

Providing information, support and access to
established, new or innovative treatments for Atrial Fibrillation

COMPLICATIONS OF ATRIAL FIBRILLATION ABLATION

Is catheter ablation safe?



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Glossary

Anti-arrhythmic drugs	Drugs used to restore/maintain the normal heart rhythm
Anticoagulant	Drugs which help to thin the blood
Arrhythmia	Heart rhythm disorder
Arrhythmia Nurse Specialist	A nurse who is trained in heart rhythm disorders
Atrial Fibrillation (AF)	Irregular heart rhythm
Cardiologist	A doctor who has specialised in the diagnosis and treatment of patients with a heart condition
Catheter ablation	A treatment which destroys a very small area inside the heart causing the AF
Electrophysiologist (EP)	A cardiologist who has specialised in heart rhythm disorders
Sinus rhythm	Normal rhythm of the heart

Introduction, definitions and general principles

In this section the potential complications that may occur during or after ablation for Atrial Fibrillation are discussed. Before listing and describing individual complications it is necessary to explore some important definitions.

The **safety** of catheter ablation refers to the **risks**, or complications, involved in the procedure. When deciding whether or not to undergo the ablation, the risks need to be balanced against the potential benefits. You may be prepared to undergo a 'high-risk' operation if the consequences of not having the operation are very severe or potentially fatal. If there is very little to be gained however, even the smallest risk may make a procedure unacceptable. When considering ablation for Atrial Fibrillation it should be remembered that the main, indeed only reason for undergoing the ablation is to improve your quality of life by reducing or abolishing symptoms that result from the Atrial Fibrillation. The amount of improvement you hope to get should be balanced against the likelihood of success, the number of ablation procedures that may need to be undertaken and the risk of complications that accompany each ablation procedure.

A **complication** is an additional medical problem that occurs as a direct or indirect result of the ablation procedure and is felt to be harmful. Complications may be described by how common or rare, mild or severe, benign or life-threatening they are. It is important to discuss potential complications when considering ablation as a treatment for Atrial Fibrillation as the risks involved need to be balanced against the benefits that could be gained. No procedure is completely free of complications and risk.

The **risk** of a complication is usually described as a percentage chance of it happening. These percentages are derived from a variety of sources. The main source of information is the publication in medical journals of large series of Atrial Fibrillation ablations, containing hundreds or thousands of patients, in which the complications from the procedures are listed. It should be remembered however, that an individual may have a higher or lower risk of particular complications than the general population due to personal factors such as age, weight, diabetes and cardiac health. The type of ablation procedure (of which there are a number of variations), the type of equipment used, the nature of the Atrial Fibrillation itself, the experience of the cardiologist and the institution may also influence the chance of a complication to a greater or lesser extent. Examples of complications of Atrial Fibrillation ablation include stroke (which is infrequent, may be mild or severe

and thus may be serious), bruising at the groin entry sites (common, usually mild, usually benign) and death (very rare and obviously severe and serious).

A **side effect** of Atrial Fibrillation ablation is a consequence other than the one for which the ablation procedure was intended. A side effect may not necessarily be regarded as a complication. An example of a side effect is post-operative chest discomfort during the first 48 hours after an ablation as a result of pericardial inflammation from the ablation burns. The chest pain is not unexpected as it is a natural consequence of the treatment, usually mild in nature and disappears after a few days treatment with simple pain killers. Another example could be the development of post-operative left Atrial Flutter, which is recognised to occur in a small proportion of patients in whom the fibrillation is abolished but the ablation lesions promote this other rhythm disturbance. Neither of these would be regarded as complications.

