



Treatment of Perianal Fournier's Gangrene with an Oxygen-Enriched Oil Based Medical Device NOVOX[®] Roll: Case Report

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Abstract

Background: Fournier's gangrene is a rare form of necrotizing fasciitis of the perineal, genital or perianal region with high morbidity and mortality rate. Standard treatment is based on medical therapy associated with surgical procedure and postoperative procedures. We report our experience with a new postoperative approach based on advanced dressings performed with NOVOX[®] Roll medical device based on an oxygen-enriched oleic matrix releasing Reactive Oxygen Species (ROS).

Case Report: A 75-year-old male patient presented to our clinic with perianal multiple swelling and discoloration associated with fever. CT scan showed the local extension of the complex cellulitis at inferior fascia of the urogenital diaphragm with Colles fascia and the presence of gases in the subcutaneous tissue. Endoanal ultrasound failed to demonstrate evidence of perianal fistula.

The patient was treated with early multiple staged large debridement with anal sphincter and scrotum preservation. Close outpatient follow-up was carried out with only advanced dressing performed with Oxygen-Enriched Oil Based Medical Device NOVOX[®] Roll. A complete closure of all lesions was observed.

Conclusion: Fournier's gangrene is a potentially fatal disease that requires a complex and multidisciplinary approach. Our experience with advanced dressing, first reported in the world literature, show that we can considered a new useful approach in the postoperative management of selected patients affected by Fournier's gangrene. A controlled randomized trial is also required to confirm this evidence.

Keywords: Fournier's gangrene; Advanced dressing; NOVOX[®]

Background

Fournier's Gangrene (FG) is a rare form of necrotizing fasciitis of the perineal, genital or perianal region caused by multiple organisms causing multiple organ failure and septic shock with an incidence rate of approximately 1.6 per 100.000 males [1]. These microbes (aerobic and anaerobic species) release enzymes, such as collagenases, that causes tissue necrosis e allow the infection to spread rapidly from the infections site to the abdominal wall and vital organ. FG can develop in advanced age patients with comorbidities such as diabetes, alcoholism, peripheral arterial disease, HIV and liver disease. This condition represents a surgical emergency with a mortality rate ranging from 0% to 67% and the treatment is initially based on the management of initial causes with targeted antibiotics, multiple stage surgical debridement and subsequently Vacuum-Assisted Closure (VAC) or Hyperbaric Oxygen Therapy (HBOT) as well as reconstructive technique for the loss substance [2-3].

Reconstructive strategies include flaps (oblique rectus abdominal myocutaneous or posteromedial thigh propeller flaps) or skin graft: The exposed tissues must be reconstructed as quickly as possible to avoid scarring and retraction of the perineal plain or genital organ. We will report a case of FG treated with a cycle of advanced dressings performed with Oxygen-Enriched Oil Based Medical Device NOVOX[®] Roll based on an oxygen-enriched oil matrix releasing Reactive Oxygen Species (ROS).

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Case Presentation

A 75-year-old male patient with poorly controlled diabetes and recent history of pulmonary embolism presented to our clinic of SOSD Proctologia (USL Toscana Centro- Florence, Italy) with perianal multiple swelling and discoloration associated with fever. The local examination revealed three different site abscesses communicating around the anus about 5 cm respectively and the abdominal-pelvis CT scan showed the local extension of the inferior fascia of the urogenital diaphragm with Colles fascia and the presence of gases in the subcutaneous tissue, but no testicular and scrotum involvement. At the endoanal ultrasound, we found a complex cellulitis limited to perianal space without evidence of perianal fistula. The Laboratory Risk Indicator for Necrotizing Fasciitis (LRINEC) was 8, indicating clearly a necrotizing soft tissue infection, and the Fournier's Gangrene Severity Index (FGSI), normally used in emergencies to determine the likelihood of survival, was 9.5 [4]. After hemodynamic stabilization and parenteral broad-spectrum antibiotics administration, the patient underwent early multiple staged large debridement in locoregional anesthesia with anal sphincter and scrotum preservation. After around 5 days, he did not deteriorate clinically and the radiological images did not show extension from the original necrotizing site. The postoperative course was uneventful and the patient was discharged from hospital seven days after the surgical procedure. Close outpatient follow-up was carried out with 3 dressings per week for the first 15 days and 2 dressings in the following two weeks. We couldn't use VAC to promote wound healing physiologically due to difficult positioning in the perineum for the anus preservation; the HBOT was not performed due to recent history of pulmonary embolism. The patient was treated only with advanced dressing performed with Oxygen-Enriched Oil Based Medical Device NOVOX[®] Roll based on an oxygen-enriched oil matrix releasing Reactive Oxygen Species (ROS) supported on an elastic cotton-polyester bandage (Figure 1, 2): The bandage was inserted through the external opening surgical



Figure 1: Perineal wound one week after surgery.



