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Research Article

Comparative Study That Evaluates the Effectiveness of Intradermotherapy with 0.5% Minoxidil Versus Topical Application of 5% Monoxidil Solution in the Treatment of Androgenetic Alopecia

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Abstract

Introduction: Androgenetic alopecia is the most common cause of hair loss, progressively affecting both men and women and causing great impact on quality of life. Among many possible treatments, intradermotherapy is a promising and controversial procedure, with few studies in the literature so far.

Objectives: Comparatively evaluate the efficacy of intradermotherapy with a 5% minoxidil solution in patients with androgenetic alopecia.

Methods: Patients were randomly divided into two groups. Group 1, with 13 participants, went through 10 sessions of intradermotherapy with 7 day intervals between each one. Group 2, with 11 participants, applied 1 ml of a topical minoxidil 5% solution on dry scalp twice a day throughout this study. All patients were evaluated with clinical and trichoscopic pictures taken before and after 12 weeks of treatment.

Results: Most patients in both groups perceived improved capillary density and thickness of hair strands, and reduced hair loss, without statistical difference between group 1 and 2. Trichoscopic evaluation performed by specialists did not find statistical difference between the groups.

Conclusion: The results of intradermotherapy with minoxidil are similar to the results of topical application of the same substance.

Keywords: Alopecia; Intradermotherapy; Minoxidil; Dermatology

Introduction

Androgenetic Alopecia (AAG) is one of the most common causes of hair loss, affecting both men and women [1]. Its prevalence increases with age, and among Caucasians, 80% of men are affected and 42-50% of women [2-4]. The prevalence in Asian, Native American and African-descendant patients is lower [4,5]. It is a chronic, non-scarring and progressive disorder, in which progressive miniaturization of the hair follicle occurs, with pattern distribution in genetically predisposed men and women [1,3,5,6].

Testosterone is the main circulating androgen in men and its conversion to Dihydrotestosterone (DHT) occurs by the enzyme 5Alpha-Reductase (5AR). Compared to testosterone, DHT has approximately 5 times greater potency on androgen receptors. There is a higher concentration of 5AR in follicles in the frontal region compared to those in the occipital region. The 5AR type 2 isoenzyme is expressed prominently in the inner and outer sheaths of the follicular root and predominantly in the dermal papillae of hair follicles in the frontal region [7]. In genetically susceptible follicles, DHT binds to androgen receptors, forming a complex

that activates the genes responsible by the gradual transformation of terminal follicles into miniaturized ones, through the acceleration of the mitotic rate of the matrix, which leads to a shortening of the hair cycle time and an increase in telogen loss, as well as an increase in the time in which the follicle is in the catagen phase [5,8].

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Clinically, AAG is characterized by progressive thinning of the hair, with a characteristic distribution pattern in men and women [1,2]. The most common pattern of presentation in men is recession of the frontal line, mainly at the temples, with subsequent rarefaction at the vertex. The most commonly observed female pattern is that characterized by diffuse thinning of the hair in the centroparietal region, with preservation of the frontal implantation line. Another pattern also found in women is the "Christmas tree" pattern, where there is also centroparietal rarefaction, but there is no preservation of the frontal line [2,9].

The main goals of AAG treatment are to stop the progression of hair loss and stimulate hair regrowth. The benefits that treatment should bring to the individual are not only stabilizing and preventing disease progression, but improving quality of life2. Topical minoxidil, oral finasteride and oral dutasteride are drug therapies currently approved by the Food and Drug Administration (FDA) for treatment of male androgenetic alopecia. Furthermore, the only drug approved by the FDA for female pattern hair loss is topical minoxidil.