An **unexpected consequence** of Atrial Fibrillation ablation is a complication or side effect that is likely to have occurred as a result of the procedure, but has not previously been reported or identified as a potential risk. As it is unexpected, by definition it must be incredibly rare, has never happened previously, has not been reported in the medical literature, or has not previously been recognised to be a consequence of Atrial Fibrillation ablation. As a result, an unexpected consequence would not have been mentioned as a potential complication during the consent process prior to the ablation procedure. An example of an unintended consequence could be the discovery after treating a patient with persistent Atrial Fibrillation that once the Atrial Fibrillation is successfully abolished, the heart's natural pacemaker, the sinus node, does not function well and an artificial pacemaker implant is required. As it is well recognised that a significant proportion of patients undergoing ablation for Atrial Fibrillation need more than one ablation procedure (some eventually undergoing 2, 3 or even 4 procedures), the failure of the procedure to adequately control the arrhythmia is not classified as a complication.

When undertaking informed consent it is impossible and indeed inappropriate to mention every conceivable complication, adverse outcome, side effect or unexpected consequence of Atrial Fibrillation. It is the cardiologist's duty to mention complications that are either frequent and/or serious as part of the informed consent process. The majority of cardiologists will quote figures derived from national and international publications. Some institutions may be able to provide locally-derived information based upon their own track record.

What complications may occur and how are they treated?

Commonly reported and serious complications arising from Atrial Fibrillation ablation are known to include the following:

A **pericardial effusion** is a collection of fluid (usually blood) contained in the sack surrounding the heart. In the setting of an ablation it is usually the result of perforation of the heart muscle with subsequent bleeding into the space around the outside of the heart. It is most likely to occur during the time of the ablation procedure and is due to trauma from the wires or burns required to perform the ablation. The blood thinners used to prevent blood clot formation may also contribute to the bleeding risk. A rapid collection of blood around the heart can compress it and reduce its ability to pump effectively, causing a fall in blood pressure (**cardiac tamponade**).

During the ablation procedure, continuous blood pressure monitoring is used to alert the medical team to the possibility of tamponade. Small pericardial effusions may not cause any disturbance. The diagnosis is confirmed by performing an ultrasound scan (echocardiogram). Small effusions usually don't require treatment but if tamponade occurs urgent action is required. A small tube (pericardial drain) is inserted under the ribs and breast bone into the pericardial space to drain away the excess fluid. The drain may stay in for a day or so until the echocardiogram shows the blood has gone and there is no further bleeding. The drain may be uncomfortable, causing sharp chest pains, and painkillers are often required. The inflammation from the pericardial effusion may even provoke an attack of Atrial Fibrillation. Blood thinning medication is often withheld for a few days before being restarted.

Very rarely, if there is ongoing bleeding which does not stop, urgent open heart surgery is required to find the damage and repair it.

Pulmonary vein stenosis (PV stenosis) is a recognized complication associated with Atrial Fibrillation ablation. The PVs are blood vessels that drain blood into the left atrium from the lungs. Stenosis of the PVs means that the veins become abnormally narrowed as a result of the ablation treatment within the region of the pulmonary veins. One or more pulmonary veins need to be severely narrowed before symptoms are noticed. It was more common when the ablation technique involved burning inside the veins however modern techniques now involve burning in the atrium rather than the vein itself and the incidence of PV stenosis

has fallen. Typical symptoms of PV stenosis include breathlessness, cough and haemoptysis (coughing-up blood). The diagnosis is made using MRI or CT scans and nuclear perfusion scans. PV stenosis can be treated by a procedure called angioplasty where a small balloon is inflated in the vessel to reopen it.

Stroke is perhaps the most feared complication of ablation for Atrial Fibrillation. It occurs when the blood supply to the brain is affected, usually by a blood clot blocking a blood vessel, but may also be due to bleeding within the brain. The ablation procedure takes place in the left atrium, from which blood is pumped out of the heart directly to the brain and other vital organs. If the ablation causes a blood clot, debris or air bubble this may be pumped into the head and block a blood vessel. To minimize this risk great care is taken during the procedure and blood thinning medication (Heparin) is infused to reduce the risk of clot formation. Most cardiologists also thin the blood with Warfarin for a period of at least a few weeks after the ablation whilst the inflammation in the left atrium is settling down. The risk of stroke is possibly also affected by age, the extent of the ablation procedure and also the individual patient's other medical problems. As the brain is essential for all bodily functions, damage to it can be variable. The effects of a stroke may be very short-lived (if a complete recovery is made within 24 hours it is called a transient ischaemic attack or **TIA**); last for days or weeks before full recovery; leave a permanent disability or even cause death. The physical effects can manifest as visual problems, difficulty with speech, altered sensation or function in the limbs and in the worst cases, paralysis and coma. Strokes are diagnosed using CT or MRI brain scans and may be treated by specialist teams.