Figure 2: NOVOX[®] Roll inserted through the external opening surgical wounds.



Figure 3: Partial closure after two weeks of treatment.



Figure 4: Perineal wound after three weeks of NOVOX[®] Roll.



Figure 5: Final result after four weeks.

wounds and covered with a hyaluronic acid layer to reduce the dispersion and absorption. After four weeks, we observed a complete closure of all lesions.

Discussion

FG is a rapidly progressing condition with high morbidity and mortality and has a better prognosis despite early diagnosis and rapid and effective surgical and medical treatment. The mortality rate, despite a new approach, still remains high: Only one study reported a mortality rate of 11.4%, but in the recent literature it was 45.4% to 67% [5-6]. FG is more common in the elderly, diabetics, alcoholic, paraplegic, and cirrhotic male patients: The clinical diagnosis is made using a combination of physical findings, imaging and the patient's risk factors. It is very important to identify the pathological process as soon as possible to reduce the complications and mortality rate. The initial symptoms such as fever, edema, swelling and skin discoloration are non-specific, but the association with crepitus and fasciitis are characteristic. Scoring with LRINEC and FGSI can be used to determine a survival probability in the affected patients. The conditions can be detected with biomarker evaluation and imaging techniques that can also determine the extent of lesions when planning surgical procedures. The multidisciplinary approach can be

immediate and needs a combination of surgical debridement to remove necrotic tissue as well as broad-spectrum antibiotic administration: The patient requires an interprofessional team. Hyperbaric Oxygen Therapy (HBOT) can be administered after surgery: The creation of an environment with high oxygen concentration slows down anaerobic bacterial proliferation and reduce local conditions of hypoxia and ischemia. However, some studies reported an increased mortality rate in patients that received HBOT [7]. In our patients, the recent embolism was a specific contraindication for this treatment. Since the introduction in 1998, various reports on the effectiveness of Vacuum-Assisted Closure (VAC) in the patients affected by FG have been published. This treatment can include be isolating the tissue from external pathogens, increasing angiogenesis and eliminating debris [8,9]. VAC treatment might be a treatment of choice with lower mortality compared to the patients who underwent debridement-only [10]. Furthermore, the VAC reduces the use of analgesic and promotes early mobilization, but increases hospital stays and it is difficult to keep the perineal region both covered with dressing and clean [11]. In our case, it was not possible to apply the device around the anus and the colostomy was not necessary, due to favorable evolution. In fact, colostomy might be necessary to keep the wound area clean but, in the literature, a higher mortality rate is reported in patients who had supportive colostomy [12]. Such as in our case, many surgeons prefer the colostomy procedure for FG involving anorectal region only in the presence of perforation, sphincter system involvement, immunosuppression or preexisting incontinence. Psychological complications are also associated in patients affected by FG. Many patients reported long term pain that leads to a decreased quality of life which cause depression and the disfiguring scars contribute to sexual dysfunction such as penile deviation or torsion and complete loss of skin sensitivity associated with erection disturbs [13,14]. We also considered all the problems linked to anal continence and stool continence. In our experience, the use of advanced dressings performed with Oxygen-Enriched Oil Based Medical Device NOVOX(®) Roll showed a very good result in terms of quality of life and contributed to reduced hospital stays. The outpatient treatment of the patient has helped to greatly reduce the stress of prolonged hospitalization by ensuring an almost home-based management of the problem, avoiding the onset of psychological problems. The simplicity of this medical approach also allowed for constant monitoring of the evolution of the lesions without compromising the stages of healing and not precluding any further approaches.

Conclusion

FG is a potentially fatal disease in which mortality is strictly dependent on age, time to surgical intervention and predisposing factors. If diagnosed and managed appropriately, most patients are satisfied with an acceptable quality of life and cosmetic end results. Our experience shows that we can consider alternative approaches such as NOVOX® Roll medical device in a selected patient also if

eligible for other treatments: This approach remains very safe, useful and effective as well as reduces hospital stays and sanitary costs when compared with HBOT and VAC. We also considered the association of this new treatment with other conventional approaches in different times if possible. A controlled randomized trial is required to prove its value.

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