Minoxidil was initially used in the 1970s for cases of refractory arterial hypertension, with hypertrichosis being observed as a side effect. It acts through the vasodilation of peripheral arteries by opening potassium channels, causing an increase in Vascular Endothelial Growth Factor (VEGF) [3,4,6]. It is also believed that hair growth occurs due to an increase in Prostaglandin E2 (PGE2) [4]. This medication also has the effect of blocking cell apoptosis, increasing the duration of the anagen phase of the hair. It can also increase hair density and thicken the hair shaft [3,4,10]. Studies have also reported antifibrotic activity of minoxidil through inhibition of the enzyme lysyl hydroxylase in human skin fibroblasts [6].

Its use in topical form, with a concentration of 2-5%, is approved and well established, having been one of the first treatments approved by FDA for the treatment of AAG. The main side effects of topical minoxidil are facial hypertrichosis, itching, local irritation and contact dermatitis, mainly due to the use of propylene glycol as an application vehicle [4]. Initial shedding is also seen, a transient increase in hair loss in the first weeks of treatment with minoxidil, which occurs due to the telogen follicles re-entering the anagen phase of hair cycle [4].

Oral minoxidil, although not approved by the FDA, appears to have similar efficacy to topical minoxidil. The used dose usually varies between 0.25 mg to 5 mg per day. It has few contraindications, the main ones being a history of pheochromocytoma and hypersensitivity to the drug11. The reported side effects are typically dose-dependent and reversible. These are mainly transient hair loss, weight gain, tachycardia, hirsutism, hypertrichosis, lightheadedness (dizziness, postural hypotension) and edema of the lower limbs [10-13]. Rarer side effects are hypotensive syncope, pericardial effusion, congestive heart failure and allergic reactions [10].

Although there are no controlled studies on its effectiveness, mesotherapy has been shown to be an option in the treatment of AAG and hair loss in general [14]. Mesotherapy is a technique that involves microinjections of medication directly into the dermis, and is also known as Intradermotherapy (IDT) [15,16]. It was first introduced in 1958 by the French doctor Michel Pistor, and was described as the intradermal injection of highly diluted drugs, suitable for this route of use. The dermis would then become a reservoir from which the products would activate receptors and slowly diffuse, using the microcirculatory route [16]. One of the main advantages of IDT is the rapid onset of action and good bioavailability, due to the short time required for the drug to reach the expected location, as well as the long period it remains there acting3. Furthermore, this method does not alter the mechanism of action of the medication at the administered site [17]. IDT has shown good application in chronic musculoskeletal pain, chronic venous insufficiency, intradermal vaccination, alopecia and some aesthetic conditions, such as cellulite, melasma and rejuvenation [5,15,17,18]. Some complications such as mycobacterial infection, urticaria, skin necrosis, panniculitis, acromia and others have already been reported, however, it is believed that these complications may be related to errors in indication, technique applied and the drugs used [3,19]. Its use in AAG is considered one of the most important in dermatology [5]. The products commonly used in this case are minoxidil, finasteride and bicalutamide, in order to stimulate hair growth [20,21]. In addition, minerals are used, such as copper, which increase the synthesis of collagen, elastin and biotin, which act on the follicle root through the regulation of mitrochondrial enzymes [20,22].

Due to the scarce scientific information about the use of mesotherapy in Trichology, as well as adequate methodology, effectiveness, mechanisms of action and complications of this technique, this study aimed to evaluate the use of intradermotherapy in the treatment of female and male androgenetic alopecia, since this is one of the most important applications of mesotherapy in Dermatology. A comparative evaluation of the efficacy and safety of intradermotherapy with 0.5% minoxidil was carried out in relation to the topical application of 5% minoxidil solution in the treatment of androgenetic alopecia and analysis of side effects of these treatment modalities, applicability of the methodologies used and degree of satisfaction of the patient.

Materials and Methods

This study is characterized by an experimental clinical trial. Twenty four patients with a clinical and trichoscopic diagnosis of Androgenetic Alopecia were selected, with any of the three main presentation patterns: Hamilton, Ludwig or Olsen. The research subjects were selected during consultation at the Trichology Outpatient Clinic of a University Hospital.

