**Supplemental digital content**

**Table A. Additional clinical data and transition probabilities**

| Parameter | Value | Range | Distribution for PSA | Source |
| --- | --- | --- | --- | --- |
| Proportion of ischaemic stroke in males | 0.7 | N/A | N/A | Wolf, 1992 [1] |
| Proportion of haemorrhagic stroke in males | 0.1 | N/A | N/A |  |
| Proportion of transient ischaemic attack in males | 0.2 | N/A | N/A |  |
| Proportion of ischaemic stroke in females | 0.76 | N/A | N/A |  |
| Proportion of haemorrhagic stroke in females | 0.1 | N/A | N/A |  |
| Proportion of transient ischaemic attack in females | 0.134 | N/A | N/A |  |
| Proportion of non-fatal stroke in males | 0.87 | 0.73-0.96 | Beta (α=41; β=6) | Wolf, 1992 [1] |
| Proportion of non-fatal stroke in females | 0.82 | 0.67-0.95 | Beta (α=33; β=7) |  |

PSA, probabilistic sensitivity analysis; N/A, not available.

**Table B. Incidence of stroke**

| Parameter | Value | Range | Distribution for PSA | Source |
| --- | --- | --- | --- | --- |
| Annual incidence of stroke in males between 35-44 years | 0.00014 | 0.0000003-0.0003200 | Beta (α=0.63;β=8,867.01) | Kolominsky-Rabas, 1998 [2] |
| Annual incidence of stroke in males between 45-54 years**-64 years\*** | 0.00128 | 0.0005600-0.0015600 | Beta (α=15.11;β=15,126.95) |
| Annual incidence of stroke in males between 55-64 years | 0.00188 | 0.0010200-0.0024000 | Beta (α=21.44;β=13,066.54) |
| Annual incidence of stroke in males between 65-74 years | 0.0061 | 0.0040100-0.0069000 | Beta (α=52.38;β=9,720.92) |
| Annual incidence of stroke in males between 75-84 years | 0,01288 | 0.0073300-0.0137700 | Beta (α=38.74;β=3,721.53) |
| Annual incidence of stroke in males after 85 years | 0.02415 | 0.0121600-0.0292000 | Beta (α=20.12;β=996.61) |
| Annual incidence of stroke in females between 35-44 years | 0.00029 | 0.0000600-0.0005600 | Beta (α=3.54;β=14,404.55) |
| Annual incidence of stroke in females between 45-54 years**-64 years\*** | 0.00081 | 0.0001100-0.0007400 | Beta (α=4.70;β=13,237.02) |
| Annual incidence of stroke in females between 55-64 years | 0.00203 | 0.0008500-0.0020600 | Beta (α=20.07;β=14,419.29) |
| Annual incidence of stroke in females between 65-74 years | 0.00437 | 0.0026500-0.0046300 | Beta (α=49.66;β=13,852.45) |
| Annual incidence of stroke in females between 75-84 years | 0.01197 | 0.0076400-0.0118500 | Beta (α=79.48;β=8,171.86) |
| Annual incidence of stroke in females after 85 years | 0.02013 | 0.01196000-0.02084000 | Beta (α=49.52;β=3,025.93) |

PSA indicates probabilistic sensitivity analysis.

**Table C. Probability of stroke in patients with heart failure**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter | Value | Range | Distribution for PSA | Source |
| Probability of stroke during 1st year of HF | 0.0184 | 0.0169-0.0199 | Beta (α=565.39;β=30,211.98) | Witt, 2007 [3] |
| Probability of stroke during 2nd year of HF | 0.0145 | 0.0136-0.0154 | Beta (α=980.65;β=66,713.52) |
| Probability of stroke during 3rd year of HF | 0.0389 | 0.0373-0.0405 | Beta (α=2,180.43;β=53,894.09) |
| Probability of stroke during 4th year of HF | 0.0314 | 0.0308-0.0320 | Beta (α=10,188.60;β=314,317.23) |
| Probability of stroke during 5th year and onwards of HF | 0.0474 | 0.0456-0.0492 | Beta (α=2,535.68;β=50,977.80) |

HF, heart failure; PSA, probabilistic sensitivity analysis.

