Doncaster & Bassetlaw Hospitals NHS Foundation Trust Formulary Guidance Concerning the Use of Midazolam.

Introduction

Midazolam overdosage following conscious sedation procedures has been identified as a risk by the National Patient Safety Agency (NPSA RRR 08/011). The purpose of this formulary guidance is to promote the safe use of midazolam within the Trust. To define what product may be used in which circumstances, and to provide practical advice concerning dosing of patients

Midazolam is used widely within the Trust for both conscious sedation and within the palliative setting

Use in Palliative Care

For more detailed information regarding the use of midazolam to control agitation in palliative care, please refer to the Palliative Care Formulary or the Palliative Care Team.

Use in Conscious Sedation

Conscious sedation has been defined as a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and technique used to provide conscious sedation should carry a margin of safety wide enough to render loss of conscious unlikely¹

It is the responsibility of the prescriber to ensure that:

- o They are competent to undertake the procedure using midazolam
- o They have undertaken a risk assessment of the patient in relation to using midazolam
- They have selected the minimum dose of midazolam to enable the procedure to taken
- Resuscitation facilities are available
- o Flumazenil is available

Use of Flumazenil

The need to use flumazenil to reverse midazolam in conscious sedation in some case may be regarded failure of care, and therefore the routine use of flumazenil should not be regards as normal practice.

Prescribers must be aware that that the duration of effect of flumazenil is much shorter than midazolam particularly in the elderly, and there is a danger that the patient may again lose consciousness after reversal by flumazenil

For all patients who receive flumazenil must be observed for a minimum of 1 hour either in the department or on the ward. If the patient needs to return to the ward a nurse must accompany them.

¹ Skelly A.M. Analgesia and sedation; in Watkinson A. and Adam A. (Eds) Interventional Radiology. Oxford:. Radcliffe Medical Press, 1996: p3-11

Availability of Midazolam and Flumazenil

Flumazenil is available as 500microgram/5ml. It must be available in all areas that stock midazolam. Before any conscious sedation procedure the availability of flumazenil must be established

Midazolam is a Schedule 3 Controlled Drug, this means that supply by the Pharmacy is only made following the receipt of a signed Controlled Drug requisition

Midazolam is available as

1mg/ml – 2ml (2mg) and 5ml (5mg) ampoules 2mg/ml – 5ml 10mg) ampoules 5mg/ml – 2ml (10mg) ampoules

In order to reduce the risk of selection error, the risk of accidental overdose the following restrictions to the stocking of midazolam injections will apply

10mg in 2ml – Is restricted to use on wards for use in syringe drivers. It will be treated as a Controlled Drug. In addition to requiring a requisition to order, the 10mg/2ml strength will be stored in a CD cupboard and receipt and administration transactions will be recorded in the ward Controlled Drug Record Book.

10mg in 5ml - Is restricted to critical care areas and theatres for use by anaesthetists

2mg in 2ml and 5mg in 5ml – These products are only products available in areas performing conscious sedation procedures in the absence of an anaesthetist.

Training and Competence

All staff undertaking conscious sedation procedures must ensure the have the appropriate knowledge, skills and competence to undertake the procedure.

It is the responsibility of consultant to ensure that their junior staff have that knowledge skills and competence to undertaken conscious sedation techniques.

Safe Practice for Midazolam Sedation

Assess patient pre procedure: Is sedation absolutely necessary for this patient?

Previous benzodiazepine exposure - may result in relative resistance to midazolam; also relative contra indication to

use of flumazenil.

Known allergies - especially to benzodiazepines.

Assign Patient to High Risk or Normal Risk

High Risk: Any of the following

Age > 70 yrs

Cardiovascular instability (impaired LV or recent bleed)

Significant comorbidity (respiratory, CNS, CVS, renal, endocrine)

Normal Risk

None of the above

Ensure monitoring, oxygen therapy, resuscitation equipment and flumazenil is available.

Ensure that a doctor/nurse or ODP is available to monitor patient. You cannot carry out a procedure and monitor a patient at the same time.

Normal risk: Minimal monitoring is pulse oximetry. ECG & NIBP should be available.

High Risk: Pulse oximetry, NIBP & ECG

Minimal resuscitation equipment is bag/ mask ventilation system + access to defibrillator

Consider administering opiate analgesia if procedure is likely to be painful

Midazolam is not an analgesic. Trying to sedate a patient for a painful procedure with midazolam may result in oversedation. Before sedation consider the use of IV morphine in 1 mg aliquots to relieve pain; subsequent sedation with midazolam will require much lower doses and potentially greater margin of safety. Exercise great caution if opiate analgesia is given to a patient prior to midazolam sedation.

Pre Procedure

Explain procedure to patient.

Check midazolam ampoule, concentration and expiry: It should be 1 mg/ml.

Check resuscitation equipment is working.

Attach patient to monitor.

Gain IV access if not already established.

Administer oxygen by face mask/nasal prongs or nasal sponge.

The aim of sedation is a relaxed, drowsy patient and possibly amnesic for the procedure. The patient should not be snoring or unresponsive to name or shaking.

Normal Risk

Draw up 5 mg of midazolam (5ml).

Administer 2 mg bolus.

Wait 2 minutes.

Give 1 mg aliquots at 2 minute intervals until adequately sedated.

Usual dose is 2-5mg.

High Risk

Draw up 2 mg midazolam (2 ml).

Administer 1 mg bolus.

Wait 2 minutes.

Give 1/2 mg aliquots at 2 minute interval until adequately sedated.

Usual dose is 1 - 5 mg.

Management of Benzodiazepine Induced Oversedation



Patient is unresponsive to name. Cannot be roused by shaking. May be snoring.

May have low oxygen saturation

Immediate Management

Airway: If snoring or obstructing, apply jaw thrust, insert guedel airway if the patient allows.

Breathing: If respiration is episodic or absent begin bag and mask ventilation. If the patient is apnoeic call the cardiac arrest team. Ensure that oxygen enrichment is given.

Circulation: Attach ECG, check NIBP, ensure venous access is adequate. Begin CPR if cardiac arrest occurs and call the team.

Secondary Management

Administer flumazenil. Give **200 micg (2 ml)**, then **100 micg** at 1 minute intervals; usual dose 300-600micg Remember that patients established on long term benzodiazepines may experience acute withdrawal symptoms (including epileptiform convulsions) when given flumazenil, The decision to give flumazenil to these patients will depend on the gravity of their situation.

Follow on Care

If the patient responds to flumazenil, they should be monitored by experienced staff in a safe environment for at least 60 minutes.

Resedation may occur because of the relatively short half life of flumazenil in comparison to midazolam. Repeated doses of flumazenil may be necessary.

If resedation occurs after flumazenil administration, contact DCC / ITU for further advice.

The use of flumazenil is an indicator of oversedation.