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Mesotherapy using Dutasteride-Containing Solution in Male Pattern Hair Loss: a Controlled Pilot Study

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Abstract

Background: *Controlled studies on the value of mesotherapy in the treatment of male pattern hair loss (MPHL) are lacking.*

Aim: *To evaluate the efficacy and safety of intradermal injection of 0.05% dutasteride-containing solution in comparison to 0.9% saline injected via nappage technique.*

Patients & Methods: *Twenty eight male patients with MPHL types III, IV and V completed the study. They were randomly assigned to two groups: group I the treated group (n=14) and group II controls (n=14). Patients received seven injections at weeks 0,1,2,3, 5, 7 and 11 and were evaluated at week 12.*

Results: *The dutasteride-containing preparation was significantly more effective ($p<0.05$) than placebo. This was evident by three assessment methods; difference in hair count, professional independent observers' assessment and patients' self assessment. The less the duration of MPHL, the better was the response to mesotherapy. Minimal side effects in the form of mild pain and headache were detected.*

Conclusion: *Mesotherapy using dutasteride-containing solution is an effective method in treating moderate degrees of MPHL, further studies using dutasteride alone and for longer periods are recommended.*

Introduction

Androgenetic alopecia, or male pattern hair loss (MPHL), affects approximately 50% of the male population[1]. Medical treatment for males includes topical minoxidil 2-5%, systemic finasteride (type II 5 α reductase inhibitor) or the newly introduced systemic dutasteride (type I & II 5 α reductase inhibitor). Response to medical treatment takes a long time and not all patients are interested in it[2]. Hair transplant surgery is an expensive alternative that does not always yield satisfactory results to the patients, is expensive and multiple treatment sessions are needed to obtain the desired hair density[3].

Mesotherapy is a technique of delivering minute amounts of pharmaceuticals or combined medications intradermally to treat conditions such as hair loss, facial rejuvenation, cellulite as well as some

gastrointestinal disturbances or sports injuries. Most formulas used are anecdotal, repeated treatments are necessary and results are mostly temporary[4,5].

Since controlled studies regarding the use of mesotherapy in the treatment of MPHL are lacking, the aim of the present study was to evaluate the efficacy of dutasteride-containing solution in the treatment of MPHL. We used a commercial preparation which contained dutasteride together with other vitamins, because at the time of start of the study this was the only preparation available in the Egyptian market that contained dutasteride. Finasteride was not used because our trials with it had shown it to be very painful on intradermal injection, so that all patients refused to continue the course of therapy. In addition dutasteride has been shown to be approximately 3 times as potent as finasteride at inhibiting type II 5α-reductase and more than 100 times as potent at inhibiting the type I enzyme [2].

Patients and Methods

Patients

In this single blinded, placebo-controlled study 34 males between the age of 20 to 50 years with moderate degree of androgenic alopecia (stages IIIv, IV, V Hamilton-Norwood classification) were recruited from the outpatient clinic of the Dermatology Department, Ain-Shams University Hospital and El-Tahreer General Hospital in the period from March 2008 to September 2008.

Informed consent and complete history were taken from each patient. Excluded from the study were patients with insulin dependent diabetes mellitus, strokes, cancer, thromboembolic phenomena, patients on anticoagulant medications (aspirin, warfarin and heparin), since these were the general contraindications for mesotherapy[6]. Patients with history of psoriasis or lichen planus were not included for fear of Koebner phenomenon. In addition patients complaining of decreased libido, erectile or ejaculatory dysfunction were excluded because these are known side effects of systemic 5α reductase inhibitors[7]. Patients taking any hair growth promoters in the past 6 months were not included. Patients were instructed not to alter their hairstyle, perm or dye their hair during the study period.

Methods

Patients were randomly assigned to two groups; Group I received a commercial preparation which contained: dutasteride 5mg, D-panthenol 500mg, biotin 20mg, and pyridoxine 200mg per vial of 10 ml (i.e. 0.05% dutasteride) (purchased from Mesodermal, USA). Group II acted as control and received 0.9% saline (placebo). All solutions used were sterilized by ultrafiltration.

