

## The management of procedural pain in the fungating malignant wounds of the cervical and facial area

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### ABSTRACT

Fungating malignant wounds (FMW) are chronic wounds defined as a skin infiltration by the tumor or metastases. They may be present as raised nodules similar to a cauliflower (proliferative), as a crateriform ulcer (destructive) or a combination of both. The FMW are often associated with different signs, most commonly odor, exudate, bleeding, related wound pain, slough/necrosis, infection and pruritus. In addition the wounds of the cervico – facial district expose the patient to psychological and social problems. Therefore patients with FMW require palliative care and proper management of the wound, not only for the control of wound-related physical symptoms, but also for the resolution of psychosocial problems. From January 1, 2016 to May 31, 2017, a total of 18 patients were observed, including 12 men and 6 women with FMW. Pain was assessed with a validated Numerical Rating Scale, with a range from 0 to 10, where 0 corresponds to the absence of pain and 10 to the maximum of imaginable pain. To evaluate the amount of pain perceived by patients during dressing changes, including the steps of Removal, Cleansing, Debridement, Perilesional skin care, Dressing application, closure and fixation. Removal: average pain 2,3 DS±1. Cleansing: average pain 3,4 DS±2. Debridement: average pain 3,4 DS±2. Dressing Application and Fixation: average pain 5,3 DS±1. In the light of the results, there is a need for better dressing related pain control. For this purpose a multidisciplinary group was formed. The working group developed appropriate therapeutic patterns differentiated in relation to the pain before the intervention and the presence or absence of supportive therapy for the underlying oncological disease. These therapeutic schemes will be tested in practice in order to evaluate their effectiveness on the management of procedural pain.

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### INTRODUCTION

Fungating Malignant Wounds (FMW) are chronic wounds defined as a skin infiltration by the tumor or metastases.<sup>1,2</sup> Unless the proliferation of neoplastic cells is controlled by specific therapies such as chemotherapy, radiotherapy or hormone therapy, the FMW may expand and, as a consequence of injury at the lesion site a combination between loss of vascularization, growth proliferative and ulceration may occur.<sup>3</sup> They may be present as raised nodules similar to a cauliflower (proliferative), as a crateriform ulcer (destructive) or a combination of both.<sup>4</sup> These wounds have an effect on lymphatic drainage, hemostasis and tissue oxygenation, which may affect the genesis of necrosis. Furthermore, rapid cell growth tumors can also influence extracellular pH with consequent alteration of the coagulation cascade, subsequent occlusion of the vessels with formation of necrosis.<sup>5,6</sup> Moreover, the alteration of the lymphatic system involves an increase of pressure of the interstitial fluid between the parts of tissue that can lead to vascular collapse causing tissue infarction, hypoxia and cell death.

In European and Anglo-Saxon countries the prevalence of these wounds varies between 5% and 10% but this value is without a doubt underestimated due, essentially, to the fact that these patients have an

important alteration of the body image that leads them to isolate themselves from the social context and not seek support in the health service.<sup>7-9</sup>

In the years to come, in view of the increase in new cancer diseases, the prevalence data of the FMW are destined to increase.

The FMW are often associated with different signs, most commonly odor, exudate, bleeding, related wound pain, slough/necrosis, infection and pruritus.<sup>4,10</sup> In addition the wounds of the cervico-facial district expose the patient to psychological and social problems.<sup>11,12</sup>

Therefore patients with FMW require palliative care and proper management of the wound, not only for the control of wound-related physical symptoms, but also for the resolution of psychosocial problems.<sup>4,12</sup>

Pain is an important problem in FMW, and is often the cause of distress with a consequent reduction in compliance in the therapeutic, diagnostic and palliative path. It is a complex phenomenon and has been described as an undesirable sensation resulting from illness, wound or emotional distress.<sup>13</sup> A more detailed definition comes from the International Association for the Study of Pain (IASP), which describes pain as an “unpleasant sensory and emotional experience associated with tissue damage, either actual or potential, or described in terms of damage”.<sup>14</sup>

Control of symptoms in the therapeutic diagnostic treatment of palliative care aims to prevent and alleviate suffering through effective management of pain and other symptoms that cause chronic disease-related distress in order to improve quality of life.<sup>15</sup>

In this context a multidisciplinary team approach is needed where the patient and the family, during the illness, are supported and directed towards goals and the patient's needs.<sup>16</sup> For these patients undergoing palliative care, the treatment of the underlying condition will result in total or partial cure ensuring the best clinical-care practice.<sup>17</sup>

## Aims

To evaluate the amount of pain perceived by patients during dressing changes, including the steps of:

- i) Removal;
- ii) Cleansing;
- iii) Debridement;

- iv) Perilesional skin care;
- v) Dressing application, closure and fixation.

