Penthrox (Methoxyflurane) SOP guideline

Penthrox (methoxyflurane) is an inhaled vapour that is used for the relief of moderate to severe pain in conscious adults with trauma and associated pain. Methoxyflurane is a fluorinated anaesthetic however Penthrox is used in significantly lower doses then required for a general anaesthetic.

Indications

Penthrox (methoxyflurane) will be offered to women having ambulatory gynaecology procedures where moderate to severe pain (pain score >4/10) is expected and where Entonox and paracervical block are currently used:

- Outpatient hysteroscopy, polypectomy, insertion/retrieval of IUD
- Endometrial ablation
- Myomectomy
- Manual vacuum aspiration
- Other procedure where woman has significant anxiety over receiving paracervical block

Penthrox would be offered in place of Entonox and alongside a paracervical block, although if found to be highly effective the block may become optional.

Contraindications

Cardiovascular disease; history of liver damage associated with use of methoxyflurane or other halogenated anaesthetics; impaired consciousness; respiratory depression; susceptibility to malignant hyperthermia [From BNF]
Full list from UK summary of product characteristics:

- Use as an anaesthetic agent.
- Hypersensitivity to methoxyflurane, any fluorinated anaesthetic or to any of the excipients listed in section 6.1 of the UK summary of product characteristics.
- Malignant hyperthermia: patients who are known to be or genetically susceptible to malignant hyperthermia.
- Patients or patients with a known family history of severe adverse reactions after being administered with inhaled anaesthetics.
- Patients who have a history of showing signs of liver damage after previous methoxyflurane use or halogenated hydrocarbon anaesthesia.

- Clinically significant renal impairment.
- Altered level of consciousness due to any cause including head injury, drugs, or alcohol.
- Clinically evident cardiovascular instability.
- Clinically evident respiratory depression.

Cautions in:

- Renal disease
- Liver disease
- Cardiovascular system depression / use in elderly
- Central nervous system (CNS) effects
- Frequent repeated use

In the unlikely event any patient attending for an ambulatory gynaecology procedure is included in one of these groups, the prescriber must follow the recommended precautions listed in the Summary of Product Characteristics (see also below).

Side Effects

- Cough
- Dry mouth
- Hypotension
- CNS symptoms including dizziness, drowsiness, amnesia, somnolence

Side effects are increased if used concomitantly with other CNS depressants.

Special Warnings:

- Nephrotoxicity

Methoxyflurane causes nephrotoxicity at high doses due to inorganic fluoride ions, a metabolic breakdown product. Nephrotoxicity is associated with serum levels greater than 40 umol/l. Following a single dose 3ml dose of methoxyflurane levels are below 10 umol/l. Despite this significant safety margin, the lowest dose of methoxyflurane should be used especially in the elderly and patients at risk of renal disease.

- Hepatotoxicity

Methoxyflurane is metabolised in the liver. Patients with hepatic impairments and at risk of hepatic impairment, including patients receiving CYP450 enzyme inducers, should not receive Penthrox.

- Elderly Patients

Potential effects on blood pressure and heart rate are not significant at analgesic doses but elderly patients may be at increased risk and caution should be exercised in the elderly.

- Occupational Exposure

To reduce occupational exposure the Penthrox inhaler should always be used with the activated carbon filter which absorbs exhaled methoxyflurane.

- Pregnancy and Breast Feeding

Caution with the use of Penthrox in pregnancy, especially in the first trimester, and in breast feeding. N.B. all patients must have either a negative pregnancy test as part of the WHO safety checklist taken in line with clinic protocol for all patients, or have a known failed pregnancy requiring treatment.

Dosage

- Starting dose one bottle of 3ml Penthrox. Onset of pain relief is rapid and should occur within 6-10 inhalations. Continuous inhalation provides analgesia for 25-30 minutes. Intermittent inhalation provides analgesia for one hour. Patients should be encouraged to assess their own level of pain and titre the amount of Penthrox inhaled for adequate pain control.
- Second bottle could be tried, If the procedure cannot be completed owing to pain or duration that exceeds two bottle of Penthrox, it should be abandoned and re-booked electively under general anaesthesia.
- Penthrox should not be administered on consecutive days and the maximum dose is 15ml in 7 days.

Staff training

There is an online training module (approximately 60-minute duration; 1CPD point) accessed on https://penthrox.co.uk/healthcare/. Successful completion generates a 'Penthrox Administrator Certificate of Competence'. Register of competence completion will be kept by GOPD manager.

Administration

Indications, counselling, prescription and administration of Penthrox will be recorded on patient's PPM+ file.

