The symptom management of fungating malignant wounds using a novel essential oil cream

KEY WORDS
- Fungating malignant wounds
- Neutralising Odour Cream
- Essential Oils

Fungating malignant wounds are a distressing complication of cancer, which can develop with locally advanced, recurrent or metastatic disease. They occur where the tumour breaks through the skin surface and can lead to protruding or crater-like lesions. Key physical symptoms include malodour, exudate, pain, excoriation of surrounding skin and bleeding. Despite an extensive choice of dressings available, there are still a number of unresolved issues, which include the production of exudate, and resultant excoriation of the surrounding skin. Poor conformability of dressings due to irregular shapes of lesions and poor long term odour control. This work provides preliminary, anecdotal data for the safe, effective use of Neutralising Odour Cream (NEOC), a product based on blended essential oils, as a management tool for symptoms of fungating malignant wounds.

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Fungating malignant wounds (FMWs) are a devastating complication of cancer that may develop in patients with locally advanced, recurrent or metastatic disease (Grocott, 2007). They occur due to direct extension of a primary tumour, or as a result of tumour cells detaching from a nearby or distant primary site and travelling via blood, lymphatic vessels or tissues to the skin surface. As the tumour spreads, the cancerous cells infiltrate the surrounding vessels and invade the skin, typically causing a 'cauliflower-shaped' lesion or ulcerative crater (Seaman, 2006).

Unless the tumour is managed by or responsive to conventional treatment (e.g. chemotherapy), the malignant cells can spread and cause damage through a loss of vascularity, proliferative growth and ulceration (Probst et al, 2013). There may also be necrosis due to distortion of the vasculature and destruction of local tissue, causing impeding blood flow and providing a perfect environment for bacteria to flourish (Benbow, 2005). Probst et al (2013) found that FMWs most commonly occur in patients with cancer of the breast (49.3%), neck (20.9%), chest (17.6%), extremities (16.6%), genitalia (16.6%) and head (13.5%), although numbers appear to be based on estimates and historical data.

Physical symptoms of FMWs include excoriation of skin (Grocott, 2007), an all-pervading malodour, profuse exudate, pain and bleeding, compounded by secondary bacterial colonisation (Lo et al, 2012). The extremity of the symptoms experienced can significantly affect quality of life for the whole family at an already emotionally trying time, often leading to feelings of depression, shame, embarrassment (Bale et al, 2004), rejection, disgust, social isolation, distress, anxiety, sadness and loneliness (da Costa Santos et al, 2010), which is made worse by the knowledge that such wounds seldom heal (Naylor, 2001).

As FMWs are rarely curable, the clinical focus tends to be around the palliation of symptoms in order to maximise the patient's quality of life (Maida et al, 2009). Although it has been noted that FMWs are not listed in cancer registries (Grocott, 2001), it has been estimated they occur

in between 5–15% of patients with metastatic disease (Maida et al, 2008; Probst et al, 2009) and in up to 9% of patients with all types of cancer (da Costa Santos et al, 2010). Such figures would suggest there are only a minority of patients who suffer from FMWs, however, it is important to recognise that this is still a large number of individuals, as in the UK in 2011 alone there were 41,500 newly diagnosed cases of breast cancer (Office for National Statistics, 2013).

Patients suffering with FMWs are a 'lost population'. As stated there is no record of FMWs in the cancer registry and, as a result, such patients are often cared for in the home or in local hospices (Hughes et al, 2005). There are no guidelines for care and limited evidence on which to base clinical practice. Recommendations even include placing cat litter around the patient to control malodour (Regnier, 2007), highlighting the haphazard nature of existing management.

Cancer care is often aimed at increasing the quantity of life, sadly this does not always equate to quality of life, in spite of the best efforts of the healthcare professionals involved (Phelps et al, 2009). FMWs are not necessarily immediately life-threatening and it is possible for someone to live for a number of months or years with this disturbing condition, particularly if the tumour is localised (Murphy, 2008). It is a tragedy that patients may choose to isolate themselves from their loved ones during their final weeks or months of life because of the unpleasant symptoms associated with FMWs (da Costa Santos et al, 2010).