## MATERIALS AND METHODS

An observational study was performed at the S.C. ENT U, Molinette Hospital, with the consent of the patient which has been requested with a specific form pursuant to Legislative Decree 196/2003. From January 1, 2016 to May 31, 2017, a total of 18 patients were observed, including 12 men and 6 women with FMW. Pain was assessed with a validated Numerical Rating Scale (NRS), with a range from 0 to 10, where 0 corresponds to the absence of pain and 10 to the maximum of imaginable pain.

### Patients/Population

The inclusion and exclusion criteria described in Table 1 were used.

### Dressing operating procedures

After the first phase of pain assessment, the dressing is removed by using a silicone spray for atraumatic removal of the polyurethane film used as reinforcement of the edges of the secondary dressing. After this procedure, the pain is re-evaluated. The cleansing of FMW (Figure 1) is carried out with nebulizer spray based on Sodium Chloride 0.9% and, subsequently, in relation to the evaluation of the wound, a debridement is performed:

- i) Autolytic/Mechanical in the presence of slough;
- ii) With cutting if there are smelly necrotic rags.

No removal treatment was performed in the presence of a dry necrotic lesion.

Particular attention is paid to the management of exudation, odor and prevention of bleeding. In this regard, specific advanced dressings have been used to avoid the excessive dryness of the wound with traumatic repercussions at the time of removal.

### Data analysis

The statistical analysis was thus carried out: the data concerning each phase of the dressing were reported in a cartesian axis system and the distribution was observed;

**Table 1.** Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Patients suffering from fungating malignant wounds in cervico-facial district	Patients with impaired cognitive status
Age $\geq 18$ years	Patients who have not expressed consent
Good compensation for basal pain (Numerical Rating Scale=0)	

being the symmetrical distribution (Gaussian Distribution – Figure 2) and as there are no outlier values in the queue, the average trend index and the variation of the Standard

Deviation (SD) value have been chosen as the central tendency index. The collected data were inserted in the Excel database and, for each phase of the dressing, the pain perceived by the patient was detected and the average and SD calculated.



**Figure 1.** Fungating malignant wounds of the cervico-facial district.

## RESULTS

In the phases of removal, cleansing and debridement, pain is controlled, settling in the threshold between mild and moderate. Figure 3 shows the perceived pain, that was  $NRS=2,3$  ( $SD\pm 1$ ) at the time of the dressing's removal; this pain tended to increase during the cleansing phase ( $NRS=3.3\pm 2$ ), while it was  $NRS=3.4\pm 2$  during the debridement phase, increasing again during the packaging and fixing phase ( $NRS=5.3\pm 4$ ).

It is also evident that the pain increases as the dressing is carried out, reaching high values in the packaging and fixing phase, with pain peaks of  $NRS=9$ .

## DISCUSSION

This observational study aims to evaluate the pain perceived by patients during the various stages of dressing change. According to the World Health Organization (WHO), palliative care is an integral part of cancer therapy and the approach to patient care must be multidisciplinary. In addition to pain control, psychological, social and spiritual aspects must be taken care of. The goal of palliative care is to achieve the best possible quality of life for patients and their families. Therapy for pain treatment, especially in oncology, must be gradual, that is a step approach, starting from the therapy with non-opioid analgesics, passing after therapy with weak opioids, up to therapy with strong opioids.<sup>18</sup> Dressings have a major impact on patient comfort: they relieve pain, reduce odor and bleeding and absorb excess of exudate. Furthermore, an appropriate medication can facilitate the patient to be socially active by masking the altered self-image. Pain management should follow the WHO guidelines with a fixed time therapy and a support dose, starting from local analgesics, especially during the dressing change, which must be applied and then removed as gently as possible to allow a better pain control and greater patient comfort.<sup>19</sup>

In the study patients were included with  $NRS=0$  in order to evaluate the actual impact caused by the pain medication alone. There was a gradual increase in pain as the dressing change phase progressed. This could be due to the greater nociceptive sensitivity of the patient resulting from his or her basic illness. For this reason, a structured approach able to guarantee absence or low levels of pain at all stages of dressing is essential.

