

Liquid formulation requirements in bariatric surgery patients

In 2006 NICE published guidelines on obesity and it recommended the use of bariatric surgery as a treatment option for patients that met certain criteria.¹ Since then the number of bariatric procedures has risen steadily. The NHS Health and Social Care Information Centre (HSCIC) reported that since 2000/01 there has been a 30-fold increase in the number of weight-loss bariatric procedures, with a 12% increase in just one year (2010/11 compared to 2009/10).²

For a short period following bariatric surgery, a patient is restricted to a liquid diet. This has implications for the drug budget as any medications that the patient is taking are often changed to liquid formulations (usually unlicensed preparations).

The prescribing of liquid formulations may not be necessary, may be initiated even before surgery, and may continue to be prescribed for much longer than the patient is restricted to a liquid diet. This bulletin provides information for prescribers on the appropriate prescribing of liquid formulations for patients that have undergone bariatric surgery.

Recommendations

- Patients might require that their tablets are crushed or switched to dispersible, chewable or soluble tablets or to a liquid form for a period usually **no longer than 6 weeks following bariatric surgery**.
- Once a patient is on solid food, they should be able to take small tablets. Larger tablets (generally with a diameter larger than 10mm) may need to be split or crushed, but only if pharmaceutically appropriate.
- Enteric coated or sustained release products should be avoided.
- Effervescent formulations should also be avoided.
- Patients who have undergone gastric bypass surgery should avoid formulations that contain sucrose, corn syrup, lactose, maltose, fructose, honey or mannitol to minimize the risk of dumping syndrome.
- Patients are usually restricted to a liquid diet following bariatric surgery so they might require that tablets are halved or crushed. If tablets cannot be halved or crushed, the options are to change to an alternative tablet that can be crushed or is chewable, dispersible or soluble, or use a licensed liquid form. The contents of open capsules may be able to be washed down with water or the contents sprinkled over a spoonful of yoghurt and then taken. Opening capsules and crushing tablets should only be done on the advice of a doctor and/or pharmacist who have assessed the risks and benefits and alternative options.
- If no suitable licensed formulation is available then consideration must be given to either prescribing an alternative medicine, to temporarily suspending the prescription or to prescribing an unlicensed liquid formulation. If an unlicensed liquid formulation is prescribed the patient's need for it should be reviewed regularly with the aim of reverting to a licensed preparation as soon as possible.
- As the patient loses weight dosing regimens as well as the continued need for medications must be reviewed regularly. Practice pharmacists may be best placed to carry out these reviews.

Background

- NICE clinical guideline CG43¹ on obesity recommends that bariatric surgery is a treatment option for adults and children if all of the following criteria are fulfilled:
 - » The person has a BMI of 40 kg/m² or more, or between 35 kg/m² and 40 kg/m² and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
 - » All appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months.
 - » The person has been receiving or will receive intensive management in a specialist obesity service.
 - » The person is generally fit for anaesthesia and surgery.
 - » The person commits to the need for long-term follow-up.
- In addition, NICE recommended bariatric surgery as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m² in whom surgical intervention is considered appropriate.¹
- However, the NHS Commissioning Board policy for commissioning complex and specialised obesity surgery, published in April 2013, states that patients with a BMI of 50kg/m² will also need to fulfill the other criteria for eligibility for bariatric surgery. These criteria are set out in the policy as well as what the risk:benefit evaluation of the individual should consider.³
- The proportion of adults that are morbidly obese with a BMI of 40kg/m² or more has risen from 0.9% in 1993-95 to 1.9% in 2006-08. These figures suggest that the number of adults with morbid obesity in England would be around 800,000; so a CCG covering a population of 500,000, would be expected to have around 8,000 adults with morbid obesity.³
- Health Survey for England data indicates that of the population recorded as being morbidly obese, 7% have a BMI of 50kg/m². Therefore, in England there is a population of 51,000 people who are potentially eligible for bariatric surgery as first line treatment for their obesity.³
- In 2010/11 the East Midlands had the highest rate of bariatric surgery, with 32 procedures for every 100,000 of the population. The North West had the lowest rate of bariatric surgery, with six procedures for every 100,000 of the population, followed by the East of England and South Central with nine procedures for every 100,000.²
- 2010 saw the first recorded decrease in seven years in the number of prescription items dispensed to treat obesity. In 2010 1.1 million items were dispensed, a 24% fall on the previous year when 1.4 million items were dispensed. The decrease could reflect the withdrawal from use of sibutramine (in 2010) and rimonabant (in 2009), which had been used to treat obesity.²

Clinical evidence

The three main types of bariatric surgery are gastric bypass, gastric band and gastric sleeve.

