Case report

Treatment of Peristomal granulomatosis with a Neem and Red Hypericum Oil application: Case studies

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Abstract

Background. Peristomal granulomatosis is a chronic inflammatory disease of uncertain aetiology, and a high recurrence rate. It frequently occurs in patients with enterostomy and urostomy. The most frequent type affects the mucocutaneous junction, causing bleeding and painful nodular lesions, which complicate management of the ostomy pouching system. Currently, only invasive treatments are available, consisting in cauterisation or surgical removal of the granuloma. Our objective was to evaluate efficacy of a topic mixture oil, composed by a 1:1 of extracts of Neem and Red Hypericum; amongst its many therapeutical properties, it is proven to inhibit the over-granulation process.

Method. Two clinical cases presenting typical peristomal granulomatosis were selected. On first access after recruitment, the patients underwent an accurate nursing anamnesis, a global assessment was carried out according to the Toven Method and an assessment of peristomal sore skin according to SACS 2.0. Granulomatosis wounds were treated with the oil mixture, applied on a hydrofiber pad, secured over the wound site by means of a transparent film. This allowed the release of active ingredients while ensuring the pouching system secure adhesion. The chosen protocol consisted in 2 dressing changes per week, while monitoring the granulomatosis wound evolution by means of a TOR Form validated data form and documenting progress by taking photographs.

Results. Initially a regression of the inflammatory process was observed, with significant decrease of bleeding and pain. Gradually, the proliferating lesions reduced in size (both width and extent), and eventually healed completely. The product was very well tolerated, the proliferating lesions reduced in size (both width and extent), and no recur-rence signs were observed either at the follow up visit 15 days from end of treatment, and in clinical case N.2 equally none were present two months after treatment.

Conclusions. Compared to conventional methods which are invasive, not resolving, and not tolerated by patients, the product was demonstrated to be an innovative therapeutical solution, easy to apply, with no side effects and well-liked by patients. The excellent results obtained require further confirmation and validation through new studies on a statistically significant number of cases. Clin Ter 2019; 170(2):e86-92. doi: 10.7417/CT.2019.2115

Key words: peristomal skin disorders, peristomal wound, peristomal granulomas, hypergranulation tissue, enterostomy, granulomatosis

Introduction

Due to enteric stomas as’ totally artificial nature, patients with such condition, regardless if it’s a temporary or permanent one, frequently suffer from complications of various kind - the most frequent being peristomal skin lesions. Amongst the various kinds of lesions one of the most frequent and complex to treat is granulomatosis. In fact, the Peristomal Granulomatosis (PG) should be clas-sed amongst the proliferating wounds which correspond to class LX according to SACS 2.0 (1) classification. Such class considers three types of lesions: granuloma, ossalates deposits, and neoplastic wounds.

Clinically, PG appears as “small areas of hypergranulation tissue characterised by flesh protrusions, looking like small spherical formations of various sizes” (2) or “small, tender and crumbly papules” (3,4). Small size granulomas can decrease spontaneously, simply by addressing and correcting some risk factors, but often they increase in size and area, entering acute inflammatory conditions, which cause pain and bleeding and make it difficult to apply the pouching system4. PG can affect the whole stoma complex, the lesions can occur on the stoma surface, in which case they go by the name of inflammatory pseudopolyps (5) or on the surrounding skin as specific fibre producing nodules (5). The area where they most frequently appear is the mucocutaneous junction, where they initially show as foreign body granulomas (5). They are the outcome of a complex chronic inflammatory reaction called granulomatosis inflammation.

In medical literature, granuloma is defined as “an inflammatory neoformation characterised by abundant cellular proliferation, accompanied by a varying extent of a neoformation of connecting tissue and blood vessels. The name derives from the histological affinity with scar granulation tissue - the difference resides in its causes, chronic evolution, production of tumefaction etc” (6).
PG can be regarded as an early complication when it appears within 15 days from the surgical procedure, in the cicatrization phase of the suture uniting the mucous membrane to the skin surface. It is considered a late complication when it appears month/years after the stoma creation procedure, often for unknown causes.

No epidemiological studies could be found in literature providing certain and homogeneous data generally on prevalence/incidence of peristomal skin alterations, nor on incidence of granulomatosis divided by type of stoma (colostomy, ileostomy etc.) or that take into consideration other parameters (gender, age, type of illness etc.)

The only source that we were able to secure is an article by Burch Jannie (2014), where the author quotes a 10% percentage in colostomies and 2% in ileostomies, without specifying if such percentages refer to prevalence or incidence (7).

As for aetiology, no specific cause was determined, but there are several hypotheses, still to be researched, so it is better to use the expression predisposing factors (8). It has been observed, moreover, that some patients are more predisposed than others to the formation of granulomas, for unknown reasons (2).

