The gastric pacemaker and its implications for dental treatment

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Abstract

Background: Gastroparesis is a chronic condition characterised by a delay in gastric emptying and can be profoundly disabling with symptoms including nausea, vomiting and abdominal bloating. In those cases refractory to medical intervention, a high-frequency gastric electrical stimulation device (gastric pacemaker) can offer an improved quality of life. Manufacturers of the device recommend that it is deactivated during any dental treatment involving use of a dental drill, the aim being to prevent electromagnetic stimulation that may damage the neurostimulator or interfere with its operation. This case report describes the patient and practitioner journey in coordinating dental care for the patient with a gastric pacemaker.

Case summary: This case study describes the management of the delivery of dental treatment for a 47 year old female patient with an Enterra® gastric pacemaker. Her gastroparesis was associated with a diagnosis of systemic sclerosis. Her presenting complaint was a fractured upper left second molar. On examination, further dental caries was noted in the upper left first molar and lower right third molar. Prior to embarking on treatment, a multidisciplinary team was consulted including a consultant in Upper Gastrointestinal Surgery and the Medtronic manufacturing team. Despite differing views on management of the device, in accordance with the manufacturing guidance it was deactivated during dental treatment. An extraction and two restorations were performed with no notable deleterious effect to the patient. The reactivation process was uneventful and the patient was satisfied with the outcome.

Conclusions: The patient with a gastric pacemaker can be managed safely in the dental setting with input from the gastroenterology team and the manufacturing team. De- and re-activation is relatively simple and ensures that the risk to both device and patient is reduced as far as is reasonably practicable.

Key words: *Special care dentistry, gastric pacemaker*

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Introduction

The gastric pacemaker is a high-frequency gastric electrical stimulation device. The primary indication for its use is gastroparesis (delayed gastric emptying) (NHS England, 2016). It also offers therapeutic potential for conditions such as short bowel syndrome, intestinal pseudo obstruction and faecal incontinence (Zhang and Chen, 2006). Additionally, the device has been proposed as an effective therapy for the management of obesity (Lebovitz, 2016). Manufacturers recommend that the gastric pacemaker is deactivated during any dental treatment involving use of a dental drill, the aim being to prevent electromagnetic stimulation that may damage the neurostimulator or interfere with its operation. This case report details the causes and clinical presentation of gastroparesis, the gastric pacemaker device, as well as describing the patient and practitioner journey in coordinating dental care for the patient with a gastric pacemaker.

Gastroparesis

Gastroparesis is a chronic condition that results in a delay in gastric emptying. It is characterised by major

impairment of gastrointestinal motility without any mechanical obstruction (NICE, 2014). The condition can be profoundly disabling due to persistent signs and symptoms such as nausea, vomiting, abdominal bloating, heartburn and epigastric pain of varying severity (NHS England, 2016). More severe symptoms may lead to dehydration from repeated vomiting, malnutrition and poor glycaemic control in those with diabetes. These symptoms can have a significant detrimental effect on general health and wellbeing (NIDDK Gastroparesis Clinical Research Consortium, 2011). In those cases refractory to medical intervention, a gastric pacemaker can offer an improved quality of life.

Gastroparesis is most commonly associated with diabetes, but is also linked to a multiplicity of other conditions, including: connective tissue disorders, Parkinson's disease, abdominal migraine, anorexia nervosa, psychological pathology or post abdominal surgery (Zhang and Chen, 2006; NICE, 2014). The patient described in this case study had developed gastroparesis as a result of severe systemic sclerosis. Systemic sclerosis (scleroderma) is a chronic autoimmune disease. The condition results from proliferative vascular lesions that lead to fibrosis of the skin and internal organs (Sallam, McNearney and Chen, 2006). As well as leading to gastroparesis, systemic sclerosis can have a range of other effects that may impact upon the provision of dental treatment including: microstomia (reduced mouth opening), sclerodactyly (tightness of skin of hands and feet that can lead to impaired dexterity), oral ulceration and xerostomia (Scerloderma and Raynaud's UK, 2016).

