

**OCTASA 400mg MR Tablets (mesalazine) and OCTASA 800mg MR Tablets (mesalazine) – Prescribing Information.** Please consult the Summary of Product Characteristics (SPC) for full prescribing information. **Presentations:** Modified Release tablets containing 400mg mesalazine or 800mg mesalazine. **Indications:** Ulcerative Colitis – Treatment of mild to moderate acute exacerbations. Maintenance of remission. Crohn's ileocolitis – Maintenance of remission. **Dosage and administration:** 400mg tablets – Adults: Acute disease: Six tablets a day in divided doses, with concomitant steroid therapy where indicated. Maintenance therapy: Three to six tablets a day in divided doses. 800mg tablets – Adults: Mild Acute Disease: 3 tablets (2.4g) once daily or in divided doses. Moderate Acute Disease: 3 to 6 tablets (2.4g–4.8g) daily. 2.4g may be taken once daily, higher doses should be taken in divided doses. Maintenance therapy: 2 to 3 tablets (1.6g to 2.4g) once daily or in divided doses. Not more than 3 tablets should be taken together. 400mg and 800mg tablets – Tablets must be swallowed whole. Elderly: Normal adult dose may be used unless renal function is impaired. Children: Limited documentation of efficacy. Dose to be determined individually. Generally recommended that half the adult dose may be given to children up to a body weight of 40 kg, and the normal adult dose to those above 40 kg. **Contraindications:** Hypersensitivity to salicylates or any of the excipients, severe impairment of hepatic or renal function (GFR less than 20 ml/min), gastric or duodenal ulcer, haemorrhagic tendency. **Warnings and Precautions:** Blood tests (differential blood count; creatinine) and urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Follow-up tests are recommended 14 days after start of treatment, then a further two to three tests at intervals of 4 weeks. If findings are normal, carry out follow-up tests every 3 months. If additional symptoms occur, perform these tests immediately. Best avoided in patients with mild-moderate renal impairment; if necessary, use with extreme caution. Caution in patients with impaired hepatic function. If dehydration occurs, correct as soon as possible. Discontinue treatment if renal function deteriorates. Monitor patients with pulmonary disease, in particular asthma, very carefully. Discontinue immediately if acute intolerance reactions occur i.e. abdominal cramps, acute abdominal pain, fever, severe headache and rash. Very rarely serious blood dyscrasias have been reported. Perform haematological investigations including a complete blood count especially if a patient develops signs and symptoms suggestive of blood dyscrasias during treatment, such as unexplained bleeding, haematoma, purpura, anaemia, persistent fever, or a sore throat. Stop treatment immediately if there is suspicion or evidence of blood dyscrasias and patients should seek immediate medical advice. Use with caution in the elderly subject to patients having normal renal function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Interactions:** Neutropenic agents (e.g. NSAIDs and azathioprine), digoxin, warfarin, azathioprine, 6-mercaptopurine or thioguanine. **Pregnancy and lactation:** Only to be used when the potential benefit outweighs the possible hazards. **Adverse reactions:** Rarely: Dizziness, headache, myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, bloating. Very rarely: Altered blood counts (aplastic anaemia, granulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia), bone marrow depression, anaemia, peripheral neuropathy, vertigo, allergic and fixed drug reactions (including dyspnoea, cough, bronchospasm, asthma, pulmonary eosinophilia, lung infiltration, pneumonitis), eosinophilic pneumonia, pancreatitis, exacerbation of disease, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, hepatic function abnormal / abnormal liver function tests, alopecia, Stevens Johnson syndrome, erythema multiforme, bullous skin reactions, urticaria, rash, myalgia, arthralgia, lupus-like syndrome with pericarditis and pleuropneumonitis as prominent symptoms as well as rash and arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure, which may be reversible on withdrawal, nephrotic syndrome, hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, paronitis, oligospermia (reversible). **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg – PL36633/0002: packs of 90 tablets (£19.50) and 120 tablets (£26.00). 800mg – PL36633/0001: packs of 90 tablets (£47.50) and 180 tablets (£85.00). **Legal category:** POM. **Marketing Authorisation Holder:** Tilotts Pharma UK Ltd, The Larnarville Suite, The Stables, Wellington Hall, Wellington, Lincolnshire, LN9 0XK, UK. 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**References**  
1. MIMS. Accessed online, May 2014.  
2. Data on file, Tilotts Pharma UK Limited. [Discontinuation profiles].  
3. Data on file, Tilotts Pharma UK Limited. [Patient years].  
4. British National Formulary. Mesalazine. Available at: <http://www.medicinescomplete.com/mc/bnf/current/PPP423-mesalazine.htm> accessed May 2014.  
UKOC0023/0514b. Date of preparation: June 2014.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Tilotts Pharma UK Ltd. (address as above) Tel: 0845 034 4476.



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## Viewpoint

# Obstructive defecation syndrome

**Mr Andrew Hextall** discusses the assessment and management of patients with bowel evacuation disorders

Constipation is a common reason for women of all ages to consult their GP. Although difficulty with bowel evacuation can result from problems with the consistency of a motion, it is increasingly recognised that many women experience obstructive defecation syndrome (ODS), often as a consequence of pelvic floor damage experienced during childbirth.