As per routine practice pre-emptive analgesia is advised at least 30 minutes before the procedure. The patient should be asked to self-administer paracetamol and/or ibuprofen in their own home prior to attendance.

Penthrox is delivered by a single use inhaler. It is self-administered by patients under the supervision of a person trained in its administration. Self-administration of the medication ensures a self-limiting dose. When a partial anaesthetic dose is achieved, the patient's hand will fall away, preventing further administration until sufficient recovery achieved to use again.

Patients using Penthrox do not require monitoring beyond that performed as part of the procedure and in recovery.

The same safeguards are used as for Entonox (i.e. under no circumstances can anybody other than the patient administer the Penthrox).

Storage and Disposal

- Penthrox must be stored in a secure, locked drugs cabinet and its use restricted to those clinicians performing the procedures listed above.
- Each use will be recorded in a controlled drugs book, kept alongside the Penthrox in the drug cabinet, that includes the date used, patient details and responsible clinician.
- When the procedure is complete, place used methoxyflurane bottles and inhalers into the sealed plastic bag provided and dispose of responsibly in a designated bin or suitable waste container (e.g. sharps bin).

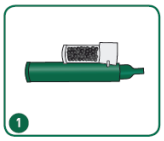
Audit

All patients are invited to complete the patient-reported outcome questionnaire. The “staff to complete” section must indicate that Penthrox has been used. Pain scores from these procedures will be compared to those from prior to its introduction.

Method of Administration
(Image used with written permission of Galen pharmaceutical)

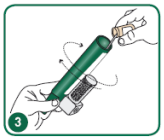
METHOD OF ADMINISTRATION

Instructions on the preparation of the PENTHROX Inhaler and correct administration are provided in the Figures below.



Ensure the Activated Carbon (AC) Chamber is inserted into the dilutor hole on the top of the PENTHROX Inhaler.

Remove the cap of the bottle by hand. Alternatively, use the base of the PENTHROX Inhaler to loosen the cap with a ½ turn. Separate the Inhaler from the bottle and remove the cap by hand.

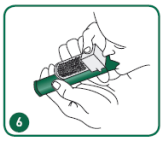


Tilt the PENTHROX Inhaler to a 45° angle and pour the total contents of one PENTHROX bottle into the base of the Inhaler whilst rotating.

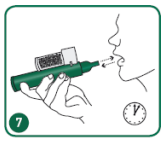
Place wrist loop over patient's wrist. Patient inhales and exhales PENTHROX through the mouthpiece to obtain analgesia. First few breaths should be gentle and then breathe normally through Inhaler.

The person trained in administering PENTHROX must provide and explain the Package Leaflet to the patient.

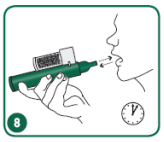
Patient exhales into the PENTHROX Inhaler. The exhaled vapour passes through the AC Chamber to adsorb any exhaled methoxyflurane.



If stronger analgesia is required, patient can cover dilutor hole on the AC chamber with finger during use.



If further pain relief is required, after the first bottle has been used use a second bottle if available. Alternatively use a second bottle from a new combination pack. Use in the same way as the first bottle in step 2 and 3. No need to remove the AC Chamber. Put used bottle into the plastic bag provided.



Patient should be instructed to inhale intermittently to achieve adequate analgesia. Continuous inhalation will reduce duration of use. Minimum dose to achieve analgesia should be administered.

Replace cap onto PENTHROX bottle. Place used PENTHROX Inhaler and used bottle in sealed plastic bag and dispose of responsibly.

Tips for successful administration of methoxyflurane analgesia:

Careful patient selection
Inform patient and proceduralist of nature of the sedation and what to expect. Ensure 'buy-in' from both.

Good seal
Ensure seal around mouthpiece adequate to reduce entrainment of air and dilution of methoxyflurane and to avoid contamination of environment with exhaled methoxyflurane

Go slow
Allow sufficient time for methoxyflurane to work; this varies from patient to patient from 6 breaths up to a few minutes. Patients may describe 'seeing double' as they approach an adequate level of analgesia

Patient feedback: stop-deepen-restart
If patient becomes uncomfortable stop procedure and deepen analgesia (deep breaths with dilutor hole covered)

In-Hold-Out
Deep breaths in, hold in lungs for few seconds and then exhale

Gentle first few breaths
Encourage patient to take gentle first few breaths while they get used to the smell and taste. Then gradually deepen breaths (± cover dilutor hole) to attain sufficient analgesia for procedure

Reassure
Patients can become disinhibited. They are often suggestible and will settle with reassurance and a calm environment

