

Treatment of minor dehiscence after endorectal advancement flap in perianal Crohn's fistulas with ozonized oil NOVOX[®]

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Introduction

Perianal Crohn's disease represents one of the most devastating conditions for Crohn's patients [1]. Fistulizing features can be seen in around 90 % of patients with perianal Crohn's disease [2]. The treatment of such fistulas is a challenging task for surgeons due to high recurrence rate. Endorectal advancement flap is one of the best choices to treat high and complex Crohn's fistulas in a background of rectal sparing disease or healed mucosa post-biological therapy. The reported success rate of endorectal advancement flap in Crohn's fistulas is 64 % [3].

Ozone (O₃) has been used as a healing promoter for diabetic ulcers, trophic and ischemic ulcers as well as other types of chronic wounds. Increment of oxygen tension in the wound area and the bactericidal, antiviral and antifungal characteristics of ozone (O₃) encourage its use as wound-healing accelerator [4]. Olive oil is one of the best reservoirs for ozone due to its ability to stabilize O₃ between the double bonds of unsaturated fatty acids [4]. Ozonized olive oil-based medication NOVOX[®] (MOSS SpA, Lesa, Novara, Italy) comes in an oily gel form in a sealed syringe.

The aim of this study is to assess the effect of NOVOX[®] in Crohn's patients with persistent tracts as a result of minor endorectal advancement flap dehiscence.

Patients and data collection

Patients with Crohn's fistulas in whom minimally draining residual fistula was clinically diagnosed at 30 days post-flap intervention were included in this study. Informed consent was obtained from all individual participants included in the study. Patients were followed in the outpatient clinic for an average time of 23.81 months. Demographic and clinical data were collected including sex, age, presence of stoma and use of biological therapy. Also, the date of last flap intervention, fistula type and use of fistula plug were documented. NOVOX[®] was administered (0.1–0.3 ml) using 5- or 1-ml syringes with a plastic needle. The needle was inserted through the external opening as close as possible to the internal orifice of the fistula; then, the gel was injected as shown in Fig. 1. NOVOX[®] was administered daily for a period ranging from 1 to 6 months. Monthly clinical assessment of fistula closure was done using a 4 grade scoring system based on clinical assessment in which grade 4 indicates closure of fistula with scar tissue [5].

Statistical methods

Data were analyzed using SPSS Statistical Software, version 20. Proportion comparisons for categorical variables were made using Chi-square tests (χ^2) to identify the effect of the favorable factors in fistula healing. Significance was set at $p < 0.05$.

Results

A total of 26 cases were entered in the study and evaluated during the 42-month study period. The mean age was 46.27 (range 28–71) years. Twenty-three (88.5 %) patients were

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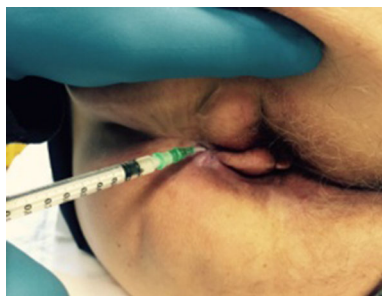


Fig. 1 Administration of NOVOX[®] through the external orifice of perianal fistula

Table 1 Types of fistulas included in the study

Type of fistula	Number of patients	%
Transsphincteric	9	34.6
Suprasphincteric	1	3.8
Rectovaginal	7	26.9
Complex multiple	2	7.7
Anterior horseshoe	3	11.5
Posterior horseshoe	4	15.4
Total	26	100

Table 2 Effect of favorable characteristics in residual fistula closure*

Characteristics	Number of patients (%)	<i>p</i> value
Ileostomy	8 (30.8 %)	0.17
Systemic biological therapy	15 (57.7 %)	0.067
Use of fistula plug alongside endorectal advancement flap	5 (19.2 %)	0.62

* None of mentioned characteristics in the table were significant (*p* value < 0.05)

females. The distribution of the original fistulas type was as shown in Table 1. The type of the fistula did not affect the healing rate (*p* value = 0.30). The mean duration of NOVOX[®] use was 3.12 ± 1.63 months. Residual fistula healing (grade 4) occurred in 65.4 % (17/26) of patients at a mean follow-up duration of 23.81 (range 2–42) months. None of the other characteristics had a statistically significant to effect on the healing rate. Further details are shown in Table 2.

Discussion

One of the obstacles facing surgeon in the management of perianal fistulas in Crohn's patients is the high recurrence rate. Injection of ozonized olive oil-based medication through the residual tract may decrease the need for re-intervention as it may accelerate closure of internal orifice of fistula in cases with minor flap dehiscence.

Conclusion

Injection of ozonized olive oil in Crohn's fistulas with persistent tracts as a result of minor endorectal advancement flap dehiscence seems to be safe and effective (65.4 % healed). A controlled randomized trial is required to prove its value.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study involving human participants were in accordance with the standards of the ethical Committee of St. Orsola-Malpighi University Hospital of Bologna, Italy.

Informed consent Informed consent was obtained from all individual participants included in this study.

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