The materials were injected in a defined area of the vertex to standardize the site of injection. Injections were delivered each week for 4 consecutive weeks (week 0, 1, 2, 3), followed by an injection every two weeks for two times (week 5, 7) the last was injected after 4 weeks (week 11). Assessment was done at week 12.

After disinfection, nappage technique was employed as follows; intradermal injections of 0.05 ml solution were done at a 1 cm interval at an angle of 30-60° using a 4 mm long 30 gauge needle (mesoneedle)[6]. The total volume injected each session ranged from 1.5 ml to 2 ml according to size of the injected area and was constant for each patient in all sessions. The patients were instructed to avoid using any proprietary hair stimulating preparations during the study period.

Assessment: Three methods were used to assess the results: hair count in a defined area of the scalp, independent observer assessment of global photographs and patients' self assessment.

At each visit digital photos were taken for the vertex at standard distance and light conditions. Counting was done in week 0 and week 12 with the help of a hand magnified lens (x 10) after hair was clipped to a length of about 1 mm in a circle 1cm diameter at the leading edge of the vertex bald spot. Reproducibility of this area was assured by using a cardboard target area template. The template had multiple holes, each of 1 cm diameter. The first

hole was 2 cm away from the beginning of the strip, the rest of the holes were 1cm apart from each other. The strip was centralized between the two ears, attached to occipital protuberance posteriorly and to the root of the nose anteriorly and the hole where counting was done was marked and fixed for each patient.

Three professional independent blinded observers examined the photos taken at week 0 and 12. The mean value of all three assessment methods was taken. Assessment was done using a score from -1= worse compared to the base line, 0= no change, 1= minimal (< 20 %), 2 = mild (20- 39 %), 3 = moderate (40- 59%), 4= good (60-79%) and 5 = excellent (80-100%) improvement.

At week 12 the patients were asked to fill a self-assessment questionnaire to evaluate the degree of improvement of hair density and hair quality (rate of hair growth, hair fall, hair thickness, its colour and brightness). The results of the patients' opinion were scored as follows: -1 = worse, 0= no change, 1= mild <25%, 2 = moderate (25-49%), 3 good = (50-74%) and 4 = excellent (>75%) improvement. As for hair quality, each parameter was given a score of -1= worse, 0= same, +1= improved.

At each visit the patients were examined and asked about possible local side effects such as pain, headache, tightness, itching, ecchymoses and puffed eyes and systemic side effects such as decreased libido, erectile or ejaculatory dysfunction.

Statistical analysis of data was done using SPSS (statistical program for social science) version 12.

Results

Demography: Out of 34 males with MPHL 28 completed the study [group I (n=14) and group II (n=14)]. Four cases discontinued as they could not tolerate the pain of injections and two were lost to follow up. The mean age of all included cases was 30.822±8.208 years (range 21-49 years). The type of baldness was as follows: Hamilton-Norwood type IIIv 54% (I: n=7 or 50%, II: n=8 or 57%), IV 18 % (I: n= 4 or 29%, II: n=1 or 7%), V 28 % (I: n=3 or 21 %, II: n=5 or 36%). The mean duration from the beginning of hair loss was 2.858±1.571 years (range 1-6 years). The mean and range of baseline hair count in a circle 1 cm diameter on the vertex was 37.107±11.325 (range 11-62).There was no significant difference between the two groups with respect to age, type and duration of baldness and baseline hair count (Table 1).

Hair Count Assessment: At week 12 of the study, mean hair count in the placebo group (group II) decreased by 0.173±0.940 hairs, while hair counts in the actively treated group (group I) increased by 7.739±1.104 hairs, the difference was statistically significant ($p < 0.001$).

There was no correlation between age of the patients or the stage of baldness and the degree of improvement, but there was a reversed correlation between duration of baldness and degree of improvement ($p= 0.008$).