CURRENT CARE

A review of the National Institute for Health and Care Excellence (NICE) website showed there were no guidelines relating to the treatment of FMWs and little research activity involved in this cohort of patients. This paucity of evidence was demonstrated in a Cochrane systematic review of topical agents and dressings for FMWs (Adderley and Smith, 2007). Despite an extensive search of any literature relating to the subject, the authors were only able to identify two randomised studies that were suitable to include in the review and, as such, had to conclude that there was insufficient evidence to direct practice. Similarly, Lloyd (2008) observed there is a scarcity of data validating the use and efficacy of standard care.

Although there is limited guidance for the management of FMWs and despite the lack of supporting evidence (Clark, 2002), metronidazole gel is commonly used in the care of such lesions for its antimicrobial effects on anaerobes (Bale et al, 2004), as are a variety of silver and iodine-based products (Hampton, 2008). Equally, charcoal dressings are frequently the dressings of choice for managing odour (Grocott, 2007). Current thinking in addressing FMWs is to use interactive dressings, such as hydrocolloids, hydro-polymer foam, alginates or Hydrofibers, depending on the level of exudate (Naylor, 2001; Wilkes et al, 2001).

It is crucial to remember, however, that the primary dressing must be non-adherent (e.g. Mepitel®, Mölnlycke Health Care) in order to prevent pain and trauma to the delicate tissues during dressing change (Benbow, 2005). A secondary absorbent dressing is also necessary (Hampton, 2008), alongside possible medical interventions, such as chemotherapy or radiotherapy to the lesion (Probst et al, 2013).

A critical part of successful wound management is to effectively assess the wound and consider patients individually in order that each symptom can be addressed and treatment evaluated appropriately. Such practice also allows nurses to provide patients with accurate information about their situation — something that is recognised as being an important factor in good-quality care (Lo et al, 2008).

Despite the extensive choice of dressings available, there are still a number of problems with current options:

- They do not stop the production of exudate, and because of the exudate produced, excoriation of the surrounding skin is sometimes inevitable. Due to the friable tissue and irregular shapes, it is difficult to get a dressing to conform to the area effectively (Grocott, 2007)
- They do not prevent malodour produced by the tumour (Bale et al, 2004)
- The dressings on offer do not always address the issue of pain relief (Benbow, 2005)
- Metronidazole gel should not be used as a long-term option and when used on a

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heavily exuding wound, it can compound the management problem because it tends to seep to the base of the dressing (Hampton, 2008).

Unfortunately, because of the lack of efficacy in management of such lesions, not only does this lead to a distressing time for patients and carers (Lo et al, 2012), it also leads to angst among nurses who are unable to effectively tend to their patients' needs, despite the issue consuming a large quantity of nursing time (Benbow, 2005).

CLINICAL USE OF ESSENTIAL OILS

Essential oils are used in aromatherapy with the assumption they have multiple effects resulting from the complex nature of the constituents of the oils (Tisserand and Balazs, 2013). Many of the constituents such as polyphenols (Daglia, 2012), terpenoids (Dorman and Deans, 2000) and flavonoids have been suggested to have antimicrobial activity (Cushnie and Lamb, 2005), but these and other components are also purported to have other physiological effects, such as the stimulation of phagocytic cells (Serafino et al, 2008), inhibition of microbial adhesion (Takarada et al, 2004) and enhanced wound healing (Woollard et al, 2007).

It is worth noting that none of these claims have been confirmed through robust clinical trials, and there is still a trend to look only at individual oils rather than comparing action between oils or looking at the combined action of blends of oils (Satchell et al, 2002), which is how they are more commonly used in clinical practice (Tisserand and Balazs, 2013). It is possible that the components of the essential oils act together against microbes, either synergistically or antagonistically (van Vuuren et al, 2009), therefore, it is important to examine the antimicrobial activity of the complete oils, rather than their individual components, as in practice they are used as mixtures.

