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Serviço de Cardiologia
Hospital de Santa Maria

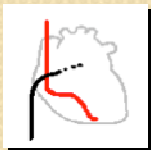
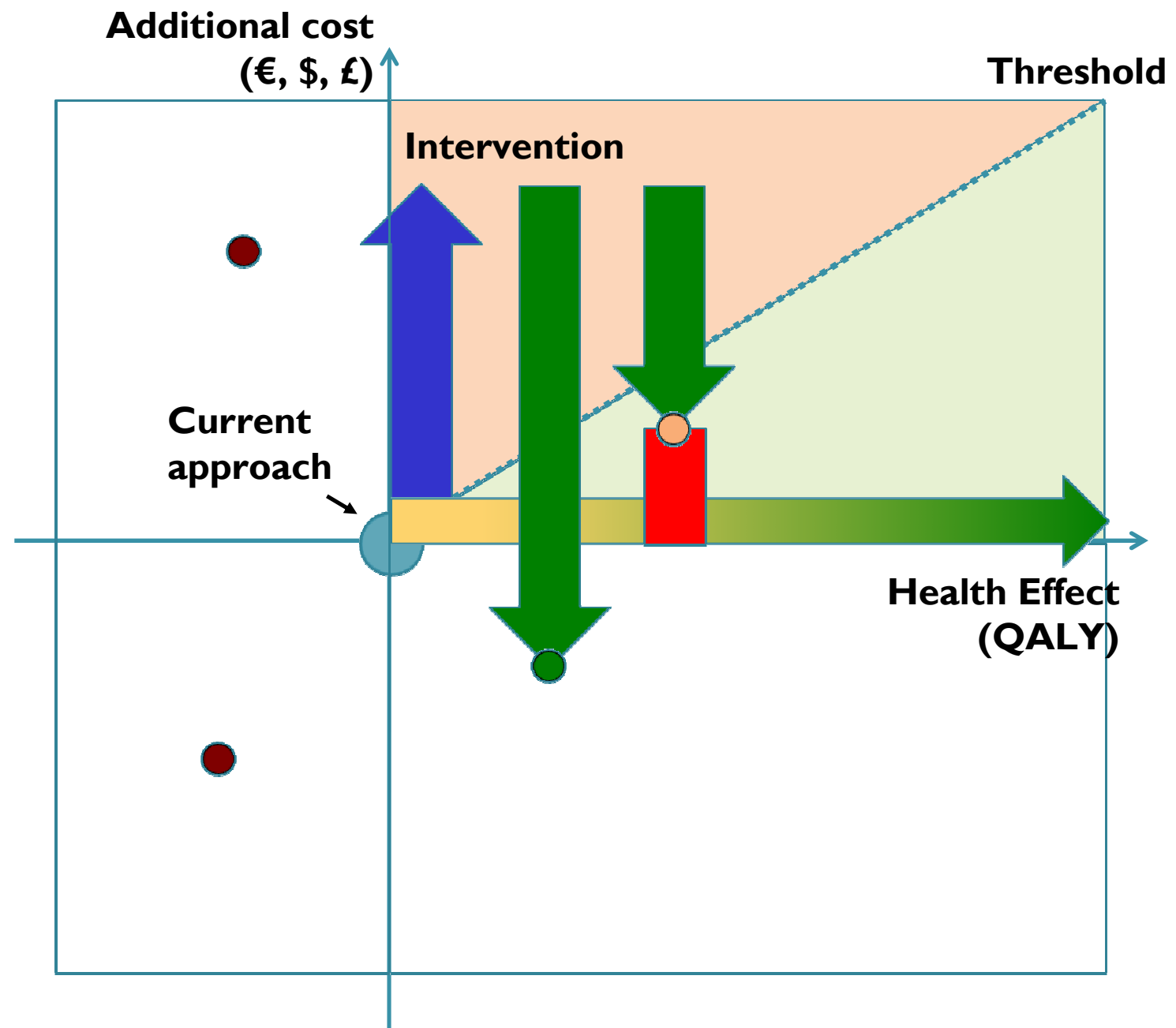
CUSTO-EFICÁCIA DA ABLAÇÃO DE FA: QUAL A EVIDÊNCIA?

1. *Health economic evaluation: princípios básicos*
2. Custo-Efectividade da Ablação de FA
3. Conclusões

Health Economics

- No health care system has enough resources to provide every clinically effective intervention to all persons who could benefit
- Prioritize interventions that are the most cost-effective
- **Cost-Effectiveness Analysis** aims to inform decisions about which practices to recommend (whether it gives good value)

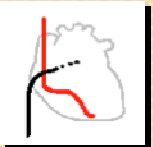
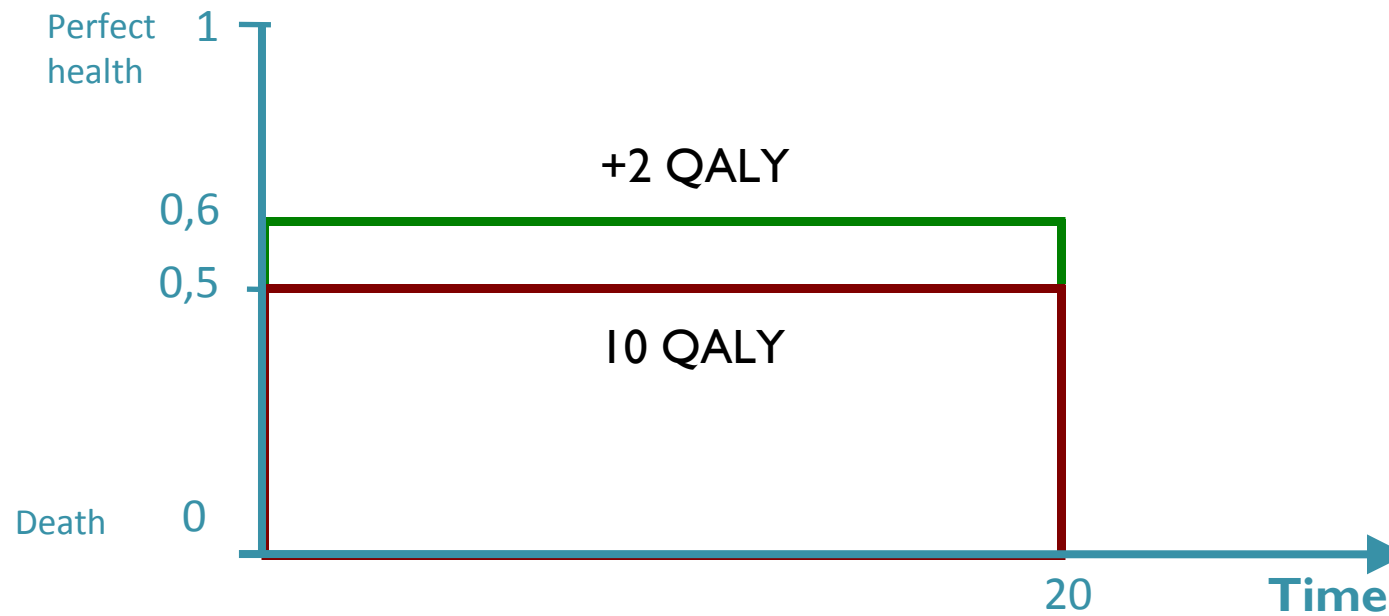




QALY = Quality Adjusted Life Years

- Primary health outcome used in economic evaluation
- Incorporates both survival and health-related quality of life

Index (“utility level”)



Limiar de custo-efectividade

- **Incremental cost-effectiveness ratio (ICER)**

- **40.000 € por QALY**

ICER da hemodiálise = 160.000€ / 4 QALYs

- **OMS:** 1 (a 3) x PIB per capita

Portugal: 16.200€

Alemanha: 31.437€

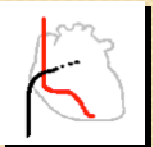
- **Limiar decidido pelos decisores políticos**

UK £20,000 per QALY; ≈23.600€ per QALY

USA \$50 000 per QALY; ≈37.400€ per QALY

<20.000€

40.000-60.000€ >60.000€



Treatment	Cost per QALY gained (€)
Cardiac rehabilitation and prevention programme	Dominant
Smoking cessation – physician counselling	2,000
Statins in secondary prevention (4S)	5,000
Primary angioplasty	11,000
AIDS drug cocktails	14,000
CRT-D in moderate-to-severe HF (CARE-HF)	19,300
New-generation drugs in Multiple Sclerosis	35,000
Kidney dialysis	40,000
Annual mamography for women aged over 70	70,000
Exercise ECG for asymptomatic men aged 40 years	95,000
Annual CT scan for former heavy smokers to detect lung cancer	1,000,000

Calvert MJ. *EurHeart J.* 2005;26:2681-88
 Bravo Vergel Y. *Heart.* 2007;93:1238-43

Probstfield JL. *Am J Cardiol* 2003; 91:22G-27G
 Johannesson M. *N Engl J Med* 1997;336:332-336
 Tengs TD, *Risk Anal* 1995;15:369-84



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Custo-eficácia da ablação de FA: Qual a evidência?

