which a plan of action could be formulated for the services provided to patients within the community who required nutritional support when having a gastrostomy inserted. In particular it reinforced the need for ongoing education to patients and those assisting them with the day-to-day management of the device and to be able to recognise the early symptoms of complications developing. The project also demonstrated that the risk of overgranulation tissue developing was a significant problem, which could occur at an early stage after the gastrostomy had been sited. It highlighted that ongoing education should include information to recognize and treat overgranulation tissue at an early stage, potentially when some of the contributing factors are initially observed. (Widgerow and Leak, 2010). The conventional treatment of using silver nitrate to treat overgranulation tissue around gastrostomy sites was also questioned, and replaced with an alternative and safer method, which was more acceptable to the patients. This was evaluated and the outcomes suggested that this is an effective approach, which requires further investigation.

Discussion

The number of patients requiring home enteral nutrition is increasing, and is estimated as a 42.78% growth over a 10 year period. (Omorogieva, 2010). This can challenge the resources of the clinicians working within the community setting who have to prevent and manage such complications as overgranulation tissue around gastrostomy exit sites. The role of the Home Enteral Nutritional Nurse Specialist is to take a strategic approach to the management of these patients to reduce the risk of complications through education and promoting evidence-based practice. It is also to ensure that all resources are used effectively, and the most effective care is delivered. This is difficult when there is very little evidence on which to base clinical practice. In the absence of good quality clinical evidence, the audit approach provided a framework in which the extent of the problem could be identified, and standards of care could be evaluated. It is the start of an ongoing project, which over time will be developed as new evidence emerges and practice is changed.

KEY POINTS

- A daily routine of cleansing the tissue around the gastrostomy site, and checking that the device is correctly positioned can prevent complications such as overgranulation tissue developing
- Poorly fitting devices which cause friction and trauma, can predispose to overgranulation tissue developing
- A number of options are available to treat overgranulation tissue, but clinical effectiveness, patient safety and comfort should be a consideration
- A strategic approach for preventing and treating overgranulation tissue ensures that patients with percutaneous gastrostomy devices receive the most effective and safe care

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Managing overgranulation tissue around gastrostomy sites

Linda Warriner and Pam Spruce

Abstract

The development of overgranulation tissue around gastrostomy devices is a common problem. While there is little evidence to suggest that one treatment is more effective than another, a review of current practice suggests that there is an opportunity to improve clinical practice and patient outcomes in this area of care. A simple practice based audit was undertaken to identify the extent of the problem within one geographical location. A care pathway approach was introduced which reinforced the basic principles of care and introduced the use of a "double foam" dressing on overgranulation tissue. A foam dressing impregnated with Polyhexamethylene Biguanide (PHMB) was used at the wound interface providing a safe and effective alternative to managing overgranulation. The outcomes of the project suggest that a strategic approach to managing overgranulation around gastrostomy devices can improve patient outcomes and improve clinical practice.

Key words: Overgranulation ■ Gastrostomy devices

The intake of food is an important part of life - it has been suggested that after breathing, eating is what we do most frequently during a lifetime. Nutrition is important for the growth and repair of cells. However for some individuals – because of illness or surgery -the ability of maintaining a healthy nutritional status is limited by their ability to take in food. When this occurs enteral support can be introduced to ensure that starvation does not occur. (Crosby and Duerksen, 2007).

Percutaneous gastrostomy feeding is often the choice of therapy for patients who require long-term nutritional support to prevent the complications of inadequate nutrition or starvation (Westaby et al, 2010). With this method of enteral feeding, liquid food supplements can be given through a small device directly into the stomach. There are a range of systems available in clinical practice to do this, some of which are the percutaneous endoscopic gastrostomy (PEG), the balloon gastrostomy, the button gastrostomy (commonly called a button tube) and the obdurated device.

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Accepted for publication: February 2012

A PEG is a device where the small tube is held in place at each end by an internal and external fixator – the role of the external fixator being to hold it securely and prevent it from being pulled into the stomach.

