



Catheter Ablation of Atrial Fibrillation

SBU ALERT REPORT NO 2005-02 • 2005-02-02 • WWW.SBU.SE/ALERT



Summary and Conclusions

TECHNOLOGY AND TARGET GROUP Atrial fibrillation is a cardiac arrhythmia, characterized by uncoordinated atrial activation with consequent deterioration of atrial mechanical function, and associated with an irregular, frequently rapid ventricular response. Atrial fibrillation is the most common rhythm disturbance. It is associated with impaired heart function and an increased risk for thromboembolic events. Antiarrhythmic drugs for maintenance of sinus rhythm or heart rate control may be effective in many patients. In patients suffering from highly symptomatic atrial fibrillation despite pharmacological treatment, other interventions may be necessary. Catheter ablation therapy is a new treatment option that involves several different techniques. Heat energy is delivered, via a catheter, to the area of the left atrium, or around the pulmonary veins that are involved in generating or maintaining atrial fibrillation. Since complication rates increase with age, and since experience in treating patients over 70 years of age is limited, the method is primarily intended for individuals below 70 years of age. In Sweden, the potential target group for this method is estimated to include approximately 850 patients per year.

PRIMARY QUESTION How effective is catheter ablation therapy in curing atrial fibrillation?

PATIENT BENEFIT The studies currently available are non-randomised, and are of low quality. Treatment results reported by these studies vary widely. This can partly be explained by differences with respect to patient selection, type of atrial fibrillation, applied method, catheterization experience, criteria for treatment effects, and follow-up time. Results from the only controlled (but not randomized) study showed lower morbidity and mortality among patients who had undergone catheter ablation therapy compared to those treated with medication. Quality of life

was influenced more favorably following ablation therapy. Catheter ablation for atrial fibrillation was less effective in patients with persistent than in those with paroxysmal atrial fibrillation. Catheter ablation therapy is associated with risks for serious complications, mainly pulmonary vein stenosis and injury to adjacent structures behind the left atrium, eg, the esophagus.

ETHICAL ASPECTS Patients with severe symptoms comprise the current target group for catheter ablation therapy. It is extremely important for these patients to receive complete information about the most recent evidence on the effects and risks of treatment.

ECONOMIC ASPECTS The cost of the procedure has been estimated at approximately 85 000 Swedish kronor (SEK). To achieve the intended effect, it may be necessary to repeat the procedure, which increases the total average cost per treated patient. Health economic assessments addressing the cost-effectiveness of this method are not available.

SBU's appraisal of the evidence

The method remains in the development phase. There is insufficient scientific evidence for drawing conclusions about benefits for patients and the method's cost-effectiveness (Evidence grade 4)*. Results from randomized controlled trials are necessary to assess fully the positive and negative effects of the method and its cost-effectiveness.

**Grading of the level of scientific evidence for conclusions. The grading scale includes four levels; Evidence grade 1 = strong scientific evidence, Evidence grade 2 = moderately strong scientific evidence, Evidence grade 3 = limited scientific evidence, Evidence grade 4 = insufficient scientific evidence.*