1. *Health economic evaluation*
2. **Custo-Efectividade da Ablação de FA**
Custos da Fibrilhação Auricular
Benefícios da Ablação
Custos da Ablação
3. *Conclusões*



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Health economic evaluation

Custo-Efectividade da
Ablação

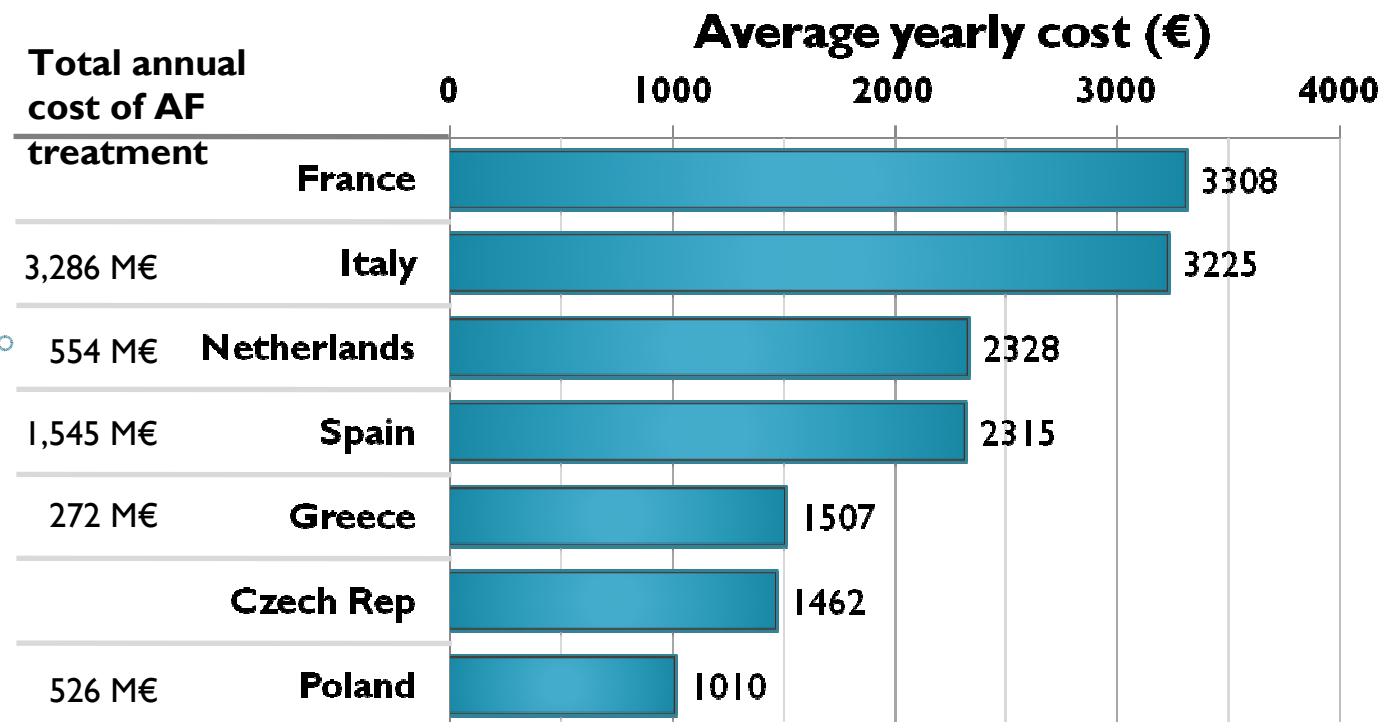
Custos da FA

Benefícios da Ablação

Custos da Ablação

Conclusões

Annual Costs of Atrial Fibrillation



Annual direct cost of AF in the UK in 2000 reached €655 million (**0.97%** of the total NHS budget)

Ringborg A, *Europace*. 2008;10:403-11
Stewart S. *Heart* 2004;90:286-92.

Moeremans K. *Value Health* 2000;6:407-16
Le Heuzey JY. *Am Heart J* 2004;147:121-6
Bulkova V. *Vnitr Lek* 2008;54:36-44



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Health economic evaluation

Custo-Efectividade da
Ablação

Custos da FA

Benefícios da Ablação

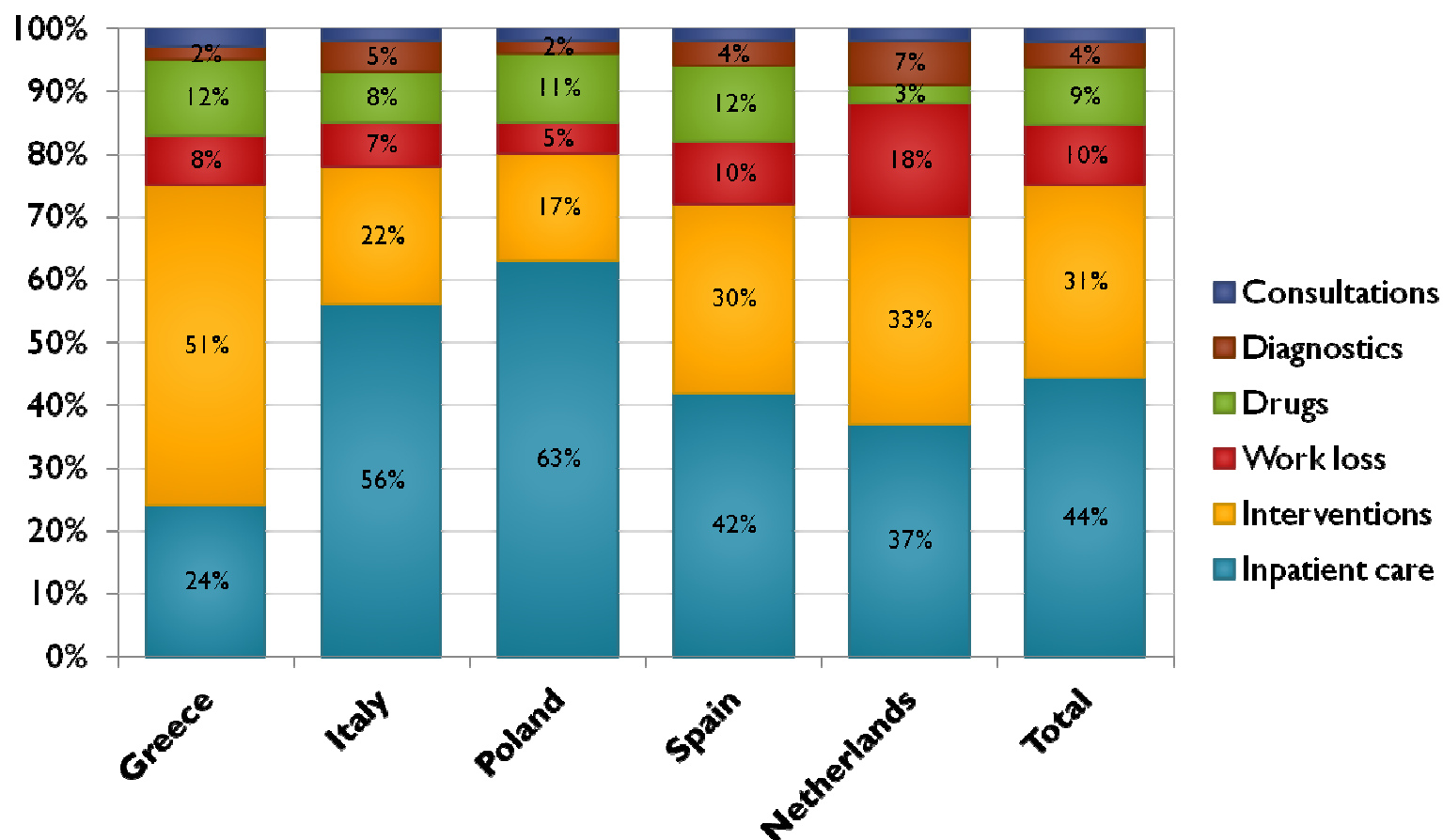
Custos da Ablação

Conclusões

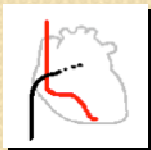
Custos do Tratamentoda FA

- Hospitalizações por FA / descompensação IC
 - AVC / embolia sistémica (hospitalizações / reabilitação)
-
- Anticoagulação crónica (fármacos/monitorização/consultas)
 - Terapêutica anti-arrítmica
 - Complicações da terapêutica anticoagulante (hemorragia sistémica, hemorragia intracraniana, eventos fatais)
 - Complicações e toxicidade da terapêutica antiarrítmica
-
- Exames diagnósticos (INR, ECG, Holter, EcoCG, análises, f tiroideia, digoxinémia)
 - Consultas médicas planeadas (médico de família, cardiologista)
 - Consultas médicas não-planeadas (médico de família, cardiologista)
-
- Dispositivos de pacing (sínd bradi-taqui, bradi-FA)

Distribution of Annual Costs of Atrial Fibrillation



Inpatient care and **interventional procedures** are the main drivers of costs, accounting for **≈70% of total annual costs**



