Insomnia Management Guideline

Guideline Development

This document is an update of existing guidance and has been developed by Barnsley CCG Medicines Management Team in consultation with colleagues from South West Yorkshire Partnership NHS Foundation Trust and Barnsley Hospital NHS Foundation Trust.

The guidance has been subject to consultation and endorsement by the Area Prescribing Committee on 11th March 2020.

Purpose

This guidance aims to support a consistent approach to the treatment of insomnia in primary care. It recommends the approach for prescribing of hypnotic medication for adults in routine practice. For patients with complex needs, severe mental health problems, or for children specialist advice should be sought.

Introduction

The risks associated with the long-term use of hypnotic drugs have been well recognised for many years. These include adverse effects, such as daytime sedation, poor motor coordination, cognitive impairment, and related concerns about driving accidents and injuries from falls as well as the risks of dependence and withdrawal. Benzodiazepines and 'Z drugs' are also associated with an increased risk of dementia[1].

National guidelines recommend non-pharmacological methods as first-line treatment for insomnia, and recommend hypnotics should be used to treat insomnia only when it is severe, disabling or subjecting the individual to severe distress[2]. Long-term chronic use is not recommended and use of hypnotics should be short-term and preferably intermittent[3]. They should be prescribed at the lowest effective dose for the shortest time possible. Maximum duration of treatment should be four weeks, including the dose-tapering phase[4].

NICE recommends the use of a hypnotic with a short half-life and lowest cost per dose[5].

Prescribing of these drugs is widespread but dependence, both physical and psychological, and tolerance occurs. This may lead to difficulty in withdrawing the drug after the patient has been taking it regularly for more than a few weeks. Patients and their carers should be made aware at the beginning of treatment that the therapeutic effects are likely to be short lived and a future plan for reduction discussed.

Key Points

1. Identify any potential causes of insomnia or exacerbating factors and treat where possible. A way of identifying these can be through the system of 5P's - physical, physiological, psychological, psychiatric and pharmacological as identified by Lader (1992). See Appendix 1.

2. Use non-drug treatments first line, including simple advice, sleep hygiene, counselling, cognitive behavioural therapy for insomnia and development of relaxation techniques. Patient Information Leaflets and sleep diaries are available from the CCG Medicines Management Team. See Appendix 2.

3. Only if the insomnia is severe, disabling, or subjecting the individual to extreme distress, consider prescribing a hypnotic as an adjunct to non-drug treatment.

4. Tolerance and dependence to hypnotics can occur rapidly (within a few days), which may complicate the prognosis. Good practice is to issue a prescription with a maximum length of treatment of two weeks, and additional or repeat prescriptions should NOT be given. Total treatment should not exceed four weeks to include the dose tapering phase[4]. Patients should be encourage to use hypnotics intermittently and only when required, continuous use is best avoided as this may increase the risk of developing tolerance and dependence e.g. Take one alternate nights.

5. Chronic insomnia is rarely benefited by hypnotics and is more often due to mild dependence caused by injudicious prescribing. This may then lead to difficulty in withdrawing the drug after the patient has been taking it regularly for a few weeks.

6. Prescribing to residents of nursing and residential homes should be avoided where at all possible.

7. Hypnotics should be very cautiously in patients with respiratory disease, severe hepatic/renal impairment, the elderly or patients prescribed other medications known to cause sedation as a side effect.

8. Be careful whenever prescribing a hypnotic; do not prescribe if the person is temporarily registered or unknown, as these drugs are commonly misused (low dose tablets are less attractive to substance misusers).

9. The prescribing of benzodiazepines to patients who have problems with illicit use is of no proven effectiveness.

   Benzodiazepines should not be prescribed to those who are known or suspected to be illicit drug users unless:

   - Prescribed by the specialist drugs service as part of a short-term opiate detoxification programme. GPs should avoid prescribing for patients actively under the care of substance misuse teams to minimise the risk of duplicate prescriptions. The specialist drug service is also better equipped to monitor and check for signs of abuse.

- Prescribed on an acute basis by specialist psychiatric services - under close supervision and monitoring.

or

- For a patient already in receipt of a long-term Benzodiazepine prescription, who appears stable on them, and has been transferred from another GP. **In this case the prescription should be reduced and stopped as soon as practically possible**

Withdrawal Symptoms[6]

These can vary between individuals from mild to severe.

Symptoms can be physical (stiffness, weakness, gastrointestinal disturbances, paraesthesia, flu-like symptoms, visual disturbances, convulsions, cognitive impairment) or psychological (anxiety, insomnia, nightmares, depersonalisation, decreased memory/concentration, delusions, hallucinations, depression or psychosis).

