

Assessment and monitoring of patients taking high dose Loperamide for high output from stoma and fistula

DOCUMENT CONTROL

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Background

Some patients with a stoma resulting from an ileostomy or jejunostomy, or with an enterocutaneous fistula can experience high volume losses. When the output is greater than 1500ml per day (or 500ml per day for fistulas), this becomes problematic and can lead to leakage or dehydration with metabolic disturbances associated with fluid and electrolyte losses (1). Several pharmacological and non-pharmacological methods have been used to reduce output from stomas and fistulas.

Introduction

Loperamide is a synthetic opioid agonist. Its antimotility action is attributed to the stimulation of mu opioid receptors on the circular and longitudinal muscle in the small intestine (2). Over the years Loperamide has been prescribed to reduce the output from colostomies or ileostomies (3). Loperamide is the preferred drug of choice instead of opiate drugs (e.g. codeine) as it is not sedative, not addictive, and does not cause fat malabsorption (4). However, the UK manufacturer of Imodium™ (Loperamide) does not recommend the use of this product to reduce stoma output in its Summaries of Product Characteristics (SPCs).

In September 2017, the UK Medicines and Healthcare products Regulatory Agency issued a Drug Safety Update on Loperamide (5). This refers to reports of cardiac events including QT prolongation, torsades de pointes, and cardiac arrest in patients who have taken high or very high doses of Loperamide as a drug of abuse or for self-treatment of opioid withdrawal.