FA paroxística
CHADS baixo

FA paroxística
Card estrutural

FA paroxística
CHADS mod-alto

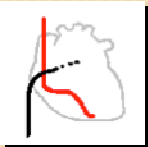
FA paroxística
Idoso

FA persist LD
CHADS baixo

FA persist LD
Card estrutural

FA persist LD
CHADS mod-alto

FA permanente



FA paroxística
CHADS baixo

FA paroxística
Card estrutural

FA paroxística
CHADS mod-alto

FA paroxística
Idoso

FA persist LD
CHADS baixo

FA persist LD
Card estrutural

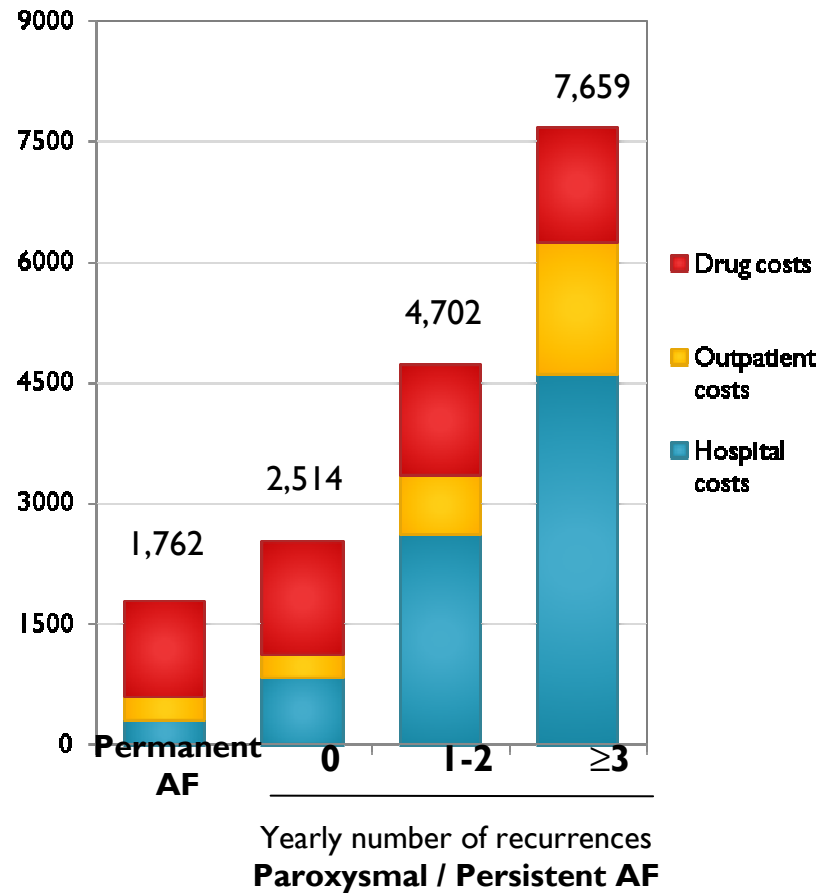
FA persist LD
CHADS mod-alto

FA permanente

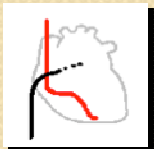
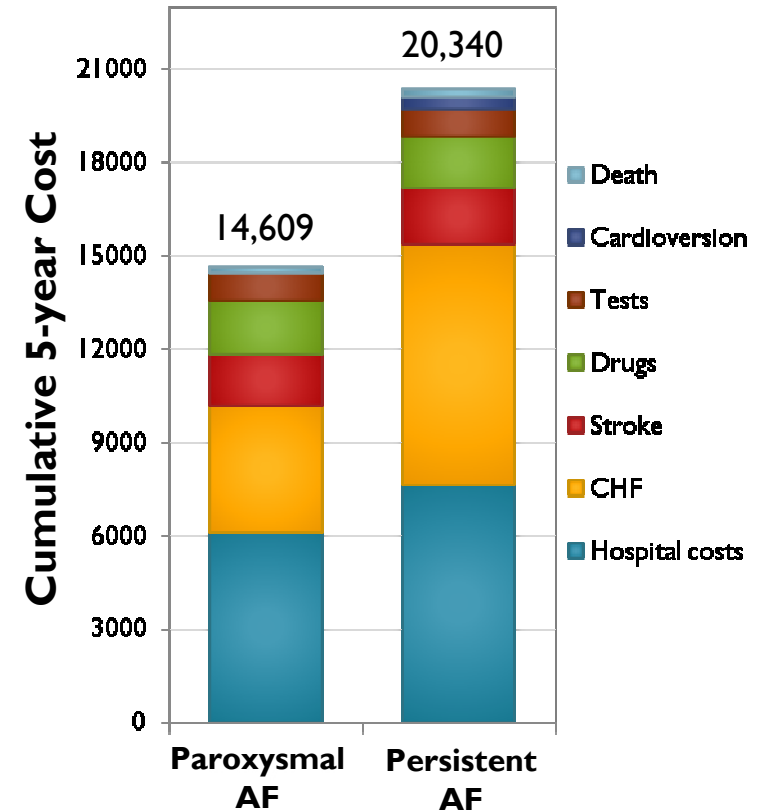


Costs according to type of AF and frequency of recurrences

€/year



€/5-year



FA paroxística
CHADS baixo

FA paroxística
Card estrutural

FA paroxística
CHADS mod-alto

FA paroxística
Idoso

Custo cumulativo da Terapêutica Médica (AAD) aos 5 anos

€/5-year

Cumulative 5-year Cost

20000
16000
12000
8000
4000
0

USA

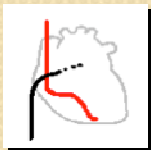
U Kingdom

France

15,352

18,030

14,609



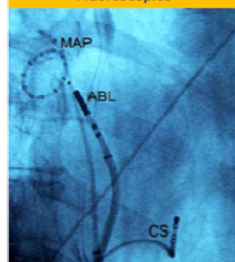
Moeremans K. *Value Health*. 2000;3(6):407-16
Reynolds MR. *Circ ArrhythmElectrophysiol*. 2009;2:362-9
McKenna C. *Heart*. 2009;95(7):542-9



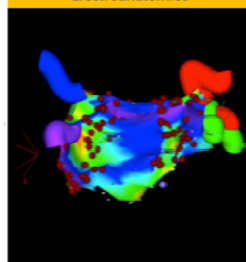
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Ablação de FA

Ablação Focal sob Controlo Fluoroscópico



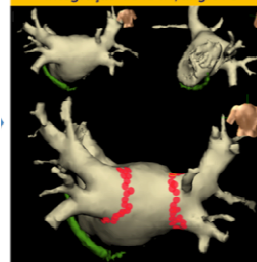
Mapeamento Electroanatómico



CARTO, Ensite NavX



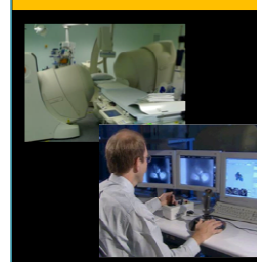
Mapeamento Electroanatómico com Integração de RMN/angioTC



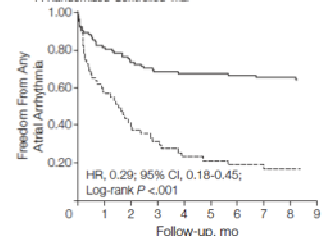
CARTO, Ensite NavX



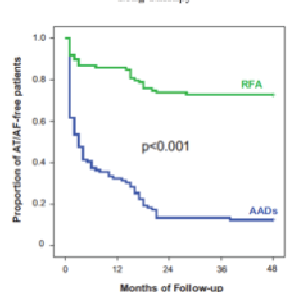
Sistemas Robóticos



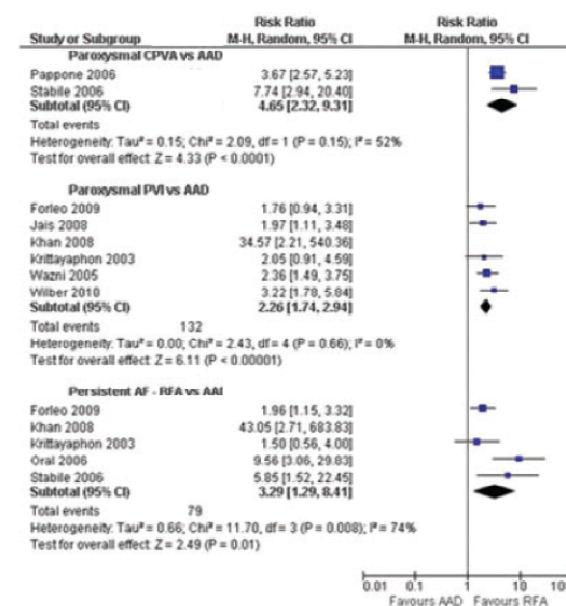
Comparison of Antiarrhythmic Drug Therapy and Radiofrequency Catheter Ablation in Patients With Paroxysmal Atrial Fibrillation
A Randomized Controlled Trial



Radiofrequency Catheter Ablation and Antiarrhythmic Drug Therapy



Metanálise: 9 RCT Abvs AAD (944dts)



Health economic evaluation

Custo-Efectividade da Ablação

Custos da FA

Benefícios da Ablação

Custos da Ablação

Conclusões

- Melhoria sintomática e redução do risco de recorrência de FA
- Probab manutenção de RS (12m): **84% vs 37% [OR: 0.10 (0.05-0.16)]**
- Follow-Up 9-12 meses (max: 5 anos)