A **false femoral aneurysm** is when blood leaks out of an artery in the leg at the site of the needle puncture, but is contained by the surrounding tissue, creating a pouch. It usually happens within a day or two of the procedure and may be the result of straining or movement. The blood thinning required after an ablation may contribute to its occurrence. It is usually painful and a lump (which may feel pulsatile) can be found. Some of the blood will clot and dissolve, causing a dramatic bruise. The diagnosis is made by examining the puncture site and confirmed using an ultrasound scan.

Treatment varies depending on the extent of the leak. In some cases observation is sufficient, as the clot will reabsorb naturally. Occasionally

a radiologist or vascular surgeon will treat the problem by injecting Thrombin, a clot-forming drug, to seal the leak. Alternatively, surgical correction to sew up the hole may be required.

A **retroperitoneal bleed** is when there is a leak from the femoral artery that enters the area around the back and kidneys rather than around the groin. It causes pain, low blood pressure and may interfere with kidney function. Treatment usually involves blood transfusion and stopping blood-thinning medication. In severe cases, vascular surgery may be required.

Pneumothorax (collapsed lung), is caused by accumulation of air or gas in the pleural cavity around the outside of the lungs, which occurs as a result of injury during insertion of the tubes into the subclavian veins which lie under the collar bone. Many operators do not insert tubes into the subclavian veins, preferring to do everything from the femoral (leg) veins. Depending on the size of the pneumothorax, treatment varies from observation to insertion of a chest drain, which allows the lung to re-inflate.

An **atrio-oesophageal fistula** is when a hole occurs between the back wall of the left atrium and the oesophagus (food pipe), as a result of the heat of the ablation treatment. It is a very rare and extremely serious complication. Signs and symptoms appear a day to weeks after the ablation and are typically fever, chills, stroke, septic shock (collapse), haematemesis (vomiting blood) and unfortunately in most cases, death. The diagnosis is made using a CT scan or special X-ray. Treatment is difficult and often involves major chest surgery.

Phrenic nerve palsy The phrenic nerve controls the diaphragm, one of the important muscles involved in breathing. There are two phrenic nerves, one supplying each side of the diaphragm. On the right, the phrenic nerve runs down immediately in front of the pulmonary veins and may be damaged during catheter ablation of atrial fibrillation and this is known as phrenic nerve palsy. Phrenic nerve palsy is seen more commonly with cryoablation than radiofrequency ablation. During cryoablation of the right sided pulmonary veins, the function of the phrenic nerve is monitored continuously so that ablation can be stopped immediately if there are warning signs of phrenic nerve palsy. Phrenic nerve palsy usually causes some degree of breathlessness. The diagnosis is confirmed by a chest x-ray. There is no specific treatment for phrenic nerve palsy. In most cases recovery is complete but can take up to a year.