**Table D. Probability of end-stage renal disease**

| Parameter | Value | Range | Distribution for PSA | Source |
| --- | --- | --- | --- | --- |
| Baseline annual probability of ESRD | 0.000045 | 0.000002052-0.000005878 | Beta (α=68.04; β= 1467,755.89) | Hsu, 2005 [4] |
| Relative risk of ESRD with SBP 120-129 mmHg | 1.62 | 1.27-2.07 | Log-normal (SElog=0.12) |
| Relative risk of ESRD with SBP 130-139 mmHg | 1.98 | 1.55-2.52 | Log-normal (SElog=0.12) |
| Relative risk of ESRD with SBP 140-159 mmHg | 2.59 | 2.07-3.25 | Log-normal (SElog=0.12) |
| Relative risk of ESRD with SBP 160-179 mmHg | 3.86 | 3.00-4.96 | Log-normal (SElog=0.13) |
| Relative risk of ESRD with SBP 180-209 mmHg | 3.88 | 2.82-5.34 | Log-normal (SElog=0.16) |
| Relative risk of ESRD with SBP >210 mmHg | 4.25 | 2.63-6.86 | Log-normal (SElog=0.24) |

ESRD, end-stage renal disease; PSA, probabilistic sensitivity analysis; SBP, systolic blood pressure.

**Table E. Relative risk of death in end-stage renal disease**

| Parameter | Value | Range | Distribution for PSA | Source |
| --- | --- | --- | --- | --- |
| RR of death on RRT, 1st year, 18-44 years old | 26.7 | 15.52-45.93 | Log-normal (SElog=0.28) | Villar, 2007 [5] |
| RR of death on RRT, 1st year, 45-64 years old | 12.8 | 10.25-15.98 | Log-normal (SElog=0.11) |
| RR of death on RRT, 1st year, 65-74 years old | 8.6 | 7.31-10.12 | Log-normal (SElog=0.08) |
| RR of death on RRT, 1st year, 75-84 years old | 7.1 | 6.21-8.12 | Log-normal (SElog=0.07) |
| RR of death on RRT, 1st year, >85 years old | 3.5 | 2.68-4.57 | Log-normal (SElog=0.14) |
| RR of death on RRT, 2nd year, 18-44 years old | 17 | 8.31-34.76 | Log-normal (SElog=0.36) |
| RR of death on RRT, 2nd year, 45-64 years old | 9.2 | 6.93-12.22 | Log-normal (SElog=0.14) |
| RR of death on RRT, 2nd year, 65-74 years old | 7.2 | 6.00-8.64 | Log-normal (SElog=0.09) |
| RR of death on RRT, 2nd year, 75-84 years old | 5.7 | 4.77-6.81 | Log-normal (SElog=0.09) |
| RR of death on RRT, 2nd year, >85 years old | 2.8 | 1.93-4.06 | Log-normal (SElog=0.19) |
| RR of death on RRT, 3rd year, 18-44 years old | 14.3 | 5.84-35.03 | Log-normal (SElog=0.46) |
| RR of death on RRT, 3rd year, 45-64 years old | 9.3 | 6.78-12.75 | Log-normal (SElog=0.16) |
| RR of death on RRT, 3rd year, 65-74 years old | 6.7 | 5.24-8.57 | Log-normal (SElog=0.13) |
| RR of death on RRT, 3rd year, 75-84 years old | 5.4 | 4.29-6.79 | Log-normal (SElog=0.12) |
| RR of death on RRT, 3rd year, >85 years old | 2.8 | 1.65-4.75 | Log-normal (SElog=0.27) |
| RR of death on RRT, 4th year, 18-44 years old | 9.9 | 2.60-37.63 | Log-normal (SElog=0.68) |
| RR of death on RRT, 4th year, 45-64 years old | 8.3 | 5.52-12.48 | Log-normal (SElog=0.21) |
| RR of death on RRT, 4th year, 65-74 years old | 8.2 | 6.29-10.69 | Log-normal (SElog=0.14) |
| RR of death on RRT, 4th year, 75-84 years old | 5.2 | 3.83-7.06 | Log-normal (SElog=0.16) |
| RR of death on RRT, 4th year, >85 years old | 3.2 | 1.57-6.51 | Log-normal (SElog=0.36) |
| RR of death on RRT, 5th year/onwards, 18-44 years old | 6.2 | 1.10-35.07 | Log-normal (SElog=0.88) |
| RR of death on RRT, 5th year/onwards, 45-64 years old | 8.1 | 5.38-12.19 | Log-normal (SElog=0.21) |
| RR of death on RRT, 5th year/onwards, 65-74 years old | 5.6 | 3.96-7.92 | Log-normal (SElog=0.18) |
| RR of death on RRT, 5th year/onwards, 75-84 years old | 4.5 | 3.08-6.57 | Log-normal (SElog=0.19) |
| RR of death on RRT, 5th year/onwards, >85 years old | 1.2 | 0.18-7.87 | Log-normal (SElog=0.96) |

PSA, probabilistic sensitivity analysis; RR, relative risk; RRT, renal replacement therapy.

