Gwent guidance for patients started historically on AMIODARONE

Amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential major toxicity and its use requires monitoring both clinically and via laboratory testing.

NICE clinical guideline on atrial fibrillation (AF) CG 36 puts greater emphasis on rate rather than rhythm control and has clarified the place of amiodarone for persistent AF.

This document should enable clinicians to review patients currently prescribed amiodarone, assess suitability for continued therapy and undertake changes to optimise treatment.

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**NICE CG 36**

1. Patients with permanent AF includes those with persistent AF who have been selected for a rate-control treatment strategy.

2. Based on stroke risk stratification algorithm (on P.47 of NICE Guideline).

3. Target a resting heart rate of less than 90 bpm (110 bpm for those with recent-onset AF). Target an exercise heart rate of less than 110 bpm (inactive), 200 minus age (active).

4. Referral for further specialist investigation should be considered especially in those with lone AF or ECG evidence of an underlying electrophysiological disorder (e.g. WPW syndrome) or where pharmacological therapy has failed.

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<table>
<thead>
<tr>
<th>Patients with permanent AF</th>
<th>1. Patients with permanent AF includes those with persistent AF who have been selected for a rate-control treatment strategy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administer appropriate thromboprophylaxis</td>
<td>2. Based on stroke risk stratification algorithm (on P.47 of NICE Guideline).</td>
</tr>
<tr>
<td>Is rate-control therapy needed?</td>
<td>3. Target a resting heart rate of less than 90 bpm (110 bpm for those with recent-onset AF). Target an exercise heart rate of less than 110 bpm (inactive), 200 minus age (active).</td>
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<tr>
<td>Beta-blocker or rate-limiting calcium antagonist</td>
<td>4. Referral for further specialist investigation should be considered especially in those with lone AF or ECG evidence of an underlying electrophysiological disorder (e.g. WPW syndrome) or where pharmacological therapy has failed.</td>
</tr>
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<td>Is further rate-control needed?</td>
<td>Yes (during normal activities)</td>
</tr>
<tr>
<td>Yes</td>
<td>Beta-blocker or rate-limiting calcium antagonist with digoxin</td>
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<td>Is further rate-control needed?</td>
<td>Yes</td>
</tr>
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<td>Specialist referral or consideration of other drugs (e.g. amiodarone)</td>
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Gwent Recommendation

Given the historic prescribing of amiodarone, often as first-line treatment of AF, both primary and secondary care clinicians have recognised that it would be beneficial to review patients on amiodarone, in the following way:

**GP practices**
- Identify patients started historically on amiodarone
- Identify those no longer under hospital follow-up
- For patients managed only in primary care, assess
  (i) Suitability for continued treatment (see below)
  (ii) Appropriate follow-up (see below)

**Hospital clinicians**
- Review the indication for amiodarone when patients are seen in Out-Patients or as in-patients
- Clearly document, in the hospital records and/or letter to the GP,
  (i) Suitability for continued amiodarone therapy
  (ii) Recommended duration of treatment

1. Identify initial indication for therapy

It should be noted that the NICE recommendations for treatment varies with the type of AF:
- comes on suddenly (acute-onset AF)
- lasts longer than a week or doesn’t stop without treatment (persistent AF)
- is more longstanding (permanent AF)
- comes and goes (paroxysmal AF)

A switch from amiodarone could be considered in primary care, without referral to secondary care, in the following patients

The initial indication for treatment has been clearly identified and

- Amiodarone was initiated first line for persistent/permanent AF
- Amiodarone was initiated for paroxysmal AF but the patient is now in permanent AF as documented in out-patient letters or a current ECG
- Amiodarone can be recommended for 3 months following CABG or cardioversion. This can be inadvertently continued. GPs may need to confirm with the initiating department that this is the only reason for amiodarone initiation.

**Recommendation: for short duration treatment, consultants write as: “amiodarone 200mg take one daily for x months only” (three to six months)**

**Patients on amiodarone for indications not listed above**

If the patient is not currently under review in secondary care (cardiology, electrophysiology, general medicine or care of the elderly), then the opinion of the initiating department should be requested.