Female or male patients were included, treated at the Dermatology Outpatient Clinic with a diagnosis of moderate androgenetic alopecia (Ludwig grade II and Hamilton-Norwood grade II to IV), obtained through history and clinical examination, aged over 18 years. These were patients who had not undergone specific treatment for baldness in the last 6 months. Patients who did not have other associated scalp diseases were also included, so tests such as ferritin, zinc, TSH and blood count were carried out before the start of the study, which can cause Telogen Effluvium when altered. Individuals who had not performed hair straightening techniques for at least 6 months were also included.

Pregnant or breastfeeding patients were excluded; women with signs and symptoms of hyperandrogenism; patients with other scalp diseases associated with AAG; carriers of active autoimmune disease or other associated serious comorbidities; coagulation disorders; active infection in the treated region or previous history of healing problems; patients who have previously undergone hair transplantation; and patients with a previous history of neoplasms. Individuals undergoing treatment with anticoagulants and immunosuppressants were not included. Individuals with poor understanding ability and inability to follow the study to the end were also excluded.

Data were collected from each participant such as age, sex, family history of baldness (male or female, among first-degree relatives), duration of the disease and previous treatments carried out. Standardized images of each patient were collected before and 12 weeks (90 days) after the start of the study. All photos were taken with the same camera, under the same lighting conditions, resolution and distance.

Patients were randomly divided into 2 groups. In Group 1, 13 patients were included, who underwent 10 intradermotherapy sessions, with an interval of 7 days between them. 2 ml of 0.5% minoxidil was used in each mesotherapy session. These medications were standardized and supplied by the same laboratory and compounding pharmacy throughout the study. In Group 2, 16 patients were included and they used Minoxidil 5% in solution, applying 1ml to the dry scalp, twice a day throughout the entire study. However, from these 16 patients in Group 2, 5 were lost to follow-up and, therefore, were excluded from the analysis, leaving 11 patients.

In this study, it was decided to use only minoxidil for intradermotherapy in order to avoid confusion bias and also to evaluate in isolation the different methods of permeation of the medication for the treatment of AAG, through clinical and trichoscopic analysis.

Immediately before the intradermal injections, the treated area was antisepsised with 70% alcohol on gauze. The medications were injected into the dermis at a 60° angle using a 3ml syringe attached to a 30 G 0.3x4 mm hypodermic needle. Several injections of 0.1 ml of the substance were performed along the affected hair area, 1 cm apart, using the point-to-point technique.

Participants were instructed not to undergo any treatment for Androgenetic Alopecia concomitantly with mesotherapy. The photographic images taken before and 12 weeks after the start of the study were evaluated by 17 dermatologists attending the Dermatology outpatient clinic. The clinical analysis of each evaluator was carried out comparatively, according to the following

scale:

1. Worsening: increase in capillary rarefaction compared to the beginning of treatment
2. No improvement: absence of hair growth
3. Small improvement: slightly noticeable partial hair growth
4. Average improvement: partial and easily noticeable hair growth
5. Great improvement: hair growth throughout the affected area

Trichoscopic analysis was performed comparatively using photos of the midline of the scalp, in the frontoparieral region, taken before and after treatment. It took into account the improvement in hair density, increase in the number of hairs per follicular unit and improvement in the variability of shaft thickness, with possible responses in relation to improvement: <25%, 25-50%, 50-75% and >75%.

Each patient was evaluated regarding their perception regarding the degree of improvement in hair density, strand thickness and hair loss, with possible answers: worsening, improving or indifferent.

Finally, each individual was also questioned about the presence of side effects, such as pain during applications, headache, itching, trichodynia, skin atrophy, edema, ecchymosis, increased body hair and menstrual irregularity. The results were analyzed using the IBM SPSS 20 statistical program and considered statistically significant when $p<0.05$.