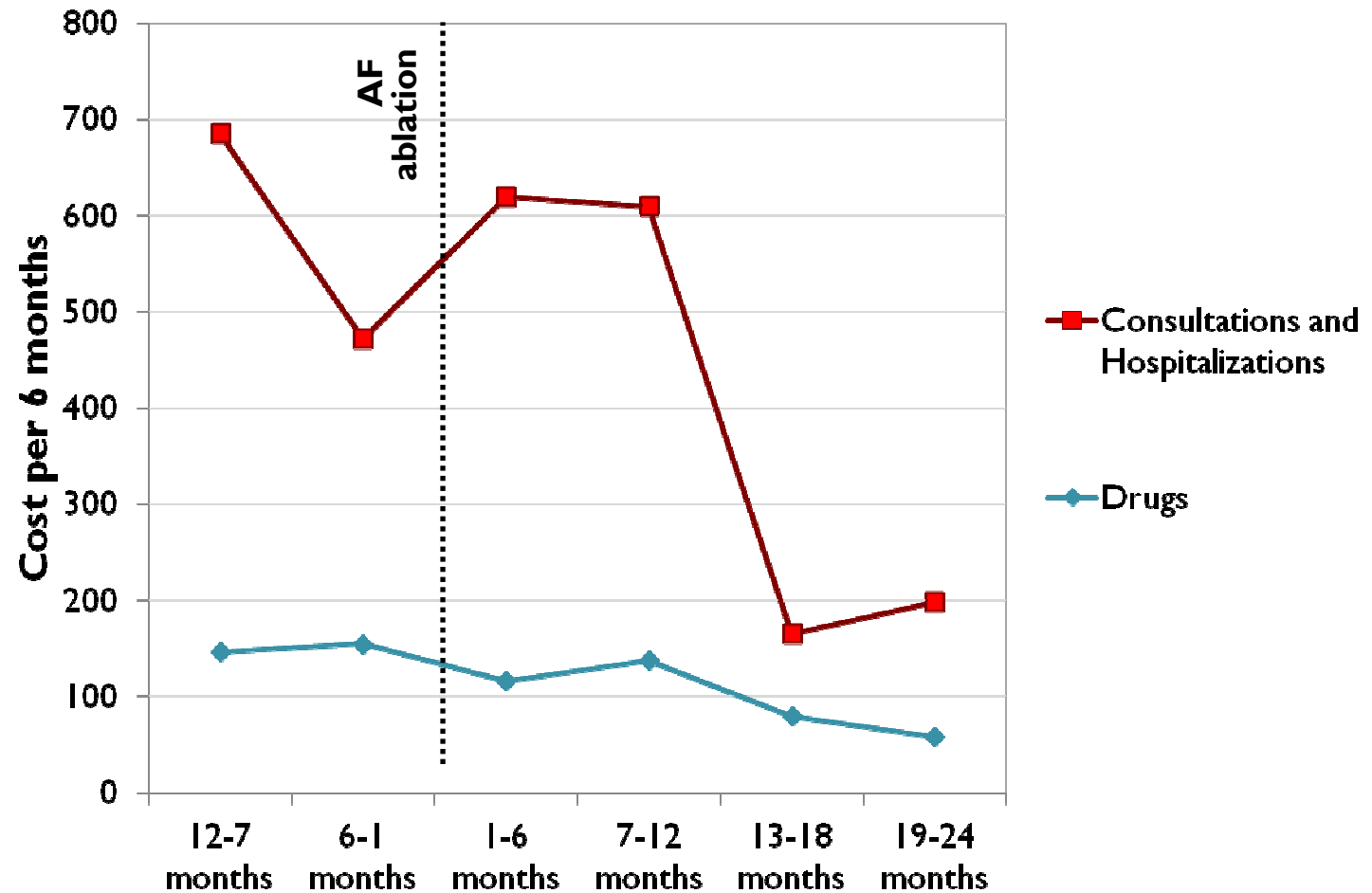
Wilber DJ. JAMA. 2010;303(4):333-40

Pappone C. Circ Arrhythm Electrophysiol. 2011;4(6):808-14

Parkash R. J Cardiovasc Electrophysiol. 2011 Jul;22(7):729-38

McKenna C. Heart. 2009;95(7):542-9

Comparison of Costs of Drugs, Consultations and Hospitalizations before and after AF Catheter Ablation



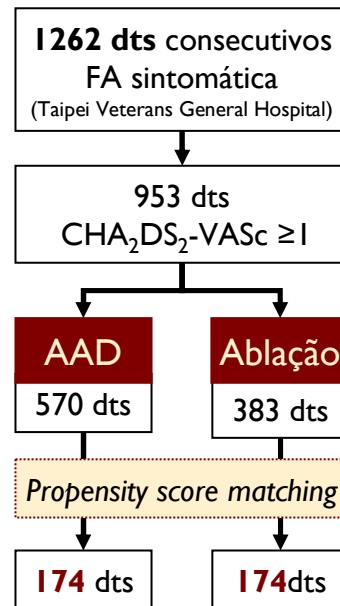
- Caso-controlo de doentes
CHA₂DS₂-VASc ≥1 com
emparelhamento *propensity score*
- Ablação: 174dts; AAD: 174dts
- Follow-Up: 47±23 meses



Europace
doi:10.1093/europace/eus336

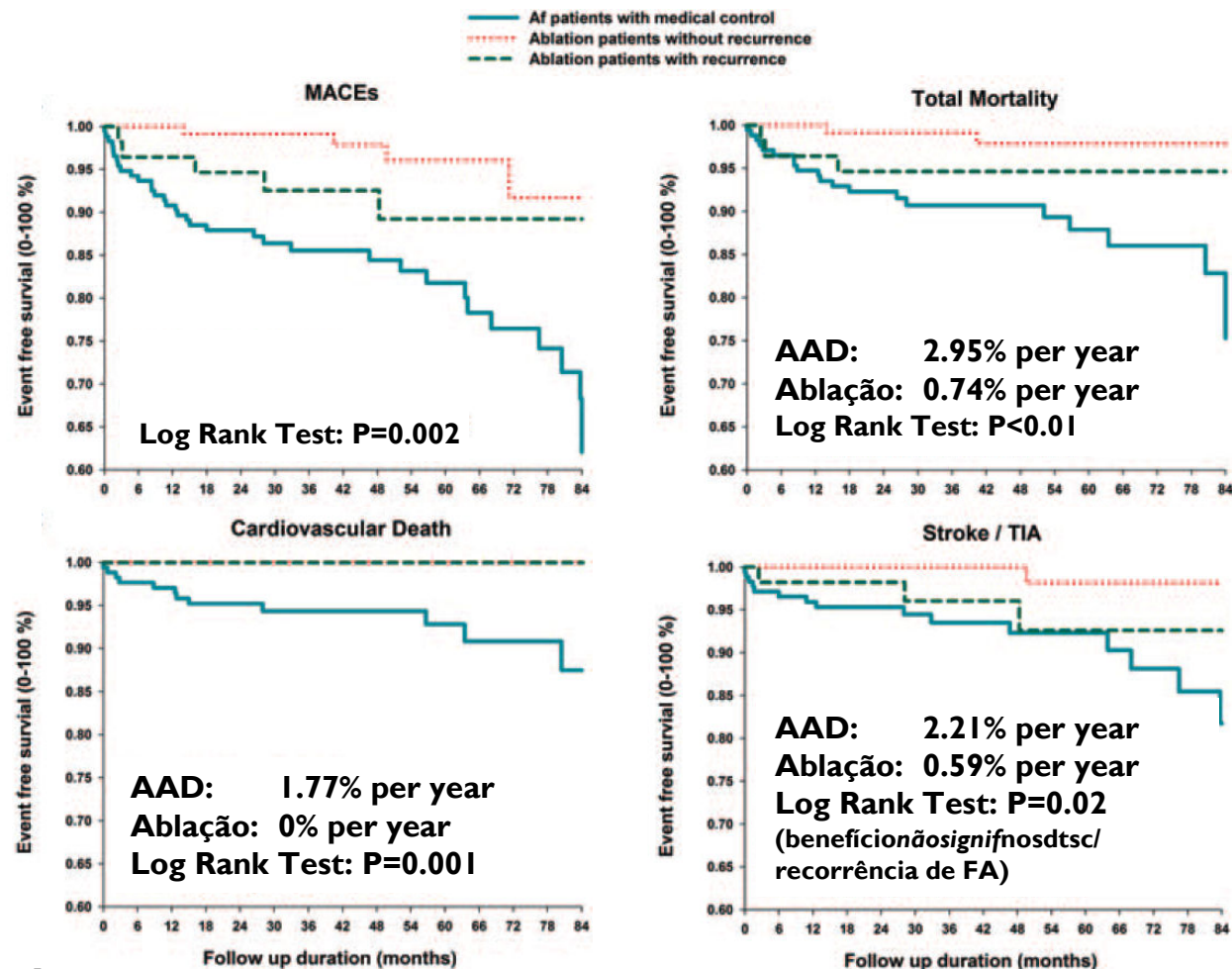
CLINICAL RESEARCH

Successful catheter ablation reduces the risk of cardiovascular events in atrial fibrillation patients with CHA₂DS₂-VASc risk score of 1 and higher