**Table F. Additional resource utilization and cost data**

| Parameter | Value | Range | Distribution for PSA | Source |
| --- | --- | --- | --- | --- |
| Cost of treatment of peri-operative wound complication, € | 2,853 | 1,426-4,279 | N/A | G-DRG 901D |
| Cost of treatment of peri-operative pocket haematoma, € | 1,902 | 951-2,853 | N/A | G-DRG 901D |
| Cost of treatment of peri-operative wound pain, € | 951 | 475-1,426 | N/A | G-DRG 901D |
| Follow-up visits to surgeon | 1 | 1-2 | Uniform | Expert assumption |
| Visits to cardiologist before and after Barostim activation | 2 | 1-2 | Uniform | Expert assumption |
| Visits to GP for standard management of hypertension | 2 | 1-4 | Uniform | Expert assumption |
| Cost of visit to cardiologist, € | 21 | 11-32 | N/A | EBM 2011 |
| Cost of visit to GP, € | 31 | 16-47 | N/A | EBM 2011 |
| Cost of visit to surgeon, € | 22 | 11-33 | N/A | EBM 2011 |
| Time of return to work after MI (calendar days) | 67 | - | - | Pilote, 1992 [6] |
| Time of return to work after stroke (calendar days) | 93 | - | - | Black-Shaffer, 1990 [7] |
| Time of return to work after TIA (calendar days) | 30 | - | - | Vohra, 2008 [8] |
| Time of return to work after renal transplant (calendar days) | 180 | - | - | van der Mei, 2011 [9] |
| Proportion of non-employed after MI | 0.37 | 0.22-0.54 | Beta (α=45; β=74) | Mittag, 2001 [10] |
| Proportion of non-employed after stroke | 0.73 | 0.51-0.92 | Beta (α=44; β=16) | Gabriele, 2009 [11] |
| Proportion of non-employed with heart failure | 0.83 | 0.69-0.94 | Beta (α=113; β=23) | Smith, 2007 [12] |
| Proportion of non-employed on dialysis | 0.72 | 0.65-0.78 | Beta (α=454; β=176) | DOPPS, 2001 [13] |
| Proportion of non-employed after renal transplant | 0.33 | 0.09-0.65 | Beta (α=10; β=20) | van der Mei, 2011 [9] |
| Time spent daily on household activity for males in Germany, hours | 1.81 | 0.90-2.71 | - | Harmonized European Time Survey data (2007) [14] |
| Time spent daily on household activity for females in Germany, hours | 3.33 | 1.66-4.99 | - |  |
| Average gross labour cost for the German employee, € per hour (2011) | 29.90 | 14.9-44.8 | N/A | The Federal Statistical Office, 2012 |
| Average net labour cost for the German home help worker, € per hour | 8.75 | 4.37-13.12 | N/A | The Federal Statistical Office, 2012 |

ACE, angiotensin converting enzyme; GP, general practitioner; MI, myocardial infarction; PSA, probabilistic sensitivity analysis; TIA, transient ischemic attack.

**Table G. Anti-hypertensive medications used and cost in treatment arms**

| Parameter | Class representative | Proportion in Barostim arm | Proportion in OMT arm | Average daily dose, mg | Daily dose cost, € |
| --- | --- | --- | --- | --- | --- |
| Proportion receiving ACE inhibitors | Captopril | 0.57 | 0.54 | 100 | 0.15 |
| Proportion receiving angiotensin II receptor blocker | Losartan | 0.47 | 0.43 | 100 | 0.74 |
| Proportion receiving beta-blockers | Atenolol | 0.86 | 0.83 | 100 | 0.33 |
| Proportion receiving calcium-channel blockers | Amlodipine | 0.65 | 0.71 | 10 | 0.21 |
| Proportion receiving diuretics | Hydrochlorothiazide | 0.96 | 0.92 | 50 | 0.51 |
| Proportion receiving aldosterone antagonists | Spironolactone | 0.17 | 0.19 | 50 | 0.35 |
| Proportion receiving direct vasodilators | Hydralazine+Beta-blocker+Hydrochlorothiazide | 0.32 | 0.30 | 100 | 1.60 |
| Proportion receiving alpha blockers | Prazosin | 0.12 | 0.18 | 6 | 1.77 |
| Proportion receiving central acting sympatholytic agents | Clonidine | 0.44 | 0.52 | 0.,4 | 0.73 |