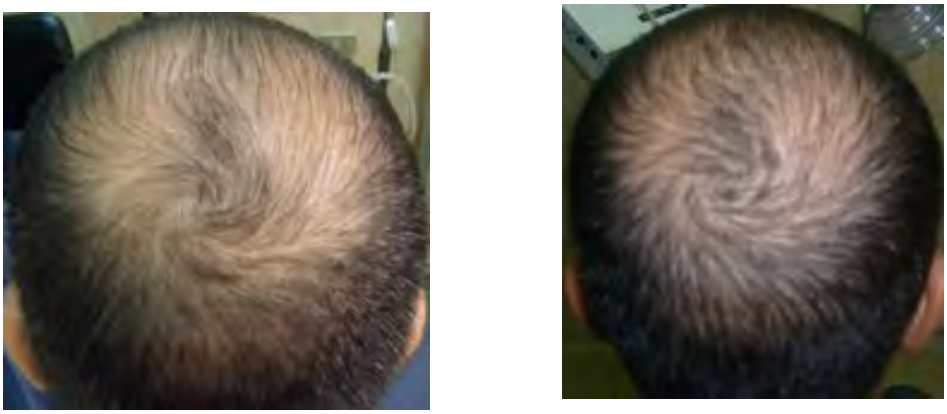
Independent observer evaluation of global photographs: Thirteen cases out of 14 (92.9 %) in the active group and 4 out of 14 in the placebo group (28.6 %) were reported as improved. The mean of the 3 independent observers' assessment scores was 2.786 and 0.143 in groups I and II respectively. The active group showed significantly greater improvement than the placebo group ($p = 0.001$) (Figs. 1 and 2). The percentage of patients judged to have obvious improvement in hair growth (improvement more than 40%) was 64% and 0% in group I and II respectively.

Subjects' self-assessment: Regarding the improvement of hair density or scalp covering assessed by the patients, 13 out of 14 (92.9 %) in the active group 1 out of 14 (7.1 %) in the placebo group reported improvement. The active group showed significantly greater improvement (mean score = 2.21) than the placebo group (mean score = 0) ($p < 0.001$). The patients who considered their improvement in hair growth obvious (improvement more than 50%) were 42.86% and 0% in group I and II respectively.

Change of hair quality: Significant decrease in the rate of hair fall ($p = 0.044$) and increase in hair growth rate ($p < 0.001$) was noticed by the patients

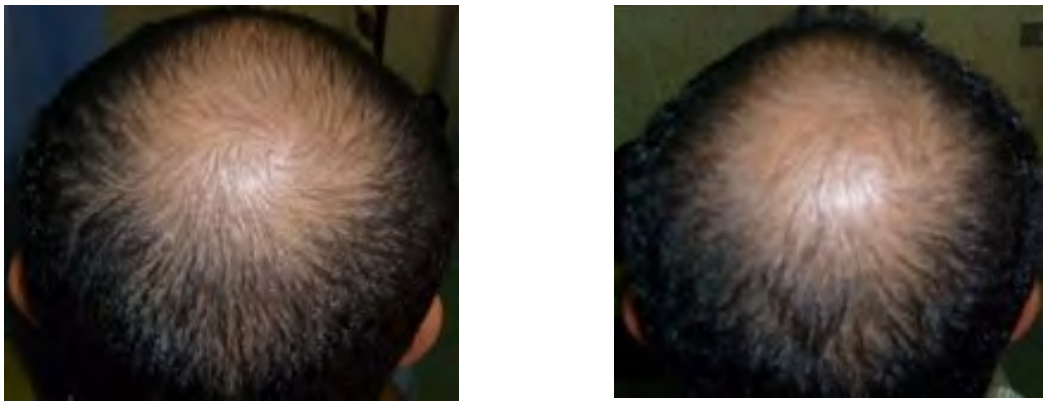
in the active and placebo group. The active group reported significant improvement of hair thickness (p = 0.009), colour and brightness (p= 0.034) compared to placebo group (Table 2).