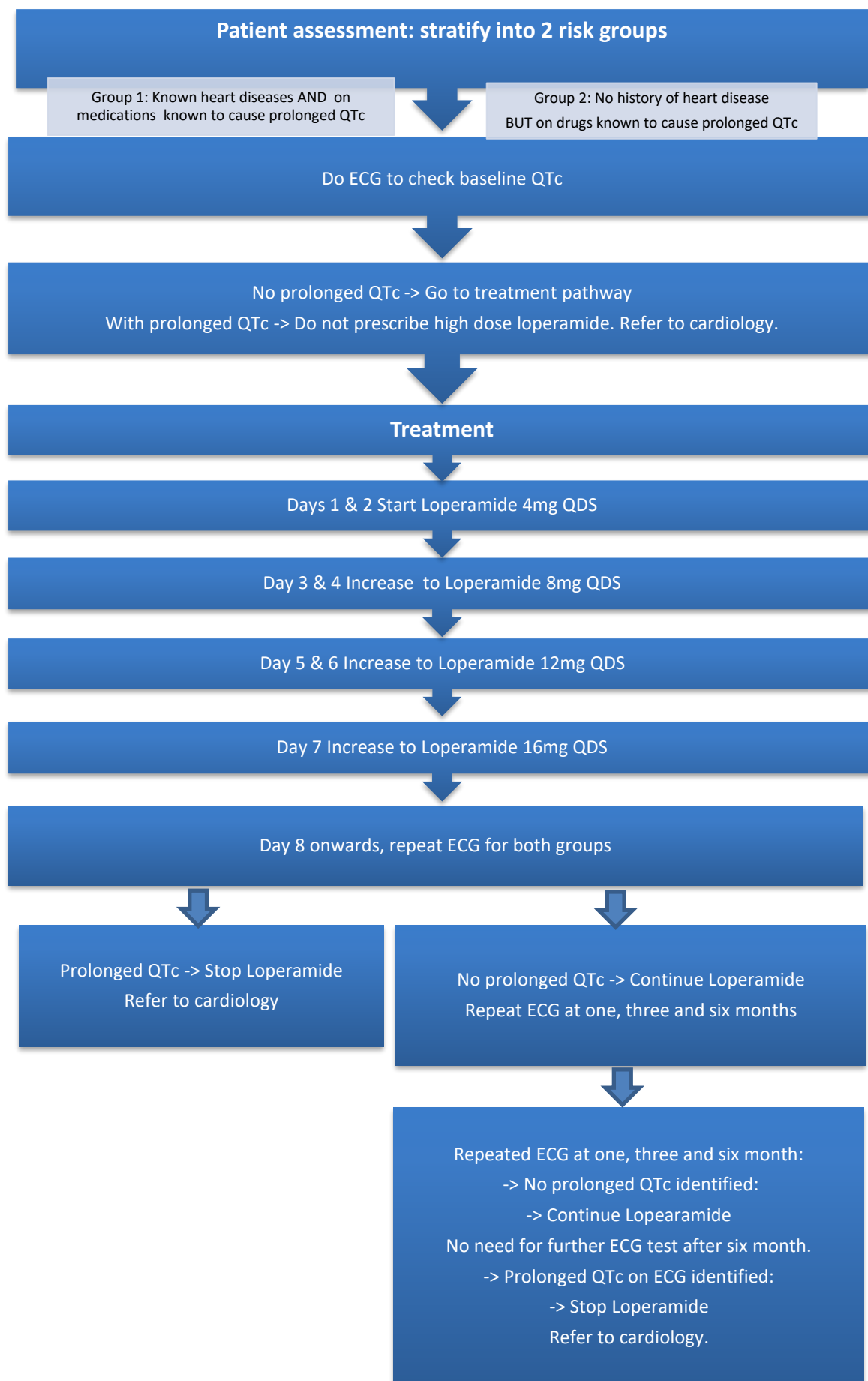
Patient assessment

All patients who require high dose Loperamide (upto 16mg QDS) to reduce output from stomas and fistulas need to be stratified into two groups depending on the presence of any concurrent cardiac diseases. For each group, the patient's medication history needs to be assessed to identify any drugs which can cause QT prolongation.

Use this link CREDIBLEMEDS <https://www.crediblemeds.org/index.php/login/dlcheck> to check if the drug can cause prolonged QT.

For patients who have no past medical history of heart disease and are not taking any medicines which are known to cause prolonged QT time, they are excluded from the need for baseline ECG monitoring prior to taking high dose Loperamide. Figure 1 illustrates the pathway for assessment, treatment and ECG monitoring for patients who require high dose Loperamide. This pathway does not apply to those who take upto a maximum of 16mg Loperamide per day as an anti-diarrhoeal in accordance with the manufacturer's SPC.

Figure 1 Pathway for patient assessment and ECG monitoring



ECG monitoring

For inpatients, the ward based medical team is responsible for requesting the ECG test. The doctor needs to review and document the results in the patient's medical notes. If prolonged QTc is detected, the doctor needs to inform the patient of the abnormal result and make a referral to cardiology. Meanwhile, the treatment with Loperamide must be discontinued.

For new and established patients on parenteral nutrition at home (or HPN), with or without home intravenous fluid therapy (HIVFT), the medical prescribers of the Sheffield HPN team will stratify their patients using the pathway described in Figure 1. For patients who meet the criteria for ECG monitoring, the HPN team will organise the test which could be done at a later date after the HPN clinic appointment. The medical prescribers are responsible for reviewing the QTc results. If prolonged QTc is detected, the HPN team needs to inform the patient of the abnormal results and make a referral to cardiology. The HPN team also needs to discuss with the patient the risks and benefits of discontinuing high dose Loperamide, and how this may affect the management of stoma losses with the potential need to make changes to the HPN prescriptions and or HIVFT.

Patient counselling

All patients who need to take high dose Loperamide should be given an information leaflet. For inpatients, advice and counselling on Loperamide can be done by ward based medical team doctors, nutrition support team, clinical pharmacists or dietitians.

Information on Loperamide high dose

[‘Loperamide - high dose PIL’](#). This gives advice and explains the warning about prolonged QTc. For patients who are under the care of the Sheffield HPN team, advice and counselling on Loperamide high dose can be done by a member of the team.

References

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