Progressão FA permanente:
AAD: 60,3%; Ablação: 9,8%

Recorrência FA após ablação:
32,2%





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Custos da Ablação de FA

- Heterogeneidade das estratégias de ablação
- Sistema de mapeamento electro-anatómico
- TAC / RMN
- Eco intracardíaco
- Monitorização da temperatura esofágica
- Duração do internamento
- Complicações (6% no Worldwide Survey)

Health economic evaluation

Custo-Efectividade da Ablação

Custos da FA

Benefícios da Ablação

Custos da Ablação

Conclusões

TABLE 4 Prevalence and Cost of Procedural Complications ^{29,31}		
Complication Type	Prevalence (%)	Cost
Tamponade	1.22	\$5,382
Stroke	0.28	\$13,700
Transient ischemic attack	0.66	\$3,958
PV stenosis	1.62	\$7,818
Total cost of complications		\$256.91

TABLE 5 Total Pulmonary Vein Ablation Cost ^{27,30,32}	
Item	Cost
Cost of anticoagulation for 1 month pre-procedure*	\$57.92
Average cost of procedure (fixed costs, patient charges, EP lab staff costs, materials, and supplies)	\$1,700.00
CT chest scan	\$356.60
Physician fees	\$1,276.00
3 months post-procedure follow-up	\$1,566.65
Cost of procedure complications	\$256.91
Catheters	\$5,374.13
Total	10,588.21

*Cost of anticoagulation in 44% of the patients who would not otherwise be anticoagulated for 1 month pre-ablation.

	3 estimates		
	Low	Medium	High
CARTO/3-D mapping case			
Diagnostic decapolar catheter	\$636.00	\$829.00	\$897.00
Navistar catheters (8 mm)	\$4,050.00	\$4,324.00	\$5,000.00
Thermocool catheters	\$4,450.00	\$5,050.00	\$5,900.00
Average of above-listed catheters	\$4,250.00	\$4,687.00	\$5,450.00
Reference patches	\$764.00	\$1,346.00	\$2,000.00
Non-CARTO/non-3-D mapping case			
Diagnostic decapolar catheter	\$636.00	\$829.00	\$897.00
Celsius catheter (8 mm)	\$786.00	\$916.00	\$1,189.00
LASSO catheter	\$1,837.00	\$2,286.00	\$2,657.00
ICE probe	NA	NA	\$4,000.00
NAVx case			
Diagnostic decapolar catheter	\$636.00	\$829.00	\$897.00
Celsius catheter (8 mm)	\$786.00	\$916.00	\$1,189.00
LASSO catheter	\$1,837.00	\$2,286.00	\$2,657.00
NAVx patch	\$1,200.00	\$1,200.00	\$1,200.00
Total CARTO/3-D mapping case (33% of total volume)	\$5,650.00	\$6,862.00	\$8,347.00
Total non-CARTO/non-3-D mapping case (33% of total volume)	\$3,259.00	\$4,031.00	\$8,743.00
Total NAVx case (33% of total volume)	\$4,459.00	\$5,231.00	\$5,943.00
Weighted average cost of catheters	\$4,455.55	\$5,374.13	\$7,676.90

NA = not applicable.



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Health economic evaluation

Custo-Efectividade da
Ablação

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Custos da Ablação

Conclusões

AF ablation total cost (1 procedure)

Canada (2007): 12,090-15,815 €

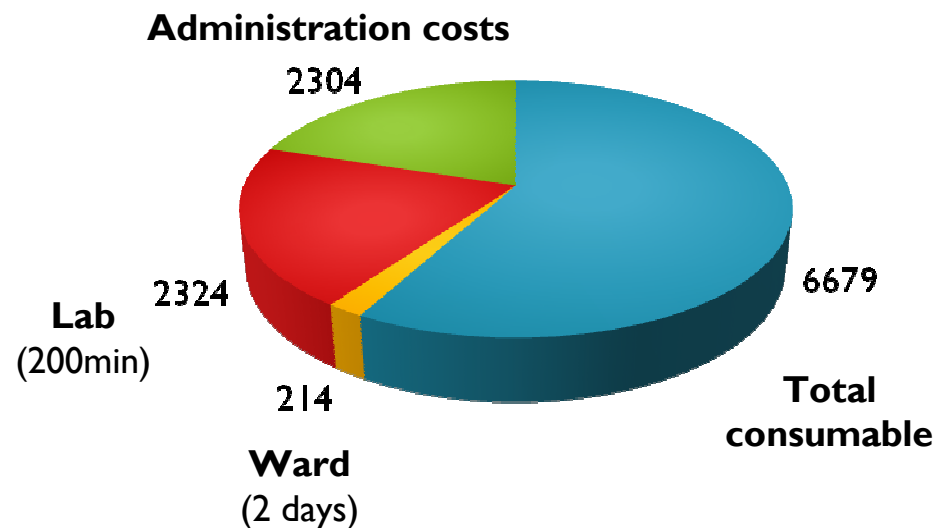
U Kingdom (2009): 11,511 €

Japão (2011): 8,604-16,350€

Khaykin Y. *J Cardiovasc Electrophysiol.* 2007;18(9):907-13

McKenna C. *Heart.* 2009;95(7):542-9

Noro M. *Circ J.* 2011;75(8):1860-6



McKenna C. *Heart.* 2009;95(7):542-9

Cost-Effectiveness of Radiofrequency Catheter Ablation Compared With Antiarrhythmic Drug Therapy for Paroxysmal Atrial Fibrillation

Matthew R. Reynolds, MD, MSc; Peter Zimetbaum, MD; Mark E. Josephson, MD; Ethan Ellis, MD; Tatyana Danilov, MD; David J. Cohen, MD, MSc

Heart rhythm disorders and pacemakers



Cost-effectiveness of radiofrequency catheter ablation for the treatment of atrial fibrillation in the United Kingdom

C McKenna,¹ S Palmer,¹ M Rodgers,² D Chambers,² N Hawkins,¹ S Golder,² S Van Hout,¹ C Pepper,³ D Todd,⁴ N Woolacott²

CADTH Technology Overviews

March 2012, Volume 2, Issue 1



Ablation Procedures for Rhythm Control in Patients with Atrial Fibrillation: Clinical and Cost-Effectiveness Analyses

Assasi N, Blackhouse G, Xie F, Gaebel K, Robertson D, Hopkins R, Healey J, Roy D, Goeree R.



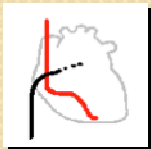
Circulation Journal
Official Journal of the Japanese Circulation Society
<http://www.j-circ.or.jp>

ORIGINAL ARTICLE
Arrhythmia/Electrophysiology

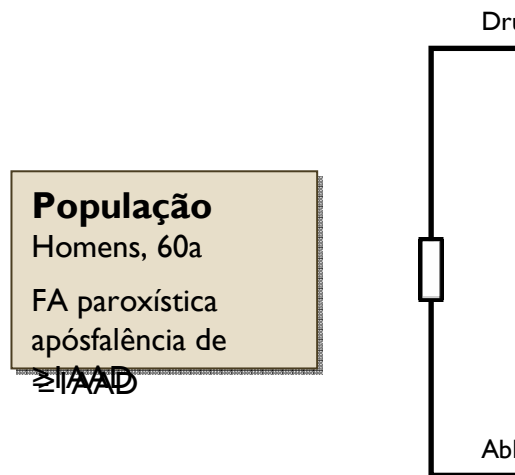
Cost Effectiveness of Radiofrequency Catheter Ablation vs. Medical Treatment for Atrial Fibrillation in Japan

– Cost Performance for Atrial Fibrillation –

Mahito Noro, MD, PhD; Shingo Kujime, MD; Naoshi Ito, MD; Yoshinari Enomoto, MD; Keijirou Nakamura, MD, PhD; Tsuyoshi Sakai, MD, PhD; Takao Sakata, MD, PhD; Kaoru Sugi, MD, PhD



5-year time horizon



Model Inputs:

Risk of death and incidence of stroke similar for both therapies

AAD

Recurrence rate within 1 year: **75%**
(65% for amiodarone)

AF Ablation

Single-procedure efficacy rate: **65%**
Rate of repeat ablation: **25%**
(1.25 procedures per patient)
Overall failure rate: **10%**