The observer assessment and patients' self assessment were concordant. Although they were higher than changes in hair count, a corresponding increase in hair count was noted (Table 3).



(a) *(b)*

Fig. 1: a) Group I before, b) 12 weeks after start of active treatment. Evaluations: grade 4 by observer assessment, grade 3 by self assessment, hair count change from 29 to 37(27.6 %).



(a) *(b)*

Fig. 2: a) Group II before, b) 12 weeks after start of saline injection. Evaluations: grade 0 by observer assessment, grade 0 by self assessment, hair count change from 29 to 28(-3.4 %).

Table 1. Demographic data of included patients

		Range			Mean	±	SD	T-test	
								t	P-value
Age	Group I	22	-	49	30.286	±	8.774	0.345	0.733
	Group II	21	-	49	31.357	±	7.642		
Duration	Group I	1	-	5	2.429	±	1.284	1.420	0.167
	Group II	1	-	6	3.286	±	1.858		
Hair count Before	Group I	26	-	62	36.571	±	10.435	0.250	0.805
	Group II	11	-	55	37.643	±	12.214		

Table 2. Patients' self assessment of hair quality

	Decreased hair fall		Increased growth rate		Thickness		Color & Brightness	
	N	%	N	%	N	%	N	%
Group I	9	64.3	10	71.4	7	50	3	21.4
Group II	3	21.4	0	0	1	7.1	0	0
P value	0.044		< 0.001		0.009		0.034	

P<0.05 is considered significant

Table 3. Comparison between the mean ranks of percentage of changes in the three parameters of assessment in both groups

		% of change					Kruskal Wallis Test	
		Range			Median	Mean rank	X^2	P-value
Group I	Observer assessment	0.000	-	100.000	60.000	27.750	19.063	0.000*
	Scalp covering	0.000	-	100.000	50.000	26.893		
	Hair count	0.000	-	34.483	13.240	9.857		
Group II	Observer assessment	-20.000	-	40.000	0.000	23.250	1.099	0.577
	Scalp covering	-25.000	-	25.000	0.000	22.286		
	Hair count	-18.182	-	6.000	-1.042	18.964		

Safety & tolerability: Side effects noted during the study were pain, headache and tightness. There was no significant difference in adverse events between the two groups ($p>0.05$). No cases were reported to have infection, ecchymosis, itching or puffed eyes, and no one complained of sexual disturbance.

All patients of both groups experienced pain during the injection, which was in 4 patients (14.3%) severe enough to necessitate premedication by a topical anaesthetic cream. Pain at injection site usually subsided shortly after the session, 12 patients (6 in each group, 42.9%) complained of pain that lasted for several hours after the session.

Headache was noticed in 2 (14.29%) and 5 (35.71 %) patients in groups I and II respectively. Headache was mild, not following each session and subsided within one day.

Only one patient from group I suffered from scalp tightness in 2 out of 7 sessions. This tightness lasted for two days.

Discussion

The role of androgens and the type II 5 α reductase enzyme in the pathogenesis of MPHL are now well established. 5 α reductase converts testosterone to its active form 5 α-dihydrotestosterone (DHT). Type II isoform is expressed in androgen-responsive tissues such as the hair follicle while type I isoform of 5 α reductase is widely expressed in many tissues including sebaceous glands and hair follicles[8,9]. Dutasteride, a dual inhibitor of both isoforms of the enzyme, was originally approved for the treatment of benign prostatic hyperplasia[10]. Few studies employed it in the treatment dutasteride in males[2,11] and one case report described its efficacy in females [12]. Hesitancy about the widespread use of dutasteride in the treatment of MPHL comes from its potential side effects on erectile, ejaculatory functions and fertility together with its long half life[7]. The possibility of using dutasteride locally would minimize these systemic side effects.