## CONCLUSIONS

In the light of the results, there is a need for better dressing related pain control. For this purpose a multidisciplinary group was formed; it is composed of:

- i) Nurses expert in Wound Care;
- ii) Physicians specialised in Analgesic Therapy;
- iii) Nurses expert in oncology;
- iv) Physicians specialised in ENT;
- v) Anesthetists.

The working group developed appropriate therapeutic patterns differentiated in relation to the pain before the intervention and the presence or absence of supportive therapy for the underlying oncological disease (Supplementary file). These therapeutic schemes will be tested in practice in order to evaluate their effectiveness on the management of procedural pain.

The patients were divided into two groups:

- i) Patients with superficial wounds;
- ii) Patients with deep and/or vegetating wounds.

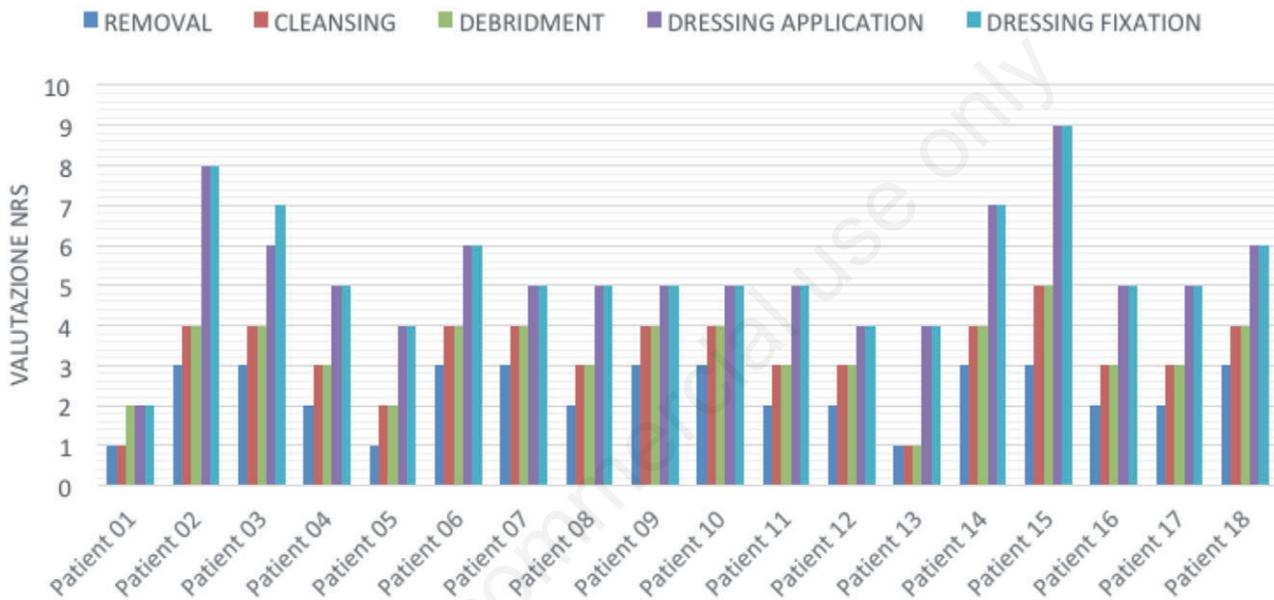


Figure 2. Data distribution.

