

Biotechnological innovations: role of a reactive oxygen species release device in the management of pilonidal cysts



Authors
Rosa Colella and Maurilio Rossi

The pilonidal cyst usually manifests by the formation of ulcers or orifices in the sacrococcygeal region. It generally affects young males aged 15-30 (Mohamadi et al, 2019), has a reported incidence rate of 26/10,000 people and affects men 2.2 times more than women (Nixon and Garza, 2020). Improper cleaning of the wound bed can slow healing and cause complications, such as infection or biofilm formation, which can lead to relapse or chronicity. In addition to surgical or conservative treatment (Gips et al, 2008), an appropriate assessment of the skin tissue is required by a nurse, or expert wound care specialist, who is able to recognise all local signs and symptoms failing to stimulate healing. Continuity of care and the pursuit of the treatment of a skin ulcer in a dedicated clinic are not always considered as part of clinical care pathways, leading patients to experience recurrent and prolonged hospitalisation for the handling of complications. It is not often considered that these problems can be handled in the clinic, by applying tissue repair principles, and by including a wound care specialist as part of the multidisciplinary team. The clinical case, described in this article presents the management of multiple recurrent pilonidal cysts in a 23-year-old woman, who underwent seven surgeries in 5 years without the wounds healing, which took place only after a correct local therapeutic approach with targeted products, using a gel containing ROS-releasing oleic matrix that stands as a therapeutic innovation. Management of multiple recidivated pilonidal cysts was undertaken in accordance with the principles of wound bed preparation (EWMA, 2004) and TIMERS (Atkin et al, 2019). To assess and monitor the lesion, the Falanga Wound Bed Score (WBS) evaluation scale was used (Falanga et al, 2006; Commissione Regionale Dispositivi Medici et al, 2016), as well as the PUSH tool supported by photographic evaluation. The Numerical Rating Scale (NRS) scale for pain assessment and quality of life index (QL index) scale (Spitzer et al, 1981) were used to monitor quality of life during the treatment regimen.

Rosa Colella is Wound Care Specialist, Clinical Trial Unit, IRCCS Foundation Policlinic San Matteo, Pavia, Italy; Maurilio Rossi is Wound Care Expert, Careggi Hospital University Company, Florence, Italy

Even today, pilonidal cysts represent a significant problem in general surgery. A large number of surgical techniques indicate the lack of a single approach that guarantees therapeutic success, the onset of frequent complications causing patient dissatisfaction and clinician frustration.

The aetiopathogenesis of a pilonidal cyst is still uncertain. It is believed that an ingrown hair in the dermis creates an inflammatory reaction that spreads to the subcutaneous cellular tissue at the level of which a cavity is formed, leading to the formation of primary and secondary orifices (Mohamadi et al, 2019; Nixon and Garza, 2020).

Figure 1. RMN performed on April 30, 2019: a fistulous tract of about 55mm is highlighted. Images courtesy of the patient.



Clinical case

This case centres on a 23-year-old woman with a history of pilonidal cysts and mild obesity. She had no allergies. She presented with a pilonidal cyst, which she had had from the age of 17 and occurred following a swelling of ingrown hair in the sacrococcygeal area. Clinical documentation from 2014 explained that an MRI showed the presence of abscess collection of 4cm (length) x 2cm (width) x 1cm (depth), median and lateral to the highlighted lesion of a 4.5cm (length) x 0.3cm (depth) orifice extending caudally from the intergluteal sulcus towards the sacrococcygeal region.

The patient underwent surgery for exeresis of pinolidal cyst with closure by primary intention with sutures. Upon the removal of the sutures, there were no signs of full healing. The lack of postoperative management led to its recurrence and infection. The patient's condition did not improve through fistulectomy surgery in 2016. The patient experienced a drop in her mood and feared her condition would never resolve. She was forced to give up sports activities. An interview with the patient determined a QL index of 5. Surgery according to the Bascom technique (Bascom, 1980) was initiated in August 2017, followed by surgery using Gips8 technique in 2018. A fistulectomy took place in June 2019 and again in October 2019 with lozenge incision, including two fistulous orifices, including the removal of the cartilage portion in the sacrococcygeal region.

To date, the patient has never been referred to a dedicated clinic, nor was under the care of a wound care expert between surgeries. Twenty days after the incision, the wound showed signs of inflammation, hyperemia and periwound redness. Negative culture swabs were performed and exudate did not reduce over time; on the contrary,

it became seropurulent. She reported a very low mood related to the fear of not getting better. Her QL index was reported as 5.

On November 10, 2019, the patient's wounds were treated by the specialist expert in wound care and the patient began a regimen of local wound management by expert specialists. A control MRI was prescribed to monitor subcutaneous damage. From the MRI it was detected that the lesion presented with three orifices, which in the cranio-caudal sense were: a) the first orifice, the length was 1.5cm with a thickness of 0.3cm, which communicates via a fistulous path with the second orifice; b) the second orifice was 3cm (length) x 0.5cm (depth), extending towards the sacrum coccygeal; c) the third orifice had dimensions of 4cm (length) x 0.5cm (depth) and was situated in the sacrococcygeal direction.

