

INGROWN TOENAILS TREATMENT IN DIABETIC PATIENTS: A PILOT STUDY OF A NEW CONSERVATIVE TREATMENT OF ORTHONYXIA

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KEYWORDS: ingrown toenail, nails disease, onychocriphosis, diabetic foot, orthonyxia

ABSTRACT

Ingrown toenail (also onychocryptosis) is one of the most frequent nail pathologies in diabetic population. Neurological and vascular complications can increase painful symptoms and suffering of tissue which can lead to ulceration, therefore surgical matricectomy is not recommended. In this research we aim to evaluate the effectiveness of a 40% urea cream treatment associated whit nail acrylic resin brace (ortonixia) versus traditional cut and resin nail's reconstruction. Diameter of nail and NRS scale were used to evaluate change of nail plate and pain before and after treatment. 32 subjects with 52 treated nails were included. About 20 nails of 13 subject were recruited in experimental group.

Differential final and initial diameter was 4.67 ± 1.55 mm in experimental group and 3.01 ± 1.26 mm in control group ($p < 0.0001$) and recurrence rate was 15% and 75% respectively ($p < 0.0001$). Also days of absence of pain, in experimental group there was a mean of 319.05 ± 113.18 days, instead in control group there was a mean of 208.31 ± 119.84 days ($p < 0.0002$).

This statistical analysis shows that effectiveness of new conservative approach is greater than in nail reconstruction method and a valid alternative to surgical treatment in diabetic patients.

INTRODUCTION

Ingrown toenail, also known as onychocryptosis, is a pathologic condition of the nail complex. It develops when periungual tissues is penetrated and traumatized from one of the edges of the nail plate. Because of this mechanic injury, there is a considerable inflammatory state leading to discomfort and pain. Granuloma and infection are the most common complications of ingrown toenails^[1]. Most common local pathogenetic factors are abnormal angle foot and hallux valgus [2-3]; shoe and digital traumas, incorrect nail-cutting habits, lateral deviation of the nail plate, obesity, pregnancy, and excessive angulation of the nail plate are closely associated with ingrown nails [4].

Diabetes is among the systemic diseases predisposing onychocryptosis [5]. In fact, vascular and neuropathic complications associated to diabetes often cause alteration of cutaneous annexes and consequently nail plate dystrophies.

The election treatment for ingrown toenail is surgical and it needs local anesthesia [6-9]. That treatment is often not recommended in diabetic patients because of polymorbidity associated to disease [10]. Alternative therapeutic strategy are a conservative treatment consisting in various and different ortonixia techniques (reeducation of the nail plate)[11-14] or reconstruction of nail plate after cutting [15].

Aim of the Study

In the section 'Diabetic Foot' of Lucca Diabetology we carried out a randomized controlled trial with the aim of evaluating the effectiveness of a new conserv-

ative ortonixia treatment compared to a traditional one in a population of diabetic patients affected by ingrown toenail.

Characteristics of the Sample

Population has been chosen by specific inclusion and exclusion criteria. Among inclusion criteria there are diagnosis of diabetes, onychocryptosis grade I-II Mozena [12] and predisposing factors of onychocryptosis as irregular or convoluted margins of nail plate. We excluded subjects with diabetic neuropathy or vasculopathy, and subjects with previous or current ulcerative lesion (risk class 3). The sample has been randomized and subdivided in two categories: subjects treated with experimental treatment (experimental group) and subjects treated with control treatment (control group). The total sample is composed by 32 subjects with 52 treated nails. There are 13 subjects with 20 treated nails in experimental group and 19 subjects with 32 treated nails in control group. In data analysis, treated nails represent the statistic units.

METHODS

The study has been carried out in blind, so subjects didn't know the group they belonged. Subjects in experimental group were treated with occlusive 40% urea cream on the nail plate for 10 days before orthonyxia treatment with acrylic resin brace. This preparation has the function to make nail plate more flexible and malleable not to resort to local anesthesia. After preparation, subjects were ready for orthonyxia procedure in which the edges of nail plate are raised up through a particular instrumentation composed by

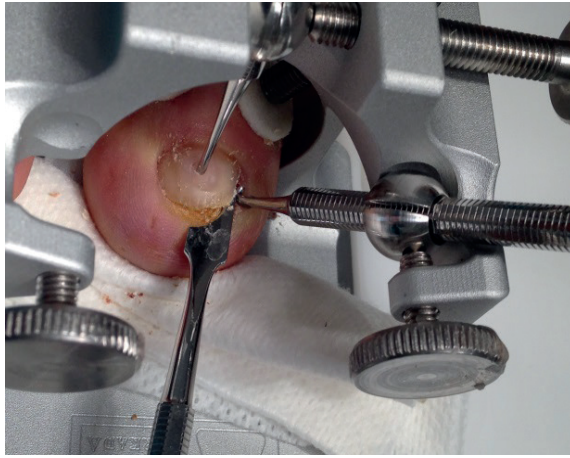


Fig. 1 - Raising up of the lateral edge of nail plate during experimental treatment.



Fig. 2 - Nail plate of one subject in experimental group before (up) and after (down) the treatment.



Fig. 3 - Nail plate in one of the subjects in control group before (up) and after (down) the treatment

special gouges (Fig.1). Then, after this operation, nail plate is fixed in that position through application of acrylic resin brace (Fig.2).

Subjects in control group have been treated with a technique including curettage of nail plate and application of acrylic resin without raising up of edges (Fig.3). The aim of acrylic resin is to increase the nail plate thickness and consequently change contact surface of nail plate edges on periungual tissues.

All the subjects have been evaluated at 6 months (time T1) and at 12 months (time T2) for the follow-up.