If after careful review of the patients medical records the initiating indication remains unclear or the GP is uncertain whether a switch from amiodarone is indicated, please write to the initiating hospital department for advice. Where the initiating department was outside the Gwent Healthcare NHS Trust and the patient is no longer under follow-up, advice should be sought from the corresponding department (cardiology, care of the elderly, general medicine etc) within Gwent, as is consistent with Clinical Futures.
2. **Confirm current heart rhythm**

Undertake ECG to exclude unexpected rhythms

3. **Alternative treatment**

NICE CG 36: Treatment for permanent AF

- In patients with permanent AF, who need treatment for rate-control:
  - beta-blockers or rate-limiting calcium antagonists [diltiazem, verapamil] should be the preferred initial monotherapy in all patients
  - digoxin should only be considered as monotherapy in predominantly sedentary patients.

If there are no contraindications to beta-blocker therapy, Gwent cardiologists usually switch to bisoprolol.

4. **When to initiate alternative therapy**

Amiodarone has a very long elimination half-life (average 50 days, range:20 to 100 days)

Amiodarone will therefore still have the potential to interact with the substituted therapy for several months or more.

However usual practice amongst cardiologists when switching from amiodarone to a beta-blocker or rate limiting calcium channel blocker is not to wait for a washout period. The change is undertaken the following day.

If a patient is considered suitable for switching but is bradycardic on amiodarone (heart rate less than 60/min), stop amiodarone and reassess approximately 7 days later. Heart rate should be over 60/min before initiating a beta-blocker or rate limiting calcium channel blocker.

In some instances amiodarone will be stopped and the patient’s heart rate remains normal and therefore no alternative therapy is needed. Some practitioners may therefore prefer to allow a washout period before initiating alternative treatment.

5. **Assess interactions**

Assess the likely effect of amiodarone withdrawal on other drug interactions. For example patients on anticoagulants will need more frequent monitoring for several months as the blood levels of amiodarone drop.

6. **Assess response**

It is recommended that a patient who has successfully switched from amiodarone to alternative therapy, should be reviewed in general practice at one (three) and six months to insure that their condition remains stable. Cardiologists tend to review patients post-cardioversion at one & six months.

7. **Patients apparently ‘lost to follow-up’**

Patients who were initiated on amiodarone for life-threatening arrhythmias and appear to be ‘lost to follow-up’ may be suitable for alternative interventions. Please write to the cardiologists requesting advice and state, where possible, the start date of amiodarone and initial indication.
8. Monitoring

Remaining patients and patients newly initiated on amiodarone require regular clinical and laboratory monitoring. Gwent Partnership Medicines & Therapeutics Committee and Gwent LMC recommends that monitoring is in accordance with their endorsed amiodarone Shared Care Protocol\(^\text{i}\).

Clinicians monitoring amiodarone may wish to consider the following;

- Do you have a register?
- Do you have a safe recall system?
- How do you identify non-attenders?
- How do you ensure that abnormal results are always followed-up?
- Have all patients had a face to face annual review documenting details relating to amiodarone?

BRIDGENG GUIDANCE 2005: Changing from Amiodarone to Bisoprolol

Pharmacological Interaction

Interaction through the co-administration of beta-blockers and amiodarone can cause symptomatic bradycardia and sinus arrest. Amiodarone should be used with caution in patients receiving beta-blockers particularly if there is suspicion of underlying dysfunction of the sinus node, such as bradycardia or sick sinus syndrome, or if there is partial AV block. Adverse effects of concomitant beta-blocker and amiodarone use include hypotension, bradycardia and cardiac arrest.

Starting Bisoprolol: Stop amiodarone and start bisoprolol 1.25 to 2.5mg once daily (check pulse and blood pressure).

Clinical Management: Monitor cardiac function.

Patients must be informed of the potential side effects and asked to contact the surgery if they experience any of the following:

<table>
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<td>Chest pain (may be related to disease and not a side effect)</td>
</tr>
<tr>
<td>Fainting or severe dizziness</td>
</tr>
<tr>
<td>Slow, fast, or irregular heartbeat</td>
</tr>
<tr>
<td>Swelling of feet or ankles</td>
</tr>
<tr>
<td>Unusual bleeding or bruising</td>
</tr>
<tr>
<td>Wheezing or trouble breathing</td>
</tr>
<tr>
<td>Yellow eyes or skin</td>
</tr>
</tbody>
</table>

\(^{\text{i}}\) Licensed indication Cordorone \(^{\text{®}}\) SPC

\(^{\text{ii}}\) AWMSG amiodarone shared care protocol

\(^{\text{iii}}\) NICE CG36  www.nice.org.uk/guidance/index.jsp?action=byID&o=10982

\(^{\text{iv}}\) GPMTC  http://www.wales.nhs.uk/sites3/page.cfm?orgId=284&pid=5988

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This guidance should be read in conjunction with the Summary of Product Characteristics