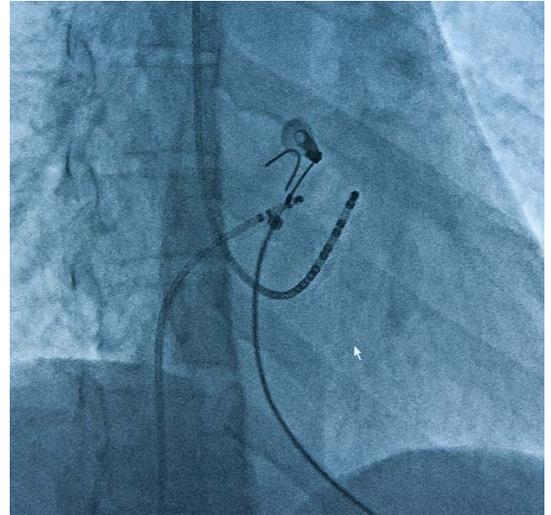


# EFFICACY AND SAFETY OF CATHETER ABLATION FOR PEOPLE WITH NON-PAROXYSMAL ATRIAL FIBRILLATION

- Original Publication: Nyong J, Amit G, Adler AJ, Owolabi OO, Perel P, Prieto-Merino D, Lambiase P, Casas JP, Morillo CA. Efficacy and safety of ablation for people with non-paroxysmal atrial fibrillation. *Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD012088
- This KCE has read for you was prepared by Chris De Laet and Patriek Mistiaen
- Published on 12 December 2017

## KEY MESSAGES FROM THE ORIGINAL PUBLICATION

- ➔ In people with non-paroxysmal atrial fibrillation evidence suggests the superiority of catheter ablation to antiarrhythmic drugs in achieving freedom from atrial arrhythmias, reducing the need for cardioversion, and reducing cardiac-related hospitalisations, at 12 months.
- ➔ This evidence should be interpreted with caution as the number of participants and event rates are low and therefore quality of evidence ranges from moderate to very low .
- ➔ There is no conclusive evidence about adverse events such as significant bradycardia (with need for a pacemaker), periprocedural complications and other safety outcomes. There is equally no evidence on other endpoints such as mortality, major adverse cardiac events, quality of life, risk of stroke or risk of embolic events .
- ➔ There is no evidence on long-term efficacy (> one year)



## SUMMARY OF THE ORIGINAL PUBLICATION

### Context

Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. This causes symptoms such as dizziness, shortness of breath, and tiredness that affect quality of life. Even more importantly, AF increases the risk of embolic events and suffering a stroke.

In the majority of people, AF is intermittent and progresses from self-terminating short episodes (paroxysmal, lasting no longer than 7 days) to longer episodes (non-paroxysmal). AF can also progress into a permanent form.

Management of AF includes control of symptoms and reducing the risk of embolic events and stroke. One strategy to achieve this is to restore and maintain a normal heart rhythm by using medication. Medical procedures of ablation by catheter or surgery were developed to treat patients with a suboptimal response to such medication. Catheter ablation involves sclerosing the tissue that causes the irregular heartbeat in a targeted manner by applying heat (radiofrequency ablation) or cold (cryoablation).

### Method

The aim of this systematic Cochrane review was to compare the benefits and harms of ablation to antiarrhythmic medication in people with non-paroxysmal AF. Although both catheter and surgical ablation were searched for, the three included trials all concern Radiofrequency Catheter Ablation.

Main outcomes are freedom from atrial arrhythmias, need for cardioversion and

cardiac-related hospitalisation after 12 months.

Several bibliographic databases were searched for publications up to April 1st 2016. The quality of the included RCTs was appraised using the Cochrane risk of bias assessment tool. The level of evidence was assessed using the GRADE tool.

### What is KCE has read for you?

KCE has read for you synthesises a recently published high-quality systematic review or health technology assessment with relevance for the Belgian health system.

The original publication was appraised and contextualised by KCE researchers.

KCE has read for you is not based on original research conducted by KCE.

More details on methodology can be found on the KCE website



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### This document includes:



- **Key findings** of the publication under evaluation
- **A contextualisation** within the Belgian healthcare system

### Not included:



- Recommendations
- Detailed descriptions

### Trustworthy original publication



The methodological quality of the systematic review was assessed with the AMSTAR tool.



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## Results

### Included studies

Three randomised trials are included comparing Radiofrequency Catheter Ablation (RFCA) (n = 159) to antiarrhythmic drugs (n = 102) for the treatment of non-paroxysmal AF. Generally, the included studies are assessed as having low or unclear risk of bias across multiple domains with reported outcomes generally lacking precision due to low participant numbers and event rates.

