Early economic evaluation of a hypothetical perfect test for predicting the effectiveness of implantable pacemaker-defibrillator devices (CRT-D) in patients with heart failure
Tomini, F.; Van Asselt, T.A.

Published in:
Value in Health

DOI:
10.1016/j.jval.2015.09.690

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2015

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

Copyright
Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment.

Take-down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.
PMID386
ECONOMIC EVALUATION OF SHORT-TERM VARIABILITY OF QT INTERVALS AS A POTENTIAL TEST FOR PREDICTING THE EFFECTIVENESS OF IMPLANTABLE defibrillator IN PATIENTS WITH HEART FAILURE
Tomini F1, Prinzen F2, van Asselt TA3
1Maastricht University Medical Center, Maastricht, The Netherlands, 2Maastricht University, Cardiovascular Research Institute Maastricht, Maastricht, The Netherlands, 3Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht University Medical Centre, Maastricht, The Netherlands

OBJECTIVES: Implantable cardioverter-defibrillators (ICD) improve survival in patients with New York Heart Association Functional Classification (NYHA) class III/IV symptoms and a left ventricular ejection fraction (LVEF) of ≤35%. Therefore, the current clinical guidelines recommend the implantation of the ICD in all the patients that fulfill the above conditions. However, as the costs of the ICD devices are relatively high, the prophylactic implantation of ICDs as per the guideline is not particularly cost-effective. A previous study demonstrated that short-term variability of QT (STVQT) may in fact reflect the increased susceptibility to SCD in patients with NYHA class III/IV since it increases with age. The variable associated with a reduced diagnosis threshold for STVQT. The objective of this study was to explore the cost-effectiveness of short-term variability of QT (STVQT) as a biomarker for implanting ICDs as secondary prevention. The cost-effectiveness analysis was performed using a hypothetical perfect STVQT biomarker for risk assessment and subsequent treatment decision in implanting ICDs. METHODS: The study uses a decision analytic model. RESULTS: We evaluated the cost-effectiveness of ICDs as secondary prevention of SCDs in heart failure patients is a cost-effective healthcare intervention. The headroom (societal willingness to pay multiplied by incremental quality-adjusted life years) available for the hypothetical perfect biomarker equals £3,836. CONCLUSIONS: The use of the QT (STVQT) as a biomarker for implanting ICDs is cost effective. Identification of patients with high-risk for SCD and implantation of ICDs only on those patients could potentially have substantial more economic value. However, further research on risk stratiﬁcation biomarker test accuracy is needed to support and strengthen the results of this modeling study.

PMID64
COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE REPLACEMENT: CURRENT DECISION-ANALYTIC MODELS AND FUTURE OPPORTUNITIES
Busca R1, Geisler BP2, Pietzsch JB2
1Medtronic International Trading Sàrl, Tolochenaz, Switzerland, 2Medtronic Ltd UK & Ireland, Watford, UK

OBJECTIVES: To identify and review the growing body of published cost-effectiveness analyses of TAVR, and to identify opportunities for future modeling and analyses in light of new evidence. METHODS: A systematic search in PubMed, Embase, Cochrane, HTA agency databases and a grey search were conducted for the period from 2005 to 2014 to identify studies examining the cost-effectiveness of aortic valve replacement using a transcatheater-based interventions. Studies, selection study, and data extraction were performed according to a predefined protocol. We only included studies on cost-effectiveness of TAVR compared with either medical management (MM) or surgery (SAVR). Appraised studies were analyzed using the CHEERS checklist. RESULTS: Our search yielded n=15 studies, comprising 13 distinct decision-analytic models set in six countries: Belgium, Brazil, Canada, Spain, United Kingdom, and U.S.A. Four of the models were developed by national HTA agencies or academic groups. In the other cases, HTA reports differed from the published results. Study quality per CHEERS criteria was poor to excellent. n=7 models compared TAVR to medical management, two to surgery, and n=5 evaluated the cost-effectiveness of TAVR compared to both n=13 studies showed efficacy gap from PARTNER A and B. Only one study used patient-level data in an “along-the-trial” design. ICR in studies comparing TAVR to MM ranged from €12,600 to US$15,600 per QALY’s. Compared with SAVR, ICR, estimates ranged from TAVR dominating to be dominated. CONCLUSIONS: Economic evaluations are lagging behind published clinical evidence. Future opportunities include economic evaluation of newer clinical trial data, long-term follow-up data from earlier studies, and more explicit evaluation of subgroups of patient cohorts. Overall model structure, quality and reporting of methods including data sources could be improved further.