Warnke et al (2006) have documented the positive outcomes of using essential oils in the management of malodorous ulcers. Summarising 30 cases, the authors report a total eradication of associated smells by either the third or fourth day of therapy. Interestingly, a secondary anti-inflammatory response was also noted with some patient's wounds starting to heal and re-epithelise. Equally, Mercier and Knevitt (2005) describe using individually prescribed and blended essential oils within the palliative care setting to reduce the debilitating symptoms associated with FMWs to good effect.

While their paper was descriptive and not a report of rigorous scientific study, it does further validate the idea of exploring the use of essential oils within this arena. Given that wound healing is not a realistic aim of treatment for FMWs (Naylor, 2002), care is focused in improving the quality of life (Maida et al, 2009); essential oil therapy may offer great potential to ease the burden these patients carry.

AIM

The aim of this work was to provide preliminary, anecdotal data for the use of Neutralising Odour Cream (NEOC) as a management tool for symptoms of FMWs.

METHODOLOGY

Within a UK Foundation Trust, referrals have for a number of years been received to treat patients struggling with symptoms of FMWs with a product containing low-dose essential oils. This is clinical practice that has been through the risk assessment and clinical governance processes of the trust and been approved. The oils chosen for use with patients struggling to manage a FMW were identified in light of properties documented in the literature and their lack of known toxicities (Tisserand and Balazs, 2013). The resultant product now titled NEOC; a base cream blended with essential oils to a concentration of 3% (for intellectual property reasons, these cannot be specified) has been in compassionate use now within the trust for a number of years.

The authors worked closely in an attempt to generate in-vitro data on the actions of the essential oils within the blend, prior to regular clinical use within the trust. This has produced preliminary data that validate the anecdotal clinical findings documented here, but funding bids to corroborate findings within the robust framework of a randomised clinical trial have so far been unsuccessful.

Once a referral is received, a suitably qualified clinician assesses the patient. Cautions and contraindications include patients with known allergies or sensitivities to essential oils or

associated compounds (e.g. perfumes). For those cases where it was considered safe and appropriate, patients were provided with verbal and written information about clinical use of essential oils generally and NEOC specifically. They were also requested to provide written consent to treatment. Once consent was obtained, supplies of NEOC were provided. The person responsible for changing dressings was instructed on integrating the NEOC into the patient's care plan and asked to continue to carry out dressing changes as per dressing protocol when clinically appropriate.

Due to the individualised nature of the lesions and variation in dressings preferred by healthcare professionals, it was not possible to standardise the dressing protocol. Each case was followed up as deemed appropriate in each individual situation; patients and carers were asked to evaluate the cream's effectiveness as they experienced it during the course of treatment and grade the symptoms on a Likert scale from 0 (no problem) to 6 (worst problem ever).

RESULTS

No formal outcome measures were used as this was a qualitative service evaluation, however, to date, there have been no adverse reactions to the NEOC, and both patients and staff have been universally positive about its efficacy. Between January and November 2013, 24 patients were seen for assessment of FMWs and provided with supplies of NEOC. Nine of these patients were only seen once, then cared for in the community with no follow-up at the trust. Consequently, there is no follow-up data. Fifteen patients were seen or contacted more than once; all 15 patients reported a reduction in rating of FMWs symptoms. Three patients (20%) did not provide a formal rating to confirm improvement; however, their hospital notes had annotations documenting reduction in symptoms — particularly malodour. The remaining 12 patients (86%) provided a rating for their improvement, of which six (50%) reported that their symptoms had reduced from a rating score of 6 to 0 (*Figure 1*).

