Fibrillazione Atriale ed Ictus Cardioembolico. Roma, 26 Novembre 2013

Analisi di Costo-Efficacia dell'Ablazione della Fibrillazione Atriale

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Epidemiology of Atrial Fibrillation

the la

Prevalence: 0.9-2.5%

Incidence: 0.2-0.34%

Estimates Trend of AF patients compared with general population in Italy

Age	Italian Population (ISTAT data)		AF Prevalence*			Estimates of AF patients					
	(2011)	(2021)	(2031)	(2041)	(2051)	%	(2011)	(2021)	(2031)	(2041)	(2051)
55-59	3.714.610	4.710.457	4.813.096	3.843.489	3.593.178	0,7	26.002	32.973,2	33.692	26.904	25.152
60-64	3.815.181	4.005.263	4.801.497	4.196.544	3.636.034	1,7	64.858	68.089,5	81.625	71.341	61.813
65-69	3.045.131	3.520.074	4.498.131	4.633.189	3.733.189	4,0	121.805	140.803	179.925	185.328	149.327
70-74	3.085.299	3.451.837	3.687.660	4.472.028	3.951.576	6,0	185.118	207.110	221.260	268.322	237.095
75-79	2.524.660	2.557.450	3.038.507	3.963.404	4.144.782	9,0	227.219	230.171	273.466	356.706	373.030
80-84	1.947.783	2.276.051	2.652.205	2.941.603	3.655.219	13,5	262.951	307.267	358.048	397.116	493.455
85-	1.709.555	2.427.646	2.903.393	3.675.619	4.835.515	17,8	304.301	432.121	516.804	654.260	860.722
Total	60.468.034	61.706.810	62.157.325	62.225.183	61.611.498		1.192.254	1.418.534	1.664.819	1.959.978 🤇	2.200.594
AF Prevalence estimates in the italian general population						1,97%	2,30%	2,68%	3,15%	3,57%	

* Heeringa J et al. Eur Heart J 2006;27:949-53

Projected Number of adults with AF in the US

ATRIA & Olmsted County study:



Olmsted County data (assuming continued increase in AF incidence)

Olmsted County data

(assuming no further increase in AF incidence)

ATRIA study data

Go AS et al. *JAMA* 2001; 285: 2370-75 Miyasaka Y et al. Circulation 2006; 114: 119-125

Atrial Fibrillation

Morbidity and Mortality:

- Quality of Live
- Thromboembolic Complications (5 times)
- Heart Failure (3 times)
- Cardiovascular Mortality (2 times)

Annual Costs of Atrial Fibrillation

Et.



Stewart S et al Heart 2004; 90: 286. **Le Heuzey JY** Am Heart J 2004; 147:121-6. **Coyne KS** Value Health 2006; 9: 348-56.

Annual Costs of Atrial Fibrillation

Total cost € 6.2 billion *Costs driven by inpatient care and interventions*



Data collected from September 3003 to August 2004 in the Euro Heart Survey

Ringborg A et al. Europace 2008; 10: 403-11

Costs of Atrial Fibrillation in Italy



€ 3286 million



Ringborg A et al. Europace 2008; 10: 403-11

Cost of care distribution in atrial fibrillation patients: The COCAF study

France:

Table II. Values of costs in societal and healthcare payer perspectives (in Euros)

	Hospitalizations	Drugs	C onsultations	Further investigations	Paramedical procedures	Loss of work
Total cost 3209 Euros	1682	737	288	256	64	193
Societal perspective (%)	52	23	9	8	2	6
Healthcare payer perspective (%)	60	21	7	7	2	3

Le Heuzey J et al. Am Heart J 2004;147:121–6

Estimation of incurred annual costs of AF in Italy



Mean annual healthcare costs according to the frequency of AF recurrence



Reynolds et al. J Cardiovasc Electrophysiol. 2007; 18:1-6

Comparison of costs of drugs, consultations, and hospitalizations before and after index AF ablation