Alternatively, a balloon held device may be used which differs from a PEG in that it is moulded in one piece and is held in the stomach by a balloon inflated with water. Examples of this type of system include a balloon gastrostomy tube which has a moveable external fixator and a button gastrostomy which is a skin level device which is specifically measured for each individual. Each system has specific requirements for care and management to prevent complications developing in or around the exit site or the device itself. The patient may have a gastrostomy inserted as an in-patient procedure where the recommended after care is daily cleansing and drying of the peristomal area using an aseptic technique (Best, 2009) with normal saline as the cleansing solution of choice. Within the practice area of the author, the procedure may also be undertaken as a day case in which the recommended exit site management may be with a "clean technique". Dressings or topical applications should be avoided if the area is clean, dry and the tissue looks healthy. If the device is a PEG, the external fixator should be managed according to the manufacturers guidelines with a daily check to ensure that it is correctly positioned approximately2mm away from the skin. It should also be rotated at least once a week if it is not sutured in place (Best 2004).

After this, the management of gastrostomy devices is fairly simple and where patients have the cognitive ability and dexterity can be self-managed with regular monitoring to check for complications from a specialist healthcare service. When the patient is a child or is unable to physically or cognitively manage the device, relatives, significant others or appropriately trained care workers can provide the necessary care.

The principles of good management include

Maintaining a daily hygiene routine

This involves cleansing around the stoma, the device and surrounding tissues with a mild soap and water (McClave and Neff,2006) using a disposable cloth, which is used specifically for this purpose. This should be of a suitable material which does not shed fibres onto the area, increasing the risk of a prolonged inflammatory response. Following this the area should be rinsed well and thoroughly dried. This procedure provides an opportunity to observe for problems around the exit site or with the device itself.

Checking the device for damage or poor fit

During the daily hygiene routine the tube should be inspected for damage such as splitting or cracking. (McClave and Neff,2006) This could allow leakage of gastric contents onto the surrounding skin resulting in breakdown or excoriation. (Omorogieva 2010). The device should be checked for correct positioning, ensuring that it is not too tight or too slack therefore reducing the risk of trauma to the tract or surrounding tissue (Best, 2004).

Managing the external fixator

The management of the external fixator varies according to the type of device in situ.If it is a PEG the external fixator should be uncoupled and moved away from the skin. The tube should then be advanced and rotated weekly before the external fixator is repositioned correctly. If a balloon gastrostomy is used the flange will need to be moved away from the skin. The tube should be then advanced and rotated and the flange repositioned correctly.

Background

A regular routine of adherence to these basic principles is thought to contribute sufficiently to preventing or the early detection of problems associated with enterostomal feeding. McClave and Neff (2006) suggest that the most common complication with long-term use of gastrostomy devices, is deterioration of the exit site, which can present as skin breakdown, maceration of the skin or an enlarging tract diameter. (Lynch and Fang, 2004)(Image 1). The development of overgranulation tissue (which is often referred to as hypergranulation tissue or granuloma) is also common, although it is cited in the literature as a minor problem (Goldberg et al, 2005). It can rub against the external fixator causing further increase in exudate production and possible bleeding and discomfort for the patient (Image 2).

Literature review

Having experienced the management of overgranulation tissue to be a problem around gastrostomy sites, a literature review was undertaken to provide further information on the extent of the problem. It was also used to identify any studies that would provide evidence to support the use of one treatment over another. However, the information specific to gastrostomy exit sites was limited so the search was extended into chronic wound management. Overgranulation tissue is described in the literature as a "spongy, friable exuberant mass of tissue" (Vuolo, 2010), which is proud of the epithelium. The surface is moist and an ideal medium for bacterial colonization and biofilm formation (McGrath, 2011) and as it is highly vascularized may bleed easily (Best, 2009). The exact mechanism of development is not clearly understood although it is thought to develop as a result of a number of factors, which together or in isolation cause a prolonged inflammatory response. (Dealey,1999). These can include the presence of infection, a reaction to foreign bodies, repeated trauma, and allergy or hypersensitivity to an agent. (McGrath,2011). Occlusive dressings or negative pressure devices used to stimulate granulation tissue formation arealso identified as contributory factors (Widgerow and Leak 2011). In gastrostomy exit sites it is a relatively common complication. (Goldberg, Kaye et al, 2005, Crosby and Duerksen 2007), thought to be caused by friction from a poorly secured tube and with excess moisture from fluid leakage causing skin breakdown in the exit site area. (Borkowski,2005). See (Image 3)

