

Catheter Ablation for Atrial Fibrillation

SBU ALERT REPORT NO 2010-06 • 2010-12-15 • WWW.SBU.SE/ALERT



Summary and conclusions

SBU's appraisal of the evidence

This document updates a report published by SBU Alert in 2005.

Atrial fibrillation is an abnormal irregular heart rhythm (atrial tachyarrhythmia) characterized by a rapid and uncoordinated activation of the upper chambers of the heart (atria), leading to an irregular and unsynchronized activation of the lower chambers (ventricles). Atrial fibrillation is the most common tachyarrhythmia and is often associated with an impaired heart function and an increased risk for embolic stroke.

Although many patients may benefit from antiarrhythmic drug treatment, catheter ablation is a treatment option for patients with severe symptoms who do not respond to or cannot tolerate antiarrhythmic drugs. Using a special ablation catheter, heat energy can be applied to tissue around the pulmonary veins (pulmonary vein isolation) and, in some cases, to certain areas in the left atrium.

- In patients with severe symptoms of atrial fibrillation, refractory to conventional treatment with medication, catheter ablation is more effective than continued pharmacotherapy in treating symptoms. Results of follow-ups (up to 12 months) show that patients with paroxysmal atrial fibrillation respond more favourably to catheter ablation than those with persistent atrial fibrillation.
- The catheter ablation treatment carries risks for serious complications, and its risk profile differs from that of continued pharmacotherapy. Hence, it is important that patients who are candidates for catheter ablation receive comprehensive and objective information about the benefits and risks.
- The scientific evidence is insufficient for drawing conclusions about the cost-effectiveness of the method, since its long-term effects are uncertain.

Technology and target group

Pulmonary vein isolation (electrical isolation of the pulmonary veins) is an invasive procedure during which an ablation catheter is used to apply heat energy around the pulmonary veins. It is currently the standard method shown to be most effective against recurrences of paroxysmal atrial fibrillation. The risk of recurrence is higher for patients with persistent atrial fibrillation, despite adjunct therapies. New ablation methods are being developed.

The experience with atrial fibrillation ablation therapy in patients above 70 years of age is relatively limited. The complication rate appears to be higher in this age group. Hence, the method is primarily recommended for people who are below 70 years of age and without marked enlargement of the left atrium. If ablation therapy is offered primarily to patients 70 years of age and younger, the potential target population for the method is estimated to be approximately 2 000 patients per year in Sweden.

Primary questions

- Is catheter ablation a more effective method than drugs in treating symptoms of atrial fibrillation?
- What complications and side effects are associated with catheter ablation?
- What does treatment cost? Is it cost-effective?

Patient benefit

- At up to 12 months of follow-up, the prevalence of symptomatic atrial fibrillation is lower among patients treated with catheter ablation than among those who were continued on antiarrhythmic drugs (Evidence grade 2)*.
- Quality of life improves more in patients who undergo catheter ablation therapy than in those who continue on antiarrhythmic drugs (Evidence grade 2)*.
- □ The outcomes are better among patients with paroxysmal atrial fibrillation than among those with persistent atrial fibrillation (Evidence grade 3)*.
- Treatment with catheter ablation carries some risk for serious complications (Evidence grade 3)*.



Studies that have compared pharmacotherapy with ablation therapy are of medium or high quality, but offer limited information about long-term effects.

Findings from several randomized trials show that symptomatic atrial fibrillation occurs less often in patients that have undergone catheter ablation therapy than in those treated with antiarrhythmic drugs. Quality of life is more favourably affected by ablation than by drugs.

Treatment results are better among patients with paroxysmal atrial fibrillation than among those with persistent atrial fibrillation.

Serious complications occur in 4–5 percent of patients treated by catheter ablation. The most serious complication following ablation in the posterior wall of the left atrium involves development of a fistula between the left atrium and the esophagus. Other serious complications are cardiac tamponade, thromboembolism, pulmonary vein stenosis, and permanent damage to structures adjacent to the left atrium, eg, the phrenic nerve.

Ethical aspects

Catheter ablation therapy can markedly improve health and quality of life in patients with pronounced symptoms and who cannot be treated effectively with drugs. The procedure carries some risk for serious complications. Hence, it is important that patients who are candidates for treatment receive comprehensive and objective information concerning the risks and the expected benefits of the method.