All three orifices were slightly reddened and hyperaemic periwound skin was evident, with 3cm from the margins of the slightly macerated lesions. There was discharge of medium-high haemorrhagic exudate. The tissue was fragile and prone to easy bleeding. The Wound Bed Score (WBS) was B3, while the Pressure Ulcer Scale for Healing (PUSH) tool score was 11.

The cleaning process started with a solution based on 0.1% polyhexanide, 0.1% betaines and 99.8% purified water for 20 minutes. These were inserted into the three orifices via a 20 gauge needle cannula. During cleansing, there was a leakage of haemorrhagic exudate; the tissue was fragile with easy bleeding.

There was a fistulous connection between the first and the second orifice. The patient reported experiencing pain during the cleansing procedure (Numerical Rating Scale [NRS] = 4), which is why the authors proceeded with caution and the patient was advised to take

painkillers before dressing changes. This was followed by the application of 0.1% cadexomer iodine powder. The clinicians tried to insert the granules as much as possible in all three orifices. A hydrofiber gauze and flat dressing were administered.

The authors continued with the same dressing regimen every 24 hours, with the aim of lowering the bacterial load and breaking up the biofilm.

Five days after the treatment, it was possible to note the healing of the first orifice – the skin was pink, appeared closed, but also very fragile. During the cleansing process, tunnelling was still noted between the first and second orifice, where a small hole had reopened with the release of antiseptic mixed with exudate, which confirmed the fragility of the tissue. The authors continued with the cleansing regimen, while iodine-powdered cadexomer was administered, followed by an application of Hydrofiber gauze, to contain the exudate, and sterile adhesive wound dressing with non-adherent pad. The patient still experienced pain during dressing change (NRS=3).

On November 25, the first orifice was healed, while the second orifice was reduced, measuring 2.5cm (length) x 0.3cm (depth). The third orifice appeared unchanged. Serous, medium, corpuscular exudate was reported. The skin around the lesions was slightly reddened, the edges and margins were active. The patient reported occasional pain during the procedure (NRS=2). With the aim of promoting proper wound antisepsis and allowing the product to penetrate deeply, a gel containing polyhexanide (PHMB) and propyl-betaine was used, using a 2.5ml syringe. Gauze containing hyaluronic acid, Hydrofiber gauze and flat dressing were all used as secondary dressings, and dressing changes took place every 48-72 hours.

On December 7, 2019, collagen was added to the treatment regimen during dressing changes, but no tangible benefit was seen. The wound appeared firm and unchanged.

Then on December 15, 2019, there was an improvement in the general condition of the wound – the two remaining orifices had serous, corpuscular exudate and the tissue was less fragile. However, there was no easy bleeding during the treatment regimen. The periwound skin was cleaned and was normochromic with active margins, but was slightly macerated. The first orifice was evaluated in the caudal skull direction and was found to be 2.5cm long by 0.3cm thick, while the second orifice was 2cm long and 0.3cm thick (WBS=A2; PUSH tool=9; NRS=1).



Figure 2a (top). November 16, 2019: WBS= B2; Push Tool = 11

Figure 2b (middle). December 15, 2019: WBS= A2 Push tool = 9

Figure 2c (bottom). January 21, 2020

The use of a gel containing an oleic matrix releasing reactive oxygen species (ROS) was evaluated, with the aim of guaranteeing effective cleansing of the wound. The gel is designed to contrast bacterial contamination and restore the conditions for the physiological inflammatory process. The device came in a 5ml syringe of product. The treatment regimen continued with cleansing based on 0.1% polyhexanide, 0.1% betaine and 99.8% purified water, as well as an application of 0.5ml gel releasing reactive oxygen species (ROS) for both orifices, covered with gauze with hyaluronic acid, Hydrofiber gauze and a flat dressing.

The same dressing regimen continued for about 10 days, with dressing changes every 72 hours. At the dressing change stage, serous exudate was leaking and of a medium-low quantity.

On December 22, 2019, improvements were observed in terms of the patient's healing. There was no longer tunneling and the upper part had now closed. At this point, the periwound skin appeared normochromic. Healed tissue appeared more rosy and resilient. The action of ROS on the local microenvironment of the wound allowed a lowering of the colonising bacterial load, breakdown of the biofilm and the decisive triggering of repairing processes. The first orifice measured 1.5cm (length) x 0.3cm (depth), while the second fistula measured 1.5cm (length) x 0.3cm (depth). There was medium and serous exudate visible. The patient's scores were: NRS=1; WBS=A2; PUSH Tool=4. The same dressing regimen continued until healing, with dressing changes performed every 72 hours.

