
Case Report**Treatment of peristomal wounds with a topic Neem and Red Hypericum Oil application: Case Studies****Maria Sole Ercolani¹, Filippo La Torre², Elena Toma³**¹Registered Nurse, Wound Care Specialist and Stoma Care Specialist, Policlinico Umberto I (Rome, Italy),²Professor in General Surgery, Department of Surgical Science, Director of I Level Master in Enterostoma Therapy, Director Department of A&E, U.O.C. Trauma and Emergency Surgery – Rectum and Pelvic Floor, “Sapienza” University of Rome (Rome, Italy)³Registered Nurse, Wound Care Specialist and Stoma Care Specialist, Independent Tissue Viability and Ostomy Consultant (Rome, Italy)

Abstract:**Background:** Peristomal skin disorders are one of the most frequent complications on the abdominal stoma. Currently therapeutic approaches do not take into account the specific characteristics of this type of wound.**Objectives:** To assess in a first series of patients not responding to treatment with traditional dressings, the effectiveness of a topic wound dressing with Neem Oil and Red Hypericum Oil, applied so as to guarantee the adhesiveness of the pouching system. This product, currently indicated to treat wounds of all aetiologies, acts as antimicrobial, bacteriostatic and mechanical barrier and promotes natural tissue repair.**Methods:** The two patients we enrolled presented peristomal wounds not responding to treatment with traditional dressings. To comply with the need of applying adhesive pouching we had to devise a suitable wound dressing. The patients were treated twice weekly, by applying the product on an hydrofiber dressing support, protected by a transparent film. No local antiseptics were used.**Results:** Complete healing of the lesions, in the first case after 14 days, in the second after 28 days, with immediate pain decrease. Both patients showed a positive attitude towards the treatment. The dressing design allowed the appliance to remain in place for three days with no complications.**Conclusions:** The use of the Neem Oil and Red Hypericum Oil dressing can be a valid therapeutic solution in the treatment of difficult to heal peristomal wounds, and therefore deserves to be confirmed through studies involving a higher number of patients.

Keywords: peristomal skin disorders, peristomal wound, peristomal skin complication, ostomy complication, peristomal wound dressing**Introduction**

Today, an enterostomy surgical procedure is a valid therapeutic solution in the treatment of intestinal chronic inflammatory and oncologic conditions. Patients requiring such a procedure are many, and their number is increasing. In Italy, 70 thousand patients are estimated to be stoma carriers [1], whereas in the United States their number ranges between 650,000 and 1 million [2]. Although there is no doubt that patients benefit from such a surgical procedure, there are possible complications. Such complications can affect either the stoma or the peristomal skin or both, and although they cannot be precisely estimated, they are very frequent [3,4]. Amongst the peristomal skin complications, the most frequent are the skin lesions which could be caused by infiltration of effluents below the collection device system, by tear and/or trauma, by mucocutaneous separation and by the presence of peristomal granulomatosis [5]. Their appearance can be caused by an incorrect management of the ostomy, or by the incorrect choice or application of the pouching system due to

the insufficient therapeutic training given to the patient, or lastly for anatomical reasons (positioning of the stoma on a skin fold or close to bone prominences) [6,7]. This situation leads to an increase of healthcare expenditure, and has a negative impact on the patient's quality of life [8,9]; in fact, issues affecting the peristomal skin can have physical, psychological, social and spiritual repercussions for the patient.

To date, treatments of peristomal wounds (PW) found in literature [10,11] appear to be generic and do not take into account the specific characteristics of the lesion; this is different than what happens in the Wound Care environment [12,13], where particular attention is given to each and every phase of treatment, from debridement [14] to choosing the most appropriate dressing [15].

In this study, we show the results of an innovative treatment approach to PWs that have not responded to treatment with traditional wound dressings. We used a topical application of the Neem Oil and Red Hypericum Oil, that, due to its bacteriostatic and antimicrobial features [16-21], was thought

to be particularly suitable for treatment of PWs that get into contact with contaminated biological effluents.