The population prevalence of gastroparesis is difficult to estimate due to inconsistencies in its diagnosis and definition. The prevalence is estimated as 20-50% of those with type I diabetes and up to 30% of those with type II diabetes (Alberta Heritage Foundation for Medical Research, 2006). An observational study including ninety-nine people with systemic sclerosis found that 70% had symptoms of oesophageal dysmotility, 38% exhibited increased gastric emptying and 68% experienced delayed oro-caecal transit time (Saravino *et al.*, 2013).

Treatment options to manage gastroparesis as an alternative to the pacemaker device include diet modification, anti-emetics, jejunostomy tube insertion, gastronomy tube insertion or pyloroplasty. However, for some patients gastroparesis fails to respond to these management approaches and thus patients may progress through ever-more invasive surgical treatments. In 2014, NICE published guidance on gastro-electrical stimulation for gastroparesis and have suggested the treatment modality as appropriate for those cases in which there is chronic intractable nausea or vomiting related to the condition. In view of this the device is being used more widely.

The Gastric Pacemaker decice

The concept of a gastric pacemaker as a method of managing gastroparesis and dysmotility was first described in 1963 (Bilgutay *et al*, 1963). The aim of the device is to enhance gastric emptying and reduce gastrointestinal symptoms. In the UK gastric pacemakers are usually reserved for those people suffering from intractable gastroparesis (NHS England, 2016).

The device consists of a neurostimulator and two leads. The Enterra® device (Medtronic, Minneapolis, USA) used by the patient in this case study was implanted into a pocket in the abdominal wall and via the lead system it delivered electrical impulses to the muscle of the antrum portion of the stomach. The device is controlled wirelessly by a hand held external programmer that enables the settings to be adjusted non-invasively, thus providing customised therapy. The device is implanted under general anaesthesia either by an open or laparoscopic approach (NICE, 2014). O'Grady *et al* (2009) reported that after implantation of a gastro-electrical device, the need for nutritional support reduced from 44% at baseline to 11% of patients at follow-up. Furthermore, the systematic review found statistically significant improvements in total symptom severity score, vomiting severity score, and nausea severity score when compared with baseline.

Despite the effectiveness of the device, as with all procedures, there are associated risks. A systematic review by Chu *et al* (2012) found that the pacemaker device significantly improved symptoms and gastric emptying but found that 7.5% of those undergoing the procedure had post-operative complications. The most common complications resulting from the implantation of a gastric pacemaker device were infection (3.9%), lead or device migration (2.7%), bowel obstruction by the leads or penetration of adjacent gastrointestinal tract (1.2%) and pain at implantation site (0.7%). The systematic review, O'Grady *et al* (2006) reported that 8.3% of patients experienced similar complications, with 2.2% of patients also experiencing erosion of the device through the skin. Zehetner *et al* (2013) reported two cases of death related to the gastric pacemaker which result from bowel infarction and heart failure.

Implications for dental treatment

The gastro-electrical stimulation device function is susceptible to electromagnetic interference. Though the majority of electrical devices and magnets encountered day-to-day will not have adverse effects on the neurostimulation, strong sources of electromagnetic interference can result in death or serious injury arising from heating of the device, system damage requiring replacement of the device or changes in symptom control. Less severe interferences with stimulation may cause a jolting or shocking sensation which does not necessarily lead to damage of the device or injury to the patient.

The Enterra® manual recommends that dental drills and ultrasonic probes are kept at least 15cm from the neurostimulator and that the device should be turned off prior to the dental procedure and reactivated once the procedure has been completed (Medtronic, 2016). Although the distance between the mouth and the device is likely to exceed 15cm, in the case study described below, both the patient and the manufacturer opted to deactivate the neurostimulator due to the perceived risk of damage to the device. Other procedures occasionally used in the dental setting that are likely to affect the device include diathermy and electrocautery. Electrocautery can cause damage to the

leads or neurostimulator. It is recommended that the neurostimulator it turned off prior to electrocautery; bipolar, as opposed to unipolar, cautery is advised. The Enterra® devices can be externally turned off and on via the hand held programmer. It is advised that the manufacturer of the device is contacted to cease and restore device function before and after the dental appointment. In addition to ensuring the appropriate management of the device during dental treatment, the patient may also require additional considerations related to the provision of dental care.