Kautzner J et al. Europace (2011) 13, ii39–ii43

Efficacy of catheter ablation vs AAD

Catheter ablation: 71-77%

AA Drugs: 52%



Calkins et al. Circ Arrhythmia Electrophysiol. 2009;2:349-61

Catheter ablation vs medical treatment

Report of Canadian Agency for Drugs and Technologies in Health:

Pooled analyses for clinical success after 1 yr

Group	Number of Studies	Number of F AF/AT-Fr PVI	Participants ee / Total PVI+	Pooled Risk Ratio (95% Cl) Random Effect Model	Test for Overall Effect	Test for Heterogeneity
RCTs						
All AF types						
First line	1	28/32	13/35	2.36 (1.50 to 3.70)	Z = 3.73 (P < 0.001)	Not applicable
Second line	5	238/308	66/265	2.93 (2.09 to 4.11)	Z = 6.25 (P < 0.001)	$\chi^2 = 9.47 (P = 0.05)$ $I^2 = 58\%$
All subgroups	6	266/340	79/300	2.82 2.13 to 3.74)	Z = 7.20 (P < 0.001)	$\chi^2 = 10.29 (P = 0.07)$ $I^2 = 51\%$
Paroxysmal AF						
Studies reporting success rate for paroxysmal AF	3	198/258	45/215	3.80 2.92 to 4.96)	Z = 9.86 (P < 0.001)	$\chi^2 = 0.03 (P = 0.99)$ $I^2 = 0\%$
Methodological quality (J	adad score)					
≥3	2	95/138	23/96	2.90 (1.80 to 4.68)	Z = 4.38 (P < 0.001)	$\chi^2 = 1.71 (P = 0.19)$ $I^2 = 42\%$
< 3	4	171/202	56/204	2.76 (1.85 to 4.12)	Z = 4.99 (P < 0.001)	$\chi^2 = 8.58 (P = 0.04)$ $I^2 = 65\%$
Non-RCTs						·
All non-RCTs	2	557/709	426/582	1.23 (1.00 to 1.50)	Z = 1.99 (P = 0.05)	$\chi^2 = 3.84 (P = 0.05)$ $I^2 = 74\%$

Assasi N et al. CADTH report 2010; 128: 1-73

Safety of catheter ablation vs AAD

Catheter ablation

Outcomes t n/N % Mortality 0.7 65 Death overall 42/5781 64 0/51920.0 Procedure-related Vascular access complications Arteriovenous fistula 32 1/28850.0 33 1/29600.0 Bleeding 0.5 Hematoma 38 17/3719 34 0/29740.0 Pneumothorax 34 15/3032 0.5Femoral artery pseudoaneurysm Periprocedure events 0.3 Stroke, ischemic 62 17/5665 TIA 60 13/5467 0.2Cardiac tamponade 63 45/5723 0.8 PE 3/5496 0.1 60 DVT 56 1/4758 0.0 Other embolism 57 10/5347 0.20.0 LA-esophageal fistula 60 0/54960.1 Other fistula 58 3/5407 Pericardial effusion 64 36/5719 0.6 PV stenosis* 65 91/5831 1.6 AV block 60 1/5496 0.0 CHF exacerbation 60 0/54960.0Need for a pacemaker 46 4/3902 0.1 Total No. of patients with events 28 97/1964 4.9

Overall Safety Outcomes n/N % t Mortality 2.8 33 Death overall 120/4291 21 Sudden death 18/2900 0.6Treatment-related death 22 15/31790.5 Not treatment-related death 20 40/3023 1.3 Adverse events CV events 10 58/1572 3.7 Bradycardia 19 44/2349 1.9 GI 16 97/1499 6.5 48/969 5.0 Neuropathy 4 Thyroid dysfunction 5 19/576 3.3 12 16/2238 0.7 Torsades Q-T* prolongation 12 5/2034 0.2 Total No. of patients with 29.8 24 989/3318 events Discontinuations 23.8 Total 32 1035/4347 32 Due to AE 384/3682 10.4 Due to inefficacy 12 229/1694 13.5 Due to noncompliance 19/457 4.2 4

AA Drugs

L.L.