Results

The study had a total of 24 participants, 18 men and 6 women with an average age of 33.37 years, ranging between 23 years and 69 years. Group 1, which performed intradermotherapy sessions with minoxidil, was made up of 13 participants, 11 men and 2 women, with an average age of 30.6 years. Group 2, which used topical minoxidil, was made up of 11 participants, 7 men and 4 women, with an average age of 36.5 years. There was no statistical difference between the mean age of groups 1 and 2. These characteristics are shown in Table 1.

Most patients had Norwood-Hamilton alopecia grades II and III, with no statistical difference between the groups. In group 1, 84.6% of patients had a family history of AAG and in group 2, 72.72%, with no statistical difference between the groups.

Characteristic	Group 1 (n = 13)	Group 2 (n= 11)
Average age (years)	30,6	36,5
Sex		
Masculine	11/13	7/11
Feminine	2/13	4/11
Family history	10/13	8/11
Degree of alopecia		
Level I	2/13	2/11
Level II	4/13	6/11
Level III	5/13	2/11
Level IV	2/13	1/11

Table 1: Epidemiological characteristics of patients included in the study.

Five patients in Group 1 had previously undergone treatment for AAG, but all patients had not been treated for more than 2 years. In group 2, 4 patients had undergone previous treatment, but all patients had not been treated for more than 1 year. The results perceived by patients in Groups 1 and 2 are represented in Fig. 1,2. In both groups, an improvement in hair density,

thickness and hair loss was noticed in most patients.

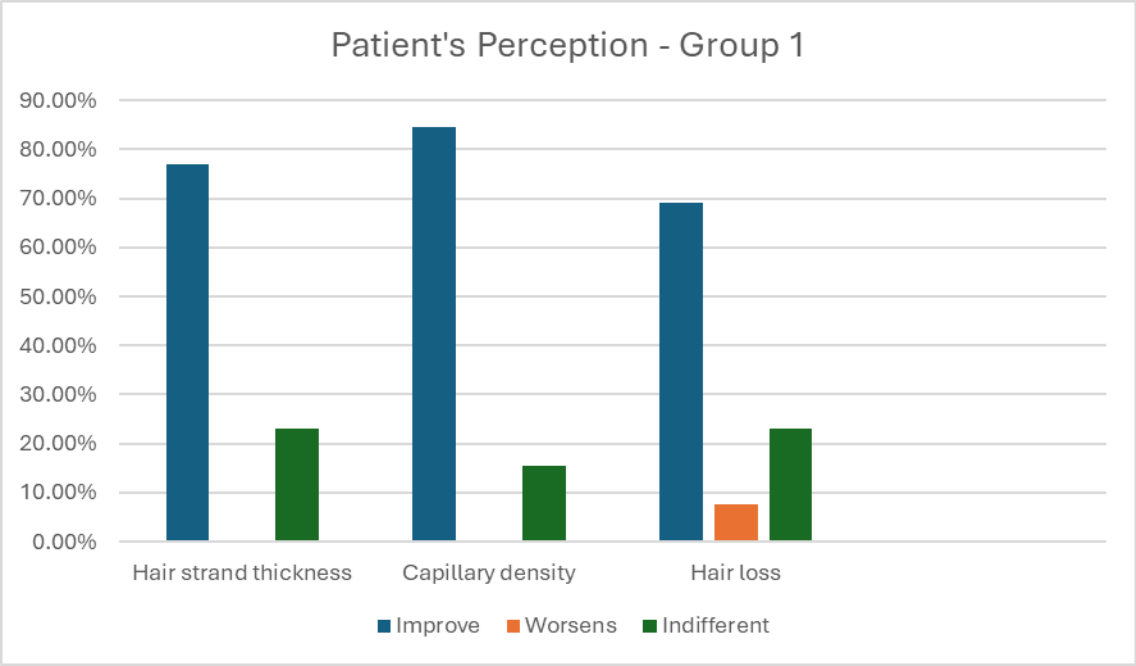

Figure 1: Patients' perception of the treatment results of Group 1, treated with Minoxidil in IDT.