ACE, angiotensin converting enzyme; OMT, optimal medical treatment

**Model validation**

Validation of the model was performed based on the results of the Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm (ASCOT-BPLA) [15, 16]. Patient characteristics from the atenolol group were used to construct a population with similar characteristics in a probabilistic model. Probabilistic distributions of each variable were performed and 10,000 simulations random value were used from the distribution of parameters. As the forced lung volume was not reported in ASCOT-BPLA, we used the average value from three studies in Germany (KORA C, SHIP-I, ECRHS-I) [17].

Because ASCOT-BPLA only reported changes in SBP at 5.5 years and (changes in SBP during the course of the study is only presented in a figure), it was assumed that atenolol lead to decreases of SBP of 5 mmHg at 6 months of follow-up, 10 mmHg – at 12 months, 15 mmHg – at 24 months, 20 mmHg – at 36 months and 25 mmHg (value reported in the study) – at 48 months.

In our model, the results at 5.5-year follow-up were compared with those of ASCOT-BPLA, and the rates of the following outcomes were compared: overall mortality, cardiovascular mortality, combined outcome of cardiovascular death, myocardial infarction, stroke and heart failure.

As only non-fatal myocardial infarction, stroke and heart failure were used in the model, and the overall cardiovascular mortality was estimated using the SCORE Project risk prediction model, it was not possible to appropriately validate our model for these parameters. However, because fatal stroke constituted 13% of the total cases for males and 18% for females in the Framingham Heart Study [1], we considered it appropriate to make a validation attempt for the rates of non-fatal stroke and transient ischemic attack in our model against the rates reported in ASCOT-BPLA although such comparisons may underestimate the stroke rate by 13-18%.

Also, considering that the development of heart failure may lead to death in some patients, we considered it appropriate to validate the non-fatal heart failure rate in our model against the rate reported in ASCOT-BPLA.

Due to differences in the definition of end-stage renal disease (ESRD) between our model and ASCOT-BPLA, we did not use this parameter for validation. In our model, ESRD was defined as any case requiring dialysis or renal transplantation while, in ASCOT-BPLA, renal impairment was determined on the basis on serum creatinine and urinalysis.

To perform the model validation, 10,000 simulations using patient characteristics and changes in baseline SBP reported in the atenolol arm of ASCOT-BPLA were performed. Mean and 95% credible intervals were estimated for each parameter. A two-fold or higher difference between the model’s and study’s results was considered as significant.

Results of the model validation are presented in the Table J.

**Table J. Model validation results against ASCOT-BPLA**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | 95% Credible interval | Mean, model | Median, model | Mean, study |
| 2.5% | 97.5% |
| Overall mortality  | 1.8% | 33% | 12% | 9% | 9% |
| Cardiovascular mortality | 0.3% | 10% | 3.7% | 2.8% | 4% |
| Combined outcome of cardiovascular death, myocardial infarction and stroke | 2.4% | 36% | 15% | 12% | 10% |
| Non-fatal heart failure | 0.05% | 8.8% | 3% | 3.5% | 2% |
| Fatal and non-fatal MI | 0.09% | 13% | 6.1% | 5.6% | 5% |
| Fatal and non-fatal stroke | 1.1% | 13% | 5.4% | 4.5% | 4% |

MI, myocardial infarction.

**Sensitivity analysis on fade-out effect**

A sensitivity analysis was performed assuming a fade-out effect of Barostim effectiveness between 1 mmHg and 5 mmHg annually from the latest available observation (4 years). Results of the sensitivity analysis are presented in the Table H.