Regular verbal contact with patient
Remove inhaler from patient's mouth if they seem to be getting too sedated; they should recover rapidly

From: Self-administered methoxyflurane for procedural analgesia: experience in a tertiary Australasian centre. Gaskell et al. Anaesthesia 2016, 71, 417–423

Monitoring compliance and effectiveness

Element to be monitored	Monitor effectiveness of Penthrox for ambulatory gynaecology and whether it adds value (is kinder for women) when compared to the current use of Entonox alongside a paracervical block.
Lead	(ambulatory lead) (nurse specialist) (clinical lead)
Tool	Patient reported outcome form to be completed for all patients receiving Penthrox, with responses compared to existing dataset. Success is defined as better patient acceptability of ambulatory procedure as defined by primary outcome measure of whether they would choose the same way of having the procedure again, and secondary outcome measures of pain score (mean and % reporting severe pain of ≥8 out of 10), feeling in control, anxiety and side-effects. Clinician and nurse feedback will also be captured.
Frequency	Patient reported outcome form will be completed for all patients receiving Penthrox during the trial period (12 months). At the end of the trial period the audit results will be presented at gynaecology clinical governance meeting.
Reporting arrangements	Report to the ambulatory gynaecology clinical lead and pharmacy team
Acting on recommendations and Lead(s)	Required changes to practice will be identified and actioned in as rapid timeframe as possible.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned. A senior member of the gynaecology department will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

Outpatient Hysteroscopy Patient Satisfaction Survey

We would appreciate your comments on the service you received today to help improve our services. This data will also be used to compare our service with the results of others around the country; all data that is recorded by us or nationally is anonymous and untraceable. The answers you provide will be anonymous, completely confidential and your participation is voluntary. If you have any questions about this survey please ask a member of staff.

Thank you
for your help

Before your consultation					
Did you receive any written information (e.g. a leaflet or instructions about where to acquire information e.g. on-line) prior to your appointment?			Yes ○	No ○	
Did you feel that the information was clear and understandable? (leave blank if you answered "No" to the question above)	Yes – I knew what to expect ○	Yes- to some extent ○	Not too sure ○	No- wish I knew what to expect ○	No- it was not useful ○
Did you receive advice to take painkillers before the appointment?	Yes – took some ○	Yes – did not take any ○	No– wish I had ○	No – no need ○	
What did you think of the waiting area, reception and facilities?	Excellent ○	Very Good ○	Good ○	Fair ○	Poor ○

About your consultation today					
Staff explained things in a way I could easily understand.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I felt able to ask questions and to Discuss any worries	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I was offered an opportunity to discuss pain relief.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
My questions were answered to my satisfaction.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I felt involved in the decisions regarding my care.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I was treated with respect and dignity.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I was given enough privacy.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
All aspects of my care were dealt with confidentially.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
The staff were courteous and polite.	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○
I was given advice regarding my recovery and management plan	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○

Please indicate (✓) what would be the worst level of discomfort or pain you might experience (or used to experience) <u>during a period</u> on the same scale of 0-10:										
0	1	2	3	4	5	6	7	8	9	10
No Pain					**Moderate pain**					**Worst pain**

experience of our service?	Excellent ○	Good ○	Fair ○	Poor ○	Very Poor ○
I would choose this way of having the procedure if I were in the same situation again?	Strongly Agree ○	Agree ○	Neither Agree or Disagree ○	Disagree ○	Strongly Disagree ○

Your experience (considering your expectations of today's consultation)					
Did you feel distressed?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○
Did you feel pain?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○
Did you feel in control?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○
Did you feel embarrassed?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○
Did you feel anxious?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○
Did you feel faint?	Not at all ○	Slightly ○	Somewhat ○	Mostly ○	Constantly ○

Please indicate (✓) what level of <u>discomfort or pain you experienced</u> during the procedure on a scale of 0-10:										
0	1	2	3	4	5	6	7	8	9 □	10
No Pain					**Moderate pain**					**Worst pain**

Please indicate (✓) How would you ***<u>rate the care</u>*** you received? On the same 0-10 scale:										
0	1	2	3	4	5	6	7	8	9	10
Bad					**Neither good nor bad**					**Excellent**

Any further comments on your experience or suggestions for improvement?

Staff use only: (Please tick all that apply)			
Diagnostic Hysteroscopy+/- biopsy	☐	**Myomectomy**	☐
Hysteroscopic biopsy	☐	**Endometrial Ablation**	☐
Hysteroscopic polypectomy	☐	**Other (Please Specify)**	
Insertion/Retrieval of IUCD/Mirena IUS	☐	**Staff code**	_____