Calkins et al. Circ Arrhythmia Electrophysiol. 2009;2:349-361

Updated National Multicenter Registry on Procedural Safety of Catheter Ablation for Atrial Fibrillation

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this procedure continues to be cause for concern. Aim of the present multicenter registry was to assess the incidence of early CA complications and detect their predictors in a contemporary, unselected AF Safety of Catheter Ablation for Atrial Fibrillation. Introduction: Despite catheter ablation (CA) becoming an accepted treatment option for symptomatic, drug-resistant atrial fibrillation (AF), safety of population

Methods and Results: From January 1, 2011 to December 31, 2011, data from 2,323 consecutive patients No procedure-related death was observed. Major complications occurred in 94 patients (4.0%): 50 patients (2.2%) suffered vascular access complications; 12 patients (0.5%) developed cardiac tamponade; 14 patients patients (0.1%) had phrenic nerve paralysis; 3 patients (0.1%) had hemothorax. Other isolated but serious (0.6%) presented with pericarditis; 5 patients (0.2%) had transient ischemic attack; 4 patients had stroke; 3 adverse events were documented in 3 patients (0.1%). Female gender (OR 2.643; 95% CI 1.686-4.143; P < 0.0001) and longer procedural duration (OR 2.195; 95% CI 1.388–3.473; P < 0.001) independently who underwent CA (median age 60 [52-67]; 72.3% male) for AF in 29 Italian centers were collected. All major complications occurring to the patient from admission to 30th postprocedural day were recorded. predicted a higher risk of complications.

Conclusion: Major complications occurred in 4.0% of the CA procedures for AF, with vascular access complications being the most frequent events. (J Cardiovasc Electrophysiol, Vol. 24, pp. 1069-1074, October

Catheter ablation vs medical treatment

Quality-of-Life Measures (SF-36):

Study	Time of Assessment (months)	Treatment (sample size)	Quality-of-Life Measure* B: Mean at Baseline, A: Mean after Intervention, C: Mean Change from Baseline [mean difference between groups, P value]							
			Physical Health			Mental Health				
			Physical Functioning	Physical Role	Pain	General Health	Vitality	Social Functioning	Emotional Role	Mental Health
Wazni et	6	Ablation (32)	B 71 ± 3,	B 73 ± 5,	B 71 ± 3,	B 57 ± 2,	$B 52 \pm 4$,	B 87 ± 3,	$B70 \pm 1$,	$B 65 \pm 4$,
al.55			A 97 ± 3	A 71 ± 2	A 97 ± 1	A 79 ± 1	A 65 ±1	A 93 ± 3	A 76 ± 1	A 65 ± 2
		AADs (35)	$B 69 \pm 2$	$B51 \pm 5$	$B70 \pm 3$	$B57 \pm 2$	$B51 \pm 1$	B 76 ± 3	$B70 \pm 1$	$B64 \pm 2$

"All studies reported an **improvement in SF-36 scores** greater than what is considered to be minimal clinically important differences (3 to 5 points) in the general health domain or in mental health and physical health."

					1 0.001	1 0.001		1 0.001	1 0.001		
Jaïs et al. ⁵⁸	12	Ablation (53)	$B 44.8^{T} \pm NR$, A 52 ± 7.6			$B 46.1^{T} \pm NR$, A 56.6 \pm 7.8					
		AADs (59)	B 43:0) ± NR, A 48.9 ±	7.2 [P = 0.0	15]	B 44	$0 \pm NR$, A 51.	9 ± 9.7 , [P = 0	0.09]	
Krittaya-	12	Ablation (15)	$B 62.7^{\dagger} \pm NR$,	NR	NR	$B46 \pm NR$,	NR	NR	NR	NR	
phong et			A $85.4^{\dagger} \pm NR$			A $66 \pm NR$					
al. ⁶¹		AADs (15)	$B 70.8^{\dagger} \pm NR$,	NR	NR	$B42 \pm NR$,	NR	NR	NR	NR	
			A $68.1^{\dagger} \pm NR$			$A 44 \pm NR$					
			[P = 0.691]			[P = 0.048]					
Pappone et	12	Ablation (109)]	$B 38.7^{T} \pm NR, A 50^{T} \pm NR$			$B 41.3^{T} \pm NR$, A $49.5^{T} \pm NR$				
ai.		AADs (102)	B 39.5	\pm NR, A 40.5 [†] :	$\pm NR [P = 0.0]$	007]	B 42.6	$5^{\dagger} \pm NR, A 43.9$	$A 43.9^{\dagger} \pm NR [P = 0.004]$		

