set for that patient. The patient will go through the model and at each event that the patient experiences, the different costs will be updated. This will continue until no more new events happen. In the next patient, patient attributes will be chosen again and the patient will experience events. When all patients are run through the model, the average costs can be calculated.

2. Parameter Estimation

The parameters that will be included in the model must be estimated. A trade-off between structure and parameter estimation must be made. When data from different parameters is not available, a choice must be made: the model can be adjusted and parameters with lacking data can be removed, or the data gap will be filled with the use of expert elicitation/calibration to find missing parameters. With regards to this study, no representative data for 3D-imaging in TAVI-procedures exists. Data

about the conventional imaging techniques will be found from MST patient data, and expert elicitation will be used to fill in the data gaps for the 3D-imaging pathway of the model.

Current input can be found in the table shown below:

General variables

Patients attributes:

- Approach *Surgery type, time and IHD will be based on the approach*
- Use of 3D-imaging (Y/N) *Corresponding variables will be loaded when 3D is used*

Post-operative, short-term:

Patient attributes

Op_approach: probability transfemoral, transapical and transaortal approach is chosen

operation access

op_succes: probability successful approach is chosen, operation access time for each surgical approach.

operation implant

implant_succes: probability successful/unsuccessful/death (with and without 3D), operation implant time.

In hospital days

IC_ihd_random: amount of IC days

vpk_ihd_random: amount of days in the nursing ward

Post-operative, outcome:

Hospital survival: Probability of 30 day outcome: can either be alive, re-operation, adverse events or death.

- Re_operation: probability of being operated again within 30 days
- Adverse_events: probability of getting adverse events within 30 days
- IHD_after_AE: probability of being re-admitted after getting adverse events

3. The model implementation

In the model implementation, the defined structure needs to be transferred into a computer program. The computer program used is R. The flowchart above will be converted into a series of assignments which the program will execute.

The implementation usually exists of Read data, Create Entities, Main Section, Remove entities, and Present Results. To simplify the modelling, multiple submodels where created. The multiple submodels are shown in the figure below. At first, an empty data frame is created for every simulated patient. In the following steps, the data frame will be updated according to the different events the patients goes through.

```

1 #creeer parameters
2 d<-data.frame(id=1:10000,approach=0,drie_d=0,state=0,valve_cost=0,operation_cost=0,ihd_cost=0,re_operation_cost=0,re
3
4 source(file = "parameters_model.R")
5 d<-data.frame(id=1:10000,approach=0,drie_d=0,state=0,valve_cost=0,operation_cost=0,ihd_cost=0,re_operation_cost=0,re
6
7 #creeer patient attributen
8 source(file = "create_patient_attributes.R")
9
10 #operation acces (Y: continue, N: second operation)
11 source(file = "operation_access_approachbased.R")
12
13 #implementation of inflatable valve (Operation time + costs)
14 source(file = "operation_implant.R")
15
16 #In hospital days (poisson verdeling: based on avarage ICD/IHD)
17 source(file = "in_hospital_days.R")
18
19 #Hospital outcome
20 source(file = "Hospital outcome.R")
21
22 #re-operations, Adverse events
23 source(file = "re_operations.R")
24 source(file = "adverse_events.R")
25

```

Figuur 1

Eventually, the data frame will be updated in every event. The main section exists of the multiple submodels, which are shown in the figure above. All different steps of the model are shown: first, the empty data frame is made, after which the patient attributes are loaded in. The patient will experience the different events, and in the end the data frame shows the cost of that patient, with or without 3D-imaging.

The most important outcome for every patient is the amount of QALYs and the costs. After the model is run, R gives back an updated data frame in which the data for all individual patient is shown (see the figure below).