On December 28, 2019, the lesion appeared superficial. The first cyst was about 0.5cm (length) by 0.3 cm (depth), while the second orifice measured approximately 1cm (length) x 0.3cm (depth) for both orifices. Exudate was medium-low, with serum blood. There was no maceration of the margins, which were active; slight periwound redness remained. The patient's scores were: WBS=A2; PUSH tool=2; NRS=0.

The wound appeared closed by January 3, 2020, and the wound skin was pink. Gauze with hyaluronic acid was applied to favour the closing phase and re-epithelialisation. On January 21, 2020, the tissue appeared lighter and stronger. The authors recommend using a zinc oxide cream as a barrier. A MRI was performed on February 17, 2020, and showed an abscess of 4cm (length) and 1.7cm x 7mm (depth) in terms of thickness in the cranio-caudal direction from S3 to the sacrococcygeal region. There was no pilonidal cyst or deep subcutaneous fistula. The patient reported that she was gradually resuming sports activities that had been suspended for years and returning to a normal life. She was showing a considerable degree of satisfaction and trust towards the clinician who had taken charge of the management of the pilonidal cysts, considering the healing times in relation to the long chronicisation of the lesion. The QL index was 9.

Results

Cleansing of the wound with antiseptic detergent allowed for a lowering of the

bacterial load, disintegration of the biofilm and the preparation of the wound bed. Before the use of ROS-releasing oleic matrix gels, a regression of the bacterial load was noted, but no progress was observed in terms of healing. The gel device, which released reactive oxygen species, allowed the reactivation of the physiological repair process, facilitating the closure of the two remaining orifices with six applications. However, a good mark of the dressing was noted for the expected time between one change and another. The pilonidal cysts completely healed in about 2 months.

After the period of isolation caused by the COVID-19 pandemic-related lockdown, the patient was able to benefit from the total healing of the lesion, avoiding infectious complications. The patient found psychological relief after 6 years of treatment, gradually resuming the activities of daily life previously suspended by the pandemic.

Conclusion

The figure of the nurse/specialist expert in wound care plays a key role in cases like the one detailed in this article and must always be considered within the multidisciplinary team set-up in the management of a patient with skin lesions, even for wounds requiring surgical management. The expert in wound care should take charge of the patient's treatment regimen, evaluating all systemic and local conditions in a holistic way. They should know the principles of tissue repair to ensure a correct reading of the tissue and fundamental elements when there are complications, such as biofilm formation and infections.

The expert in wound care knows and puts into practice treatment strategies, based on the principles of the clinical tool TIMERS (Tissue, Infection/Inflammation, Moisture, Wound edge, Repair/Regeneration, Social), and prepares the wound bed, promoting all those tissue conditions to restart physiological repair. The correct local treatment strategy, in addition to the systemic pharmacological one, plays a fundamental role in the treatment process and, if not considered, can favour the non-resolution of the lesion itself.

Through appropriate therapeutic decisions, the experienced professional is able to optimise the resources used and ensure effective quality of care by involving both the client and family members in the process. This case must be a reason for reflection and

underline the importance of the various professional figures involved in the team, and it can be a starting point to dedicate other studies and consider innovative treatments for this type of injury. **Wint**

References

- Atkin L, Bučko Z, Montero E et al (2019) Implementing TIMERS: the race against hard-to-heal wounds. *J Wound Care* 23(Sup3a): S1-50
- Bascom J (1980) Pilonidal disease: origin from follicles of hairs and results of follicle removal as treatment. *Surgery* 87: 567-72
- Commissione Regionale Dispositivi Medici, Direzione Generale Sanità e Politiche Sociali e per l'Integrazione (2016) *Le Medicazioni Avanzate Per il Trattamento Delle Ferite Acute e Croniche. Allegato 4: Strumenti di Classificazione e Monitoraggio Delle Lesioni Cutanee*. Servizio Assistenza Territoriale - Area Farmaco e Dispositivi Medici, gennaio. Available at: <https://bit.ly/3B3uqr1> (accessed 23.08.2021)
- European Wound Management Association (2004) *Position Document: Wound Bed Preparation in Practice*. London: MEP Ltd. Available at: <https://bit.ly/2ULNr11> (accessed 25.08.2021)
- Falanga V, Saap LJ, Ozonoff A (2006) Wound bed score and its correlation with healing of chronic wounds. *Dermatol Ther* 19(6): 383-90
- Gips M, Melki Y, Salem L et al (2008) Minimal surgery for pilonidal disease using trephines: description of a new technique and long-term outcomes in 1,358 patients. *Dis Colon Rectum* 51(11): 1656-62; discussion 1662-3
- Mohamadi S, Norooznehad AH, Mostafaei S et al (2019) A randomized controlled trial of effectiveness of platelet-rich plasma gel and regular dressing on wound healing time in pilonidal sinus surgery: Role of different affecting factors. *Biomed J* 42(6): 403-10
- Nixon AT, Garza RF (2020) Pilonidal cyst and sinus. In: *StatPearls [Internet]*. Treasure Island (FL): StatPearls Publishing