PMID85
COST-UTILITY ANALYSIS OF SACRAL NERVE STIMULATION FOR THE TREATMENT OF FECAL INCONTINENCE: REFRACTORY TO CONSERVATIVE TREATMENT: FOR OPTIMAL TREATMENT PATHWAY
Pochon M1, Plisko R2, Drali R1, Bana M1, Sekewicz B1, Dudding T1, Knowles C1, Gral M1, Vally A1
1HTA Consulting, Krakow, Poland, 2University Hospital Southampton NHS Foundation Trust, Southampton, UK, 3Queen Mary University of London, London, UK, 4Medtronic International Trading Sàrl, Tolochenaz, Switzerland, 5Medtronic Ltd UK & Ireland, Watford, UK

OBJECTIVES: To evaluate the cost-utility of including sacral nerve stimulation (SNS) in different treatment pathways for refractory fecal incontinence (FI). METHODS: The treatment pathways were surgically repairable SNS, defecatory (SD) and without (WSD), were modeled through a patient-level simulation model. Three comparators to SNS were included: sphincter repair (SR), NASHA/Dx and percutaneous tibial nerve stimulation. The NASHA/Dx and percutaneous tibial nerve stimulation were modeled as last resort. Clinical data were based on a systematic literature review and expert opinion (EO). Resource use was based on EO, while cost data were based on hospital costs and national tariffs (GBP 2015-16). The UK NHS perspective (Threshold: 30,000 GBP/QALY) and a lifetime horizon were used. RESULTS: For SD patients, the most effective treatment pathway was SNS followed by SR, however it was not cost-effective vs SR followed by SNS (ICUR = 44,562 GBP/QALY). Adding SNS after or before SR was cost-effective vs SR only in cases of SNS used after SR the gain in QALY was equal to 0.48, with ICUR equal to 5,607 GBP/QALY. Adding SNS before SR corresponded to a QALY gain of 0.62, with ICUR at 5,957 GBP/QALY. The most cost-effective treatment pathway for WSD patients was NASHA/Dx followed by SNS, with a maximum ICUR of 5,928 GBP/QALY vs the other treatment pathways analysed. In comparison with treatment pathway excluding SNS, 0.55 QALY are gained. CONCLUSIONS: SNS is a relevant treatment option in patients with refractory FI when included SNS into the treatment pathway for refractory FI may provide value-for-money in the UK NHS perspective.

PMID86
EARLY ECONOMIC EVALUATION OF A HYPOTHETICAL PERFECT TEST FOR PREDICTING THE EFFECTIVENESS OF IMPLANTABLE FACEMASKER-DEFIBRILLATOR DEVICES (CRT-D) IN PATIENTS WITH HEART FAILURE
Tomini F1, van Asselt TA3
1Maastricht University Medical Center, Maastricht, The Netherlands, 2University of Groningen, Groningen, The Netherlands

OBJECTIVES: Cardiac resynchronization therapy (CRT) either via a pacing device (CRT-P) or an implantable defibrillator (CRT-D) are indicated in patients with heart failure for treatment of patients with congestive heart failure (CHF) and disturbances in heart rhythm (arrhythmias) having New York Heart Association (NYHA) class II, III and IV symptoms. However, due to the large numbers of patients, which do not get additional benefits from CRT-D, and also due to large costs of implementation and
follow-up this may not always be the most cost-effective alternative. In fact, economic analysis that includes the incremental cost-effectiveness ratio (ICER) of CRT-D may be substantially higher than for comparators. A recent study demonstrated that certain biomarkers may in fact reflect the increased susceptibility to SCD in patients with HF and this may further contribute to increase cost-effectiveness of the CRT-D. The study also highlighted the need for risk stratification of biomarkers to better identify patients with high-risk for SCD and for whom implantation of CRT-D reduces risks of death. However, further research of risk stratifying biomarkers test accuracy is needed to support and strengthen the results of this modeling study.

PMD89  
**LONG-TERM COST-EFFECTIVENESS OF TRANSMURAL IRRIGATION IN PATIENTS WITH NEUROGENIC BOWEL DYSFUNCTION WHO HAVE FAILED STANDARD BOWEL CARE**  
Emmanuel A1, Christensen P2, Kumar G3, Passananti V4, Mealing S5, Stooring ZM6, Anderson P7, Soo Hoo Y8, Kuan Lim S9

1University College London Hospital, London, UK, 2Aarhus University Hospital, Aarhus, Denmark, 3IClare Health Economics, Oxford, UK, 4IClare Health Economics and Epidemiology, Oxford, UK, 5Coloplast A/S, Humlebaek, Denmark, 6Rutgers New Jersey Medical School, Newark, NJ, USA

**OBJECTIVES:** To estimate the long-term cost-effectiveness of transmural irrigation (TI) as secondary-line management in patients with neurogenic bowel dysfunction (NBD) who have failed first-line standard bowel care (SBC). 

