

Joint position statement from The Royal College of Radiologists and the British Society of Gastrointestinal and Abdominal Radiologists

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

Foreword

Following receiving reports of the deaths of eight patients who received intravenous or intramuscular injections of Buscopan®, the Medicines and Healthcare Products Regulatory Agency (MHRA) 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 Royal College of Radiologists (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, radiology information system (RIS) 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 alert¹ in response to a coroner's inquest² has provided an opportunity to re-appraise 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 in 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 one hour and a small increase in diastolic [blood pressure] 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, 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 co-morbidity 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 computed tomography (CT) and magnetic resonance imaging (MRI), fluoroscopy, vascular and endoscopic intervention suites, that such facilities will always have access to such support.

References

1. www.gov.uk/drug-safety-update/hyoscine-butylbromide-buscopan-injection-risk-of-serious-adverse-effects-in-patients-with-underlying-cardiac-disease (last accessed 05/07/2017)
2. www.judiciary.gov.uk/wp-content/uploads/2016/11/Woodward-2016-0308.pdf (last accessed 05/07/2017)
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; **63**(7): 739–743.

The Royal College of Radiologists and
British Society of Gastrointestinal and Abdominal Radiologists
July 2017