Main predisposing (8) factors are: surgical sutures; mechanical irritation (due to applying and removing the stoma appliance); chemical irritation (due to prolonged contact with highly alkaline effluents in case of base adhesive plate (9); allergic reaction to the components of the appliance system; return to an acute stage of a chronic bowel inflammatory disease (e.g. Crohn Disease); dissemination/transplant of mucosa due to incorrect surgical technique of suturing of intestinal mucosa to the skin; parastomal hernia (a Japanese study from 2012 (10) showed that patients with colostomy complicated by parastomal hernia had a higher predisposition to granulomatosis).

Some of the authors we researched agree in stating that granulomatosis should be treated only when it becomes troublesome (3,8) the fibrous-producing nodules increase in size, number and extension, causing pain and bleeding and great patient discomfort. On the other hand, others (2) maintain that it is necessary to start treatment at the first signs of PG to prevent pouching system plaque adherence issues.

Before starting any therapeutical treatment, it is important to carry out a careful assessment of lesions (11), in order to differentiate them from wounds of other nature and identify any risk factors deriving from an incorrect management of drainable appliance.

Currently available therapeutic treatments are: chemical cautery (11), topical application of corticosteroids (13-15), cryotherapy (16), surgical curettage, laser ablation.

**Materials**

We chose 1 Primary Wound Dressing® (1PWD), a 100% natural oil mixture with strong anti-inflammatory, antibacterial, immunomodulating and re-epithelising properties, that, most of all, inhibits the overgranulation process (17). Also, there are no known local or systemic side effects, and, since March 2018, it has been approved even for neonatal paediatric use.

We decided to test this dressing after consulting all the literature produced on its use in treating acute and chronic hard to heal wounds, both in human medicine (17-20) and in veterinary medicine (21,22).

We found particularly enlightening consulting some studies carried out in the veterinary medicine, on healing of overgranulating wounds (proud flesh) on horses distal leg extremities (21,22).

In scientific literature the particular predisposition of horses to suffer lesions to the distal leg extremities is widely documented (21), and this anatomical site is characterised by its tendency to develop hypergranulating tissue (21), more than other body parts. It has been demonstrated that, by treating such wounds with the 1PWD in association with a permanent occlusive bandage, a homogeneous cicatrization speed was observed, along with a high quality of the resulting scar tissue. In fact it was shown to inhibit the formation of overgranulation starting from the formation of the first keloid buttons at 7-15 days from trauma (21).

The product application instructions recommend spraying directly on the wound bed and covering with a slightly compressive secondary dressing. In our type of indication, since the collection device would not stick to an oily surface, it was necessary to prepare a dedicated advanced wound dressing by spraying 1PWD on a hydrofiber pad cut to measure to adapt to the sore skin, and secured on site by means of an adhesive film dressing.

**Methods**

**Initial recruitment visit**

At the recruiting stage, an accurate nursing assessment, a global assessment according to the method Toven (23) and an evaluation of the sore skin status according to SACS 2.0 Scale (1) were carried out.

Toven Mehtod takes into consideration the patient in global complexity, assessing thanks to reputable measuring scales many important parameters such as: autonomy status, risk levels (falls, risk of pressure lesion onset, malnutrition), pain level at rest and during dressing changes, as well as a correct assessment of the wound in order to plan a correct treatment aiming at a quick healing.

All data collected were entered in the purposely designed end validated case data collection

TOR Form (Toma Ostomy Research) (24) divided in two sections:

1. Patient’s general data at the first recruitment visit, consisting in anthropometric data (weight/height/BMI), ostomy type, type of ostomy pouching system in use, type of hygiene followed by the patient, assessment of
wounds according to SACS 2.0, index of Barthel (23,25) and pain assessment according to NRS (Numerical Rating Scale) (23,26).
2. data on monitoring of the stoma and the surrounding skin (27-31) (aspect, colour, protrusion, mucocutaneous junction, sore skin, complications) and the evolution of the wound checked at predefined intervals.

We decided on a minimum period of treatment/observation of 28 days. The check points were as follows: T0 - initial recruitment visit, T1 - after 7 days, T2 - after 14 days, T3 after 28 days.

Follow up at least 15 days after end of treatment. The evaluation of granulomatosis wounds and of the healing process has been documented with a photographic support by means of a digital camera.

Treatment Protocol

As for the granulomatosis wound treatment, we had to resort to a custom-devised wound dressing: after cleansing the stoma and surrounding skin with an antiseptic free detergent, a hydrofiber dressing was cut to size to fit the lesion, sprayed with a sufficient quantity of 1PWD and positioned in place (Fig. 1). Then the hydrofiber dressing was secured to the skin by means of an adhesive transparent film (Fig. 2) which allowed the collection device to stick properly.

We need to specify that the hydrofiber pad used had no interaction with 1PWD components, and its only use is to create a base which would allow the active therapeutical elements to stay on the wound site.

Clinical case 1 (CC1)

Male patient, age 36, with temporary protective ileostomy for approximately the last 5 years, performed in 2013 after a proctocolectomy surgical procedure to remove a large anaplastic wide cells lymphoma - the patient suffered from Ulcerated Rectal Colitis since 2001.