Assasi

et al. CADTH report 2010:

2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design

Indications for catheter ablation of AF	Class	Level
Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication		
Paroxysmal: Catheter ablation is recommended*	I	А
Persistent: Catheter ablation is reasonable	IIa	В
Longstanding Persistent: Catheter ablation may be considered	IIb	В
Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent		
Paroxysmal: Catheter ablation is reasonable	IIa	В
Persistent: Catheter ablation may be considered	IIb	С
Longstanding Persistent: Catheter ablation may be considered	IIb	C

Calkins H et al. *Heart Rhythm* 2012

Linee guida AIAC per la gestione e il trattamento della fibrillazione atriale. Aggiornamento 2013

Antonio Raviele (Chairman)¹, Marcello Disertori² (Co-Chairman), Paolo Alboni³, Emanuele Bertaglia⁴, Gianluca Botto⁵, Michele Brignole⁶, Riccardo Cappato⁷, Alessandro Capucci⁸, Maurizio Del Greco², Roberto De Ponti⁹, Matteo Di Biase¹⁰, Giuseppe Di Pasquale¹¹, Michele Gulizia¹², Federico Lombardi¹³, Sakis Themistoclakis¹⁴, Massimo Tritto¹⁵



	Classe ^a	Livello			
• FA parossistica/persistente, senza o con lieve cardiopatia sintomatica (con compromissione	I	А		Classe ^a	Livell
significativa della qualità di vita), refrattaria ad almeno un farmaco antiaritmico, quando la strategia clinica preferibile sia il mantenimento del ritmo sinusale stabile.			 FA parossistica/persistente o persistente di lunga durata, quando la comparsa e la persistenza dell'aritmia comportano un 	lla	В
 FA parossistica, età relativamente giovane (<60 anni) senza o con lieve cardiopatia, senza o con lieve dilatazione atriale sinistra, sintomatica (con compromissione significativa) 	lla	A	di pompa del cuore, nonostante adeguata terapia farmacologica antiaritmica e per l'insufficienza cardiaca.		
della qualità di vita), come terapia di prima scelta, in alternativa ai farmaci antiaritmici.			• FA persistente di lunga durata, con cardiopatia strutturale sintomatica (con compromissione	llb	С
• FA persistente di lunga durata, senza o con lieve cardiopatia sintomatica (con compromissione significativa della qualità di vita), refrattaria ad almeno un farmaco antiaritmico, quando la	lla	С	significativa della qualità di vita), refrattaria ad almeno un farmaco antiaritmico, quando la strategia clinica preferibile sia il mantenimento del ritmo sinusale stabile.		
strategia clinica preferibile sia il mantenimento del ritmo sinusale stabile.			Pazienti che opportunamente resi edotti dei rischi-benefici delle diverse opzioni terapeutiche	llb	С
• FA parossistica/persistente con cardiopatia strutturale sintomatica (con compromissione	lla	С	scelgono la terapia ablativa per motivi psicologici o professionali.		
significativa della qualità di vita), refrattaria ad almeno un farmaco antiaritmico, quando la strategia clinica preferibile sia il mantenimento del ritmo sinusale stabile			G Ital Ca	rdiol 20	13.14(

G Ital Cardiol 2013;14(3)

ESC 2010 Recommendations for AF ablation

Recommendations	Class ^a	Level ^b
Catheter ablation for paroxysmal AF should be considered in symptomatic patients who have previously failed a trial of antiarrhythmic medication.	lla	A
Ablation of persistent symptomatic AF that is refractory to antiarrhythmic therapy should be considered a treatment option.	lla	В