Source	Worldwide	California, USA	USA and Italy
Number of centres	181	1	3
Type of study	Survey	Case series	Case series
		High risk patients	Patients over 75 years old
Date started	Jan-95	Mar-00	Jan-01
Date finished	Dec-02	Feb-06	May-06
Number of procedures/patients in study	8,745 procedures	634 patients (1,064 procedures)	194 procedures 174 patients
Proportion paroxysmal	Unreported	40%	
Age	Unreported	67 +/- 12	77 +/- 6
% female	Unreported	33.00%	37%
Length of follow up	Unreported	863 days +/-605	9 months
Overall major complications	6.00%		3.61%
Stroke or transient ischaemic attack	0.77%	0.47%	
Stroke with persistent neurological problem	0.23%		1.55%
Pericardial effusion			
Pericardial effusion requiring drainage	1.22%	0.85%	0.00%
Access site complications	0.96%	1.22%	1.55%
Pulmonary vein stenosis	1.34%	0.00%	0.00%
Haemothorax	0.16%	0.00%	0.52%
Atrio-oesophageal fistula	0.00%	0.00%	0.00%
Death	0.05%	0.10%	0.00%
Other complications	Pneumothorax (0.02%), Aortic dissection (0.03%), Sepsis, Heart valve damage, Permanent diaphragmatic paralysis (0.1%)	Heart block (0.19%), pulmonary oedema (0.28%)	1 further stroke occurred 6 weeks after the procedure
Reference	Worldwide survey on the methods, efficacy, and safety of catheter ablation for human Atrial Fibrillation. Cappato et al. Circulation. 2005 Mar 8;111(9):1100-5.	Clinical Outcomes of Catheter Substrate Ablation for High-Risk Patients With Atrial Fibrillation. Nadamanee et a JACC 2008 Feb 51(8): 843-9	Efficacy, Safety, and Outcome of Atrial Fibrillation Ablation in Septuagenarians. Corrado et al. J Cardiovasc Electrophysiol August 2008, 19;807-811

Complication rates are either per procedure, or overall
Complications are included if they occur within 30 days of the procedure

Italy	Worldwide	John Hopkins Hospital,	Baltimore, USA Pennsylvania, USA
10	1	1	1
Real world study	Real world study	Real world study	Real world study
Apr-05	Jan-03	Feb-01	Nov-00
Oct-06	Dec-06	Jun-07	Jul-07
1,011 procedures	20,825 procedures	641 procedures	1,506 procedures (1,165 patients)
60%		54%	64%
57.9 +/- 10.2		57.2 +/- 11.1	55
26%	40.20%	22%	22.70%
30 days		30 days	3 months
3.90%	4.50%	5.00%	3.85%
0.50%	0.94%	1.09%	0.40%
0.40%	0.23%	0.47%	0.07%
1.40%			
0.60%	1.31%	1.25%	0.80%
1.20%		1.72%	1.59%
0.40%		0.16%	0.40%
0.10%		0.00%	0.00%
0.00%	0.20%	0.00%	0.07%
0.00%	0.15%	0.00%	0.00%
0.5% (Aortic root puncture, Complete heart block, Transient phrenic nerve palsy, pneumothorax)	pneumothorax (0.07%)	None reported	Transient phrenic nerve palsy (0.07%), Radiation burn (0.07%), Fluid overload (0.14%), Deep venous thrombosis (0.07%), Anaphylaxis(0.14%)
Early complications of pulmonary vein catheter ablation for Atrial Fibrillation: A multicenter prospective registry on procedural safety, Bertaglia et al. Heart Rhythm.2007 Oct;4(10):1265-71	Cappato R et al. Europe AF Meeting 2008	Complications of Catheter Ablation for Atrial Fibrillation: Incidence and Predictors. Spragg et al. J Cardiovasc Electrophysiol. 2008 May 5	Long-Term Clinical Efficacy and Risk of Catheter Ablation for Atrial Fibrillation in the Elderly. Zado et al. J Cardiovasc Electrophysiol. 2008 May 5

all per patient as detailed in the column for that patient.
procedure or directly attributable to complications of the procedure.

Death is fortunately a very rare complication of catheter ablation. It could potentially result from a number of mechanisms including stroke, cardiac tamponade, myocardial infarction (heart attack), aortic dissection or atrio-oesophageal fistula. Extremely rare drug reactions or anaesthetic complications are also a remote possibility.

What are the risks of me suffering a complication if I undergo ablation for Atrial Fibrillation?