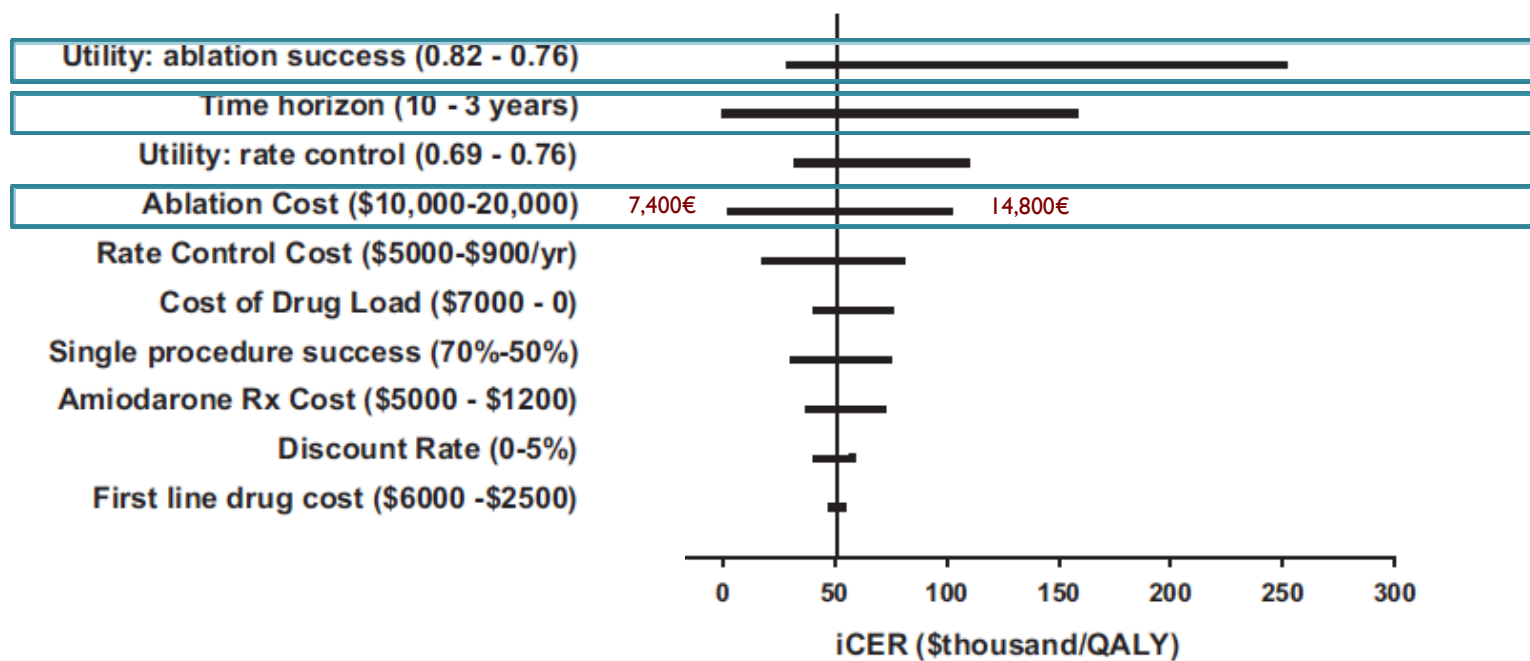
Table 1 Summary of input parameters applied in the bioactive model

[illegible]

Table 11 Continued

Variables	Value	Low CI	High CI	Description	Ref
Age (months), last exam ^a	26.6			Female	2
MRV head - stroke (no exam) ^b	2.68			Female	2
Stroke (last 1)	2.51			Female	14
Stroke - 2 years, no exam ^c	2.61			Female	11
WVW in 3 mtd (no, last exam) ^d	1.9			Female	29
Age in 2% (no, last, no exam)	2.0			Female	2
1.64 (last)	1.68			Female	36
Reversible (no, last exam)	1.41			Female	21
Prevalence (last, 2% last exam)	1.58			Female	29
Mean (last exam)	1.53			Female	26
Eds in (last exam)	2.7			Female	28

Incremental Cost-Effectiveness: RFA vs. AAD



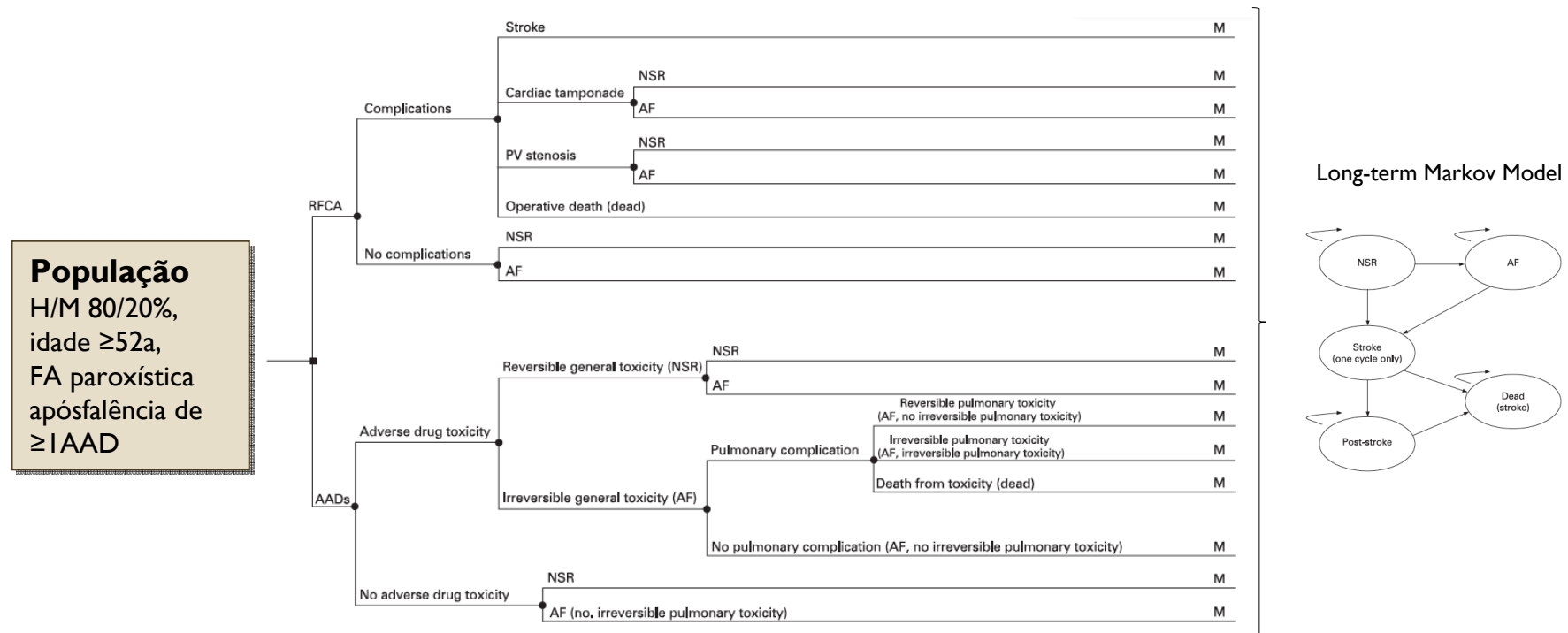
5-year analysis	Ablation	AAD
Cumulative cost	19,745 €	14,779 €
QALY over 5-year	3.51	3.38

$$\frac{17,745 - 14,779}{3.51 - 3.38} = \frac{4,966 \text{ €}}{0.13 \text{ QALY}}$$

ICER = **38,199 €** per QALY*

* 51,431 US\$ per QALY

5-year and lifetime analyses



Model Inputs:

Stroke risk sensitive to the rhythm (60% higher during AF), CHADS and OAC use
Risk of death similar for both therapies (but 7,40 times higher after stroke)

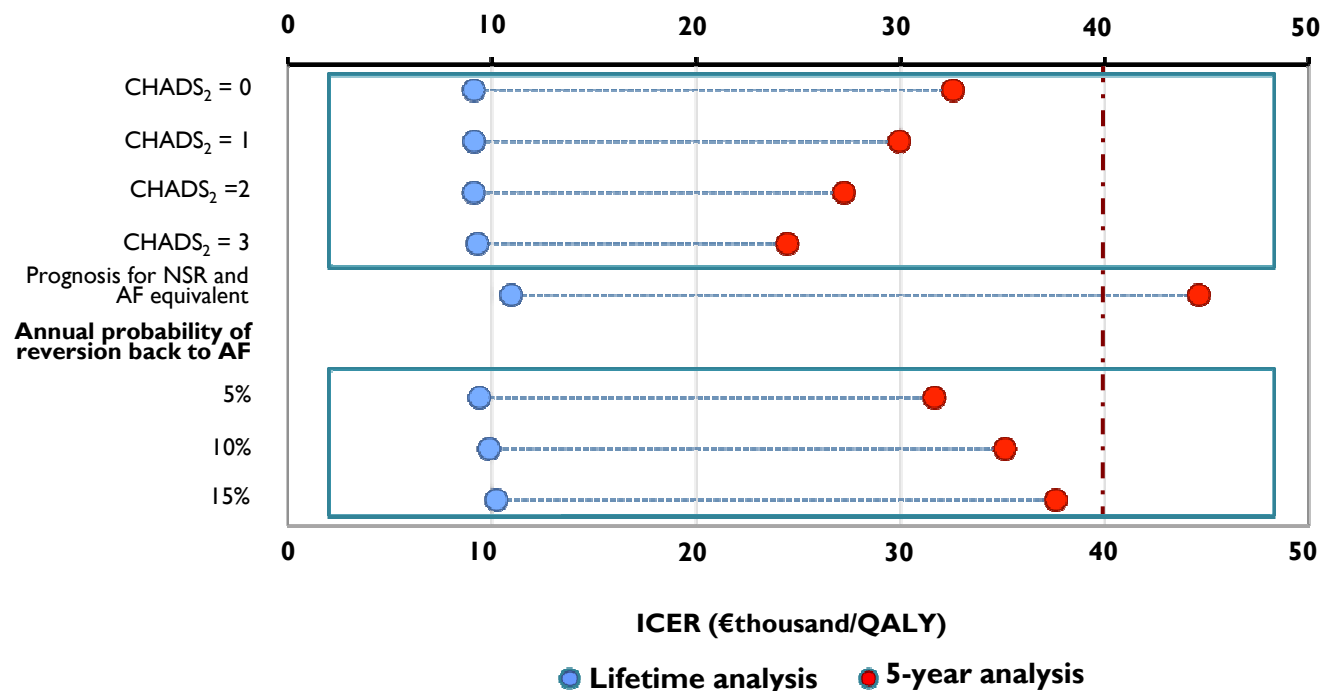
AAD (all AAD patients treated with amiodarone)