While the presence of overgranulation tissue is not life threatening, the resulting bleeding, exudate and odour may severely affect the quality of life for the patient. (Johnson, 2007). Before any treatment is initiated it is recommended that the underlying cause is identified and corrected. Within the literature search a range of treatment options were identified. These include:-

- Surgical removal of the overgranulation tissue (McClave and Neff, 2006)
- The use of silver nitrate to cauterize the overgranulation. This technique is historically the one most commonly used within gastrostomy site management. (McClave and Neff, 2006) However, it is now discouraged when used by inexperienced clinicians because of the risk of causing damage to the tube and possible chemical burns to the site, (Johnson 2007, Goldberg et al, 2005, Nelson 1999). The mode of action of silver nitrate causes trauma to the wound, promoting further inflammation and increasing the risk of infection developing, (Harris and Rolstad 1999). It can also be distressing for the patient as it can cause pain and increase the exudate levels, (Oldfield, 2009) which can damage the peri-stomal skin.
- Low dose steroids have also been traditionally used to reduce the inflammatory response and production of overgranulation tissue. (Steven Haynes and Hampton,2010). Some steroidal products in use are not approved or indicated for overgranulation tissue or open wounds. (Widgerow and Leak,2010), although there is now a specific dressing (Haelen Tape, Typharm) which is a tape impregnated with an appropriate steroidal agent, recommended as a treatment for this problem (Oldfield 2009, Johnson 2007)
- Topical antimicrobial agents to reduce the bioburden in the tissue. Traditionally topical antibiotic preparations were used but because of the risk of antibiotic resistance they have been effectively replaced with agents such as silver, honey, iodine and polyhexamethylene biguanide (PHMB). (Leak 2002)
- Foam dressings used to reduce the oedema and apply pressure to flatten the overgranulation tissue. (Best, 2004) This technique has been modified using two pieces of foam to increase the pressure. (Steven-Haynes and Hampton 2010)
- In gastrostomy site management, replacing the tube it is an option if no other measures work. (Best 2004)

The literature search was inconclusive in providing an evidence based solution to treating overgranulation tissue around peristomal sites and demonstrated that a wide range of treatments were available. However, there was no information to support the use of one approach over another, although the use of antimicrobial foam dressings appeared to be safe and easy to use. It was of concern that Informal observation of current practice and discussions with colleagues within the speciality of Nutritional Feeding and Tissue Viability also provided anecdotal evidence to suggest that some products are used "off license" to treat overgranulation tissue, including those which contain topical steroids or antibiotics.

Project proposal

Because of the lack of good quality evidence, the prevention and management of overgranulation tissue is often a challenge for Nutritional Specialist Nurses who are faced with reviewing treatment options for this condition. While this type of tissue is also observed in chronic wound management and other exit sites such as long term supra-pubic catheters and tracheostomies (Russel and Matta, 2004, Johnson, 2007), published studies which review this problem suggest that it is not considered prevalent enough to warrant a full randomized study (Vuolo, 2010). However, its presence is problematic around gastrosomy sites with one study was identifying it as the most common reason for patients with a peri-stomal gastrostomy to seek expert advice,(Crosby and Duerkson,2006). The prevention and treatment of overgranulation was also a challenge for the author and therefore a local project to review the extent of the problem, with the most effective option for treatment was warranted.