## Causes

Failure to relax the anal sphincter or pelvic floor muscles while trying to defecate is a common functional cause of obstructive defecation – this is also known as anismus or pelvic floor dyssynergia. This condition often improves with pelvic floor physiotherapy and biofeedback.<sup>1</sup>

The mechanical causes of ODS include:

- Rectocele: a weakness in the rectovaginal septum allows the rectum to push forward against the posterior vaginal wall and herniate. Some women will become aware of a bulge in the vagina, sometimes causing problems with intercourse, while others can feel a dragging

sensation, particularly towards the end of the day if they have been lifting or spent a lot of time standing.

- Intussusception: internal rectal prolapse (rectal intussusception) can obstruct the bowel lumen/passage of faeces and often coexists with a rectocele.
- Enterocoele: a hernia of the small bowel or sigmoid colon through the Pouch of Douglas can obstruct defecation and cause difficulty with evacuation.

## Clinical assessment

A detailed history will give many clues as to the possible cause of the defecatory disorder.

Red flag symptoms, such as recent change in bowel habit or rectal bleeding, need to be excluded.

Frequency of bowel opening and the consistency of the motion passed are important, as is a description of the difficulty the patient is experiencing. Coexistent gynaecological or urological symptoms need to be considered and may help when deciding where to make a referral.

Examination should include palpation of the abdomen to exclude a



Vaginal wall prolapse: a common cause of obstructive defecation

“Many women experience obstructive defecation syndrome, often as a consequence of pelvic floor damage during childbirth”

pelvic mass, vaginal examination to look for prolapse or uterine enlargement, and a rectal assessment to rule out any low sinister pathology.

## Investigations

History and examination may help to decide if further investigations are necessary.

Sometimes it is worth considering trying stool softeners or referring the patient to a specialist women's health physiotherapist before requesting any investigations.

For those women who do not respond to simple measures, the following studies can be useful.

## Defecation proctography

Contrast medium is inserted into the rectum, then defecation is imaged, usually by X-ray. Movement of the rectum and pelvic floor can be assessed dynamically, with rectocele and intussusception being frequent findings in patients with ODS.

Some women with anismus are unable to relax their pelvic floor and anal sphincter, leading to incomplete evacuation.

## Colonic transit studies

These can be useful if there is a suspicion that the patient has a slow colonic transit time and true constipation.

## Dynamic MRI

As there is no irradiation and soft tissue structures can be imaged, this investigation is increasingly replacing conventional defecography.

## Anorectal manometry and imaging

This is particularly useful when patients appear to have difficulty relaxing their anal sphincter or have coexistent faecal incontinence.

## Multidisciplinary team

A multidisciplinary team approach is considered essential to obtain the best outcome.

Patients often complain of coexistent colorectal, gynaecological and urological symptoms, which need to be considered in context with a radiologist who has performed a defecating proctogram or other imaging.

The presence of a specialist women's health physiotherapist helps to ensure that conservative as well as surgical treatments are offered.

## Where to refer?

Patients who are significantly troubled by their symptoms and fail to improve with conservative measures should be referred to the local pelvic floor service, if available, or to a urogynaecologist or colorectal surgeon with an interest in pelvic floor problems.

## Conservative treatment

Patients should be advised to eat a healthy balanced diet and drink about two litres of water a day, depending on their activity levels and the ambient temperature.

It may be necessary to prescribe stool softeners. Particular attention should be paid to developing a regular bowel habit, especially for women with a busy lifestyle.

Pelvic floor physiotherapy is the first-line treatment for most patients and includes instruction on:

- Positioning on the toilet.
- Relaxation of the abdominal and pelvic floor muscles.
- Avoidance of straining and breath holding.
- Promoting correct techniques to allow unobstructed defecation.

## Surgery

The type of surgery is usually tailored to the patient after a failed trial of conservative therapy and discussion by the pelvic floor multidisciplinary team. The most commonly performed procedures are:

- Rectocele repair: a standard posterior repair, sometimes with perineorrhaphy, is the most common procedure when patients complain of ODS and a bulge in the vagina secondary to a rectocele.
- Stapled transanal resection of rectum: a transanal approach can be used to treat a rectocele and prolapsing rectal mucosa causing intussusception.<sup>2</sup>
- Laparoscopic ventral rectopexy: this is particularly suitable for women with a visible external prolapse of the rectum and obstructive defecation, although the operation can also be performed for those with intussusception on defecography.<sup>3</sup>

## Conclusion

Constipation and ODS are common problems in primary care. Initial assessment and treatment using pelvic floor physiotherapy can often be undertaken without the need for referral. Investigation and discussion by a pelvic floor multidisciplinary team are increasingly seen as essential before surgery is undertaken.

• Mr Hextall is consultant obstetrician and gynaecologist/urogynaecologist, Spire Bushey Hospital and St Albans City Hospital, West Hertfordshire Hospitals NHS Trust

## Learning points

- Obstructive defecation syndrome is a common problem in women.
- Conservative measures, such as pelvic floor physiotherapy, often help.
- Consider referral to the local pelvic floor service.
- Imaging, including defecography, is useful when planning surgery.
- Most patients should be discussed by the pelvic floor multidisciplinary team before having definitive treatment.
- A number of different surgical options are available.

## References

1. Ho YH, Tan M, Goh HS. Clinical and physiologic effects of biofeedback in outlet obstruction constipation. *Dis Colon Rectum* 1996; 39: 520-4.
2. Ommer A, Albrecht K, Wengler F et al. Stapled transanal rectal resection (STARR): a new option in the treatment of obstructive defecation syndrome. *Langenbecks Arch Surg* 2006; 391(1): 32-7.
3. McCall JE, Thomson JR. Rectopexy for internal rectal intussusception. *Br J Surg* 1990; 77: 632-4.