For each group the following data have been collected:

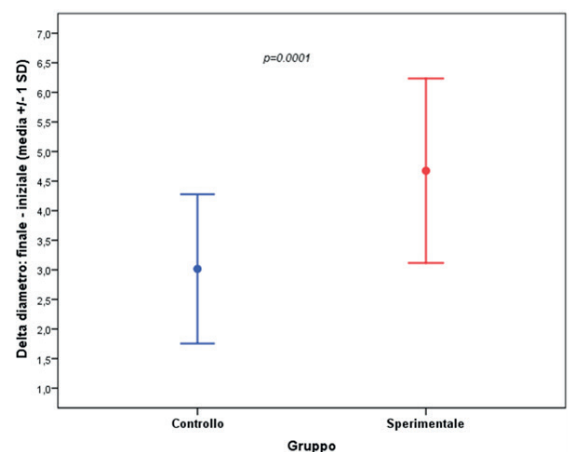
- at the moment of treatment, initial diameter (before treatment) and final diameter (after treatment) of nail plate in millimeters,
- difference in millimeters between final and initial diameters of the nail plate,
- nail plate diameters in millimeters at T1 and T2,
- pain evaluation with scale NRS before treatment, at T1 and T2,
- duration in days of absence of pain,
- eventual recurrence consisting in reappearance of pain.

Data Analysis

All analysis were performed by software SPSS v.24. Quantitative data have been described by means and standard deviations, qualitative data by frequencies distributions. Comparisons between means of groups were assessed by chi-squared test with significance fixed at 0.01.

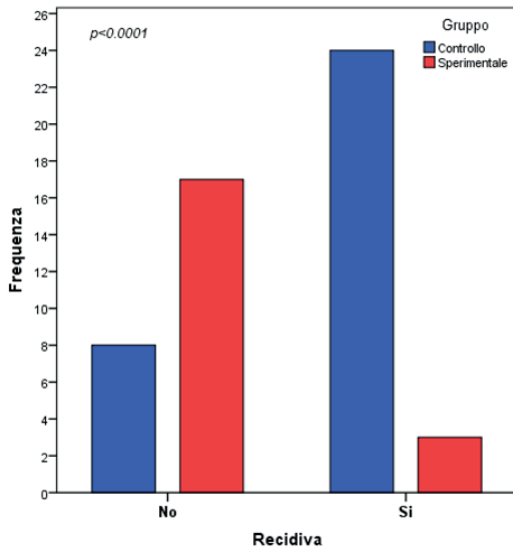
RESULTS

The mean difference between final and initial diameter is 4.67 ± 1.55 mm in experimental group and 3.01 ± 1.26 mm in control group. This difference between two groups is statistically significant with high significance ($p < 0.0001$) (Graph 1).

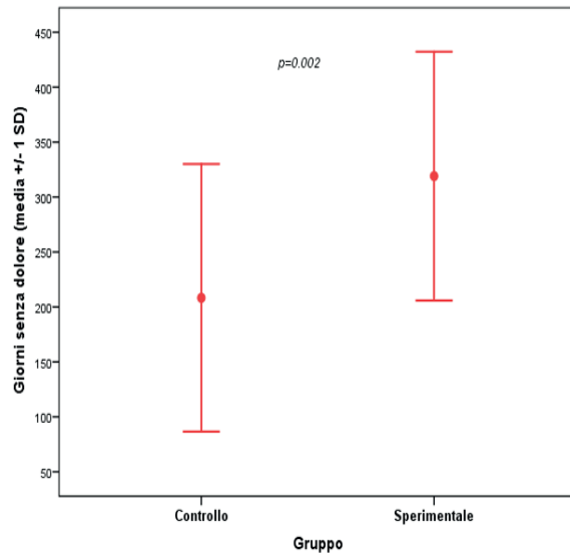


Graph 1 - Difference between final diameter and initial diameter of nail plate in experimental and control group. That difference is higher in experimental group.

Referring to recurrences during 12 months, in experimental group we observed 3 recurrences on 20 statistic units (15%), in control group there were 24 recurrences on 32 statistic units (75%). So, we can affirm that recurrence is associated to control group and that



Graph 2 - Frequency of recurrence in experimental and control groups. Recurrence is associated to control group.



Graph 3 - Days of absence of pain in experimental and control group (mean higher in experimental group).

difference between two groups is statistically significant with high significance ($p < 0.0001$) (Graph 2).

Analyzing the days of absence of pain, in experimental group there is a mean of 319.05 ± 113.18 days, instead in control group there is a mean of 208.31 ± 119.84 days. The mean days of absence of pain are higher in experimental group, and also this difference between groups is highly statistically significant ($p < 0.0002$). (Graph 3).

DISCUSSION AND CONCLUSION

Data analysis shows that subjects treated with experimental treatment have a mean increasing of nail plate diameter higher than control group. This increasing of diameter, together with increasing of nail plate thickness due to application of acrylic resin, determines lesser pressure on periungual tissues and so lesser pain and trend to ingrowing toenail. Furthermore, we can observe the incidence of recurrence, lesser

in experimental group compared to control group. A clarification is important: in T1 and T2 we observed, in experimental group, that nail plate diameters were lesser than the moment immediately after treatment. Despite this observation, the mean days of absence of pain are higher in experimental group compared to control group. So, we can infer that soft tissues, particularly nail bed, undergo a remodeling because of the change of relationships between nail plate and surrounding soft tissues. We highlight that all the differences between groups have very high statistical power ($p < 0.0001$ and $p < 0.0002$).

In this randomized controlled trial we show that the new experimental technique of ortonixia could be a valid conservative treatment for ingrown toenail particularly in diabetic patients. In fact, it doesn't need anesthesia, it is not invasive, it has not contraindications, it has effectiveness in resolving pain and preventing recurrences.

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