Recommendations	Class ^a	Level ^b
Catheter ablation of AF in patients with heart failure may be considered when antiarrhythmic medication, including amiodarone, fails to control symptoms.	IIb	В
Catheter ablation of AF may be considered prior to antiarrhythmic drug therapy in symptomatic patients despite adequate rate control with paroxysmal symptomatic AF and no significant underlying heart disease.	IIb	В
Catheter ablation of AF may be considered in patients with symptomatic long-standing persistent AF refractory to antiarrhythmic drugs.	IIb	С

Camm AJ et al. *Eur Heart J* 2010; 31:2369-2429



AF Ablation Barriers

AF Patients candidates for ablation are not receiving treatment due to several barriers:



Health Technology Assessment Report Atrial Fibrillation Catheter Ablation

Chairmen:

Sakis Themistoclakis (Venezia-Mestre), Massimo Tritto (Castellanza)

Working Group Members:

Manuel Bertaglia (Mirano), Patrizia Berto (Verona), MariaGrazia Bongiorni (Pisa), Domenico Catanzariti (Rovereto), Giuseppe De Fabrizio (Lecce), Roberto De Ponti (Varese), Massimo Grimaldi (Acquaviva delle Fonti), Claudio Pandozzi (Roma), Claudio Tondo (Milano), Michele Gulizia (Catania)



AIAC Survey on quantities of resources use & costs of AF ablation

- Collected data on resource utilization in the 2008 from 52/87 centers (60% response rate)
- Obtained detailed cost data from 4 selected hospitals (Bottom-up cost analysis)

Total EP procedure: 33.745
AF ablation: 4561 (13.5%)





Questionnaire:

- N. of ablation procedure
- In-hospital resource use & unit costs :
 - Standard pre- post procedural test/diagnostics
 - Disposables
 - EP lab utilization: occupancy time, equipment, staff employed, sedation/general anesthesia
 - Length of hospitalization
- Resource use & unit costs during follow up :
 - Out-patients visits and diagnostics performed during 2 yrs f-up after successful ablation

In-Hospital Costs of Catheter Ablation

Cost/patient (Weighted Mean): 8.868 € (Linear mean: 9.455 €)

- Disposables: 64.2 %
- Hospitalization: 14.7 %
- Personnel & EP Lab occupancy costs: 13.6%
- EP Lab equipment: 3,8%
- Pre-procedural care: 3,7%



Distribution of costs of disposables



Comparison between DRG-518 reimbursement values and In-hospital costs

	Linear Mean	Weighted Mean
DRG 518 (€)	5.376	5.376
In-hospital Costs (€)	9.455	8.868
Difference of DRG-518 vs hospital incurred costs		
• Euros	-4.079	-3.492
Percentage	-43%	-35%

TOTAL (*In-hospital* + *Follow-up*) costs of AF Ablation

Cost/patient (Weighted Mean): € 9.632



The cost-effectiveness plane



Andrikopoulos et al. *Europace* 2009; 11: 147–151

and the

Cost-effectiveness of catheter ablation vs AAD for AF treatment

Incremental costs/QALY (€):

Time Horizon	5 years	Lifetime
Chan ²⁰⁰⁶	8.774-21.019	
McKenna ²⁰⁰⁹	23.928-31.870	8.917-9.086
Reynolds ²⁰⁰⁹	37.190	<723
Eckard ²⁰⁰⁹		Abl. dominate
CADTH ²⁰¹⁰	42.229	Abl. dominate

Budget Impact of Proposed Increased Payment

Variable	Value	Data Source
DRG 518 Reimbursement (mean)	5.376 €	National Agency for Regional Healthcare (AGENAS)
Cost of Ablation Procedure (weighted mean)	8.868 €	AIAC Survey
Cost of Follow-up, 1st Year (weighted mean)	381,5€	AIAC Survey
Cost of Follow-up, 2nd Year (weighted mean)	381.5€	AIAC Survey
Cost of Patient with AF per Year	3225 €	RingBorg et al. Europace 2008; 10:403-411
Average Number of Procedures per Patient	1.3	Cappato et al. Circ Arrhythm Electrophysiol. 2010;3:32- 8
Success Rate	76%	Nair et al. JCE 2009;20: 138-44
Average Annual Increase in Procedures due to Higher Reimbursement	5-10%	AIAC estimates
Annual Late Recurrence Rate	3.4%	NICE (Rogers et al HTA 2008) CADTH (Assasi et al HTA 2010)