	Filter									
	id	approach	drie_d	state	valve_cost	operation_cost	ihd_cost	re_operation_cost	readmittance_cost	imaging_cost
1	1	2	0	9	21962	8711	8436	0	0	0
2	2	2	0	9	21962	8711	6972	0	0	0
3	3	1	0	100	21962	8711	6375	0	0	0
4	4	1	1	9	21962	8711	5643	0	0	120
5	5	2	0	9	21962	8711	4314	1584	0	0
6	6	1	1	9	21962	8711	6510	0	0	120
7	7	2	0	9	21962	8711	5778	0	0	0
8	8	2	1	9	21962	8711	5778	0	0	120
9	9	2	0	9	21962	8711	6375	0	0	0
10	10	2	0	21	21962	8711	3852	0	1000	0
11	11	1	1	9	21962	8711	1926	0	0	120

The whole data frame is split into two smaller frames, based on whether or not 3D imaging was used for the patient or not. In the data frame, a “0” means that conventional imaging was used, and a “1” means that 3D-imaging was used next to the conventional imaging techniques. From those 2 smaller data frames, the mean of the different costs are calculated. See the figure on the right.

```

Console C:/Users/max/Dropbox/Thesis/RStudio/
> print(uitkomst_geen_dried)
  valve_cost  operation_cost      ihd_cost
  22846.2181     8839.4859    5984.2980
re_operation_cost readmittance_cost      imaging_cost
   140.0656      373.9286          0.0000
> print(uitkomst_dried)
  valve_cost  operation_cost      ihd_cost
  22336.61068    8794.91090   4435.15412
re_operation_cost readmittance_cost      imaging_cost
   95.88682     140.77865    120.00000
> totale_kosten_geen_dried<-sum(uitkomst_geen_dried)
> totale_kosten_dried<-sum(uitkomst_dried)
> print(totale_kosten_geen_dried)
[1] 38184
> print(totale_kosten_dried)
[1] 35923.34
>

```

Appendix IV

Expert Elicitation

Introduction

Three-Dimensional imaging could be beneficial to the outcome of TAVI procedures. However, no data exists about TAVI procedures in combination with 3D-imaging techniques. The main objective of this study is to determine the cost-effectiveness of using 3D-imaging prior to TAVI procedures. Determining the clinical performance of the 3D-imaging techniques is difficult. Specificity, sensitivity and usability are one of the many features of the system that influence the impact of the system on the outcome of TAVI surgery.

To establish the clinical performance, a ‘belief-elicitation method’ can be used to determine the priors. Using expert elicitation to fill in the data gaps must be done correctly, in order to have as little bias as possible. The framework from Haakma et. al. (2014) will be used in order to minimize bias.