Once the neurostimulation has ceased, the patient may experience a return of gastrointestinal symptoms including nausea and vomiting. If general anaesthesia or sedation are being considered, the safe management of the patient pre-, intra- and post-operatively should be discussed with the anaesthetist, dental team and device manufacturers. The patient may be at an increased risk of vomiting and subsequent aspiration of stomach contents. In view of this, it is important to record the severity of symptoms when the device is turned off and report adherence to any medication regimes including anti-emetics.

The following case report describes the management of a patient with an implanted Enterra II® device and the multi-disciplinary treatment planning required to ensure safe delivery of dental care.

Case report

Dental history

A 47-year-old female, patient X, was initially referred by her consultant rheumatologist to the Oral Medicine department based at a London teaching hospital for management of the oral features of systemic sclerosis. The patient was concerned that the erosion of her teeth was progressing due to daily vomiting. She regularly attended a general dental practitioner (GDP) and had expressed concerns about her ability to undergo dental treatment due to reduced mouth opening. At assessment, mild microstomia with an inter-incisal distance of 25mm was observed. Other oral features of systemic sclerosis, such as telangiectasia and xerostomia, were not noted. Dental erosion, caries and periodontal disease were noted. In view of this, patient X was referred to the School of Hygiene and Therapy for oral hygiene advice, and to the Restorative Dentistry department for the management of the dental erosion.

Subsequently, patient X had three appointments with the School of Hygiene and Therapy, where she received oral hygiene instructions, supragingival scaling, and prescription of sodium fluoride 1.1% toothpaste for twice daily use. The restorative dentistry team confirmed that the patient had mild dental erosion and multiple carious lesions. Conservative management of the dental erosion was advised, and the patient was deemed suitable to be seen by a GDP for management of the dental caries and long-term review. Patient X attended a three months follow up appointment with Oral Medicine, but failed to attend future appointments and was therefore discharged.

In August 2016, patient X was re-referred by her consultant gastroenterologist for specialist dental management with the Special Care Dentistry team. There was concern that her oral health had declined and oral access was increasingly limited due to progressive systemic sclerosis.

At her initial appointment the patient presented with a six-month history of a fractured upper left molar, without associated pain or swelling. In addition, she was concerned that her mouth opening had reduced and her gastric reflux had worsened. She indicated that vomiting due to gastroparesis secondary to systemic sclerosis had worsened. An Enterra® gastric pacemaker device had been fitted to improve the symptoms of gastroparesis but the patient was concerned that dental treatment would interfere with the device. Patient X reinforced that prior to the deterioration in her general health she was a regular dental attender in general dental practice, and had uneventful dental procedures under local anaesthesia.

Relevant medical history

In 2010, patient X was diagnosed with systemic sclerosis, with severe gastrointestinal, skin and joint involvement. Her quality-of-life had been significantly reduced by the gastrointestinal symptoms including gastritis, pan-gastrointestinal dysmotility, and intestinal failure which subsequently led to gastroparesis. Further consequences of the gastrointestinal involvement were chronic anaemia and low body mass index, with reliance on total parenteral nutrition. The intractable symptoms and failure to respond to other therapeutic measures led to the decision to implant a gastric electrical stimulation system (gastric pacemaker), for the management of gastroparesis. In June 2014 at University College London Hospital, the pacemaker device was placed in the subcutaneous pocket on the left of her abdomen adjacent to the greater curve of the stomach.