Before most people agree to undergo an ablation they want to know what the chances are that they will suffer a complication so they can weigh up the risks and benefits of the procedure. Although it can be very difficult to find out the precise risks in your particular case, there is information available that helps to estimate the risk based on the incidence of previously reported complications. In this section we describe the various methods and sources you can look at to establish the risks of complications following ablation for Atrial Fibrillation and also some of the pitfalls in interpreting this data, particularly when using it to compare results from different centres. We also produce a table showing the reported risks of complications from a number of published studies by large institutions.

Places to look to find out the risk of complications following ablation:

1) Experience in your own hospital:

Your specialist will be able to tell you the frequency of complications in patients who have undergone ablation in their hospital. Many hospitals will also publish their results and complication rates on the Internet. Data from individual hospitals may sometimes be inaccurate for the following reasons.

a) Small numbers:

Many of the most serious complications occur rarely, perhaps affecting one patient in every one to two hundred patients. This means that one extra patient suffering a particular complication affects the statistics quite significantly. For example, if one hospital does 50 ablations in a year and no patients have a stroke, their complication rate is zero. If another, equally-good hospital does 50 ablations in a year and has 1 stroke, their complication rate is 2%, even though the difference between the two hospitals in that year is probably purely down to chance. The following year the situation may be reversed and thus over a 2 year period both hospitals have one patient with a stroke after 100 ablations and therefore

a 1% stroke rate. Thus any individual hospital's statistics for rare complications are more reliable when collected over many years and when a high number of ablations (e.g. more than 300) are taken into account. The few hospitals that do more than 2-300 Atrial Fibrillation ablations per year can provide the most reliable, up-to-date statistics.

b) Changing techniques and the learning curve:

The practice of ablation of Atrial Fibrillation is changing all the time as doctors learn more about the condition and get more experienced at performing ablation. This naturally leads to an improvement in outcomes over time ("the learning curve") and makes it difficult to rely on complication rates from procedures carried out even a few years ago. To further complicate the issue, as hospitals get better at doing procedures, they tend to carry them out in more difficult patients – those who have been in Atrial Fibrillation longest, those with other heart conditions, the very elderly or very overweight. These sicker or more challenging patients are at higher risk of complications and therefore skew the hospitals statistics, making them look worse than hospitals that may be less experienced but only choose to do procedures on very low risk patients.

c) Under reporting:

Hospitals can only report complications if they know about them. Most ablations for Atrial Fibrillation are performed at large hospitals that are referred patients from surrounding smaller district hospitals. If complications occur after a patient has been discharged they may be managed by the smaller hospital and thus the hospital where the ablation was performed might not be aware of the complication and it may not appear in their results.

d) Defining the complication:

The complications of an ablation can vary enormously in their severity. Often if they are mild they cause no symptoms at all and settle with no intervention – it is then difficult to know whether they should be counted as complications or not. Different hospitals or published reports may have different definitions of which complications to include in their results. This can lead to two equally good hospitals apparently having very different rates of complications. An example of this is the accumulation of fluid around the heart, called a pericardial effusion. Often this is extremely small, causes no trouble to the patient and is only detected by chance, disappearing without any treatment. In contrast, large pericardial effusions are much more serious (causing cardiac tamponade) and often

require immediate insertion of a drain into the space around the heart to allow it to continue to pump. When looking at a hospital's complication rate it is therefore important to try and distinguish between these two situations, however they are often reported as a single figure. In addition some hospitals carry out routine scans to look for this, whilst other hospitals will only perform scans if patients become unwell. This may lead to large differences in the number of small pericardial effusions detected by each hospital after AF ablations.

2) Case series and registries:

Many large centres or even groups of hospitals report their results in medical journals. These can be very helpful in showing us the risk of complications following ablations. By combining results from a number of hospitals, data on large numbers of patients allows us to get a good estimate of the real frequency of the less common but more severe complications (such as stroke and death) following ablation. It should be remembered however that these reports have many of the same problems as the data reported by individual hospitals described above.