Method

Selected Experts

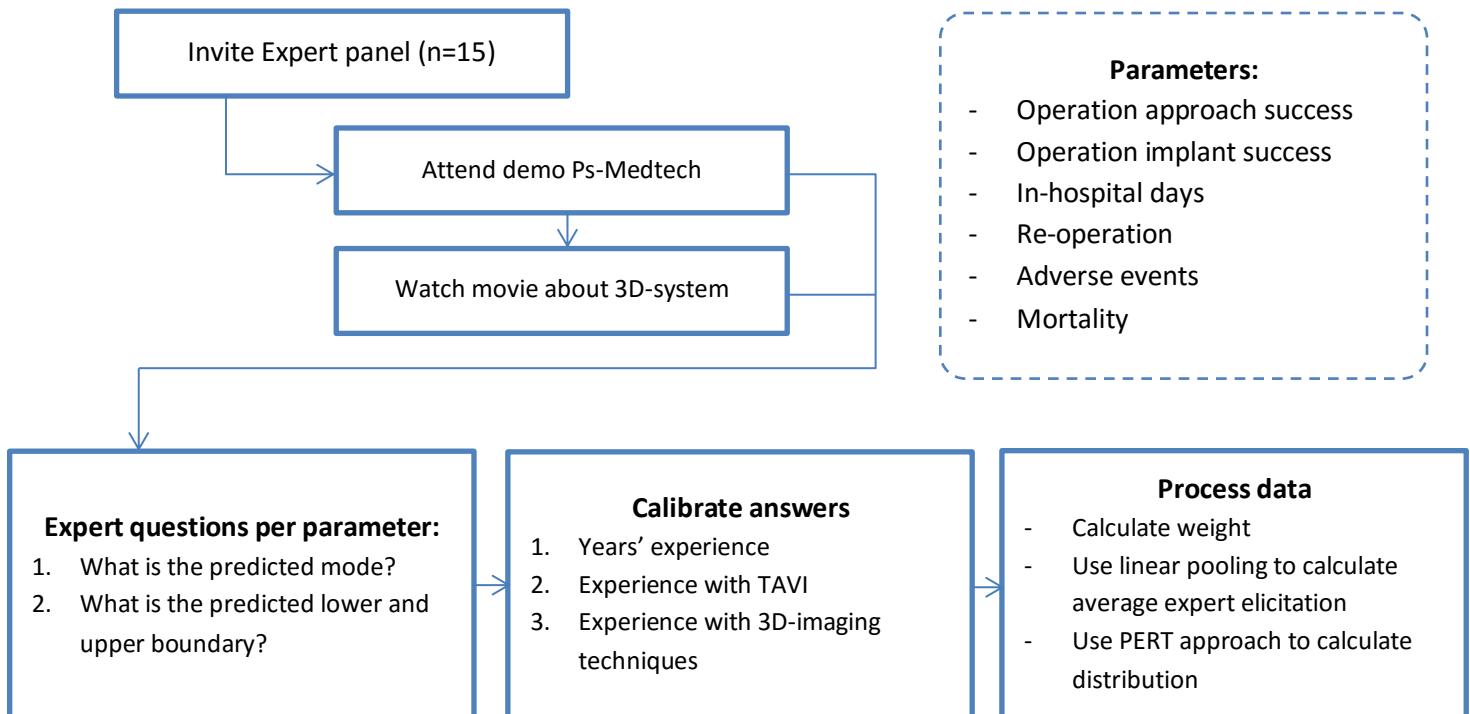
In this study, experts included are interventional cardiologist and thoracic surgeons from the Netherlands, preferably with experiences in TAVI procedures. The aim is to include 15 experts in this study, since it has been argued that after 12 experts, the benefit of adding more experts starts to decrease (Haakma et. al., 2014). All 15 experts will receive an invitation to attend a demonstration of a 3D-imaging system from Ps-Medtech (Amsterdam, the Netherlands), to make sure every expert understands the system and all have equal information.

Elicitation procedure overview

The experts included in this study will be asked to estimate the procedural differences and the changes in outcome when using 3D-imaging prior to TAVI procedures. Experts will be asked about ‘operation approach success’, ‘operation implant success’, ‘in-hospital days’, ‘re-operation’, ‘adverse events’ and ‘mortality’. In multiple questions, an elicitation of the probability for the different parameters will be derived from the experts. Experts will be asked to give the most likely value for a parameter (the mode), followed by the lowest and highest likely value. These distributions will be plotted as a Probability Density Function (PDF). All estimations derived will then be compared to the conventional imaging data. When all data is collected, a calibration procedure is applied in order to account for heterogeneity between experts.

After the calibration questions are answered, data can be processed. The weight of each expert will be calculated, and by using the linear pooling function the average probability distribution is calculated. To graphically display the data, the PERT approach is used.

A schematic overview of the procedure can be found in the figure below.



The Expert Elicitation procedure

Direct elicitation

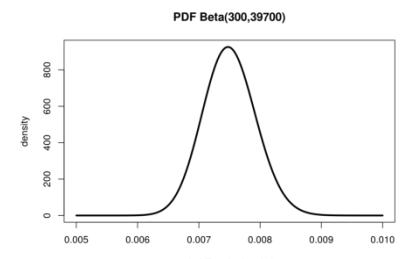
At first, the panel will be invited to attend a demonstration. Ps-Medtech will give a demo in which they show their product and where experts are invited to use the product in practical cases that they have experienced. If experts are not able to attend the demo, a movie will be shown in which the product is explained to provide insight in the product. Whether an expert has seen de movie or attended the demo will influence the weight of the answer.