Abrupt withdrawal may produce confusion, toxic psychosis, convulsions, or a condition resembling delirium tremens in severe cases.

Choice of hypnotic

Use of hypnotics should be short-term and preferably intermittent. NICE recommends the use of a hypnotic with a short half-life. For further information please consult individual drug SPCs in the Medicines Compendium at www.medicines.org.uk or information in the British National Formulary at: https://www.medicinescomplete.com/#/browse/bnf/_145873037._269993973._806085624

First line choice:

- **Zopiclone** 3.75mg to 7.5mg at night (3.75mg in elderly).

Second line choices:

- **Zolpidem** 5 to 10mg at night (5mg maximum licensed dose for elderly or debilitated). Zolpidem is associated with next day drowsiness and may impair driving ability the next day[7].
- **Promethazine** 25 to 50mg at night where other hypnotics are not suitable. Use only if hangover effect will not cause problems for the patient due to its long half-life and higher potential for hang over effect. Is it worth adding that promethazine has significant anticholinergic effect, caution particularity in the elderly or suffering from dementia with patients already prescribed anticholinergic medication as may worsen cognitive impartment, constipation, urinary retention, dry eyes

Restricted options:

- Temazepam 10 to 20mg at night- *restricted to existing users due to history as a drug of abuse. Occasionally used by specialist services.*
- Nitrazepam 5 to 10mg at night - *restricted to existing users and those undergoing withdrawal from opiates /specialist services.*

Where insomnia is associated with anxiety, please refer to anxiety guidelines for recommended treatments.

1. NICE recommends that switching hypnotics should only occur if there are documented adverse effects from a particular agent. If one hypnotic is not effective an alternative should not be prescribed.

2. Hypnotics should be withdrawn gradually when the time is appropriate for the patient, by gradual tapering of the dose to zero[3, 8].

3. It is the responsibility of the prescriber to ensure hypnotics are regularly reviewed. All advice and review dates should be clearly documented in the patient's records.

4. Hypnotics increase the risk of road traffic accidents, as they can impair driving performance. Patients who are taking benzodiazepines and drive should be advised in line with the Department of Transport guidance 2014[9]. Since March 2015 it has been a criminal offence to drive if you have over the specified limits of certain drugs in your blood and you have not been prescribed them, or to drive with legal drugs in your body if it impairs your ability to drive safely. The benzodiazepines diazepam, lorazepam, oxazepam and temazepam are included in the list of specified drugs.

Hospital Prescribing

Hospital prescribers are advised to avoid initiating new prescribing wherever possible; the decision to treat should ONLY be taken after verification of a sleeping problem following an assessment and after any modifiable causes have been addressed. Alternate night dosing is recommended to minimise dependence. Hypnotics newly prescribed for in-patients will be queried prior to discharge.

Other Hypnotics

Melatonin - Circadin® is indicated as monotherapy for the short-term treatment (up to 13 weeks) of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over. It is classified as a Grey Drug in the Barnsley traffic light list for adults and is not included in the local formulary for this indication.

Melatonin is prescribed by specialist services (under a shared care protocol) as a treatment for insomnia in children where behavioural management has been tried and failed to achieve satisfactory results.

Chloral derivatives (clomethiazole and cloral betaine) are restricted to existing users.

Appendix 1

Sleep disturbance – The System of 5Ps

Causes of sleep disturbance can vary widely. The first step towards improving the sleep pattern is to establish and treat the primary cause. Insomnia should be considered as a symptom not a disease. Primary insomnia is rare, an underlying remediable cause can usually be found for sleep disturbance.

Any factor, which increases activity in arousal systems or disrupts activity in sleep systems, may cause disturbance of sleep. A way of identifying these can be through the system of 5P's - physical, physiological, psychological, psychiatric and pharmacological as identified by Lader (1992).

Physical
Acute or chronic pain, cardiovascular disease, endocrine disturbances, respiratory disease, tinnitus, Parkinson's disease, myalgic encephalitis, myoclonus, restless legs, cramps, sleep apnoea syndrome, nocturia, pregnancy.

Physiological
External stimulation (snoring partner, strange bed), disruption of circadian rhythm (jet lag, shift work), late night exercise or heavy meals, increasing age.

Psychological
Emotional factors (stress, tension, grief, anger), abnormal concern about sleeping.

Psychiatric
Affective disorder (depression, hypomania, mania), psychosis, dementia, anxiety disorder.

Pharmacological
CNS stimulants (including caffeine, nicotine, "Ecstasy"), withdrawal of CNS depressants (including opiates, alcohol and benzodiazepines), cimetidine, clonidine, beta-blockers, corticosteroids.