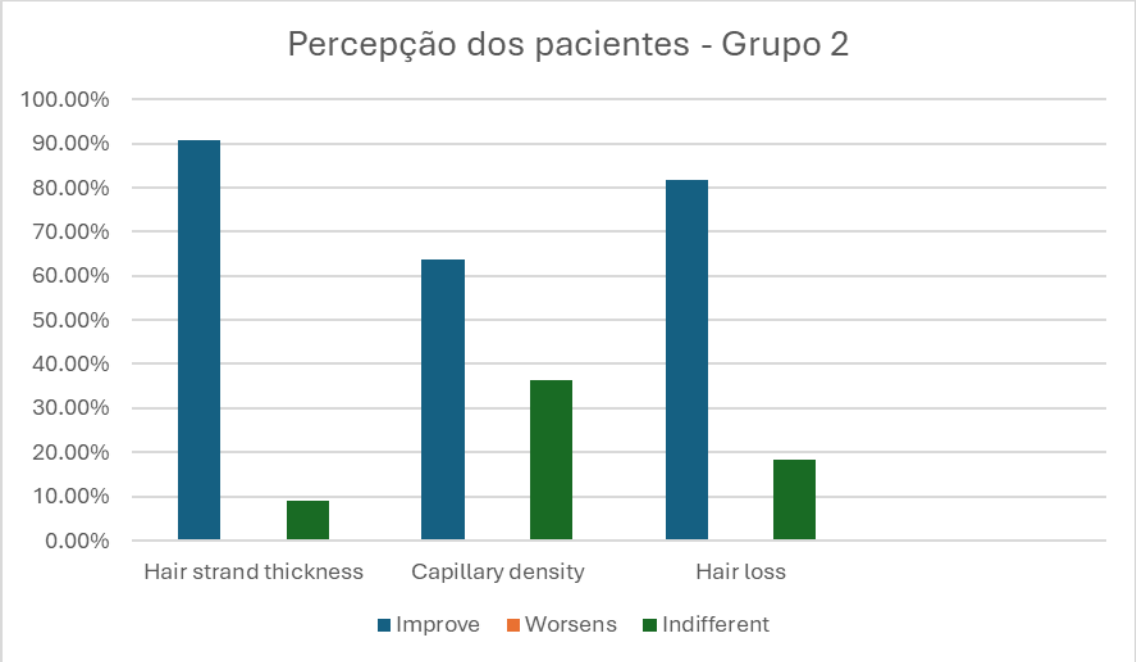

Figure 2: Patients' perception of the treatment results in Group 2, treated with topical Minoxidil.

Regarding the evaluation of dermatologists, when we carried out an analysis using means and medians of the responses given to both participant groups (using Student's T and Mann-Withney tests) we observed that, according to the requested trichoscopic criteria, the majority of the experts had a perception of improvement between 25-50% for all of them (density, hairs per follicular unit and thickness of the shafts). In clinical analysis, using the perception of improvement scale, the most common response was small improvement, where hair growth was considered partial and slightly noticeable. For all analyzed criteria, both trichoscopic and clinical, there was no statistically significant difference between the groups.

Regarding side effects, illustrated in Table 2, in the intradermotherapy group (Group 1) 7 patients (53.84%) had pain when applying the medication, 2 patients (30.75%) had headache after application, 5 patients (38.45%) reported pain in the scalp after

application, 2 patients (30.75%) reported increased hairiness, 1 of them on the shoulder and the other on the chin, and 1 patient (7.69%) reported a feeling of swelling on the scalp. No patient in this group reported pruritus, thinning of the scalp skin and ecchymoses or bruises. In the group that used topical minoxidil (Group 2), 1 patient (9.09%) reported increased hairiness in the beard region and itching on the scalp by 2 patients (18.18%). In both groups, no woman reported menstrual irregularity.