As a result, a proposal was submitted to the local Primary Care Trust Research Governance Audit Committee outlining the process and potential benefits of undertaking this piece of work. These included a more effective service for patients with gastrostomies, and potential cost savings in terms of reducing the number of inappropriate products used to manage overgranulation. It proposed that a baseline audit should be undertaken on a cohort of patients who were receiving enteral feeding therapy using a peri-stomal device. The audit process was used in a simple practice-based project, which was designed to give a preliminary overview of the care and management of patients with gastrostomies within a defined geographical location. As such it was recognized that there were a number of limitations, which may be resolved in a larger study. These included:-

- Using a convenience sample of patients who were being referred to or reviewed by the Home Enteral Nutrition Team. Information was collected from nursing records, and observations made of the device and the exit site during patient visits by this service. While this was an opportunity to maintain the quality of the data, a large number of patients were not included
- A data capture form was used to record patient information including the relevant medical history, the type of device used, who gave the care whether the basic principles were followed and whether any complications such as infection or overgranulation were observed. If overgranulation tissue was observed, further retrospective information was recorded to identify when it developed and what treatment had been given. The data capture tool was initially piloted with a small patient sample and peer reviewed with other colleagues in this speciality, but would need further validation for a more widespread project.

The next stage of the process was to evaluate the effectiveness of a standardized approach to treatment. Prior to the audit, the options for treating overgranulation tissue were considered using information taken from the literature review, using the experiences of colleagues who were specialists in Tissue Viability and undertaking evaluations of recommended products on peristomal exit sites. A simple flow chart was complied using this information and the outcomes of the evaluation to suggest a pathway of care options with time scales for evaluation. (Table 1 Flow Chart)

The baseline principle was to reduce the risk of problems developing by reinforcing the daily routine of cleansing and care of the device as recommended earlier. It provided an opportunity to re-educate and re-establish a daily routine of care for the patient and to observe for any problems with the device or peristomal tissue. The next step would be to treat any overgranulation tissue present with a safe and acceptable therapy, which would manage the complications of excess exudate and bacterial bacteria colonization, and apply sufficient gentle pressure to reduce the extent of the affected tissue. Based on the information derived from the literature review, the treatment of choice was to use a topical antimicrobial agent impregnated into a polyurethane dressing,(KendallTM AMD antimicrobial foam dressing), over which a standard polyurethane dressing was used to provide the necessary pressure. (Image 4)

While a number of safe antimicrobial agents impregnated within a foam dressing were available, Polyhexamethylene biguanide (PHMB) was the preferred choice of agent for first line treatment. This decision was made after reviewing published information which suggested its safety in use (Gilbert 2006, Hubner and Kramer,2010), current evidence where it was used effectively (Sibbald et al, 2011, Moore and Gray, 2007) and the observations made when it was evaluated on patients with overgranulation tissue around the gastrostomy site. This suggested that it was effective as a treatment and was easy to use and acceptable to patients and their carers. The literature search specifically reviewing the use of antimicrobial agents demonstrated that the use of PHMB in wound management is relatively new although it has been used in a number of other applications such as cosmetics, baby wipes, swimming pool cleaners and contact lens disinfectants for almost 70 years. It is described as "lethal " to a broad spectrum of bacteria, with a very low toxicity to human cells (Sibbald et al, 2011) and to date there is no known resistance. (Gilbert 2006). It is effective against a range of bacteria, (including Methicillin Staphylococcus Aureus), bacteria and fungi. Bacterial infection around the gastrostomy site is fairly common with incidence rates reported in up to 30% of patients, which is reported to respond to treatment with good wound care and systemic antibiotics where necessary(McClave and Neff 2006). Fungal infections are also problematic in gastrostomy site infections, causing skin irritation and possible degradation and damage to the tube. (Lynch and Fang 2004, McClave and Neff, 2006). A further advantage of PHMB over other antimicrobial agents is that it is not deactivated in the presence of organic substances such as blood or pus, (Hubner and Kramer 2010) suggesting that it is suitable for the highly exuding gastrostomy sites where overgranulation tissue is problematic. There is also evidence to demonstrate that it significantly reduced pain when used within a foam dressing (KendallTM AMD Antimicrobial Foam Dressing) in a multi-centre double blind randomized-controlled trial (Sibbald, et al 2011). Within the care pathway, the exit site was evaluated at two weekly intervals, and if after six weeks there was no improvement, the regime of cleansing was modified to include the use of a solution of 1% PHMB (Prontosan) instead of soap and water. This solution combines PHMB with a surfactant (betaine), which is thought to have an increased ability to remove debris, bacteria and biofilms from a wound. (Bradbury and Fletcher, 2011). It was used in conjunction with the previous double foam system, and again evaluated at two weekly intervals for six weeks.