Mesotherapy is one of the newer treatment modalities of hair fall, and is being applied by many cosmetic dermatologists and hair specialists without relying on controlled studies on its efficacy[6]. In the present study we used dutasteride-containing solution intralesionally by means of the newer available "nappage" technique of mesotherapy and compared it to 0.9% saline as placebo. At the start of this study, the only available mesotherapy preparation in the Egyptian market contained in addition to 0.05% dutasteride, D-panthenol, biotin and pyridoxine. The latter constituents are general hair growth promoters that do not specifically treat MPHL[13,14,15].

The dutasteride-containing preparation was found to be significantly more effective than placebo in males with moderate degrees of MPHL. Three assessment methods were employed: difference in hair count, professional independent blinded observers and lastly patients' self assessment of the condition before and 12 weeks after initiation of treatment.

In a randomized placebo-controlled study the efficacy and safety of systemic dutasteride at different doses (0.05, 0.1, 0.5, 2.5 mg) versus oral finasteride (5 mg) in the treatment of MPHL was investigated by Olsen et al.[2]. Patients were evaluated at 12 and 24 weeks. At 24 weeks, dutasteride 0.1 or 0.5 mg daily were comparable to finasteride 5 mg daily, and dutasteride 2.5 mg was superior to finasteride in stimulating hair growth and suppressing scalp and serum DHT. Assessment was done using hair count, expert panel's and investigators' assessment of global photographs.

Stough[11] found that in 15 out of 16 sets of identical twins that completed his study, dutasteride was significantly more effective than placebo in treating MPHL over 1 year. Hair growth was evaluated using standardized clinical photographs, hair counts, and patients' self-assessment questionnaires.

In the present study, the improvement noticed might be attributed to stimulation by the injection's trauma, the improvement being however; signifi-

cantly more in the treatment group precludes such explanation.

To the best of our knowledge, no studies were conducted evaluating topical, intralesional dutasteride or intralesional finasteride. Topical finasteride has been evaluated in two studies. While a 0.05% of finasteride solution applied to the scalp was well absorbed and produced a 40% reduction in serum DHT, it had no effect on hair regrowth[16]. On the other hand, in a double-blind study that compared topical to oral finasteride, no significant differences between the two groups as regards hair thickness, hair counts and the size of bald area was detected. Both groups showed significant increase in hair counts and terminal hair counts indicating efficacy of both routes of administration[17]. We refrained from using finasteride in mesotherapy of MPHL because of the intolerable pain experienced by all patients when we tried the currently available solutions.

In the present study, independent observer assessment and patients' self assessment were high compared to results of hair count. Changes in hair density or the apparent scalp covering is not only due to increase in the number of hair, but also due to improvement in hair thickness, colour and shine, which the patients reported to improve greatly. Improvement in hair quality may not result from dutasteride alone, but could also be attributed to biotin, pyridoxine and pantothenic acid present in the formulation used, since they are known to improve hair colour, texture and thickness[13,14,15,18,19].

A reversed correlation was found between the duration of MPHL and the response to treatment. The less the duration, the better was the improvement. On the other hand, there was no correlation between the age of the patients, and the stage of baldness with response to mesotherapy injections. We therefore suggest that, similar to the response previously reported with minoxidil[1,20], patients who best respond to dutasteride, are those in whom the balding process was at an early stage. This could be explained by the fact that histopathologically, with the advance in time and severity of MPHL, terminal hair follicles are replaced by diminutive or persistent telogen epithelial remnants. These structures no longer respond to stimuli to return to anagen growth[21].

Side effects reported herein were minimal and did not differ between the two groups. These included pain during injection, mild headache or tightness for one to two days. No cases reported having infection, ecchymosis, itching or puffed eyes. Kadry et al.[22] reported multifocal scalp abscesses with subcutaneous fat necrosis and scarring alopecia as a complication of scalp mesotherapy in a Saudi female who received a collection of multivitamins, procaine and saline. Other studies reported the occurrence of infections, especially atypical mycobacterial infection secondary to mesotherapy[23,24,25,26], which should prompt mesotherapists to choose solutions of good quality and take proper aseptic measures during handling these solutions to avoid such complications.