**METHODS:** A decision model was developed to project the long-term economic outcomes, including quality-adjusted life expectancy (QALE), episodes of faecal incontinence (FI), urinary tract infections (UTIs), and stoma surgery when using TI compared to continuing SBC. Patients could transition from TI to (a) another secondary-line (e.g., line in patients with surgically created anterior or colostomy surgery), (b) another TI, or (c) another stoma as the absorbing state. Transition probabilities and QALE estimates were based on real-world data collected from 3 UK clinics in 2007-2014, in NBD patients compared to surgical continence. Life-time cost-savings of €61,620 per patient was estimated for TI versus SBC in a SCI patient, primarily due to avoided hospitalisations and stoma surgeries. Incremental cost difference can vary due to altered life-expectancy (and age of diagnosis) in the patient. 

**RESULTS:** The model predicts that the model is more sensitive to variations in utilities on TI and SBC treatment. CONCLUSIONS: TI is a cost-saving treatment strategy reducing risk of stoma surgery and improving QALE for NBD patients who have failed SBC. 

PMD90  
**REDUCTION OF COMPLICATIONS AND ASSOCIATED COSTS FOR TYPE 2 DIABETIC PATIENTS USING CONTINUOUS SUBCUTANEOUS INSULIN INFUSION IN THE UK**  
Roze N1, Duteil E2, Hallas N3, de Portu S4

1IHEVA HEOR Sarl, Lyon, France, 2IHEVA HEOR, Lyon, France, 3Medtronic, Watford, UK, 4Medtronic International Sàrl, Tolochenaz, Switzerland

**OBJECTIVES:** To assess the reductions of complications and costs with continuous subcutaneous insulin infusion (CSII) versus multiple daily injections (MDI) in uncontrolled type 2 diabetic patients (T2D) in the UK. 

**RESULTS:** The incidence of diabetes-related complications was calculated based on the Core Diabets Model. The population characteristics, the reduction of HbA1c, and insulin dose were based on the OpTimise study (Reznik et al., Lancet 2014) (mean age 56 years (SD 9.6); mean diabetes duration 15 years (SD 0.75)). For a baseline HbA1c of 9.0%, the reduction in HbA1c was -1.1 % versus -0.4%, respectively, for CSII vs MDI. Costs were UK-specific and expressed in EUR in 2014. The diabetes-related complications were reduced with CSII. At 5 years, the incidence reduction in complications associated with eye diseases, renal diseases, ulcer/amebrosis and cardiovascular diseases were -24%, -26%, -19% and -10%, respectively, in favour of CSII. This equates to a cost reduction of 12% over 5 years per patient. 

**CONCLUSIONS:** The model is more sensitive to variations in utilities on TI and SBC treatment. CONCLUSIONS: TI is a cost-saving treatment strategy reducing risk of stoma surgery and improving QALE for NBD patients who have failed SBC. 

PMD91  
**COST-UTILITY ANALYSIS OF CONTINUOUS INFUSION PUMP WITH INTEGRATED MONITORING COMPARED WITH MULTIPLE DAILY INJECTION TREATMENT FOR PATIENTS 15 YEARS-OR OLDER WITH TYPE 1 DIABETES MELLITUS IN COLOMBIA**  
Quispe H1, Gamsz AM1, Garcia Peña AA2, Arciniegas J3, Iragorri N4, Mantilla B5, Gomez-Restrepo C6, Rosselli D7

1Pontificia Universidad Javeriana, Bogota, Colombia, 2Pontificia Universidad Javeriana, Bogota, Colombia

**OBJECTIVES:** To estimate the incremental cost-utility ratio (ICUR) for the use of a continuous infusion pump with integrated monitoring (SAP) compared with the application of multiple daily injections (MDI) in adult (>15-year-old) patients with type 1 diabetes mellitus (T1DM). The model assumed a life-time time horizon. The model compared DM1 with the clinical benefits of a modified life span cycle Markov model, with transition probabilities obtained from a systematic review of the literature. Outcomes included in the search were ketoadipocysis, severe hypoglycemia, hospitalization, treatment satisfaction and quality of life (expressed in quality-adjusted life years, QALYs, and obtained from Tufts database), as well as mortality. Other features of the model were: discount rate 3.5% for costs and QALYs, third party payer perspective (only direct medical costs), and a life expectancy in Colombia (mortality) of 71.9 years. The threshold used was the incurrence of one additional QALY gained. Sensitivity analysis shows that the only critical variable is the annual cost of continuous infusion pump treatment, which would have to be reduced by 40% to reach the cost-effectiveness threshold. 

**CONCLUSIONS:** Under the assumptions of the model, treatment with continuous insulin pumps would not be cost-effective for the average adult DM1 patient in Colombia. Further analysis would be required, addressed to certain selected subgroups of patients.