Recurrence rate within 1 year: **65%** (29%/year thereafter)

AF Ablation

Recurrence rate within 1 year: **16%** (3%/year thereafter)

Incremental Cost-Effectiveness: RFA vs. AAD



5-year analysis	Ablation	AAD
Cumulative cost	31,676 €	19,377 €
QALY over 5-year	10.97	10.52

$$\frac{31,676 - 19,377}{10.97 - 10.52} = \frac{12,301 \text{ €}}{0.45 \text{ QALY}}$$

ICER = **27,332 €** per QALY*

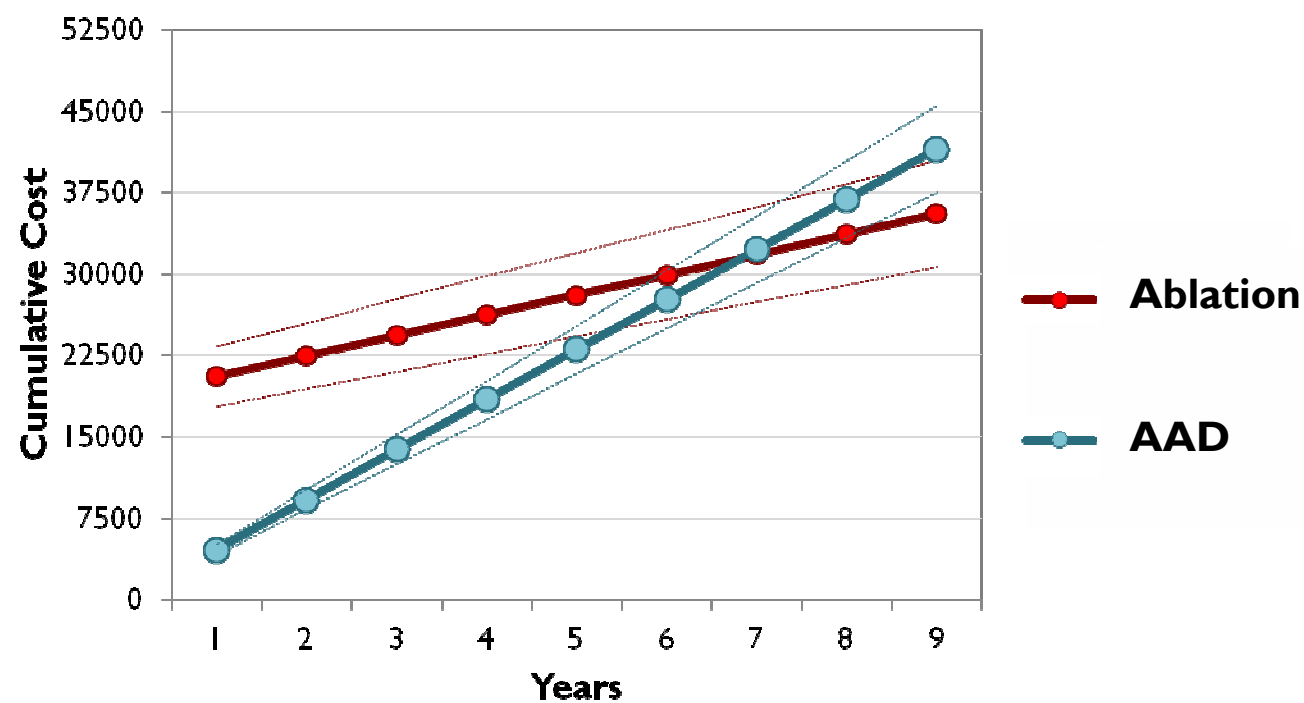
assuming CHADS₂ score = 2

* 36,800 US\$ per QALY McKenna C. *Heart*. 2009;95(7):542-9



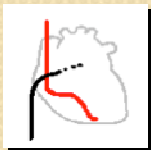
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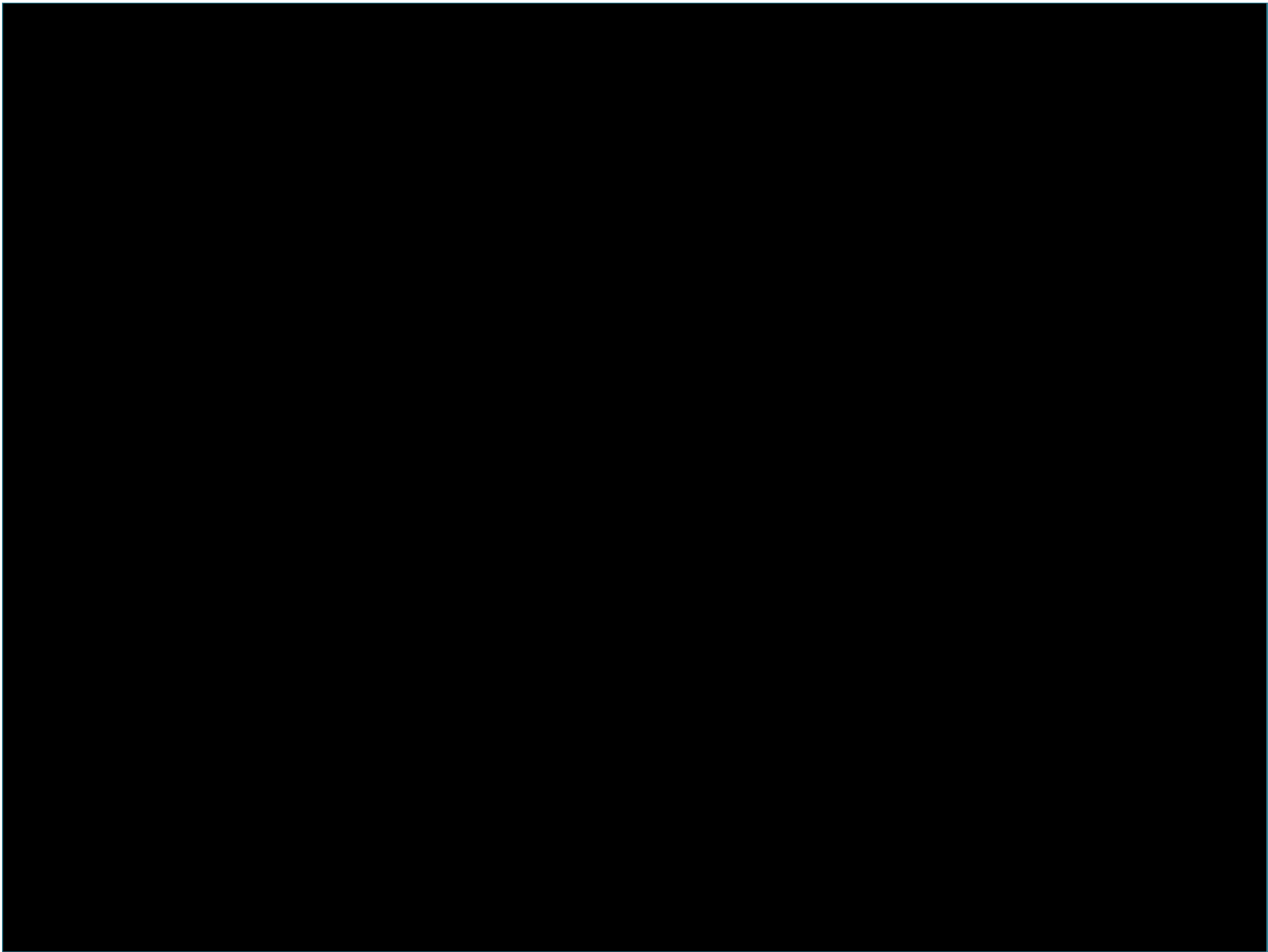
Cost neutrality between 3.2 and 8.4 years (average: 4 years)

