Medical Device/Diagnostics – Cost Studies

PMD10

IMPACT ANALYSES OF FRACTIONAL FLOW RESERVE-GUIDED PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH MULTIVESSEL DISEASE IN FRANCE AND BELGIUM

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OBJECTIVES: The FAME Study is an international multicenter randomized clinical trial (n=1,005), which proved a significant improvement in health outcomes for patients undergoing multivessel percutaneous coronary intervention (PCI) guided by fractional flow reserve (FFR) measurement compared to PCI guided by angiography alone (ANGIO). The objective of this study is to estimate the impact of FFR-guided PCI on public health and on healthcare budget in France and Belgium and to compare these results with those of other European countries. **METHODS:** We used original patient-level data of the FAME Study (Tonino et al., NEJM 2009) to estimate health effects for France and Belgium. Utilities were measured with EQ-5D using French (time trade-off based) and Belgian Torrance transformed (visual analogue scale based) weights. Costs were based on French and Belgian prices and DRG catalogues. The size of the population eligible for the intervention was taken from national PCI registries to calculate number of major adverse cardiac events (MACE) avoided, quality-adjusted life years (QALYs) gained, and cost savings during a 2-year budget period (2011-2012) from the payer's perspective. We estimated ranges based on best and worst case scenarios regarding benefits, costs and FFR uptake. **RESULTS:** For both countries, FFR led to more QALYs, less MACE and lower costs under different scenarios within 2-year time horizon. The public health impact of implementing FFR-guided PCI ranged from 6 to 44 QALYs gained in France and 12 to 234 in Belgium. MACEs avoided ranged from 284 to 2108 and from 23 to 467, respectively. Cost savings ranged from 4.8 to 28.9 and from 0.43 to 7.7 million EUR, respectively. **CONCLUSIONS:** Our impact study shows that FFR-guided PCI in patients with multivessel coronary disease is dominant and leads to considerably reduced numbers of MACE, more QALYs and substantial cost savings in the French and Belgian health care systems.

PMD11

TREATMENT OF OVERACTIVE BLADDER AND FECAL INCONTINENCE PATIENTS FROM THE CANARY ISLANDS WITH SACRAL NEUROMODULATION: IS IT WORTH TO HAVE REGIONAL CENTERS OF EXCELLENCE?

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OBJECTIVES: Sacral Neuromodulation (SNM) has proven to be an effective, safe and cost-effective therapy that should be available for refractory Overactive Bladder (OAB) and Fecal Incontinence (FI) patients. Canary Islands are divided into two provinces: Las Palmas and Santa Cruz de Tenerife. Refractory OAB and FI patients from Las Palmas are referred to other Spanish regions to receive SNM. This Budget Impact Analysis (BIA) approaches two possible referral programs from the perspective of Canary Islands Health Service (CHS): the treatment of these patients in Tenerife in a regional Center of Excellence or in Madrid as representative of the mainland. **METHODS:** A BIA was developed to analyze the different direct costs related to each of the options for a refractory population of 11 OAB and 4 FI patients during 1 year. The net economic impact caused by the treatment of patients from Las Palmas with SNM therapy was calculated based on two previous cost-effectiveness models and was assumed to be similar in both cases. Costs related to hospitalization, travelling, and living expenses for the patient and the caregiver were also considered, as these costs are reimbursed by the CHS to the patients and caregivers. **RESULTS:** The net economic impact for the CHS of treating 15 new patients from Las Palmas with SNM in Madrid would be €118,871 for the first year of the therapy, while treating these patients in Tenerife's Center of Excellence would be related to a net impact of €50,780. The savings provided by a referral program inside the Region would amount to €68,091; driven by differences in hospitalization, travelling and living expenses. **CONCLUSIONS:** In Canary Islands, the designation of Regional Centers of Excellence for specialized and effective treatments, such as SNM, would lead to important savings for the CHS, driven by differences in hospitalization, travelling and living expenses due to referral programs.

PMD12

ECONOMIC IMPACT ANALYSIS OF STERILIZATION OF RIGID ENDOSCOPES WITH STERRADTM VERSUS STEAM IN SPAIN

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OBJECTIVES: The increasing penetration of endoscopic techniques in surgical procedures has resulted in a more frequent use of rigid endoscopes (RE). Several studies have reported significant reductions in the number of damaged RE and repairs when reprocessed with Sterrad™ instead of Steam. The aim of this study was to analyze the economic consequences of RE sterilization with Sterrad™ versus Steam from a hospital perspective. **METHODS:** A dynamic excel-based decision-analytic model was developed. Published literature was used to estimate the two key variables (% of RE damage with Steam as well as with Sterrad™). A two-way sensitivity analysis was conducted (varying the two key variables up to ±25%, thus generating 121 different scenarios). Input data for the model collected as an average from four Spanish hospitals were: 1000 RE sterilization units (StU) annually, 2000€ cost for every RE repair and 0,56€ in consumables/StU with Steam. 11,99€ in consumables/StU with Sterrad™ was calculated based on list prices and an average of 2.5 RE per sterilization cycle. The analysis covered a one year time horizon and assumed 100% utilization for each sterilization technology. **RESULTS:** A 21% budget impact decrease was achieved with Sterrad™ versus Steam, leading to 11,870€ in annual savings. The more costly sterilization process (11,986€ versus 560€ per year) was clearly more than compensated by the reduction of 23,296€ in RE repair costs. The sensitivity analysis showed in 100% of the scenarios that Sterrad™ was cost-saving compared to Steam. **CONCLUSIONS:** This analysis adds a new component of support for the sterilization of rigid endoscopes with Sterrad™ by demonstrating that it is cost-saving compared to reprocessing with Steam. Despite the conservative approach of the model which may be in favour of Steam, use of Sterrad™ led to savings of 21% in the hospital budget.