After this the antimicrobial at the wound interface was changed to a silver product used under the standard polyurethane foam. If this was not effective the final recommended treatment was to use a steroidal cream. At this point it was assumed that any possible risk of infection had been eliminated, and would be a low risk option. (McGrath, 2010)

Methodology

The baseline audit was undertaken on a cohort of adult patients who were referred to or reviewed by the Home Enteral Nursing Service over six months. Information was collated from a number of sources, which included current practice, retrospective data from the nursing and medical notes, and recording observations during the patient visits. A simple analysis of the data was undertaken to provide information on the prevalence and treatment of patients with an enterostomal feeding system who had developed overgranulation tissue around the exit site.

Results

In total 58 patients who were included in the audit of which 48% were female (n=28) and 52% male (n=30). The data indicated that 57% (n=33) were living at home, with the remaining 38% resident in a nursing home (n=22) and 5% (n=3) in a residential home. Only 43% (n= 25) received support from District Nurses. The results of the audit provided important information on which to develop a strategy to prevent and effectively treat overgranulation tissue.

Baseline care

- After using the PHMB impregnated foam dressing and standard foam for two weeks the overgranulation tissue in one third (n=8) of the patients had resolved.
- At the four week review this was observed in a further 3 patients.
- A further 3 patients were recorded to have a resolution of overgranulation at the six week review, the total at this stage being 16 patients.

The information from the project indicated that there were implications for clinical practice to improve standards of care and reduce complications associated with the development of overgranulation tissue.

Conclusion

The results of the audit provided important information on The required level of baseline care to the exit site and device as described earlier was only being delivered in 57% of patients (n=33). The routine care of rotating the device was undertaken daily in 88% (n=51) of patients. In the devices where advancing the tube was recommended - this was undertaken in only 45% of cases (n=27).

Observed problems at the exit site

In 13% patients (n=6) trauma was caused to the site by the patient pulling the tube. Increased bacterial colonization is difficult to differentiate in these wounds (McNave and Neff, 2011), and this was reflected in the observation that only 16% (n=9) of patients were considered to have an infection in or around the stoma.

In patients where overgranulation tissue was observed or recorded as being treated currently or in the past

55% (n= 36) received no treatment for the overgranulation tissue. 45% (n= 22) had treatment with a number of products which included silver dressings and creams, barrier creams, hydrocortisone preparations, foam dressings and cautery. There was no evidence to suggest that a formal review process or rationale had been used. In some patients there was overuse of products outside the prescribed timescales, and others products were changed to an alternative too frequently.

Overall 41% (n=24) of the initial group of 58 patients presented with overgranulation tissue around the exit site. Further analysis of data on these patients identified that:-

- In 42% (n=10) of patients there was no information (either recorded or verbal) to demonstrate how long the overgranulation had been present.
- In patients where information was available, overgranulation tissue was observed to develop in the first three months post insertion of the device. This occurred in 46% (n=9) of patients.
- Excessive movement of the external portion of the tube was identified in 50% (n=12) of the patients.
- 50% of the patients where overgranulation tissue was observed had a PEG in situ, 42% a ballon gastrostomy and 8% had an obdurated device.

Implementing A Care Pathway

The care pathway for treatment was then introduced in the cohort of patients where overgranulation tissue was present, and who wished to participate, After cleansing and drying the peristomal area, the device was checked and repositioned. The process of cleansing the exit site and managing the device was re-addressed with the patient and carers , reinforcing the use of a disposable, non fibre shedding cloth for cleansing, with a mild non allergenic soap. The next stage was to treat the overgranulation tissue using a PHMB impregnated foam dressing, cut to a keyhole shape and fitted around the device. This was covered with a standard polyurethane foam dressing to apply the extra pressure. This was changed after the daily gastrostomy care was given. After a period of six months the outcomes of using this care pathway were evaluated. The data from patient records and observation of the exit site demonstrated that:-