Patient X also had other features of systemic sclerosis including Raynaud's phenomena, sclerodactyly with associated digital ulceration, pulmonary fibrosis, pulmonary artery hypertension (PAH), inflammatory arthritis and myositis (Steen, 1998; Shah and Wigley, 2013). She had also been diagnosed with cataracts secondary to corticosteroid treatment.

Regular medications consisted of bosentan (endothelin receptor antagonist for PAH), esomeprazole (proton pump inhibitor), ranitidine (histamine-2 blocker), methotrexate, rituximab, rifaximin, neomycin cream, folic acid and Gaviscon®.

Clinical findings

Patient X was noted to be underweight due to gastrointestinal malabsorption. She had mild sclerodactyly with history of digital ulceration. Her fingers had curled inwards slightly with an associated reduction in movement. The facial skin was stiff, tight and shiny leading to a mask-like appearance in relation to the upper third of the face, and to a lesser extent around the mouth. The inter-incisal opening was 20mm, a reduction by 5mm over the four year period when this was previously recorded by the Oral Medicine department. A right temporomandibular joint click and bilateral tenderness on palpation in the right masseteric area were also noted.

Intra-orally, there was bilateral stiffening / fibrosis of the buccal mucosa. Minimal plaque and calculus deposits were present. Additionally, there was generalised tooth surface

loss with features of erosion, attrition and abrasion but no associated sensitivity or pulpal exposure.

Unrestorable caries of the upper left second permanent molar and restorable caries of the upper left first permanent molar and lower right permanent third molar were noted clinically and radiographically.

Dental procedures

At the consultation appointment, tailored oral hygiene instructions and preventative advice were given, ensuring the patient could undertake these with her reduced oral access and impaired manual dexterity. The patient was offered oral hygiene advice in alignment with Delivering Better Oral Health (2014) guidance: twice daily brushing, to continue using sodium fluoride 1.1% toothpaste, dietary advice to limit frequency of sugar intake and a demonstration of dental floss. Sodium fluoride varnish 2.26% (22,6000ppm) was applied to the carious upper left first and second molars to stabilise these teeth whilst advice was sought regarding the peri-operative management of the gastric pacemaker device.

The Special Care dental consultant subsequently contacted the patient's gastrointestinal surgeon and the Medtronic Pacemaker Device advice team. The surgeon did not raise any concerns regarding dental intervention. However, the Medtronic team highlighted that delivery of dental treatment should take into account the potential for any dental drilling to cause an interference with the device, with the potential for it to stop functioning. It was advised that the device should be switched off before dental treatment and then reactivated after completion. Unfortunately this could not be undertaken by the patient but the company agreed to send a representative to do this using a master controller at each dental appointment. The patient was contacted to discuss the difference in advice received from the surgeon and the manufacturer of the gastric pacemaker. It was agreed that the manufacturer's advice should be followed as the impact to the patient should the gastric pacemaker cease functioning would be profound.

The Medtronic team arranged to send a representative to each dental appointment to undertake the de- and re-activation of the gastric pacemaker device using their master controller. The patient attended for two further appointments where scaling, extraction of the upper left second molar, and restorations of the upper left first molar and lower right third molar were provided under local anaesthesia.

In view of the fact that the patient was at increased risk of nausea and vomiting when the gastric pacemaker was deactivated, each appointment was no longer than one hour. The patient was only partially reclined to 45 degrees to reduce the potential for gastric acid and/or stomach contents to be aspirated. The de- and re-activation of the gastric pacemaker were uneventful and the dental treatment completed with no notable deleterious effects to the patient.

Implications for dental management

There were multiple factors to consider as part of the risk assessment process prior to delivering safe dental care for patient X. These were in relation to the patient's primary diagnosis of systemic sclerosis and also in relation to the Medtronic gastric pacemaker device. The factors considered in the risk assessment included:

- Risk of vomiting and gastric acid reflux with subsequent aspiration
- Extremely low body weight / malabsorption – impact on prescribing medication
- Reduced oral access due to microstomia
- Reduced manual dexterity due to sclerodactyly
- Fragility of the oral mucosa and blood vessels, especially in relation to dental extractions
- Increased tooth surface loss due to gastric acid reflux and vomiting
- Risk associated with the gastric pacemaker and electromagnetic interference caused by dental drilling
- Psychological distress related the underlying systemic sclerosis to de-activating gastric pacemaker device and the dental extraction procedure
- Reduced quality of life.