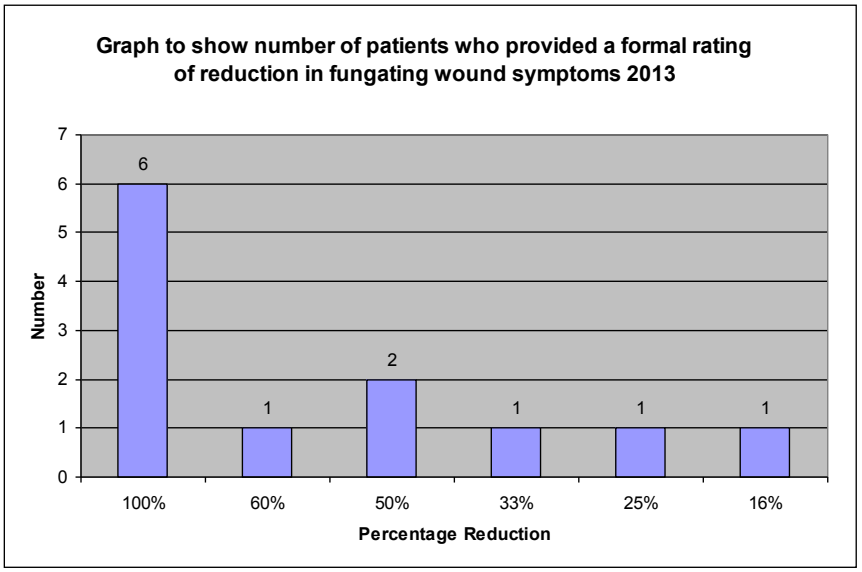

Figure 1. Number of patients that provided a formal rating of percentage decrease in fungating wound symptoms in 2013.

DISCUSSION

The anecdotal reports of patients, carers and staff following the use of NEOC to manage symptoms relating to FMWs over a period of 11 months, have been collated. They appear to suggest that, when NEOC is applied topically under a secondary dressing, it provides relief of some/all symptoms listed as being associated with FMWs with no documented adverse reactions and to date, 100% user acceptability.

The comments made by patients, carers and staff to the team carrying out the evaluations, have been overwhelmingly positive. From the families'/carers' perspective, they see their loved ones more confident and relaxed in their presence, hugging them when they would not have been happy to do so previously and keen to see both young children and old friends. Possibly the most rewarding response, however, has been from the patients themselves. They smile, chat, interact and enjoy being with people again. One lady was reported to say: "I feel and smell like a woman again; it makes me feel so much better."

The results of the combined clinical and laboratory work at the Trust have suggested a promising potential product for management of FMWs. It is, therefore, essential in view of the apparent lack of a consistently effective package of care for such patients, to evaluate the treatment rigorously.

LIMITATIONS

As previously stated, the authors note that the method of evaluation in the cases listed is not robust. No recognised outcome measures were used and only basic baseline data were collected for comparison. Therefore, the results shown are the opinions of the patients, carers and staff. Although not objective, the findings demonstrate that quality of life was subjectively improved. Before the NEOC is espoused as a possible treatment option, it must be exposed to controlled clinical trials.

CONCLUSION AND FUTURE DIRECTIONS

Integration of this potentially useful product into orthodox medical care requires a methodologically rigorous approach that is currently not financially viable. Specifically, a systematic strategy is required to qualify, quantify and justify how, why and when NEOC may be most effectively used and integrate it into a comprehensive algorithm of care effective for all patients struggling with these debilitating, distressing conditions.

The Trust in which this clinical evaluation was carried out is working with a company to get the cream registered as a medical device in order that patients throughout the UK can have access to it and hopefully, a clinical team not involved in its development will work towards formal assessment of the cream through clinical trials. WUK

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Table 1. Summary of recent case studies of patients with fungating malignant wounds (FMWs).