Appendix 2

THE GOOD SLEEP GUIDE

DURING THE DAY

- Establish a fixed time for waking up (and avoid sleeping in after a poor night's sleep). Set the alarm clock for the same time each day.
- Take some exercise and generally try to keep yourself fit. However, do not do any strenuous exercise within four hours of bedtime.
- Do not sleep or 'cat nap' during the day no matter how tired you are. **Keep your sleep for bedtime.**
- Do not have any food, or drinks that contain caffeine or other stimulants for six hours before bedtime. e.g. tea, coffee or energy drinks. Some people have found that cutting out caffeine completely through the day helps.
- Do not smoke within six hours of bedtime.

GETTING READY FOR BED

- Wind down during the course of the evening and put the day to rest e.g. a stroll followed by a bath, some reading, and a warm drink.
- Do not start worrying about tomorrow today.
- Do not do anything too mentally demanding within 90 minutes of bedtime.
- Avoid eating a large meal just before bedtime.
- Soft relaxing music can help some people relax before going to bed. Try a player with a time switch that turns the music off after about 30 minutes.

AT BEDTIME

- Establish fixed times for going to bed.
- Put the light out when you get into bed.
- Do not work, read or watch TV in bed. Keep these activities for another room.
- Make sure your bed and bedroom are comfortable - not too cold, too warm and not too noisy.
- Earplugs and eyeshades may be helpful if you are sleeping with a snoring or wakeful partner.
- Make sure the bedroom is dark with good curtains to block out early morning sunlight.
- Do not 'watch the clock' - keep your alarm clock somewhere where you cannot see it. Many people will clock-watch and this does not help you to get off to sleep.

IF YOU HAVE PROBLEMS GETTING OFF TO SLEEP

- Remember that sleep problems are quite common and they are not damaging as you might think. Try not to get upset or frustrated.
- If you cannot get off to sleep within 20-30 minutes, then get up and go into another room if you can. Do something else such as reading or watching TV rather than brooding in bed. Go back to bed when sleepy. You can repeat this as often as necessary until you are asleep.
- Don't worry about tomorrow. People usually cope quite well even after a sleepless night.
- Remember that a good sleep pattern may take a number of weeks to establish.
- Do not drink alcohol to aid your sleep - it usually upsets sleep.

FURTHER INFORMATION

How much sleep do I need?

- Everyone needs different amounts of sleep. On average, most people need 6-8 hours per night, but some people find that 3-4 hours is enough.
- As you become older it is normal to sleep less.
- What is important is that the amount of sleep that you get is enough for you and does not affect your day-to-day activities.
- Short periods of waking each night are normal so try not to worry if you find yourself awake in the night.
- Worrying about poor sleep can itself make things worse.
- It is common to have a few bad nights if you have a period of stress, anxiety or worry. This is often just for a short time and a normal sleep pattern should return after a few days.

What about sleeping tablets?

Nowadays, sleeping tablets <u>are not</u> usually advised
In the past, sleeping tablets were commonly prescribed. However, there are increasing concerns about their long-term effects. They:

Can cause a 'hang-over' effect the next day
Are known to cause memory loss and falls
Can increase the risk of developing dementia
Can affect the ability to drive the next day
Can stop working properly as the body gets used to them
Are highly addictive and long-term use causes 'dependence'
Can cause anxiety, **sleeplessness** and depression

It is now an offence to drive if you have more than a specified amount of certain drugs in your body whether your ability to drive is affected by the medication or not. This includes certain medication used as sleeping tablets. You could be prosecuted if you drive with certain levels of these drugs in your body if you haven't been prescribed them.

What if my doctor decides a sleeping tablet is necessary?

- Your doctor will probably only prescribe sleeping tablets for a short period (a week or so) to get over a particularly bad patch.

- You may be asked to take your sleeping tablets on only 2 or 3 nights per week, rather than every night.

- You should not drive after taking the medication or the next day if you feel drowsy, dizzy, unable to concentrate or make decisions. It is against the law to drive if you feel unfit to do so due to the effects of medication.

What if I have been taking sleeping tablets for some time?

- Your doctor may suggest that you reduce how many you are taking or gradually try and stop them.
- Sleeping tablets should not be stopped suddenly as this may cause withdrawal problems.
- Please speak to your doctor if you would like to discuss your sleeping medication or if you think you are experiencing withdrawal symptoms.

Further help and advice

Sleep Council Tel: 01756 791089 or 0800 018 7923 (leaflet line)
www.sleepcouncil.org.uk

Patient UK information - Insomnia http://www.patient.co.uk/health/insomnia-poor-sleep

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