Economic aspects

The scientific evidence is insufficient* for drawing conclusions about the cost-effectiveness of the method since its long-term effects are uncertain.

The cost of the procedure is estimated at approximately 85 000 Swedish kronor (SEK), including examinations and 2 to 4 days of hospitalization. To achieve its intended effects, the procedure may need to be repeated. Economic analyses suggest that catheter ablation can be a cost-effective treatment method in patients where antiarrhythmic agents have not yielded the desired effects. However, there is some uncertainty concerning the extent to which the positive effects on patients' quality of life continue over the long-term.

* Criteria for evidence grading SBU's conclusions

Evidence grade 1 – Strong scientific evidence. The conclusion is corroborated by at least two independent studies with high quality, or a good systematic overview.

Evidence grade 2 – Moderately strong scientific evidence. The conclusion is corroborated by one study with high quality, and at least two studies with medium quality.

Evidence grade 3 – Limited scientific evidence. The conclusion is corroborated by at least two studies with medium quality.

Insufficient scientific evidence – No conclusions can be drawn when there are not any studies that meet the criteria for quality.

Contradictory scientific evidence – No conclusions can be drawn when there are studies with the same quality whose findings contradict each other.



Project group

- Carina Blomström Lundqvist, Professor, Department of Cardiology, Uppsala University Hospital, Uppsala
- Jan Liliemark, Professor, Project Manager, SBU, liliemark@sbu.se
- Ingemar Eckerlund, Health Economist, Project Manager, SBU
- SBU Staff: Karin Rydin, Literature Searcher, Lena Wallgren, Project Assistant, Madelene Lusth Sjöberg, Project Assistant

Scientific reviewers

- Jonas Schwieler, Associate Professor, Department of Cardiology, Karolinska University Hospital, Stockholm
- Thomas Mooe, Associate Professor, Cardiology Unit, Östersund Hospital, Östersund

References

Our conclusions are based on the studies listed below. For a complete list of references used in the report see www.sbu.se/201006e.

- Dagres N, Varounis C, Flevari P, Piorkowski C, Bode K, Rallidis LS, et al. Mortality after catheter ablation for atrial fibrillation compared with antiarrhythmic drug therapy. A meta-analysis of randomized trials. Am Heart J 2009;158(1):15-20.
- 23. Pappone C, Augello G, Sala S, Gugliotta F, Vicedomini G, Gulletta S, et al. A randomized trial of circumferential pulmonary vein ablation versus antiarrhythmic drug therapy in paroxysmal atrial fibrillation: the APAF Study. J Am Coll Cardiol 2006;48(11):2340-7.
- 24. Wazni OM, Marrouche NF, Martin DO, Verma A, Bhargava M, Saliba W, et al. Radiofrequency ablation vs antiarrhythmic drugs as first-line treatment of symptomatic atrial fibrillation: a randomized trial. JAMA 2005;293(21):2634-40.
- 25. Wilber DJ, Pappone C, Neuzil P, De Paola A, Marchlinski F, Natale A, et al. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. JAMA 2010;303(4):333-40.
- 26. Oral H, Pappone C, Chugh A, Good E, Bogun F, Pelosi F Jr, et al. Circumferential pulmonary-vein ablation for chronic atrial fibrillation. N Engl J Med 2006;354(9):934-41.
- 27. Forleo GB, Mantica M, De Luca L, Leo R, Santini L, Panigada S, et al. Catheter ablation of atrial fibrillation in patients with diabetes mellitus type 2: results from a randomized study comparing pulmonary vein isolation versus antiarrhythmic drug therapy. J Cardiovasc Electrophysiol 2009;20(1):22-8.
- 28. Krittayaphong R, Raungrattanaamporn O, Bhuripanyo K, Sriratanasathavorn C, Pooranawattanakul S, Punlee K, et al. A randomized clinical trial of the efficacy of radiofrequency catheter ablation and amiodarone in the treatment of symptomatic atrial fibrillation. J Med Assoc Thai 2003;86(Suppl 1):8-16.
- 29. Stabile G, Bertaglia E, Senatore G, De Simone A, Zoppo F, Donnici G, et al. Catheter ablation treatment in patients with drug-refractory atrial fibrillation: a prospective, multi-centre, randomized, controlled study (Catheter Ablation For The Cure Of Atrial Fibrillation Study). Eur Heart J 2006;27(2):216-21.
- 30. Nair GM, Nery PB, Diwakaramenon S, Healey JS, Connolly SJ, Morillo CA. A systematic review of randomized trials comparing radiofrequency ablation with antiarrhythmic medications in

patients with atrial fibrillation. J Cardiovasc Electrophysiol 2009;20(2):138-44.