Variable	Group 1	Group 2
Headache	2/13	0/11
Itching	0/13	2/11
Pain	5/13	0/11
Swelling	1/13	0/11
Bruise	0/13	0/11
Hypertrichosis	2/13	1/11

Table 2: Side effects reported by patients in groups 1 and 2.

Discussion

AAG is a chronic, progressive disease with a major impact on the quality of life of affected patients. The disease generally begins between 12 and 40 years of age, increasing in prevalence with age [5]. In this study, patients were between 23 and 69 years of age, with no statistical difference in age between the groups.

Furthermore, in both groups, most patients had a positive family history. This data is compatible with the current literature on AAG, highlighting the genetic component of the disease. As explained by Azam and Morsi, it is believed that the genetic inheritance of AAG occurs through an autosomal dominant gene with variable penetrance, but it is not possible to rule out the possibility of polygenic inheritance [5].

The sample of this study was mainly composed of patients with Norwood-Hamilton alopecia classification of grades II and III, as in the study by Gajjar, et al., with no statistical difference between the groups [9].

Regarding IDT, carried out in Group 1 of this study, the technique for carrying it out may vary according to the author due to the lack of a methodological standard. However, current literature recommends that the needle be introduced into the skin perpendicularly or at an angle of 30º to 60º. The depth of the injection seeks to reach the dermis and should not exceed 4 mm, since the intradermal route has its own pharmacokinetics. The use of a Lebel needle (4 mm long) is recommended. The injections must only cover the area to be treated and the distance between them also varies between 1 cm and 4 cm between them [16]. In general, the volume of product applied to each puncture can vary from 0.1 to 0.2 ml [17]. According to a consensus published by the Italian Mesotherapy Society, the treatment protocol (choice of drug, duration of treatment, patient management and follow-up) varies according to the nature, severity and location of the pathology to be treated [17].

The majority of members of Group 1, who underwent 10 IDT sessions at 1-week intervals, noticed an improvement in hair density, hair thickness and improvement in hair loss. Only 1 patient in the study reported worsening hair loss. In the study by Uzel et al, a comparison was made between placebo and IDT with minoxidil in women with AAG, following the same application protocol as the present study (10 sessions at one-week intervals). It was shown that 25% of patients in the placebo group reported loss of hair volume, with no patient in the IDT group reporting loss of volume. Furthermore, 69.2% of patients who underwent IDT noticed an improvement in hair loss, in contrast to 37.5% in the placebo group [19].

In Group 2, which applied topical minoxidil 5%, most patients noticed an improvement in hair density, hair thickness and improvement in hair loss. Topical minoxidil is an established therapy for treating AAG, with multiple studies validating its use. In a 1-year study of 904 men with AAG, 62% of patients showed a significant decrease in the area of rarefaction in the scalp region when treated with topical minoxidil 5% twice daily and 84.3% of patients reported hair growth to varying degrees [23].

Multiple double-blind, randomized, placebo-controlled studies and meta-analyses support its use in clinical practice [4].
In the present study, there was no significant difference between the results observed by patients in Group 1 and Group 2, nor between the groups' assessments by experts. This result contrasts with that found by an Egyptian study carried out with 60 female patients, in which IDT with minoxidil was superior to the application of topical minoxidil [5]. The author points out two factors that may be responsible for the superiority observed: direct inoculation of minoxidil into the dermis inferior was responsible for the more powerful action of the medication and the multiple microtrauma may have stimulated cytokines and growth factors [5]. Another study carried out with 126 women, which evaluated the efficacy and safety of mesotherapy with dutasteride in the treatment of female pattern alopecia, concluded through clinical and ultrastructural evaluations, that IDT with that medication is tolerable, safe and an effective form of minimally invasive treatment [8]. Another study, published in 2011, evaluated the clinical changes caused by mesotherapy in 15 men and 8 women with AAG. Applications were carried out with formulations based on minoxidil, biotin, d-panthenol, herbal complex and procaine, and compared regarding the number of strands, shaft thickness, scalp quality and hair loss. The results demonstrated the effectiveness of mesotherapy and there were no side effects during or after applications with statistical significance ($p<0.05$) [24]. Recently, a study published in 2019 demonstrated that after using IDT with a mixture containing amino acids, minerals, vitamins, hyaluronic acid and Ginko biloba extract, there was a greater increase in the number of hair follicles after treatment when compared to the topical application of Minoxidil ($p=0.001$), but there was no evidence of change in follicular diameter ($p=0.105$) [25]. Another study published in 2019, comparing topical minoxidil with IDT with a mixture containing amino acids, vitamins, nucleic acids and minerals, found no statistical difference between the groups [9].