### Efficacy

Evidence shows RFCA to be superior to antiarrhythmic drugs in achieving freedom from atrial arrhythmias (RR=1.84; 95% CI: 1.17 to 2.88; low-quality evidence), reducing the need for cardioversion (RR=0.62; 95% CI: 0.47 to 0.82; moderate-quality evidence), and reducing cardiac-related hospitalisation (RR=0.27; 95% CI: 0.10 to

0.72; low-quality evidence) at one-year follow-up. No evidence on all-cause mortality, fatal or non-fatal stroke, any embolic events, major adverse cardiac events and health-related quality of life is reported.

### Adverse events

There is no conclusive evidence on the effect of RFCA compared to antiarrhythmic drugs regarding significant bradycardia with need for a pacemaker (RR=0.20; 95%CI: 0.02 to 1.63; low-quality evidence from only one RCT) or periprocedural complications and other safety outcomes (RR=0.94, 95% CI: 0.16 to 5.68; very low-quality evidence)

## Conclusion

In people with non-paroxysmal AF the one-year evidence suggests a superiority of RFCA to antiarrhythmic drugs in soft endpoints such as achieving freedom from atrial arrhythmias, reducing the need for cardioversion, and reducing cardiac-related hospitalisations. There

is large uncertainty surrounding adverse events. Evidence should be interpreted with caution, as event rates are low and quality of evidence ranges from moderate to very low. No evidence on the longer term or on hard endpoints is available.

## KCE VIEWPOINT

### Quality of the publication

Two KCE researchers independently appraised the quality of this review using the AMSTAR tool. The score obtained by the review is 10/11 which is very good. However, the resulting evidence should be interpreted with caution as evidence quality ranged from moderate to very low across the different outcomes due to the limitations of the three original RCTs (total n=261). Moreover, one of the RCTs also included patients with paroxysmal AF.

This review includes one recent RCT from 2014 (Mont) including 146 patients with non-paroxysmal (persistent) AF not included in a previous KCE report (report KCE 184). This RCT concludes that in non-paroxysmal AF the reoccurrence rates are lower in the ablation group after one year. The reoccurrence rates in intervention and control groups are within the ranges previously reported in the KCE report.

## REFERENCES

- Nyong J, Amit G, Adler AJ, Owolabi OO, Perel P, Prieto-Merino D, Lambiase P, Casas JP, Morillo CA. Efficacy and safety of ablation for people with non-paroxysmal atrial fibrillation. *Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD012088
- Mont L, Bisbal F, Hernández-Madrid A, Pérez-Castellano N, Viñolas X, Arenal A, et al: SARA Investigators. Catheter ablation vs. antiarrhythmic drug treatment of persistent atrial fibrillation: a multicentre, randomized, controlled trial (SARA study). *European Heart Journal* 2014;35(8): 501–7.
- Van Brabant H, Neyt M, Devos C. Catheter ablation of atrial fibrillation. *Health Technology Assessment (HTA)*. Brussels: Belgian Health Care Knowledge Centre (KCE). 2012. KCE Report 184C. D/2012/10.273/57. .

### Belgian context

In 2013 the KCE published a report on catheter ablation concerning both paroxysmal and non-paroxysmal AF and reported poor evidence on soft endpoints. This new review basically confirms the uncertainties surrounding the procedure. Still, no evidence beyond one year nor evidence on hard endpoints such as symptoms, mortality or risk of stroke is available.

Despite the lack of solid evidence on its long term impact on clinical endpoints, the use of catheter ablation for AF continues to increase in Belgium. Over time the yearly number of these procedures has increased from almost a thousand in 2008 to over two thousand in 2010 and it further increased to over five thousand in 2015. In 2009 the reimbursement for procedure and devices was € 8.5 million and this reimbursement increased to almost € 27 million in 2015.

#### What is the Cochrane Collaboration?

The Cochrane Collaboration is an international independent network of researchers, healthcare professionals and users of healthcare, carers, and people interested in health that aims to promote evidence-informed health decision making by producing systematic reviews.

#### What is GRADE?

GRADE (Grading of Recommendations Assessment, Development and Evaluation) offers a system for rating quality of evidence in, amongst other, systematic review.

More information on:

- [GRADE website](#)
- [the KCE Process book](#).

#### What is the Cochrane's tool for assessing risk of bias?

This Cochrane's tool for assessing risk of bias provides judgements made on six domains including randomisation sequence generation, allocation concealment methods, blinding (participants, personnel and outcome assessors), incomplete outcome data, selective outcome reporting, and any other relevant biases. For each domains, one of the following risk level can be attributed: low, unclear, or high risk.