In addition none of our patients complained of decreased libido, erectile or ejaculatory dysfunction as previously reported with oral form[7], suggesting potential safety of local dutasteride, but further studies on the serum DHT and testosterone level after intralesional dutasteride would further confirm its safety.

As is often the case with previously untested new techniques, this study raises more questions than it answers. Would the results be better if the subjects were evaluated at 24 weeks, if the course of treatment was more prolonged (more than seven injections) or if another treatment regimen adopted? What is the ideal interval between maintenance sessions to keep the results constant? Does the multivitamin mixture have a considerable role in these results? What about the combination with topical minoxidil? What about the effect of intralesional finasteride compared to dutasteride? What is the effect of this combination in female pattern hair loss? Further studies are needed to answer these questions.

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حقن الدوتاستيرايد عن طريق الميزوثيرابى ذو فاعلية فى علاج الصلع المعتاد عند الرجال
أو
الميزوثيرابى فى علاج الصلع الوراثى عند الرجال باستخدام محلول يحتوى على الدوتاستيرايد

الخلفية :- افتقاد الدراسات المحكمة عن قدرة الميزوثيرابى فى علاج الصلع الوراثى عند الرجال.

الهدف :- تقييم مدى قدرة وأمان حقن محلول يحتوى على ٠,٥ % دوتاستيرايد بالمقارنة مع محلول ملح ٠,٩ % عندما يتم الحقن بطريقة ناباج فى علاج الصلع الوراثى عند الرجال.

المرضى و طريقة العمل:- تم تقسيم 28 رجلا كانوا قد أكملوا الدراسة وكانو يعانون من الصلع الوراثى فى مراحلة المتوسطة (3، 4، 5 بتقسيم هاملتون نوروود) بشكل عشوائى الى مجموعتين:- المجموعة الأولى وهى المجموعة التى تلقت العلاج وكان عددها 14 رجلا ، أما المجموعة الثانية فكانت تعمل كضابط للمجموعة الأولى وكانت تحتوى على نفس العدد. تلقى المرضى سبع جلسات من الحقن داخل الجلد فى الاسابيع 0 ، 1 ، 2 ، 3 ، 5 ، 7 و 11 بينما تم تقييم الحالات فى الاسبوع 12.

النتائج :- أظهر المحلول المحتوى على الدوتاستيرايد فاعلية اكبر من محلول الملح بقيمة معنية (ب < ٠,٠٥ %) فى علاج الصلع الوراثى عند الرجال. وقد تم تقييم هذة النتائج بثلاث طرق:- الأولى الفرق فى عدد الشعر قبل تلقى العلاج و بعدة والثانية تقييم ملاحظين خارجيين متخصصين لصور تم أخذها للشعر قبل تلقى العلاج و بعدة أما الثالثة فكانت تقييم المرضى أنفسهم لمدى تحسنهم. هذا وقد تم ملاحظة أنة كلما كانت حالة الصلع حديثة أى لها تاريخ مرضى أقصر كلما كانت الأستجابة للعلاج بالميزوثيرابى أفضل. أما عن المضاعفات الملحوظة فكانت بسيطة ومحدودة فى صورة الام خفيفة وصداع.

الخلاصة:- الميزوثيرابى باستخدام محلول يحتوى على الدوتاستيرايد ذو فاعلية فى علاج الحالات المتوسطة الشدة من الصلع الهرمونى عند الرجال ولذلك نوصى بعمل دراسات أخرى بأستخدام الدوتاستيرايد بمفرده ولفترات أطول.

كلمات الدخول :- الميزوثيرابى ، الحقن داخل الجلد ، الصلع الوراثى ، فقدان الشعر ذكورى الشكل ، الدوتاستيرايد ، بيوتين ، حمض البانتوثينيك و البيروديكسين.