When the expert is familiar with the system, a questionnaire will be provided. For each parameter, the expert is asked to give a prediction about what they think the outcome will be. This is, of course, not simple. Based on previous studies, the mode (most likely value) is expected to be the most intuitive parameter to estimate for experts¹⁾.

The value is not directly asked, but starts with a broad question en will be more specified until a value (the mode) and lower/upper boundaries can be given to ensure that the answer of the expert will be correspondent to what they actually think.

For every parameter, the expert is first asked whether using 3D-imaging influences the parameter negatively, positively or not at all. After that, an estimation of the impact is made by assessing how big the effect would be (for example: in the death <30 days parameter, would the amount of casualties within 30 days change with: 0-10%, 10-20% etc.). In the last question, the predicted value and the lower and upper 95% confidence interval must be given.

When the expert gives the mode and the lower/upper boundaries, their answer will be graphically represented in a Probability Density Function (PDF) (figure ADF). Answers can be adjusted after seeing the PDF and disagreeing.



¹⁾: Haakma W, Steuten LMG, Bojke L, IJzerman MJ. Belief elicitation to populate health economic models of medical diagnostic devices in development. Appl Health Econ Health Policy. 2014;12(3):327-34.

The PDF is calculated with the Project Evaluation and Review Technique²⁾.

With PERT, the mean (eq. 1), standard deviation (eq. 2), alpha (eq. 3) and beta (eq. 4) will be used to represent the PDF.

The following equations are used:

$$(1) \quad Mean = \frac{min + 4 * mode + max}{6}$$

$$(2) \quad Standard Deviation = \frac{max - min}{6}$$

$$(3) \quad Alpha (\alpha) = \left(\frac{mean - min}{max - min} \right) * \left(\frac{mean - min * (max - mean)}{standard deviation^2} \right)$$

$$(4) \quad Beta (\beta) = \left(\frac{max - mean}{mean - min} \right) * \alpha$$

The elicitation of the experts and their weights were combined using the linear pooling method³⁾. The weights are established and used to get an overall weighted distribution, as shown in equation 5.

Where $\rho(\theta)$ is the probability distribution and w_i is the weight of the expert.

$$(5) \quad \rho(\theta) = \sum_{i=1}^n w_i p_i(\theta)$$

Calibration procedure

Experts will be given weights to assess their expertise, in order to account for the heterogeneity of the results. More experienced experts will have greater influence than the experts with less experience. The calibration will be based on two aspects that is believed to influence the answers of the expert: the experience with TAVI procedures, and the experience with 3D-imaging techniques. See table XDFSAD below.

Experience with TAVI procedures	score	Experience with 3D-imaging techniques	score
No experience whatsoever	1	None	1
Involved in the planning of TAVIs	2	Attended the demo	2
Involved in the performance of TAVIs	3	Work with 3D-imaging technology	3

The score of the experts is used when calculating the pooled data. The minimal score is 2, and the maximum score is 6.

²⁾: van Dorp RJ, Kotz S. A novel extension of the triangular distribution and its parameter estimation. J R Stat Soc Ser d-Sta. 2002;51(1):62-79.

³⁾: Bojke L, Claxton K, Bravo-Vergel Y, et al. Eliciting distributions to populate decision analytic models. Val Health. 2010;13(5):557-64

Appendix V

Expert Elicitation questionnaire



Thorax Centrum Twente

Geachte,

Mijn naam is Max Analbers en onder begeleiding van dr. Grandjean doe ik onderzoek naar het potentiële effect van 3D-beeldvorming bij TAVI procedures.