- Noheria A, Kumar A, Wylie JV Jr, Josephson ME. Catheter ablation vs antiarrhythmic drug therapy for atrial fibrillation: a systematic review. Arch Intern Med 2008;168(6):581-6.
- 32. Piccini JP, Lopes RD, Kong MH, Hasselblad V, Jackson K, Al-Khatib SM. Pulmonary vein isolation for the maintenance of sinus rhythm in patients with atrial fibrillation: a meta-analysis of randomized, controlled trials. Circ Arrhythm Electrophysiol 2009;2(6):626-33.
- 33. Rodgers M, McKenna C, Palmer S, Chambers D, Van Hout S, Golder S, et al. Curative catheter ablation in atrial fibrillation and typical atrial flutter: systematic review and economic evaluation. Health Technol Assess 2008;12(34):iii-iv, xi-xiii, 1-198.
- 34. Terasawa T, Balk EM, Chung M, Garlitski AC, Alsheikh-Ali AA, Lau J, et al. Systematic review: comparative effectiveness of radiofrequency catheter ablation for atrial fibrillation. Ann Intern Med 2009;151(3):191-202.
- 35. Calkins H, Reynolds MR, Spector P, Sondhi M, Xu Y, Martin A, et al. Treatment of atrial fibrillation with antiarrhythmic drugs or radiofrequency ablation: two systematic literature reviews and meta-analyses. Circ Arrhythm Electrophysiol 2009;2(4):349-61.
- 36. Bhargava M, Di Biase L, Mohanty P, Prasad S, Martin DO, Williams-Andrews M, et al. Impact of type of atrial fibrillation and repeat catheter ablation on long-term freedom from atrial fibrillation: results from a multicenter study. Heart Rhythm 2009;6(10):1403-12.
- 38. Nademanee K, Schwab MC, Kosar EM, Karwecki M, Moran MD, Visessook N, et al. Clinical outcomes of catheter substrate ablation for high-risk patients with atrial fibrillation. J Am Coll Cardiol 2008;51(8):843-9.
- 39. Oral H, Chugh A, Yoshida K, Sarrazin JF, Kuhne M, Crawford T, et al. A randomized assessment of the incremental role of ablation of complex fractionated atrial electrograms after antral pulmonary vein isolation for long-lasting persistent atrial fibrillation. J Am Coll Cardiol 2009;53(9):782-9.
- 76. Della Bella P, Fassini G, Cireddu M, Riva S, Carbucicchio C, Giraldi F, et al. Image integration-guided catheter ablation of atrial fibrillation: a prospective randomized study. J Cardiovasc Electrophysiol 2009;20(3):258-65.
- 77. Wang XH, Liu X, Sun YM, Shi HF, Zhou L, Gu JN. Pulmonary vein isolation combined with superior vena cava isolation for atrial fibrillation ablation: a prospective randomized study. Europace 2008;10(5):600-5.
- 78. Fiala M, Chovancik J, Nevralova R, Neuwirth R, Jiravsky O, Nykl I, et al. Pulmonary vein isolation using segmental versus electroanatomical circumferential ablation for paroxysmal atrial fibrillation: over 3-year results of a prospective randomized study. J Interv Card Electrophysiol 2008;22(1):13-21.
- 79. Sheikh I, Krum D, Cooley R, Dhala A, Blanck Z, Bhatia A, et al. Pulmonary vein isolation and linear lesions in atrial fibrillation ablation. J Interv Card Electrophysiol 2006;17(2):103-9.
- 80. Fassini G, Riva S, Chiodelli R, Trevisi N, Berti M, Carbucicchio C, et al. Left mitral isthmus ablation associated with PV Isolation: long-term results of a prospective randomized study. J Cardiovasc Electrophysiol 2005;16(11):1150-6.
- 81. Gaita F, Caponi D, Scaglione M, Montefusco A, Corleto A, Di Monte F, et al. Long-term clinical results of 2 different ablation strategies in patients with paroxysmal and persistent atrial fibrillation. Circ Arrhythm Electrophysiol 2008;1(4):269-75.
- 82. Arentz T, Weber R, Burkle G, Herrera C, Blum T, Stockinger J, et al. Small or large isolation areas around the pulmonary veins for the treatment of atrial fibrillation? Results from a prospective randomized study. Circulation 2007;115(24):3057-63.
- 83. Nilsson B, Chen X, Pehrson S, Kober L, Hilden J, Svendsen JH. Recurrence of pulmonary vein conduction and atrial fibrillation after pulmonary vein isolation for atrial fibrillation: a randomized trial of the ostial versus the extraostial ablation strategy. Am Heart J 2006;152(3):537 e1-8.
- 84.Di Biase L, Elayi CS, Fahmy TS, Martin DO, Ching CK, Barrett C, et al. Atrial fibrillation ablation strategies for paroxysmal patients:



randomized comparison between different techniques. Circ Arrhythm Electrophysiol 2009;2(2):113-9.

- 85. Elayi CS, Verma A, Di Biase L, Ching CK, Patel D, Barrett C, et al. Ablation for longstanding permanent atrial fibrillation: results from a randomized study comparing three different strategies. Heart Rhythm 2008;5(12):1658-64.
- 86. Willems S, Klemm H, Rostock T, Brandstrup B, Ventura R, Steven D, et al. Substrate modification combined with pulmonary vein isolation improves outcome of catheter ablation in patients with persistent atrial fibrillation: a prospective randomized comparison. Eur Heart J 2006;27(23):2871-8.
- 87. Calò L, Lamberti F, Loricchio ML, De Ruvo E, Colivicchi F, Bianconi L, et al. Left atrial ablation versus biatrial ablation for persistent and permanent atrial fibrillation: a prospective and randomized study. J Am Coll Cardiol 2006;47(12):2504-12.
- 88. Oral H, Chugh A, Good E, Igic P, Elmouchi D, Tschopp DR, et al. Randomized comparison of encircling and nonencircling left atrial ablation for chronic atrial fibrillation. Heart Rhythm 2005;2(11):1165-72.

SBU evaluates healthcare technology

The Swedish Council on Health Technology Assessment (SBU) is a national governmental agency that assesses healthcare technologies. SBU analyzes the benefits, risks, and costs of different methods and compares the scientific facts to prevailing practices in Sweden. SBU's goal is to provide stronger evidence for everyone engaged in shaping the delivery of health services.

The SBU Alert reports are produced in collaboration with experts from the respective subject areas, the National Board of Health and Welfare, the Medical Products Agency, the Swedish Association of Local Authorities and Regions, and a special advisory panel (the Alert Advisory Board).

This assessment was published in 2010. Findings based on strong scientific evidence usually continue to apply well into the future. However, findings based on insufficient, limited, or contradictory evidence might have already been replaced by more recent findings.

The complete report is available in Swedish.

The Alert Advisory Board

Jan-Erik Johansson, Chairman, Professor Christel Bahtsevani, PhD Lars Borgquist, Professor Bo Carlberg, Associate Professor Jane Carlsson, Professor Per Carlsson, Professor Björn-Erik Erlandsson, Professor Mårten Fernö, Professor Stefan Jutterdal, Director of Improvement Viveca Odlind, Professor Anders Rydh, Associate Professor Anders Tegnell, PhD Jan Wahlström, Professor Emeritus Anna Åberg Wistedt, Professor

SBU Board Subcommittee

Susanna Axelsson, David Bergqvist, Håkan Ceder, Tove Hellerström, Jan Liliemark, Nina Rehnqvist, Måns Rosén, Ewalotte Ränzlöv, Juliette Säwe

Publisher: Måns Rosén, Director, SBU Program Manager: Jan Liliemark, SBU Graphic Production: Elin Rye-Danjelsen, SBU

4