PMD13

COST ANALYSIS OF VASCULAR CLOSURE DEVICES (VCD) IN THE UNITED STATES

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OBJECTIVES: Recent literature suggests complication rates associated with current VCDs are comparable or reduced when compared to manual compression (MC). However, well-documented differences exist among VCDs regarding the type and magnitude of complications. An indirect comparison was conducted to estimate the cost savings associated with use of novel VCD EXOSEAL™ vs. VCDs ANGIOSEAL™, MYNX™, PERCLOSE™ and STARCLOSE™ from the US hospital system perspective. **METHODS:** Crude VCD-specific complication rates were calculated for occlusion, access-site infection (ASI), femoral pseudoaneurysm (FAP), retroperitoneal hemorrhage (RPH), other access-site bleeds (OASB), and arteriovenous fistula (AVF) using prospective clinical studies identified in the most recent VCD instructions for use. A literature review (i.e., 2005 to current) was conducted to identify rates of complication consequences (i.e., amputation, vascular surgery, endovascular procedure, transfusion, ultrasound-guided intervention) and associated US costs were then applied to clinical consequence rates. The one-year budget impact was estimated assuming 100% use of EXOSEAL™ vs. current VCD market-share for percutaneous coronary intervention (PCI) procedures. Device costs were assumed identical. **RESULTS:** Complication rates for occlusion, ASI, RPH, FAP, OASB, and AVF were calculated for each VCD as follows: EXOSEAL™ [0.00%, 0.00%, 0.56%, 0.00%, 0.00%, 0.00%], ANGIOSEAL™ [0.33%, 0.00%, 0.33%, 0.00%, 0.00%, 0.33%], MYNX™ [0.00%, 0.00%, 0.00%, 0.53%, 0.53%, 0.00%], PERCLOSE™ [0.00%, 0.78%, 0.52%, 0.26%, 0.52%, 0.00%] and STARCLOSE™ [0.20%, 0.00%, 0.00%, 0.20%, 0.41%, 0.00%]. Results predicted that 100% use of EXOSEAL™ vs. combined use of VCDs could save approximately $70 USD per procedure and approximately $70,240 USD per 1,000 annual PCI procedures (i.e., typical hospital). Assuming 550,000 PCIs that use VCDs annually in the US, this translates to a predicted yearly cost-savings of $38,631,949 USD for the US hospital system. **CONCLUSIONS:** This analysis suggests use of EXOSEAL™ in patients undergoing PCI procedures may result in important cost-savings for US hospitals. Additional data will be required to confirm low complication rates with EXOSEAL™.

PMD14

BUDGET IMPACT ANALYSIS OF TWO DRUG-ELUTING STENTS FOR DIABETIC PATIENTS IN SPAIN

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OBJECTIVES: The presence of diabetes in patients needing percutaneous coronary intervention (PCI) is associated with increased risk of adverse outcomes, such as target lesion revascularization (TLR), and thus an additional cost burden. A recent indirect treatment comparison (ITC) showed that the drug-eluting stent (DES) CYPHER™ improved clinical outcomes vs other DES resulting in cost-savings in diabetic patients. Based on this ITC, the objective is to conduct an adaptation to Spain and compare CYPHER vs. XIENCE™ from a hospital perspective with global annual budget. **METHODS:** A global budget-impact model was adapted to Spain using a previously reported ITC of DES in diabetic patients. In brief, the ITC included pair-wise meta-analyses of randomized trials with a common comparator to obtain relative treatment effects for different DES and absolute TLR risk. These reported clinical estimates were added to the Spain model, along with reported use and reimbursement rates for diagnosis-related groups (DRGs) of index procedures and re-interventions in Spain. Budget-impact was estimated for 100 annual PCIs with DES for diabetic patients in a typical Spanish hospital, assuming 100% utilization for each stent and identical stent acquisition cost. Analyses were conducted using two methods for estimating TLR risk. **RESULTS:** Results predicted that CYPHER, if used instead of XIENCE, could save approximately 320€ to 407€ per diabetic patient annually depending on TLR risk estimation method. Assuming 100 annual PCIs in diabetic patients, this translates to cost-savings varying from 32,048€ to 40,710€. These savings are driven by reduction in secondary interventions achieved by choosing the DES with the best TLR outcomes. **CONCLUSIONS:** This analysis indicates that use of CYPHER versus XIENCE in diabetic patients undergoing PCI can produce important savings for hospitals. Further cost research and clinical expert validation are needed to confirm results of this local adaptation.