Objectives

The objective was to verify, in an initial set of patients with PWs not responding to treatment with traditional dressings, the effectiveness of a Neem Oil and Red Hypericum Oil topical application, applied using a specific procedure to ensure the adhesiveness of the pouching system. The product's effectiveness has already been proven in *Wound Care* [18,19]; however, due to its oily texture, it is difficult to use within *Stoma Care* due to the possible issues with the collection device's adhesiveness issues. In order to confirm the results previously obtained, we monitored in standard times two compliant patients who willingly followed the treatment through.

Materials

We chose *1 Primary Wound Dressing*® (1PWD), specially formulated from a proprietary combination of two plant's derived oils, Neem Oil and Red Hypericum (St. John's Wort, *Oleum Hyperici*) Oil. The product dates back to 2003, when its triple action as anti-inflammatory, insect repellent and antimicrobial was proven, and it gave very good results when tested in *Wound Care* [16-21]. In March 2018 the product obtained authorisation by the Italian Ministry of Health for use on neonatal paediatric patients.

This product, currently indicated to treat wounds of all aetiologies, promotes natural tissue repair, forming an oily coating on the wound surface, acting as antimicrobial, bacteriostatic and mechanical barrier.

1PWD is a compound of medium-long chain saturated and unsaturated fatty acids, which oxydise incorporating and trapping free radicals instead of live cells membrane structures, maintaining the right superficial hydration and supporting healing. The antibacterial spectrum of free fatty acids has a non-specific mode of action; as a consequence, there is no resistance effect, while the double fatty layer of the bacterial cell membrane disintegrates [22]. Thanks to the oily texture, 1PWD prevents the secondary dressing sticking to the wound, allowing pain and trauma free removal.

Therefore, this mechanism could be particularly appropriate when treating PWs with high exposure to contaminated biological effluents. On the other hand, there are no studies in current literature on use of the product for the treatment of peristomal lesions, probably due to the difficulties encountered in managing the appliance, due to the dressing's oily texture. To overcome this issue, we used a hydrofiber dressing as a support, and a transparent film dressing to isolate the wound dressing from the effluents and allow adhesion of the pouching system. The hydrofiber dressing does not interfere with the oil and therefore the latter's properties are not modified.

Methods

We used a distinct two-phase methodology:

1. Patient evaluation and monitoring,

2. Dressing making and application.

1. We monitored two patients, each with a different type of ostomy, with presence of PWs and not responding to the treatment, with a plaque incorporated in the appliance and management of the seepage with traditional devices.

We carried out the patient's global evaluation using the *Toven Method* [23], and the peristomal wounds assessment with SACS 2.0 Scale [24]. We established standard monitoring times using the validated *TOR Form* (Toma Ostomy Research) [5,25].

The monitoring form includes a part on the patient's global assessment, with a section on personal data (type of ostomy, type of appliance, type of hygiene procedures followed, presence of pain), and a part on the stoma monitoring (observing and describing appearance, colour, protrusion, mucocutaneous junction, peristomal skin). It is also possible to note the presence of complications such as retraction, prolapse, necrosis, hernias or mucocutaneous separation [26].

The final section deals with the description of the lesion's evolution in distinct pre-established times:

- T0 - enrollment and initial assessment,
- T1 - 7 days from start of treatment,
- T2 - 14 days from start of treatment,
- T3 - 28 days from start of treatment.

2. The dressing was assembled by applying 1PWD on a hydrofiber base (Photo 1) fixed in place on the peristomal site with a transparent film dressing (Photo 2). We devised this method in order to give the product a base, favouring direct contact with the wound bed and at the same time to create a base for the adhesion of the pouching system, and the hydrofiber pad used had no interaction with 1PWD components. To ensure patient's comfort we decided to change the dressing at the same time of the collection device. We did not use local antiseptics and the dressing was changed twice weekly.



Photo 1 – The product is applied on the hydrofiber dressing



Photo 2 - Fixing the dressing in the peristomal site

Clinical Case 1 (CC1)

The first case is a 70 years old male patient, with ileostomy following surgical procedure of colic resection to remove a neoplasia in the right colon.