References

- Go AS, Hylek EM, Phillips KA, Chang Y, Henault LE, Selby JV et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. *JAMA* 2001;285(18):2370-5.
- Benjamin EJ, Levy D, Vaziri SM, D'Agostino RB, Belanger AJ, Wolf PA. Independent risk factors for atrial fibrillation in a population-based cohort. The Framingham Heart Study. *JAMA* 1994;271(11):840-4.
- Lönnnerholm S, Blomström P, Nilsson L, Oxelbark S, Jideus L, Blomström-Lundqvist C. Effects of the maze operation on health-related quality of life in patients with atrial fibrillation. *Circulation* 2000;101(22):2607-11.
- Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke* 1991;22(8):983-8.
- Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz H, Kannel WB, Levy D. Impact of atrial fibrillation on the risk of death: the Framingham Heart Study. *Circulation* 1998;98(10):946-52.
- Schwartzman D, Bazaz R, Nossbisch J. Catheter ablation to suppress atrial fibrillation: evolution of technique at a single center. *J Interv Card Electrophysiol* 2003;9(2):295-300.
- Marchlinski FE, Callans D, Dixit S, Gerstenfeld EP, Rho R, Ren JF et al. Efficacy and safety of targeted focal ablation versus PV isolation assisted by magnetic electroanatomic mapping. *J Cardiovasc Electrophysiol* 2003;14(4):358-65.
- Pappone C, Oreto G, Rosanio S, Vicedomini G, Tocchi M, Gugliotta F et al. Atrial electroanatomic remodeling after circumferential radiofrequency pulmonary vein ablation: efficacy of an anatomic approach in a large cohort of patients with atrial fibrillation. *Circulation* 2001;104(21):2539-44.
- Nademanee K, McKenzie J, Kosar E, Schwab M, Sunsaneewitayakul B, Vasavakul T et al. A new approach for catheter ablation of atrial fibrillation: mapping of the electrophysiologic substrate. *J Am Coll Cardiol* 2004;43(11):2044-53.
- Bhargava M, Marrouche NF, Martin DO, Schweikert RA, Saliba W, Saad EB et al. Impact of age on the outcome of pulmonary vein isolation for atrial fibrillation using circular mapping technique and cooled-tip ablation catheter. *J Cardiovasc Electrophysiol* 2004;15(1):8-13.
- Stewart S, Hart CL, Hole DJ, McMurray JJ. Population prevalence, incidence, and predictors of atrial fibrillation in the Renfrew/Paisley study. *Heart* 2001;86(5):516-21.
- Benjamin EJ, Levy D, Vaziri SM, D'Agostino RB, Belanger AJ, Wolf PA. Independent risk factors for atrial fibrillation in a population-based cohort. The Framingham Heart Study. *JAMA* 1994;271(11):840-4.
- Gronefeld G, Bender B, Li YG, Hohnloser SH. Pharmacological therapy of atrial fibrillation. *Thorac Cardiovasc Surg* 1999;47 Suppl 3:334-8. Review.
- Cox JL, Schuessler RB, Lappas DG, Boineau JP. An 8 1/2-year clinical experience with surgery for atrial fibrillation. *Ann Surg* 1996;224(3):267-73.
- Wood MA, Brown-Mahoney C, Kay GN, Ellenbogen KA. Clinical outcomes after ablation and pacing therapy for atrial fibrillation: a meta-analysis. *Circulation* 2000;101(10):1138-44.
- Brignole M, Gianfranchi L, Menozzi C, Alboni P, Musso G, Bongiorni MG et al. Assessment of atrioventricular junction ablation and DDDR mode-switching pacemaker versus pharmacological treatment in patients with severely symptomatic paroxysmal atrial fibrillation: a randomized controlled study. *Circulation* 1997;96(8):2617-24.
- Wellens HJ, Lau CP, Luderitz B, Akhtar M, Waldo AL, Camm AJ et al. Atrioverter: an implantable device for the treatment of atrial fibrillation. *Circulation* 1998;98(16):1651-6.
- Pappone C, Rosanio S, Augello G, Gallus G, Vicedomini G, Mazzone P et al. Mortality, morbidity, and quality of life after circumferential pulmonary vein ablation for atrial fibrillation: outcomes from a controlled nonrandomized long-term study. *J Am Coll Cardiol* 2003;42(2):185-97.
- Deisenhofer I, Schneider MA, Bohlen-Knauf M, Zrenner B, Ndrepepa G, Schmieder S et al. Circumferential mapping and electric isolation of pulmonary veins in patients with atrial fibrillation. *Am J Cardiol* 2003;91(2):159-63.
- Oral H, Knight BP, Tada H, Ozaydin M, Chugh A, Hassan S et al. Pulmonary vein isolation for paroxysmal and persistent atrial fibrillation. *Circulation* 2002;105(9):1077-81.
- Haissaguerre M, Shah DC, Jais P, Hocini M, Yamane T, Deisenhofer II et al. Mapping-guided ablation of pulmonary veins to cure atrial fibrillation. *Am J Cardiol* 2000;86(9 Suppl 1):K9-K19.
- Ernst S, Antz M, Ouyang F, Vogtmann T, Goya M, Bansch D et al. Ostial PV isolation: is there a role for three-dimensional mapping? *Pacing Clin Electrophysiol* 2003;26(7 Pt 2):1624-30.