- **Gastric bypass surgery** is irreversible and involves creating a gastric pouch at the top of the stomach, either by stapling or vertically banding most of the stomach or by removing portions of the stomach. The gastric pouch is then connected to the small intestine, thereby bypassing the duodenum and some or all of the jejunum. In this way calorie and nutrient absorption is substantially reduced.^{4,5}

Impact on medicines:

- » The dissolution and disintegration rate, as well as the absorption of drugs are affected by gastric bypass.
- » The size of a tablet is not an issue unless it is very big (generally with a diameter greater than 10mm) as there is the potential that it will remain undissolved in the gastric pouch.
- » If a formulation has a high sugar content it can cause 'dumping syndrome' and this should be avoided by using sugar-free formulations where possible.⁶

- During **gastric band surgery** an adjustable band is placed around the top part of the stomach to create a small pouch that reduces the amount of food that can be held in the stomach. This procedure is reversible. The band is attached via an access port to a thin tube that runs under the skin to sit, usually, below the breastbone. This tube can be filled with fluid and this has the effect of reducing the diameter of the stoma created by the band between the stomach and the pouch. The narrower the stoma, the longer it takes for the pouch to empty into the body of the stomach. The aim is for patients to feel fuller on smaller portions of food and for longer.

Impact on medicines:

- » The size of a tablet or capsule may be significant but a gastric band does not affect the absorption of drugs.
 - » If a tablet does get stuck in the pouch, the band can be loosened to allow it to pass through into the stomach.^{4,7}
- A **gastric sleeve** is irreversible and involves the removal of up to 75% of the stomach. Appetite is reduced but, as there is no bypass, the effect on absorption of nutrients and drugs is far less than it is with gastric bypass surgery.^{4,5}

Impact on medicines:

- » The dissolution and disintegration of tablets and capsules might be affected by the significantly reduced size of the stomach.

What happens in practice

There is no national guidance on when patients undergoing bariatric surgery should resume solid dosage forms. Therefore, in practice the advice in hospitals to their patients can vary.

- Musgrove Park Hospital advise that patients undergoing bariatric surgery will need to crush their tablets or have chewable or liquid forms for six weeks post-surgery or until they are on solid food. They can resume tablets after this point but may need to break them into smaller pieces.⁹ The advice about a patient's medication formulation requirements can differ depending on which hospital they have their surgery at.
- Whittington Hospital advises their gastric band patients that they will need to continue crushing or taking a liquid or chewable form of their medicines for life. They advise their gastric bypass and gastric sleeve patients to initially crush their tablets or take liquids or chewable forms of their medicines. Gastric bypass patients can resume solid tablets after 3 months while gastric sleeve patients can do this sooner, after 1 month.⁵ However, patients having any of the three types of bariatric surgery can resume solid foods after 4-5 weeks so small tablets and capsules are unlikely to cause problems.
- The advice at University Hospitals of Leicester NHS Trust to gastric band patients is to continue liquid medicines for 2-3 months until oedema has settled. They recommend that gastric bypass patients remain on liquid or crushed medicines long-term.⁸
- Healthier Weight, a private company specialising in obesity surgery, advises that patients will usually be able to continue with regular medication after a gastric bypass operation or gastric band. Tablets that are enteric coated or sustained release should not be used. If tablets are large, it may be necessary to split or crush them. Patients can be instructed to try their tablets first and if they feel they are sticking they can split them or crush them and take with a spoonful of yoghurt. Capsules are soft and designed to soften and melt inside the stomach. If they are too large it may be possible to open them and sprinkle the contents over a spoonful of yoghurt and then taken.¹⁰ Opening capsules and crushing tablets should only be done on the advice of a doctor and/or pharmacist who have assessed the risks and benefits and alternative options.¹¹
- Effervescent formulations should be avoided because the build-up of gas trapped in the pouch can be uncomfortable for the patient. The excess sodium in these formulations is also not appropriate for bariatric patients with hypertension.⁶

- As patients lose weight, they will often see improvements in co-morbidities, like diabetes control and lipid levels, and this has implications for their medicines. Also as the patient loses weight, their volume of distribution will change so pharmacokinetics for their medications may alter. Therefore, the need for medications as well as dosing regimens should be regularly reviewed post-bariatric surgery.⁶
- The volume of liquid medicine given also needs to be considered. Often, the volume of the remaining stomach pouch is 30-50ml. If many of the patient's medicines are given as liquids at the same time, it would not take much to fill the stomach, especially if taken with food so it may be beneficial to stagger doses.⁸

Useful resources

Consult the "NEWT Guidelines" (visitor's site) for advice and practical information on whether a tablet can be crushed or a capsule opened. Subscription required for drug specific information.

<http://www.newtguidelines.com/visitor.html>

White, R. and Bradnam, V. (2010) Handbook of Drug Administration via Enteral Feeding Tubes. Second Edition. Pharmaceutical Press, London.

UKMI's Medicines Q&A published in July 2013 on 'What are the therapeutic options for patients unable to take solid dosage forms?' includes a table of alternative formulations arranged according to commonly prescribed drug classes.

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