In view of all the factors above, patient X required a patient-centred, multidisciplinary team approach. Patient engagement was key to achieving a successful outcome, ensuring that she was aware that the risks had been considered and interventions put in place to mitigate them.

The patient's primary concern was that her gastric pacemaker function should not be impaired in any way as she had been advised that should it stop working she would be at significant risk of aspiration of stomach contents and even at risk of death. Despite the distance between the mouth and the device exceeding the 15cm electromagnetic field risk zone, the patient wished for deactivation of the device. The Montgomery ruling states "The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in proposed treatment, and of reasonable alternatives. A risk is 'material' if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor is or should reasonably be aware that their patient would be likely to attach significance to it." (Montgomery v Lanarkshire Health Board Scotland, 2015). The patient in this case study was involved in a shared decision making process, the gastric pacemaker device had offered her considerable improvement in daily functioning since its insertion and the patient wanted to ensure the device was not damaged during the dental procedure. The relative risks and benefits of deactivating the device or maintaining its activated state were discussed with the patient, her Upper Gastrointestinal surgeon and the Medtronic team. The practicality of arranging a company representative to attend each dental appointment to deactivate the device and the risks of deactivating the device were weighed against the physiological and psychological risk to the patient of leaving the device activated during dental procedures involving drilling and took into account the patient's preference.

Patient engagement in the positioning process was another important factor in the safe delivery of dental care; this particular patient was able to indicate clearly the position in which she felt most comfortable receiving dental treatment and understood the risks of aspiration. She also appreciated that the appointments should not be extended to

beyond the planned one hour due to the risk of gastric acid accumulation, vomiting and risk of subsequent aspiration. The All Wales Special Interest Group for Special Oral Healthcare (SIG) (2014) have developed guidance for those patients with dysphagia who are at risk of aspiration during dental treatment. Their recommendations include:

- Regular oral suctioning maintained throughout treatment - use of saliva ejector
- Raising the body to 30-45 degree angle
- Tilting the head to one side
- Using a chin-tuck position during dental treatment
- Reduced water flow of high speed handpiece and ultrasonic.

The SIG do not make specific reference to fasting prior to performing dental treatment to reduce the risk of aspiration of stomach contents in those patients who may be at increased risk of vomiting. The patient in this case study was severely underweight and commonly experienced weakness and fatigue, given that the Special Care Dentistry team used the above precautions to reduce the risk of aspiration during the patient's dental treatment, we did not feel that a fasted state was required.

Preventative advice was given which considered the potential loss of manual dexterity, and high fluoride toothpaste prescribed to manage the tooth surface loss. Issues related to reduced oral access and handling of the soft tissues were addressed by ensuring that Vaseline was used to lubricate the lips, paediatric handpieces and burs were available and gauze applied to the soft tissues prior to retraction or use of suction. It was noted that if medication such as antibiotics were required, the dose should be reduced and given in a form which enabled parenteral administration.

Furthermore, severe systemic sclerosis significantly impacts upon quality of life for patients with dental treatment needs which, in addition to frequent medical care, may be overwhelming for the patient. All aspects of the patient's care, including dental, medical and social factors were considered to ensure that she was able to attend, felt fully supported during the dental procedures, and had appropriate travel and home care arrangements.

Conclusions and learning points

The patient with a gastric pacemaker can be managed safely in the dental setting with input from the gastroenterology team and the manufacturing team. Risk assessment should include factors linked to both the management of the pacemaker device and any medical comorbidities associated with the onset of gastroparesis. De- and re-activation is relatively simple and ensures that the risk to both device and patient is reduced as far as is reasonably practicable.

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