Case	Diagnosis	Presenting complaint	Treatment concurrent to NEOC	Treatment evaluation	Further comments
1	54-year-old, white female. Breast carcinoma with FMWs not managed by chemotherapy	Presenting at eight hand-spans length, malodorous+++, exuding+++, dressing changes 4x daily. Patient (pt) in side room. Pain.	Nil	Day 5 — complete malodour eradication, even during dressing changes. Exudate stemmed. Dressing changes on alternate days. Reduction in bleeding and pain.	Pt's mood also improved and now being nursed on the main ward.
2	40-year-old, white male. Squamous cell carcinoma (SCC) of perineum infiltrating buttock, upper thigh, penis and scrotum	FMWs secondary to SCC. Malodorous+++, exuding+++. Surrounding tissue inflamed and excoriated. Difficulty lying flat. Dressing changes 3x daily and painful, requiring entenox.	Cisplatin Capecitabine	24hr follow-up – Pt reports NEOC to be cooling and making area comfortable. Notes malodour reduced. Day 29 – Dressing changes reduced to 2x daily and less painful. Exudate reduced. Malodour eradicated. Area reduced in size and surrounding tissue less inflamed and excoriated.	Pt reports feeling more relaxed, improved mood and better sleeping pattern.
3	60-year-old, white female. Metastatic breast cancer with FMWs	Presenting at one hand-span in length, malodorous+++. Pt very distressed by smell and feeling of social isolation.	Metronidazole gel stopped when NEOC started	Day 3 – Malodour completely eradicated, even during dressing changes. Pt reports feeling a 'peace of mind' at not having to worry about other people noticing the smell.	Pt told consultant about the benefits of the NEOC. On day 4, transferred to hospice.
4	52-year-old, white male. Squamous cell carcinoma of anus.	Fungating tumour presenting as malodorous+++ and surrounding inflammation. Pt unable to sit or lie flat, requiring MST 90mg BD & PRN oramorph.	Cisplatin Radiotherapy	Day 6 – Improvement in pain and malodour reported by pt. He enjoys soothing sensation on application. Day 2 – Pt noted reduction in pain and malodour. Day 49 – Area clean and healing well. Pt continues with cream as he is happy with results. Reports greater ease in sitting down.	
5	81-year-old, white male. Locally advanced squamous cell carcinoma of left pinna	Fungating tumour around external meatus, malodorous+++, exuding+++ and skin inflammation secondary to radiotherapy.	Radical radiotherapy (daily for 4 weeks)	Day 6 – Malodour, exudate and skin inflammation all vastly reduced compared to baseline. Day 18 – Pt reports continued reduction in malodour. He approximates 60/70% reduction in exudate compared to baseline. Notes an improvement to inflamed skin and enjoys soothing aspect of NEOC Radiotherapy staff found NEOC helpful in respect of malodour and condition of the ear area.	Staff noted area much cleaner, healthier and reduced exudate. They comment on marked difference between this case and a comparable one that did not get NEOC. They cite benefit to other pts in waiting area also.
6	60-year-old, white female. Breast carcinoma	Fungating wound spreading to chest wall and axilla. Minimal malodour and uncomfortable but not painful.	Metronidazole gel stopped when NEOC started	Day 8 – Pt notes no changes in either malodour or comfort.	
7	67-year-old, Afro-Caribbean female. Metastatic disease with fungating right breast wound	Fungating wound causing malodour+++, pain+++ and bleeding+++.	Tamoxifen	Day 8 – malodour eradicated, bleeding reduced and more comfortable. Pt reports she used to chase up district nurses for dressing changes as the wound felt 'awful'. However, hasn't felt the need to do this since using NEOC.	Pt reports NEOC stung for first two applications that she attributes to the area being raw.
8	75-year-old, white female. Metastatic disease with left breast carcinoma spread to chest wall	Fungating wound causing malodour++, bleeding, pain and exuding serous fluid. Pt c/o burning sensation originating from peri-wound irritation	Capecitabine	Day 6 – Malodour eradicated, exudate improved. Pt found cream soothing to apply. Reports burning sensation at 33% original intensity and frequency. Improved pain, pt reduced dose paracetamol to 500mg QDS.	Pt reports additional benefit of improvement in sleeping pattern.
9	60-year-old white female, metastatic GI tumour	Fungating tumour on abdominal wall causing malodour +++ and excoriation of surrounding skin, patient anxious as is sensitive to many skin products including charcoal dressings	Palliative XRT	Day 3 – Staff and patient report reduction in the malodour, itching, soreness and irritation at the site.	Pt did not suffer any sensitivities following use of the cream. Ongoing relief 3 months later.
10	40-year-old white female with metastatic breast cancer	Fungating chest wall disease, malodour +++.	Cisplatin and Capecitabine	Day 3 – Patient and district nurses very happy with response — malodour minimal.	Lifting of necrotic tissue from the tumour.