Guidance regarding MHRA alert 20 February 2017: Hyoscine butylbromide (Buscopan) injection: risk of serious adverse effects in patients with underlying cardiac disease

PURPOSE

In February 2017 the Medicines and Healthcare Products Regulatory Agency (MHRA) issued an alert regarding the risk of serious adverse effects in patients with underlying cardiac disease when injected with Buscopan. Dr Damian Tolan and Dr Ashley Roberts, on behalf of the British Society of Gastrointestinal and Abdominal Radiology (BSGAR), produced guidance - see appendix A - in response to this alert.

KEY POINTS

The guidance highlights the importance for radiologists to balance the benefits of improved image quality and diagnostic performance against serious cardiovascular complications. It highlights that the risk calculation should be made on a case by case basis, by an experienced clinical radiologist and in conjunction with colleagues in other specialties as necessary.

CONSULTATION

Clinical Radiology Officers had opportunity to input to the guidance, and the final draft was circulated to PSSB and Faculty Board for comments.

This was approved by PSSB on 25 May, and the foreword has subsequently been developed by Dr Rob Holmes to include key points from within the guidance.

ACTION

Faculty Board is asked to approve this guidance, subject to any amendments highlighted at the meeting.

Anna Abela
Executive Officer

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FOREWORD

Following receiving reports of the deaths of 8 patients who received intravenous or intramuscular injections of Buscopan, the Medicines and Healthcare Products Regulatory Agency issued an alert advising of a very small risk of serious adverse reactions in patients with underlying cardiac disease. This has caused considerable concern in Radiology departments around the UK, and in aiming to clarify the current situation, the RCR is extremely grateful to Dr Damian Tolan and Dr Ashley Roberts who have produced this guidance on behalf of the British Society of Gastrointestinal and Abdominal Radiologists (BSGAR).

KEY POINTS

Practical application of this guidance may include some or all of the points below:

1. Enquiry as to the presence of any of the following, as these would typically result in Buscopan being withheld:
    - Recent acute coronary syndrome, including myocardial infarction and unstable angina
    - Uncontrolled cardiac failure
    - Cardiac tachyarrhythmia

2. Radiologists evaluating the risk-benefit ratio, in conjunction with Clinicians when necessary, on a case by case basis to determine whether the potential for improved diagnostic performance outweighs the risk of Buscopan injection.

3. Close observation of patients during and immediately after procedures.

4. The consideration of accurate documentation of decisions in pre/post-procedure checklists, RIS (Radiology Information System) and Radiological reports for example.

GUIDANCE

The radiological pharmacopeia is limited. Buscopan is one of the few drugs prescribed routinely to optimise image quality in examinations that may be

compromised by bowel peristalsis. A recent MHRA alert[1] in response to a coroners inquest[2] has provided an opportunity to reappraise how radiology departments should manage cardiovascular risks associated with Buscopan, and in particular those with ischaemic heart disease.

Cardiovascular effects on the parasympathetic nervous system from Buscopan are well known, causing a rise in heart rate and fall blood pressure due to acetyl choline muscarinic receptor blockade. '*Concern regarding the cardiac side effects of Buscopan is understandable, as in radiological practice it is mainly used for examinations performed on the elderly, and yet, if the drug is restricted to patients with no cardiac risk factors, then its use will be significantly restricted. Simply obtaining a positive history of cardiac disease is also insufficient to identify patients most at risk, as these patients are likely to be receiving treatment and so may be at lower risk than patients of a similar age with no prior cardiac history and clinically silent cardiac disease.*'[3]

'*The physiological effect of an increase in heart rate of 20 beats/min for up to 1 h and a small increase in diastolic BP is unlikely to warrant any absolute contraindication to patients with cardiac disease as long as the patient is fit enough to undergo the investigation in the first place. However, caution is needed in patients who are unstable, such as those recently admitted with acute coronary syndrome, recurrent cardiac pain at rest, uncontrolled left ventricular failure, and recent ventricular arrhythmias. Clinicians should be alert to this risk and notify the radiology department when referring such patients so that a decision can be made as to whether it is appropriate to proceed with the investigation, whether Buscopan should be used, and whether the patient should be appropriately monitored.*'[3]

In such patients, it is important for radiologists to balance the benefits of improved image quality and diagnostic performance against real but rare serious cardiovascular complications. The danger of false positive or false negative radiological diagnosis arising from suboptimal imaging is also well recognised, which may lead to missed cancer diagnosis or unnecessary investigation or patient distress, for example from colonoscopy. This risk calculation should be made by an experienced clinical radiologist on a case by case basis, where necessary in conjunction with colleagues in other specialties.

Prior to the procedure, it is advised that patients with significant cardiac comorbidity such as uncontrolled heart failure, unstable angina, recent myocardial infarction and

cardiac tachyarrhythmia are identified, as Buscopan would typically be withheld in such patients.

Patients should be closely observed during procedures and not left unattended by the healthcare professionals performing the examination. In the event of a serious cardiac complication being recognised, there must be immediate access to resuscitation equipment on a 'crash trolley' and appropriately trained personnel to administer emergency care. It is expected that since Buscopan is typically administered in CT and MRI, fluoroscopy, vascular and endoscopic intervention suites, that such facilities will always have access to such support.

REFERENCES

1. https://www.gov.uk/drug-safety-update/hyoscine-butylbromide-buscopan-injection-risk-of-serious-adverse-effects-in-patients-with-underlying-cardiac-disease

2. https://www.judiciary.gov.uk/wp-content/uploads/2016/11/Woodward-2016-0308.pdf

3. Dyde R, Chapman AH, Gale R, Mackintosh A, Tolan DJ. Precautions to be taken by radiologists and radiographers when prescribing hyoscine-N-butylbromide. Clin Radiol. 2008 Jul;63(7):739-43. doi: 10.1016/j.crad.2008.02.008. Review. PubMed PMID: 18555031.