This study was conducted over 10 weeks, making it possible to exclude interference from the effect of the initial shedding caused by minoxidil on the final results of both groups. Furthermore, IDT was performed only with minoxidil, excluding a possible bias in the results when applied in conjunction with other substances. Similar to the study by Carvalho, et al., in which was analyzed the effect of IDT with only bicalutamide [21].

Regarding the side effects observed in Group 1, in which IDT was performed, the main side effects were pain (38.4% of patients), headache (15.3%), swelling (7.69%) and hypertrichosis (15 .3%). In the study by Gajjar, et al., patients who underwent IDT using mixture mainly reported headache, redness and swelling, similar to the effects found in our study [9]. Another study, published in 2019, using IDT with mixture had similar results, with reports of pain in 66.7% of patients and headache in 33.3% [25]. The study by Carvalho, et al., the patients reported local pain, ecchymosis, and transitory edema after IDT using bicalutamide [21]. In a study evaluating the effectiveness of IDT with minoxidil, there were also reports of pain in 5.6% of patients, burning in 11.1% and itching in 11.1% [19]. In none of the studies mentioned was the occurrence of hypertrichosis observed with the use of IDT, however, this effect was reported by 2 patients in our study. Hypertrichosis was noticed by more patients in the IDT group (Group 1) than in the topical minoxidil group (Group 2). No serious adverse effects or effects that would lead to treatment discontinuation were observed in any of the studies mentioned. In the study presented here, although pain was the main side effect, it can be said to be expected due to the performance of several punctures in the scalp, which did not influence patients' adherence to the procedure, and no patient withdrew from the study due to this effect.

In Group 2, in which topical application of minoxidil was performed, reports of itching were observed in 2 patients (18.18%) and hypertrichosis in 1 patient (9.09%). These effects are compatible with data from current literature. In the study by Hunter, et al., patients who used topical minoxidil reported hypertrichosis in 6.7% of cases, itching in 66.7% and peeling in 20% [25]. In the study by Gajjar, et al., the side effects most reported by patients after the use of topical minoxidil, headache (17%), erythema (8%), hair loss (33%) and peeling (29%) were observed [9]. In this group, no side effects that would lead to treatment discontinuation were observed.

This study has some limitations such as limited sampling, short follow-up, lack of comparison with a placebo group and possible biases due to patients' expectations regarding each of the treatments evaluated. More studies with larger samples, double-blind, randomized, placebo-controlled are needed to better validate the IDT technique as a treatment for AAG. Furthermore, although established in the therapeutic arsenal of AAG, minoxidil has no effect on the course of the disease, since it acts mainly by thickening the hair by prolonging the anagen phase. With this in mind, we can state that to demonstrate greater effectiveness of IDT in the treatment of AAG, future studies would be interesting in which Minoxidil would be used in conjunction with antiandrogenic medications, which are considered true modifiers of the course of the disease.

Conclusion

The conclusion of this study is that there was no statistical difference between the topical minoxidil and IDT with minoxidil groups. Therefore, it is indicated that IDT is not inferior to the topical application of the medication, being a possible therapeutic alternative. Most patients in both groups noticed an improvement in hair density, hair thickness and improvement in hair loss.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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