It is also important to be aware of so called "reporting bias". This can take two forms and leads with the reported complication rate being lower than the "real world" complication rate. Firstly, those centres publishing series with the largest number of patients will often be the very biggest centres where the techniques for ablation were first developed. This means that the procedures will have been carried out by the most experienced electrophysiologists who might be expected to have the lowest complication rates. Secondly, hospitals and doctors are only likely to publish their results if they think they are impressive and show their hospital in a good light. If a hospital has more complications than expected they are less likely to contribute their data, even if this is purely the result of chance. In order to get round this, large registries and case series have been collected containing data from hundreds of hospitals. Unless reporting of complications is compulsory as part of a national or regional system these reports may still be inaccurate.

3) Published trials:

A large number of scientific studies are carried out each year into the ablation of Atrial Fibrillation. The results of these studies are often published in scientific journals. These reports will almost always include details of the number of complications experienced by the patients in the studies. The data from these published reports has a number of

advantages. Patients in studies are usually followed up extremely closely even after they have left hospital, so it is less likely that complications will be missed. All the patients in a particular study will in general have undergone ablation using a particular technique so the results are more specific to ablation performed in that way. Finally all published studies will have been peer-reviewed – expertly assessed by other experts from other centres prior to publication to ensure the data and conclusions are accurate and reasonable. The downsides of using randomised controlled trials to assess the risk of complications are firstly that most of these studies only involve small numbers, so it is very difficult to use them to assess the risk of rarer complications. Secondly, trials are usually performed using very specific techniques or equipment which may not be available or be used in most hospitals. Finally, most trials are performed by the most experienced centres that have performed the most ablations and are thus likely to have the fewest complications. It is important to understand whether risks quoted are per ablation procedure, or per patient (bearing in mind a significant proportion of patients undergo two or more ablation procedures over a period of time). The most important statistic is the risk of a complication occurring [per ablation procedure](#).

Other significant factors that affect risk

As described above, the risk of any particular complication is estimated by looking at large groups of patients and seeing how often a particular complication occurs. The percentage risk derived from this applies to that group, but patients are individuals. A particular individual's risk is significantly affected by their own characteristics, such as age, weight and comorbidities (other medical conditions including high blood pressure, diabetes, heart failure or previous stroke). Although a hospital may report its overall risk of stroke as 1%, that hospital may have performed 500 ablations; 400 in younger, healthy patients with only one having a stroke and 100 elderly patients with comorbidities, with 4 having strokes. The young patients have a 0.25% (1 in 400) stroke risk, the elderly a 4% (4 in 100) risk, but the overall risk in that hospital's series is 1% (5 in 500).

Conclusion

It can be challenging to give a precise risk of a particular complication to an individual undergoing ablation for Atrial Fibrillation. The best estimate

is taken by looking at a large published series of patients, an individual hospital's own record of complications and then modifying this risk, if appropriate, based on an individual's characteristics. We have summarized in a table form in the centre page some of the largest case series looking at the risk of complications following ablation for Atrial Fibrillation.

Summary

- The risk of suffering any major complication following ablation for Atrial Fibrillation is probably between 4 and 6% for all-comers.
- There is around a 1% risk of a stroke, although in around half the cases the symptoms resolve. The risk of stroke may be higher in older patients, i.e. those >65 years of age.
- The risk of significant narrowing of one of the veins draining into the heart from the lung (pulmonary stenosis) is between 0% and 1.5% but seems lower in more recent studies.
- The risk of bleeding around the heart requiring the insertion of a drain (cardiac tamponade) is between 0.5% and 2%.
- The risk of a problem with the arteries or veins in the groin which are used to place catheters in the heart is between 1% and 2%.
- The risk of death as a result of an ablation is about 0.1% or 1 in 1000 procedures.

Further information

Helpline: +44 (0) 1789 451837

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Telephone: 01789 451 837 Email: info@afa.org.uk

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PO Box 1219, Chew Magna, Bristol, BS40 8WB, UK

Tel: +44 (0)1789 451 837

Email: info@afa.org.uk



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Please remember these are general guidelines
and individuals should always discuss
their condition with their own doctor.