Via het 'Vesalius 3D' systeem, in combinatie met het 'C-Station', heeft Ps-Medtech uit Amsterdam een product ontwikkeld welke CT-, MRI- en Echobeelden om kan vormen naar een 3D beeld. Dit beeld kan vervolgens intuïtief onderzocht worden om zo betere keuzes te maken voorafgaand aan operaties. U kunt hiervoor op youtube zoeken naar Ps-Medtech om in verschillende (korte) filmpjes te zien hoe dit werkt.

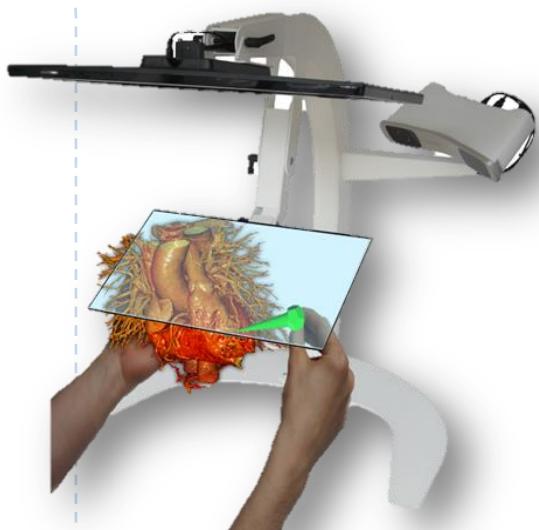
Het systeem van Ps-Medtech wordt momenteel al ingezet in meerdere ziekenhuizen in Nederland, bij onder andere cardio-thoracale en gynaecologische ingrepen.

Voor dit onderzoek wil ik u vragen om de volgende enquête in te vullen. Het is mogelijk dat u hiervoor ook al een mail heeft ontvangen.

Hou er bij het invullen rekening mee dat dit niet de werkelijkheid kan zijn! Het is een schatting, en probeer een zo goed mogelijke schatting te maken. Ook als u denkt dat u het niet weet wil ik u vragen toch een antwoord op te schrijven. Hiermee kan ook een verwachtingspatroon van het 3D-systeem opgesteld worden; een belangrijk deel van het onderzoek. Het invullen kost maximaal 5 minuten. Ook als u persoonlijk niet betrokken bent bij TAVI's hoop ik op uw medewerking.

Graag hoop ik deze enquête zsm op te kunnen halen bij uw bureau, of mag u hem afgeven aan dr. Grandjean.

Namens mijzelf en dr. Grandjean: Bedankt!



Effect van 3D-beeldvorming bij TAVI procedures

Dit gedeelte is opgesteld om te onderzoeken wat het nut is van 3D-beeldvorming binnen uw specialisme. U wordt gevraagd om uw mening omtrent de inzetbaarheid en potentiële effect van het gebruik van 3D-beeldvorming

Alvast bedankt voor uw deelname!

Naam:

Functie:

Waarvoor denkt u 3D-beeldvorming specifiek te gebruiken binnen uw specialisme?

.....
.....
.....
.....
.....

Hoe vaak denkt u 3D-beeldvorming te gebruiken en bij welke patiënten?

.....
.....
.....
.....
.....

Wat zijn de (eventuele) voordelen bij het gebruik van 3D-beeldvorming?

.....
.....
.....
.....
.....

Wat zijn de (eventuele) nadelen/tekortkomingen bij het gebruik van 3D-beeldvorming?

.....
.....
.....
.....
.....



Effect van 3D-beeldvorming bij TAVI procedures

Dit deel is opgesteld om te onderzoeken wat het potentiële effect is van 3D-beeldvorming bij TAVI procedures. U wordt gevraagd om bij verschillende onderwerpen in te schatten hoe 3D-beeldvorming de operatie uitkomst beïnvloedt. Niet alles is even goed in te schatten, maar probeer overal een antwoord te geven waarbij u denkt dat dit overeen zal komen met de werkelijkheid.
Alvast bedankt voor uw deelname!