**Table H. Sensitivity analysis on fade-out effect of Barostim effectiveness**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention** | **Cost, €** | **QALY** | **LYG** | **∆ Cost, €** | **∆ QALY** | **∆ LYG** | **ICER €/QALY** |
| 1 mmHg annual fade-out effect |
| Barostim | 148,203 | 15.83 | 17.35 | 17,130 | 1.89 | 1.42 | 9,054 |
| OMT | 131,073 | 13.93 | 15.92 | - | - | - | - |
| 2 mmHg annual fade-out effect |
| Barostim | 148,331 | 15.58 | 17.13 | 17,257 | 1.64 | 1.20 | 10,498 |
| OMT | 131,073 | 13.93 | 15.92 | - | - | - | - |
| 3 mmHg annual fade-out effect |
| Barostim | 148,473 | 15.40 | 16.98 | 17,400 | 1.46 | 1.05 | 11,879 |
| OMT | 131,073 | 13.93 | 15.92 | - | - | - | - |
| 4 mmHg annual fade-out effect |
| Barostim | 148,641 | 15.28 | 16.88 | 17,568 | 1.35 | 0.95 | 13,003 |
| OMT | 131,073 | 13.93 | 15.92 | - | - | - | - |
| 5 mmHg annual fade-out effect |
| Barostim | 148,708 | 15.17 | 16.78 | 17,635 | 1.23 | 0.85 | 14,286 |
| OMT | 131,073 | 13.93 | 15.92 | - | - | - | - |

ICER, incremental cost-effectiveness ratio; LYG, life-year gained; OMT, optimal medical treatment; QALY, quality-adjusted life years.

Lifetime risk of negative outcomes in each of fade-out effect scenarios is presented in the Table I.

**Table I. Lifetime risk of end-organ damage in sensitivity analysis on fade-out effect of Barostim effectiveness**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **MI total** | **Stroke/****TIA total** | **HF** | **ESRD** | **MI 1st episode** | **MI recurrent episode** | **Stroke 1st episode** | **Stroke recurrent episode** |
| 1 mmHg fade-out | 0.46 | 0.25 | 0.24 | 0.07 | 0.39 | 0.06 | 0.17 | 0.04 |
| 2 mmHg fade-out | 0.47 | 0.26 | 0.25 | 0.08 | 0.39 | 0.07 | 0.18 | 0.05 |
| 3 mmHg fade-out | 0.48 | 0.27 | 0.25 | 0.08 | 0.39 | 0.08 | 0.19 | 0.05 |
| 4 mmHg fade-out | 0.48 | 0.28 | 0.25 | 0.08 | 0.40 | 0.08 | 0.19 | 0.05 |
| 5 mmHg fade-out | 0.48 | 0.28 | 0.25 | 0.08 | 0.40 | 0.08 | 0.20 | 0.05 |
| Rate in optimal medical management arm | 0.55 | 0.33 | 0.27 | 0.09 | 0.43 | 0.11 | 0.23 | 0.07 |

ESRD, end-stage renal disease; HF, heart failure; MI, myocardial infarction; TIA, transient ischaemic attack.

The sensitivity analysis showed that even with a maximal 5 mmHg annual fade-out effect in Barostim arm, Barostim remained a cost-effective option with an ICER of 14,286 €/QALY. The limited impact of the fade-out effect may be partly be explained by how the risk of cardiovascular mortality (using SCORE project algorithm) and end-organ damage (using Framingham equation and data from cohort study on risk of ESRD) are calculated. Thus, cardiovascular mortality, non-fatal myocardial infarction, stroke and TIA are predicted with a 10-year interval, heart failure is predicted with a 4-year interval and ESRD is predicted annually depending on the level of SBP. Thus, even in scenario with a 5 mmHg annual fade-out effect, the risk of cardiovascular mortality will be updated only after 10 years when the impact of SBP will be reduced by 50%. This approach reflects the current knowledge in the utilization of risk prediction models in cardiology.

**Sensitivity analysis on discount rates**

Sensitivity analysis was performed using different discount rates. Results are presented in the Table K.

**Table K. Sensitivity analysis on different discount rates**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention** | **Cost, €** | **QALY** | **LYG** | **∆ Cost, €** | **∆ QALY** | **∆ LYG** | **ICER €/QALY** |
| Costs and benefits discounted at 5% |
| Barostim | 122,271 | 13.09 | 14.20 | 16,559 | 1.46 | 1.07 | 11,313 |
| OMT | 105,711 | 11.62 | 13.13 |  |  |  |  |
| Costs and benefits discounted at 0% |
| Barostim | 210,634 | 23.59 | 26.03 | 20,421 | 4.24 | 3.47 | 4,812 |
| OMT | 190,212 | 19.35 | 22.56 |  |  |  |  |
| Costs discounted at 3% and benefits discounted at 0% |
| Barostim | 147,964 | 23.59 | 26.03 | 16,891 | 4.24 | 3.47 | 3,980 |
| OMT | 131,073 | 19.35 | 22.56 |  |  |  |  |

ICER, incremental cost-effectiveness ratio; LYG, life-year gained; OMT, optimal medical treatment; QALY, quality-adjusted life years.

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