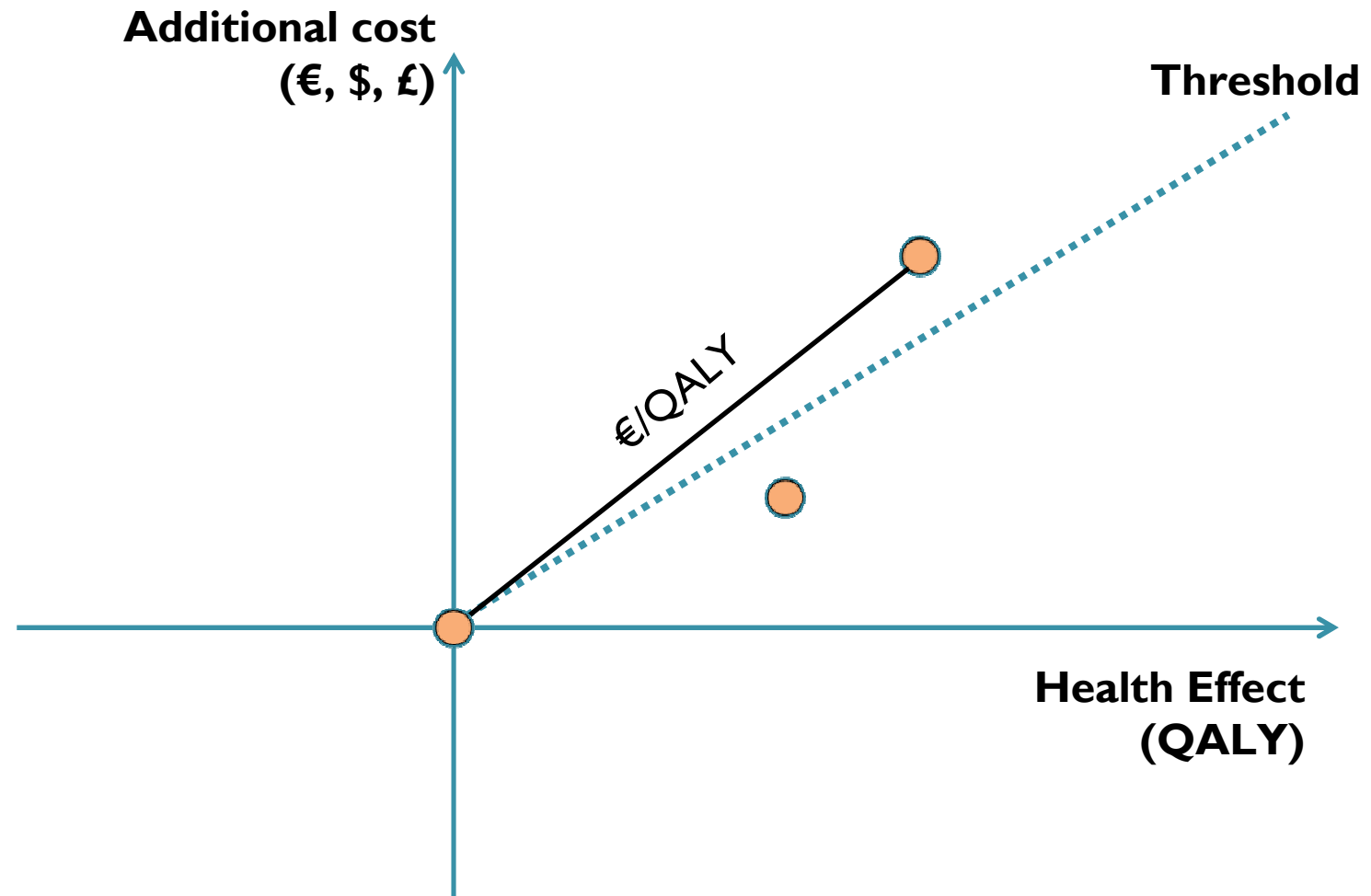


Conclusões

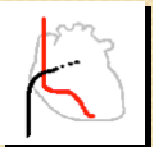
- Ablação de FA é custo-efectiva em doentes com FA paroxística e sintomas refractários a AAD
- Custo inicialmente elevado é compensado pelo decréscimo dos custos (hospitalizações)
- Neutralidade de custos atingida após 5-10 anos (*assumindo que os resultados da ablação se mantêm a longo prazo...*)
- Evidência actual sugere que a ablação dificilmente será custo-efectiva em doentes sem sintomas significativos (custo-efectividade dependente da melhoria sintomática)
- Se for confirmado o impacto favorável na mortalidade e risco de AIT/AVC em ensaios clínicos controlados e aleatorizados, a relação custo-efectividade da ablação de FA tornar-se-á muito favorável, eventualmente mesmo noutros grupos de doentes







Incremental cost-effectiveness ratio (ICER) - difference between the mean costs of each strategy divided by the difference in mean health outcome (the slope of the line that connects the strategies).



Annual Follow-Up Costs - Medical Therapy

	Rhythm Control		Rate Control		
	Warfarin	ASA	Warfarin	ASA	Total
Percentage of patients (in Ontario)	26.39	10.77	43.64	19.20	
Clinical tests (number/year)					
INR	14	0	14	0	
ECG	3.11	2.63	3.11	2.63	
Holter monitoring	1.06	0.69	0.15	0.3	
Echocardiography	0.67	0.73	0.67	0.73	
Exercise testing	0.05	0.1	0.05	0.1	
Thyroid function	0.03	0	0.03	0	
Digoxin levels	0	0	0.28	0.28	
Weighted annual cost	\$176.95	\$31.46	\$254.18	\$49.60	\$512.18
Physician visits no CHF (per year, 45% patients without CHF)					
GP	6.6	5.56	7.44	5.67	
Specialist	2.6	2.11	2	1.67	
Hospital days	1.4	0.5	0.69	0.76	
Weighted cost	\$123.02	\$29.91	\$146.54	\$58.14	\$357.61
Physician visits CHF (per year, 55% CHF prevalence)					
GP	11.22	10.14	10.89	8.13	
Specialist	3.89	3.5	3	2.75	
Hospital days	5	4.14	4.13	3.57	
Weighted cost	\$388.79	\$134.41	\$530.59	\$197.47	\$1,251.26
Unscheduled visits (per year)					
Cardiologist	0.99	0.99	0.39	0.39	
Hospital days (assumed ICU)	2.01	2.01	0.49	0.49	
Weighted cost	\$707.38	\$288.69	\$293.27	\$129.03	\$1,418.37
Annual weighted cost of clinical tests and visits					\$3,539.42

Proportions of patients in each therapeutic strategy was derived from the CARAF registry.

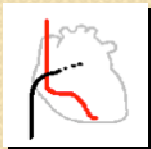
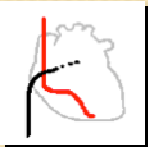


Table 2. Quality of Life Assessment With Change From Baseline to 3 Months

Scale	Absolute Change From Baseline				Mean Difference Between Groups (95% CI)	P Value
	Catheter Ablation		Antiarrhythmic Drug Therapy			
	No. of Patients	Mean Change (95% CI)	No. of Patients	Mean Change (95% CI)		
SF-36 mental	90	8.5 (5.9 to 11.1)	39	1.6 (−1.1 to 4.3)	6.9 (2.6 to 11.2)	<.001
SF-36 physical	90	6.9 (5.2 to 8.6)	39	0.4 (−1.7 to 2.6)	6.6 (3.6 to 9.4)	<.001
Symptom frequency	82	−11.1 (−12.9 to −9.3)	29	0.7 (−2.4 to 3.9)	−11.8 (−15.4 to −8.3)	<.001
Symptom severity	65	−9.4 (−10.9 to −7.9)	23	0.0 (−3.3 to 3.4)	−9.4 (−12.6 to −6.3)	<.001

Abbreviations: CI, confidence interval; SF-36, 36-item Short-Form Health Survey.

Wilber. JAMA. 2010





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Sucesso da Ablação de FA

- Benefícios sintomático, redução das recorrências e hospitalizações por FA
- Benefício potencial mas não demonstrado nos riscos de AVC, IC e morte
- Heterogeneidade dos resultados da ablação (estratégias, experiência, volume)
- RCTs: conduzidos em Centros não representativos da prática clínica; FUp 6-12 meses

Worldwide Survey of Catheter Ablation for Human Atrial Fibrillation N=8.000 pts

TABLE 3. Success Rates Relative to Different Ranges of Follow-Up Duration

Range of Follow-Up Duration, mo	No. of Centers	No. of Patients	Success Without AADs			Success With AADs			Overall Success	
			n	Rate, %	(Range), %	n	Rate, %	(Range), %	n	Rate, %
0-3	4	179	39	21.8	(15.6-48.9)	83	46.4	(32.6-57.8)	122	68.2
4-6	16	906	312	34.4	(23.5-58.6)	303	33.4	(21.9-46.3)	615	67.8
7-9	14	1271	661	52.0	(34.6-78.1)	278	21.9	(10.1-32.8)	939	73.9
10-12	15	1537	1009	65.6	(37.5-87.3)	374	24.3	(11.8-38.5)	1383	89.9
13-18	17	2607	1616	62.0	(41.2-84.3)	419	16.1	(5.2-29.4)	2035	78.1
19-24	8	467	179	38.3	(16.4-55.9)	147	31.5	(17.0-42.1)	326	69.8
>24	6	1619	688	42.5	(21.7-58.5)	437	27.0	(18.5-35.7)	1125	69.5

Health economic evaluation

Custo-Efectividade da Ablação

Custos da FA

Benefícios da Ablação

Custos da Ablação

Limitações e tendências

Conclusões