Wat is uw ervaring met TAVI procedures?

- Geen ervaring
- Ik ben betrokken bij de planning en bespreking van TAVIs
- Ik ben betrokken bij de uitvoering van TAVIs

Wat is uw ervaring met 3D-beeldvorming?

- Geen ervaring
- Ik heb de demo bijgewoond en ben bekend met het systeem
- Ik werk met het 3D-beeldvorming systeem

De data die gebruikt wordt in de volgende situaties is gebaseerd op retrospectief verkregen patiëntendata omtrent TAVI procedures uitgevoerd in 2015 en 2016 binnen het MST (n=70).

Succesvolle aanpak van de operatie:

Op dit moment zijn er gemiddeld, per 1000 operaties, 15 waarbij niet de juiste operatie aanpak wordt gekozen. Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, hoe vaak zou de verkeerde operatieaanpak dan gekozen worden?

Geef hierbij de waarde wat u denkt, en de waarde in een 'best' en 'worst' case.

Met het gebruik van 3D-beeldvorming denk ik dat de verkeerde operatieaanpak gekozen wordt in van de 1000 operaties.

Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.

Succesvolle implantatie van de hartklep:

Op dit moment zijn er gemiddeld, per 1000 operaties, 45 waarbij de hartklep niet in één keer juist is geplaatst. Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, hoe vaak denkt u dat een klepimplantaat niet juist wordt geplaatst?

Geef hierbij de waarde wat u denkt, en de waarde in een 'best' en 'worst' case.

Met het gebruik van 3D-beeldvorming denk ik dat de hartklep niet juist geplaatst wordt in van de 1000 operaties.

Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.



Ligdagen in het ziekenhuis:

Op dit moment is de gemiddelde ligduur 5,5 dagen. Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, wat zou de ligduur van de TAVI worden?

Geef hierbij de waarde wat u denkt, en de waarde in een ‘best’ en ‘worst’ case.

Met het gebruik van 3D-beeldvorming denk ik dat de ligduur na een TAVI dagen zal worden. Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.

Heroperaties:

Op dit moment zijn er gemiddeld, per 1000 operaties, 117 waarbij een patiënt opnieuw geopereerd moet worden (pacemaker implantatie en thoraxdrain verwijdering). Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, hoe vaak denkt u dat heroperaties plaats zullen vinden?

Geef hierbij de waarde wat u denkt, en de waarde in een ‘best’ en ‘worst’ case.

Met het gebruik van 3D-beeldvorming denk ik dat heroperaties voorkomen in van de 1000 operaties.

Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.

Postoperatieve complicaties:

Op dit moment is de gemiddeld, per 1000 operaties, 308 waarbij postoperatieve complicaties optreden. Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, hoe vaak denkt u dat postoperatieve complicaties op zullen treden?

Geef hierbij de waarde wat u denkt, en de waarde in een ‘best’ en ‘worst’ case.

Met het gebruik van 3D-beeldvorming denk ik dat postoperatieve complicaties na een TAVI voor zal komen in van de 1000 operaties.

Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.

Risico op overlijden binnen 30 dagen:

Op dit moment zijn er gemiddeld, per 1000 operaties, 57 waarbij een patiënt binnen 30 dagen overlijdt. Met het gebruik van 3D-beeldvorming en op basis van uw vorige antwoorden, wat is de kans dat een patiënt overlijdt binnen 30 dagen na de TAVI procedure?

Geef hierbij de waarde wat u denkt, en de waarde in een ‘best’ en ‘worst’ case.

Met het gebruik van 3D-beeldvorming denk ik dat overlijden binnen 30 dagen voorkomt in van de 1000 operaties.

Waarbij verwacht wordt dat dit maximaal is en waarbij dit minimaal is.

Appendix VI

Results Expert Elicitation.