The patient referred that he was never followed by a Stomal Therapy Nurse (STN), and that he looked after his stoma himself, including the management of ostomy appliance, thus underestimating the presence of a severe peristomal dermatitis.

Nursing Diagnosis (NANDA II International): Alteration of skin and tissue integrity peri-stoma in right iliac crest (00044-46).

General Assessment: Barthel Index - 90/100, patient is almost fully able to self-care;
BMI - 30kg/m2 (1 degree obesity).

Wound Assessment: the wound, classed as “simil papillomatosis” (Fig. 3), covered an area from the mucocutaneous junction up to the skin barrier covered by the pouching system, affecting all the peristomal skin wound LX, TV (according to SACS 2.0). The sore skin appeared to be hyperaemic, moderately exuding, with thickened skin. Fibre-producing nodules were present, particularly in the mucocutaneous junction, mixed with whitish concretion. Wound-related pain at rest: NRS 7/10.

The lesion suggested a prolonged contact with highly alkaline effluents (such as the ones flowing through an ileostomy) caused by incorrect management of the ostomy appliance (the hole was excessively large for the stoma diameter). The patient refers strong stinging pain and great difficulty in management of the pouch.
Having started treatment with 1PWD, within the first 14 days we observed a progressive reduction of both exudate and hyperaemia; flattening of the fibre-producing nodules and of the skin thickness was also noted (Fig. 4). As early as the second application a significant reduction of pain was referred by patient. Pain was immediately reduced, already from the second dressing change. Moreover, contact of the product with the mucous membrane was issue-free.

On 28th day we noted a complete flattening of simill-papillomatosis lesions (Fig. 5), with no further pain and full patient compliance, happy at last, since the disappearance of the lesions enabled him to manage the collecting device.

The follow up check at 15 days from end of treatment showed that the lesion was healing well and the patient was advised to continue the dressing treatment by himself at home (Fig. 6).

Clinical case 2 (CC2)

Female patient, age 35, with ileostomy following endometriosis; peristomal granulomatosis occurred 20 days postsurgery. The patient asked for help due to pain and bleeding caused by PG which prevented her from self-managing the ostomy pouching system.

Nursing diagnosis (NANDA II International): Alteration of skin tissue integrity peri-stoma in left iliac crest (00044-46).

General Assessment: Barthel Index - 90/100: the patient is fully able to self-care;
BMI – 16 kg/m2 (underweight).
Wound assessment: On the mucocutaneous junction suture stitches several hypergranulating lesions are present in all areas, and therefore classed as LX, TV (according to SACS 2.0). They are painful and easily bleed when changing the ostomy appliance. Wound-related pain NRS 8/10 in contact and 4/10 at rest. Peristomal skin is pink and normal in structure. The lesions suggest presence of chronic granulomatosis inflammation as a reaction to suture stitches or hyperplasia caused by abnormal cicatrisation process of the surgical wound (Fig. 7).

As documented by the photos, after starting treatment with the advanced dressing combination described above, within the first 15 days we observed a decrease of hypergranulating lesions both in height and dimensions, with resulting decrease of pain and bleeding (Fig. 8).

Due to the closeness of the lesions to the stoma, it was impossible to prevent contact of the product to the mucous membrane (Fig. 9). The patient did not report any problems, she considered the feeling of relief experienced at every dressing change as a consequence of product application.

On 28th day, a small residual overgranulation tissue is present (Fig. 10); pain and bleeding completely disappeared. The treatment continued with self-medication until 32nd day, when the lesions disappeared completely and the treatment was stopped. At T4 follow up, 2 months after end of treatment (Fig. 11), no recurrence signs were observed.
Throughout the monitoring period the patient liked the treatment and actively cooperated to the therapeutic plan.

**Results**

1 Primary Wound Dressing® topical wound dressing proved to be particularly effective in the treatment of PG. From the early phases of treatment it has been possible to achieve a good pain control and to reduce bleeding, thanks to its antiinflammatory properties.

In later treatment stages we observed a reduction in size and height of granulomatosis lesions, up to their complete healing (CC2); this confirmed the IPWD modulating properties and its effective action inhibiting tissue hypergranulation.

**Conclusions**

Compared to traditional invasive and not resolving treatments, badly tolerated by patients, 1 Primary Wound Dressing® has been proven to be an innovative therapeutic solution, of a conservative type, respecting skin integrity, easy to handle, with no side effects and well-liked by patients.

The only drawback for its use in peristomal lesions is the difficulty of applying the pouching system following direct application of the product, and the consequent need to devise a suitable dressing.

The excellent results obtained deserve to be further researched, especially as regards the specific way of action of the product on granulomatosis, and require testing on a statistically significant number of patients. Should the results continue to be as promising, the suggested therapeutic approach would represent a turning point in the peristomal granulomatosis therapy.

**References**

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