Budget Impact Analysis

Break-even at 5-6 years:



Cost Comparison of Catheter Ablation and Medical Therapy in Atrial Fibrillation

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Catheter Ablation and Medical Therapy. Introduction: There is emerging evidence for clinical superiority of catheter ablation over rate and rhythm control strategies in paroxysmal atrial fibrillation (PAF). The objective of this study was to compare costs related to medical therapy versus catheter ablation for PAF in Ontario (Canada).

Methods: Costs related to medical therapy in the analysis included the cost of anticoagulation, rate and rhythm control medications, noninvasive testing, physician follow-up visits, and hospital admissions, lation were assumed to include the cost of the ablation tools (electroanatomic mapping or intracardiac echocardiography-guided pulmonary vein ablation), hospital and physician billings, and costs related to the Canadian Registry of Atrial Fibrillation (CARAF), government fee schedules, and published data. Sensitivity analyses looking at a range of initial success rates (50–75%) and late attrition rates (1–5%), periprocedural medical care and complications. Costs related to these various elements were obtained from as well as the cost of complications related to this management strategy. Costs related to catheter abResults: The cost of catheter ablation ranged from \$16,278 to \$21,294, with an annual cost of \$1,597 to \$2,132. The annual cost of medical therapy ranged from \$4,176 to \$5,060. Costs of ongoing medical therapy and catheter ablation for PAF equalized at 3.2–8.4 years of follow-up.

Conclusion: Catheter ablation is a fiscally sensible alternative to medical therapy in PAF with cost equivalence after 4 years. (J Cardiovasc Electrophysiol, Vol. 18, pp. 907-913, September 2007)

Decreto Ministeriale (DM) 18/10/2012

Rideterminazione delle tariffe DRG

Valore perentorio per le sole Regioni in piano di rientro (PdR)Abbattimento di molti DRG

DRG 518→ Ablazione transcatetere	
Ante DM 18/10/2012	€ 5.376
Post DM 18/10/2012	€ 3.900

Reimbursement Overwiev in European Countries

Austria	8.700 €
Belgium	2.350 € disposables 633 € for 3D mapping system 2.500 € physician <u>5.483 €</u> TOTAL w/o hospital stay
France	Based on the level of complexity (Public hospital): Level 1: <u>6.040 € (</u> 2013 vs 2012: +21,6%) Level 2: 10.297€ (2013 vs 2012: +21,6%) Level 3: 13.914 € (2013 vs 2012: -2.8%) Level 4: <u>17.558 € (</u> 2013 vs 2012- 8.3%)
Germany	8.514 € for ablation with 3D mapping system and contact force ablation catheter
Italy	<u>5.367 €</u>
UK	<u>4.260 – 8.730 €</u> _based on the level of complexity and for elective or non-elective procedure
Swiss	23.484 € for ablation with 3D mapping system

 AF catheter ablation appears to be reasonably costeffective compared with AAD therapy alone from the prospective of healthcare systems.

 The cost-effectiveness was found more favourable when time horizons longer than 5 yrs were used.

- AF poses a major public health burden and requires higher awareness and adequate healthcare resources
- AF catheter ablation appears to be reasonably costeffective compared with AAD therapy alone from the prospective of healthcare systems.
- The cost-effectiveness was found more favourable when time horizons longer than 5 yrs were used.

Current reimbursement is insufficient covering about 60% of the costs of ablation procedure in Italy.

Insufficient reimbursement may serve as a disincentive to perform procedure, limiting the number of patients that have access to treatment.

 From healthcare care systems perspective the budget impact of reimbursement adequate to a cost covering level may be absorbed in the short term.

 After 5 years the initial higher costs for ablation were offset by hospitalization and other costs avoided.



