DEGAM S1- procedure recommendation

**New oral anticoagulants**
(in non-valvular atrial fibrillation)

**Version 1.0 (July 2013)**

**Question of care:**

The standard for oral anticoagulation is the treatment with vitamin K antagonists (VKA)\(^1\). Recently, new agents, the so-called new oral anticoagulants (NOACs) have been approved for the indication of non-valvular atrial fibrillation\(^1\). There are varying recommendations and ratings concerning the use of the NOACs.

This recommendation and the following algorithm contain advice from the German Society of General Practice and Family Medicine (Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin, DEGAM) on the use of NOACs and is solely intended for use in outpatient care in general practitioners’ practices. This recommendation is meant to support general practitioners in making necessary decisions in daily practice. It does not claim to be comprehensive and is only valid until newer recommendations replace it.

Please check the DEGAM homepage for updates: [http://www.degam.de](http://www.degam.de).

This procedure recommendation refers solely to patients with non-valvular atrial fibrillation and an indication for long-term anticoagulation according to the CHADS\(_2\)- or CHA\(_2\)DS\(_2\)-VASc-Score.

**Chances and risks of NOAC:**

NOACs are a possible alternative for patients who are not eligible for VKA (see page 2). Coagulation monitoring is not necessary (and not possible).

Before and during the use of NOACs the renal function (creatinine clearance according to Cockcroft-Gault, [http://www.mcdmlc.com](http://www.mcdmlc.com)) should be monitored. The dose has to be adapted depending on the substance used and patient-specific comorbidities, as well as renal insufficiency, higher age, certain co-medications, low body weight, intestinal problems and/or a high risk for bleeding.

Indication, contra-indication, posology and warnings on the summary of product characteristics have to be taken into account.

Every patient with NOAC should receive a patient ID card, be informed about the risks of the therapy and the necessity of regular controls, as well be aware of the problem of a lacking anticoagulant.

**Statement:**

Overall in Germany, the DEGAM found no advantage in treating patients with atrial fibrillation (who can be treated with VKAs) with NOACs instead of VKAs as a prophylaxis of cardioembolic sequelae. Criticism of the three registration trials which are non-inferiority trials has to be taken seriously. Furthermore, the clinical relevance of an ascertained marginal risk-reduction\(^2\) – especially in patients who are well-managed and control their INR themselves – remains unclear.

There are unknown risks for patients with higher age, low body weight, polymedication, uncertain adherence, intake of anti-platelet agents and/or NSAID, multimorbidity, gastric- and bleeding disorders and an elevated risk of bleeding.

The lack of long-term experience in general use has to be taken into account. NOACs requires a higher attention.

Adverse events should be reported at the Drug Commission of the German Medical Association (Arzneimittelkommission der Deutschen Ärzteschaft, AkDA) [http://www.akda.de](http://www.akda.de).

**Further Information:**

note: link leads to the updated version 2.0: Sept. 2016


1. VKA: warfarin, phenprocoumon (Marcumar\(^*\)), acenocoumarol, phenoxyacin (Coumarin\(^*\))
2. NOAC: Factor Xa-inhibitor rivaroxaban (Xaravio\(^*\)) and apixaban (Eliquis\(^*\)) and the thrombin inhibitor dabigatran (Pradaxa\(^*\))
3. CHADS\(_2\)-Score (Congestive heart failure, hypertension, age \(>75\), diabetes mellitus, stroke were translated 2 points in the VKA population in a benefit assessment according to: 35sGSGV en 27.03.2013
4. Evidence for an additional benefit of apixaban in comparison to warfarin has been found.

**Oral anticoagulation in non-valvular atrial fibrillation**

![Diagram](http://www.degam.de)

<table>
<thead>
<tr>
<th>Therapy with NOAC has already started (with NOAC or VKA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOACs might be an option for patients who don't respond well to VKA, and have a higher risk for interactions. Are these conditions met?</td>
</tr>
<tr>
<td>yes</td>
</tr>
<tr>
<td>no</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Therapy with VKA has already started (with NOAC or VKA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a therapy with VKA been difficult in the past or is it reasonable that it might become difficult and/or is a regular control of the INR difficult? And/or is there a high-risk for food interactions or drug-drug interactions of VKA?</td>
</tr>
<tr>
<td>yes</td>
</tr>
<tr>
<td>no</td>
</tr>
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**NOACs**:

<table>
<thead>
<tr>
<th>NOACs</th>
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<tbody>
<tr>
<td>VKA indicated</td>
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<tr>
<td>NOAC indicated</td>
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</table>

**Recommendation**

- **NOAC**:
  - oral anticoagulant
  - NOAC: new oral anticoagulant

**VKA**:

- vitamin K antagonist

**INR**:

- international normalized ratio

**NOAC**:

- novel oral anticoagulant

**Primary indication**

- VKA: vitamin K antagonist

**Risk of bleeding**

- high risk of bleeding

**VKA indications**

- NOACs: good response to VKA - INR stabilly within target range - high risk of bleeding, high HAS-BLED-Score ([http://www.medcalc.com](http://www.medcalc.com)) >2 (caution missing anticoagulation) - bleeding under VKA in INR target range

**Further contraindications for NOAC**

- pregnancy, breastfeeding, children and adolescents, systemic anticoagulants, macrodilant anticoagulants, HIV protease inhibitors, dialysis, CrCl < 30 ml/min with Caucasian, else < 15 ml/min, high risk of bleeding

**A change from NOAC to VKA**

- should always be well reflected upon and planned. In principle, there is an elevated risk for bleeding and thromboembolism during the changeover period.

**Further Information:**

- [http://www.degam.de](http://www.degam.de)
- [http://www.akda.de](http://www.akda.de)
- [http://www.sign.ac.uk](http://www.sign.ac.uk)