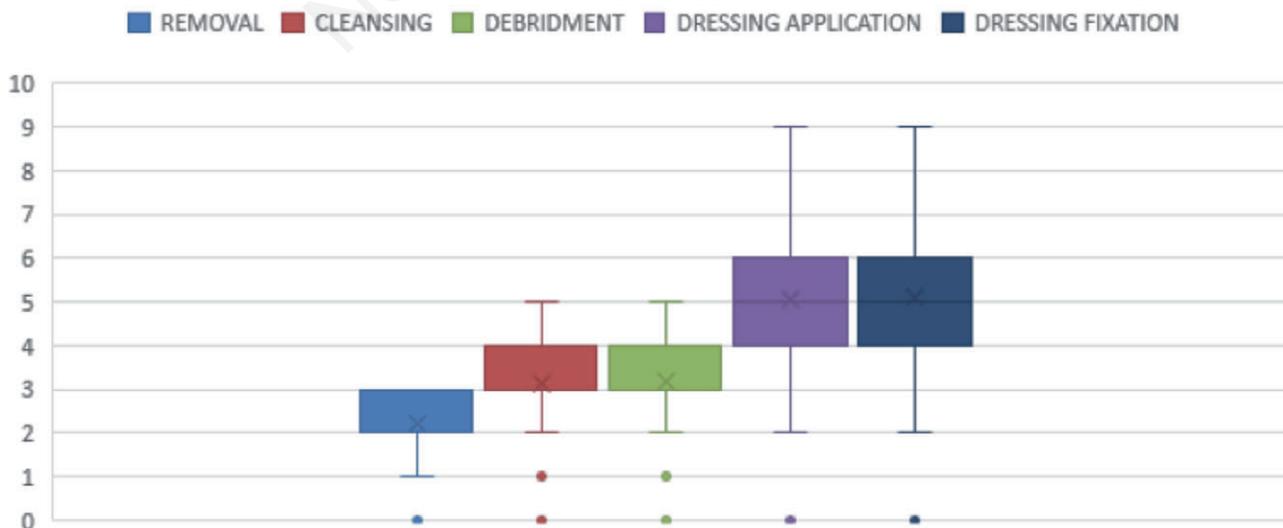


Figure 3. Average pain.

Patients with superficial wounds with NRS<3 are not subjected to any preventive treatment. If NRS > 3, 5% Lidocaine cream is applied to the wound and the peri-wound skin, and, if pain is not controlled, in combination with Paracetamol 1 gr. Alternatively Tramadol 50-100 mg in physiological solution is administered in relation to body weight (50-100 kg). After the decision is taken, the patient is examined also by a physician specialist to set up a pharmacological treatment for the control of the underlying disease.

Patients with deep and/or vegetative wounds, in the absence of basic painkilling therapy, are given Lidocaine cream 5% + Fentanyl 100 mcg sub-lingual if affected by nasal wound; or nasal administration of Fentanyl 50 mcg if present oral lesion and/or impossibility to sub-lingual administration (always with the consent of the patient since both off-label administration). Lidocaine cream 5% is always given to the patient with analgesic therapy with basic opioids; at this treatment, on the basis of the pharmacological molecule used for the management of basal pain, a dose equal to 1/6 of the daily dosage is administered before the change of dressing. Patients treated with Morphine can perform the rescue dose with transmucosal Fentanyl according to the following procedures:

- i) If Morphine <60 mg: Fentanyl 100 mcg;
- ii) If Morphine >60 mg and <100 mg: Fentanyl 100 mcg;
- iii) If Morphine >180 mg: Fentanyl 400 mcg.

As an alternative to the above treatment, the rescue dose can be performed with Morphine 5-7 mg.

If the patient is on Oxycodone per OS (example 60 mg), the rescue dose can be carried out:

- i) Oxycodone 10 mg slow release per OS;
- ii) Fentanyl 200 mcg via trans-mucosal;
- iii) Morphine 5-7 mg intravenously/subcutaneously (Morphine 5 mg as the equivalent dose of Oxycodone 10 mg slow release per OS and Morphine 7 mg as a dose equivalent to Fentanyl 200 mcg via trans-mucosal).

Patients with ongoing primary therapy with intravenous/subcutaneous Morphine, carry out the rescue dose equal to 1/6 of the total daily dose. Alternatively use:

- i) Fentanyl 100 mcg if total daily dosage with Morphine is <30 mg;
- ii) Fentanyl 200 mcg if total daily dosage with Morphine is >30 mg and <90 mg;
- iii) Fentanyl 400 mcg if total daily dosage with Morphine is >90 mg.

For patients with current baseline therapy with transdermal (TD) Fentanyl, the rescue dose is carried out

with intravenous Morphine or alternatively with transmucosal Fentanyl (Figure S3 in Supplementary file).

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