General assessment:

- vigilant, conscious and cooperating, preserved objectivity;
 - Body Index Mass (BMI) - 19 kg/m² (normal weight), referred a body weight loss of 7 kg in the last month;
 - Self-sufficiency state Barthel Index - 90/100;
 - no chemotherapy in progress;
 - no other pathologies which could lead to the onset of wounds.
- Nursing diagnoses (of NANDA II International system):** Peristomal skin and tissues integrity affected in the left iliac fossa (00044-46), Altered nutrition, less than required (00002).

Wound assessment: Upon enrollment the patient presented a PW type L2 (erosive wound) located in TV area (according to SACS 2.0) and a surgical dehiscence start, located in TIV area (Photo 3). The skin damage originated due to leakage/undermining of the seal of the pouching system, which provoked an irritative contact dermatitis.

The ostomy had been opened close to the iliac crest, and, although the appliance had been correctly adhering, there was no sign of healing.



Photo 3 - CC1 on initial assessment (T0)

The patient couldn't manage nutrition [27], and had frequent liquid and plentiful discharges. For the first dressing changes we had to insert a rectal tube for the time of dressing application, so as to avoid contamination of the dressing site (Photo 3).

Pain due to dressing change and application was assessed with NRS Scale (*Numerical Rating Scale*) [23,28]. Pain at T0: NRS 6/10 .



Photo 4 - CC1 wound dressing



Photo 5 - CC1 complete healing at T2 (14 days)

The wound dressing was assembled by applying 1PWD on a hydrofiber base fixed in place on the peristomal site with a transparent film dressing (Photo 4).

In 14 days (T2), we observed a resolution of the erosive wound with healing of the surgical dehiscence (Photo 5). Healing occurred before expected time (about 28 days). Pain at dressing change gradually decreased until it was completely absent.

Clinical Case 2 (CC2)

The second clinical case is a 60 years old female patient, with colostomy created following the second surgical procedure to remove a colon neoplasia.

General assessment:

- vigilant, conscious and cooperating, preserved objectivity;
- BMI 28 kg/m² (overweight);
- Self-sufficiency state: Barthel Index 100/100;
- no chemotherapy in progress;

- no other pathologies which could lead to the onset of wounds.

Nursing diagnoses (of NANDA II International system):

Peristomal skin and tissues integrity affected in the left iliac fossa (00044-46)

Wound Assessment: On enrollment the patient presented a PW type L2 (erosive wound) located in TIII/TIV area (according to SACS 2.0) and a type L4 (ulcerative wound) for the mucocutaneous separation, located in TII/TIII area, with devitalised tissue present (Photo 6). Pain assessed at first dressing change: NRS 8/10.

The wound dressing was assembled in accordance with the procedure referred (Photo 2).

14 days from start of treatment (T2), we observed the wound debridement with a cleansing of the wound bed (Photo 7).



Photo 6 - CC2 initial assessment (T0).



Photo 7 - CC2 at T2 (14 days)

In 28 days we observed the complete healing of the skin damage (Photo 8). We also observed a gradual reduction of the stoma site oedema present in T0. We concluded that 1PWD was not aggressive on the mucous membrane, on the contrary, it had positive effects. Pain at dressing changes gradually decreased, until complete disappearance.



Photo 8. - CC2 complete healing at T4 (28 days from start of treatment).

Results

At the end of treatment, we observed in both cases the healing of wounds, assessed with SACS 2.0 Scale, with gradual decrease of pain. No signs of aggression of the product on the mucous membrane were observed.

The specific method adopted for making the dressing allowed it to stay on site for three days without complications.

Both patients expressed a positive attitude towards the treatment and satisfaction for the results achieved.

Conclusions

In the cases treated, the use of 1 Primary Wound Dressing®, composed of two plant derived oils, Neem Oil and Red Hypericum Oil, proved to be a valid therapeutic solution in the treatment of PWs not responding to traditional treatment. The results could be confirmed with studies on a higher number of patients to validate conclusions on a statistically significant basis. Besides confirming the effectiveness of the product, the results show the appropriateness of applying Wound Care principles to Stoma Care, comparing the treatment of PWs to that of skin wounds.

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