- Saad EB, Marrouche NF, Saad CP, Ha E, Bash D, White RD et al. Pulmonary vein stenosis after catheter ablation of atrial fibrillation: emergence of a new clinical syndrome. *Ann Intern Med* 2003;138(8):634-8.
- Marrouche NF, Martin DO, Wazni O, Gillinov AM, Klein A, Bhargava M et al. Phased-array intracardiac echocardiography monitoring during pulmonary vein isolation in patients with atrial fibrillation: impact on outcome and complications. *Circulation* 2003;107(21):2710-6.
- Hsieh MH, Tai CT, Tsai CF, Lin WS, Lin YK, Tsao HM et al. Clinical outcome of very late recurrence of atrial fibrillation after catheter ablation of paroxysmal atrial fibrillation. *J Cardiovasc Electrophysiol* 2003;14(6):598-601.
- Chen MS, Marrouche NF, Khaykin Y, Gillinov AM, Wazni O, Martin DO et al. Pulmonary vein isolation for paroxysmal atrial fibrillation in patients with impaired systolic function. *J Am Coll Cardiol* 2004;43(6):1004-9.
- Tada H, Naito S, Kurosaki K, Ueda M, Ito S, Shinbo G et al. Segmental pulmonary vein isolation for paroxysmal atrial fibrillation improves quality of life and clinical outcomes. *Circ J* 2003;67(10):861-5.
- Stabile G, Turco P, La Rocca V, Nocerino P, Stabile E, De Simone A. Is pulmonary vein isolation necessary for curing atrial fibrillation? *Circulation* 2003;108(6):657-60.
- Pappone C, Santinelli V, Manguso F, Vicedomini G, Gugliotta F, Augello G et al. Pulmonary vein denervation enhances long-term benefit after circumferential ablation for paroxysmal atrial fibrillation. *Circulation* 2004;109(3):327-34.
- Knight BP, Oral H, Chugh A, Scharf C, Lai SW, Pelosi F Jr et al. Effects of operator experience on the outcome and duration of pulmonary vein isolation procedures for atrial fibrillation. *Am J Cardiol* 2003;91(6):673-7.
- Marrouche NF, Dresing T, Cole C, Bash D, Saad E, Balaban K et al. Circular mapping and ablation of the pulmonary vein for treatment of atrial fibrillation: impact of different catheter technologies. *J Am Coll Cardiol* 2002;40(3):464-74.
- Tse HF, Reek S, Timmermans C, Lee KL, Geller JC, Rodriguez LM et al. Pulmonary vein isolation using transvenous catheter cryoablation for treatment of atrial fibrillation without risk of pulmonary vein stenosis. *J Am Coll Cardiol* 2003;42(4):752-8.
- Oral H, Scharf C, Chugh A, Hall B, Cheung P, Good E et al. Catheter ablation for paroxysmal atrial fibrillation: segmental pulmonary vein ostial ablation versus left atrial ablation. *Circulation* 2003;108(19):2355-60.
- Saad EB, Rossillo A, Saad CP, Martin DO, Bhargava M, Erciyes D et al. Pulmonary vein stenosis after radiofrequency ablation of atrial fibrillation: functional characterization, evolution, and influence of the ablation strategy. *Circulation* 2003;108(25):3102-7.
- Ernst S, Ouyang F, Goya M, Lober F, Schneider C, Hoffmann-Riem M et al. Total pulmonary vein occlusion as a consequence of catheter ablation for atrial fibrillation mimicking primary lung disease. *J Cardiovasc Electrophysiol* 2003;14(4):366-70.
- Nilsson B, Chen X, Pehrson S, Jensen HL, Sondergaard L, Helvind M et al. Acute fatal pulmonary vein occlusion after catheter ablation of atrial fibrillation. *J Interv Card Electrophysiol* 2004;11(2):127-30.
- Pappone C, Oral H, Santinelli V, Vicedomini G, Lang CC, Manguso F et al. Atrio-esophageal fistula as a complication of percutaneous transcatheter ablation of atrial fibrillation. *Circulation* 2004;109(22):2724-6.
- Stewart S, Murphy N, Walker A, McGuire A, McMurray JJ. Cost of an emerging epidemic: an economic analysis of atrial fibrillation in the UK. *Heart* 2004;90(3):286-92.
- Weerasooriya R, Jais P, Le Heuzey JY, Scavee C, Choi KJ, Macle L et al. Cost analysis of catheter ablation for paroxysmal atrial fibrillation. *Pacing Clin Electrophysiol* 2003;26(1 Pt 2):292-4.

SBU – The Swedish Council on Technology Assessment in Health Care

SBU is an independent public authority which has the mandate of the Swedish Government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. SBU Alert is a system for identification and early assessment of new methods in health care.

P.O. Box 5650, SE-114 86 Stockholm, Sweden • alert@sbu.se

This summary is based on a report prepared at SBU in collaboration with:

- Prof. **Carina Blomström Lundqvist** (expert), Uppsala University Hospital, Uppsala,
- Prof. **Lennart Bergfeldt** (reviewer), Sahlgrenska University Hospital, Göteborg

The complete report is available only in Swedish.