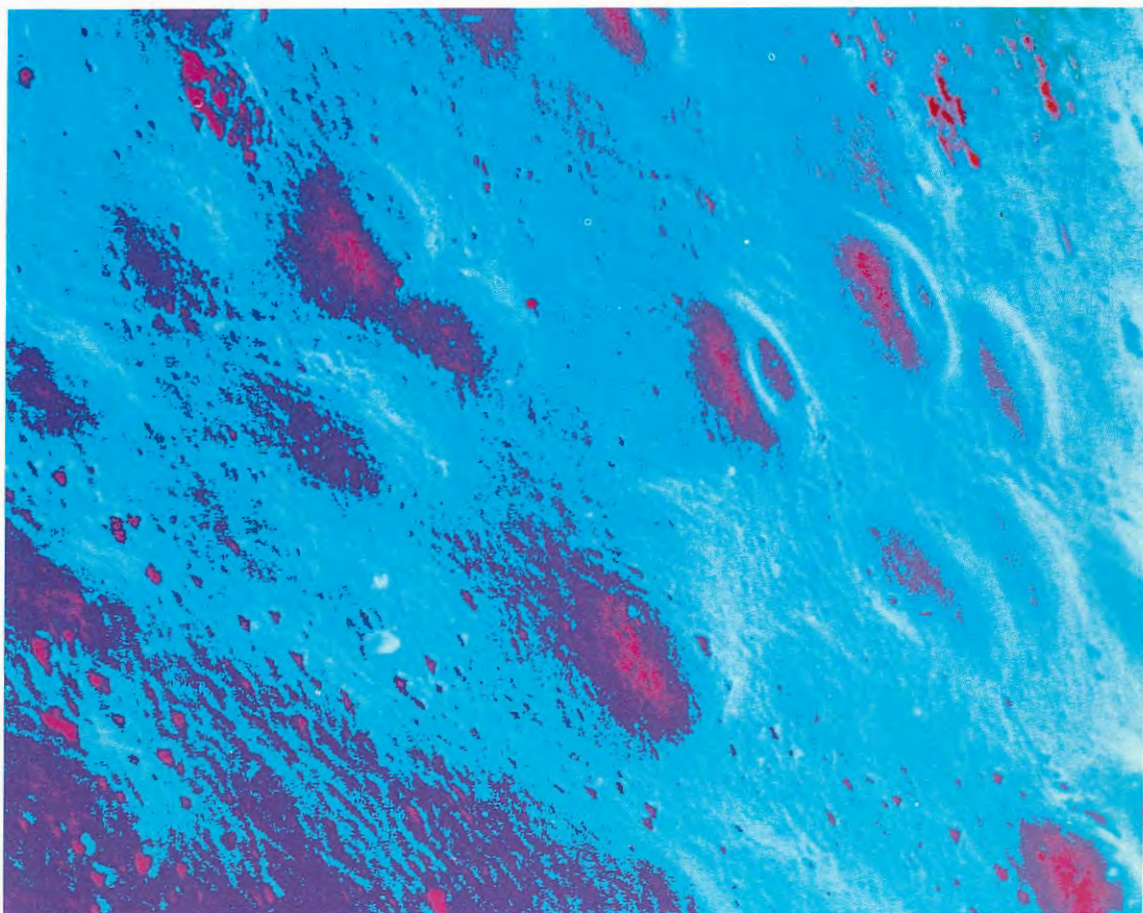


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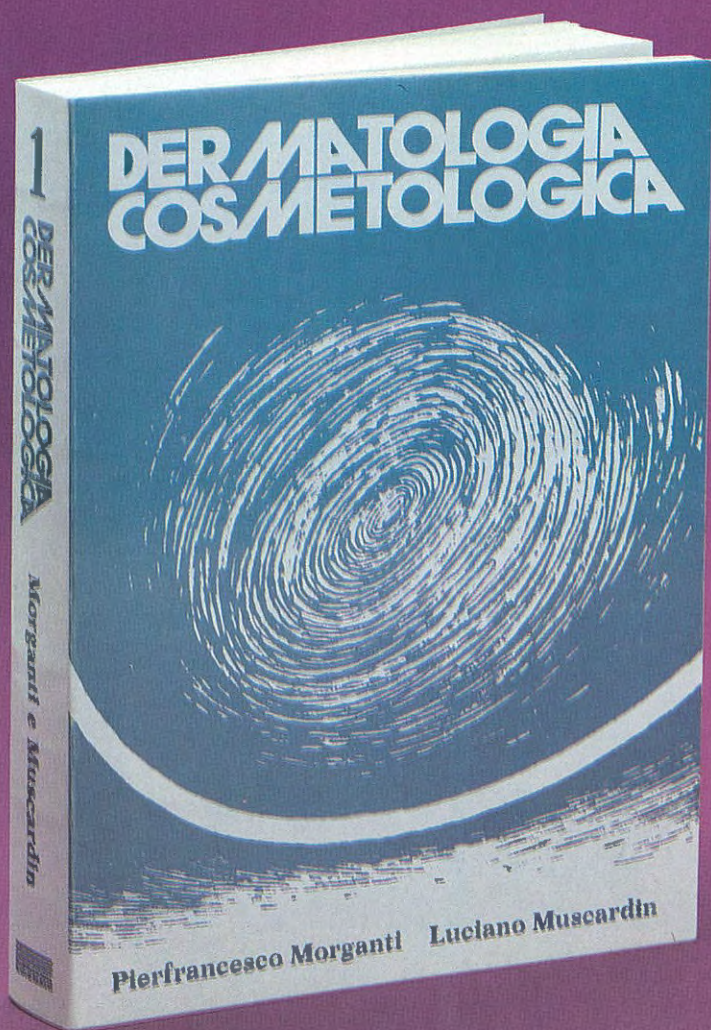
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DERMATOLOGIA COSMETOLOGICA

A cura di P. Morganti e L. Muscardin
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Brussels, Belgium, 8-10 October 1992.

TREATMENT OF HIRSUTISM

Vortrag, Schmidt J.B.

Department of Dermatology II, Medical School, University of Vienna

Received: October 27, 1989. Presented at the 3rd INTERNATIONAL CONGRESS ON COSMETIC DERMATOLOGY, "PROGRESS IN COSMETIC DERMATOLOGY", Vienna (AUSTRIA) October 27-29, 1989

Key words: Hirsutism; Androgen Receptor; Androgen Serum Level; Cyproterone Acetate; Cimetidine; Spironolactone; Medroxyprogesterone Acetate;

Synopsis

The hormonal sources of hirsutism to a great extent go back to increased local androgen metabolism in the skin. Elevated androgen receptor binding sites in hirsute areas of body hair as well as elevated peripheral androgens contribute to the overstimulation of the androgen dependent hair follicles.

Prior to treatment of hirsutism a careful hormonal investigation should evaluate the origin of hyperandrogenaemia in order to establish a causative treatment.

Antiandrogens act by blocking the androgen receptors in skin tissue. Besides, they may suppress serum androgens.

Cyproterone acetate (CPA) can be applied in various dosages.

Besides a monthly, parenterally applied bolus CPA showed good effects and minimal side effects.

Other antiandrogens - spironolactone and cimetidine - are not convincing as mono-treatment and should be preserved for additional therapy in severe cases.

Medroxyprogesterone acetate implantants show good effects by 6 weekly intramuscular application or intracutaneous injection into hairy areas and is mainly apt for menopausal females.

Riassunto

In linea di massima a livello ormonale l'irsutismo provoca un aumento del metabolismo cutaneo locale degli androgeni. Nelle aree affette da irsutismo l'elevata presenza degli androgeni periferici e dei relativi siti recettoriali contribuisce alla elevata stimolazione dei follicoli piliferi androgeno dipendenti. Prima di iniziare il trattamento dell'irsutismo deve essere condotta un'attenta disamina ormonale per ben valutare l'origine dell'iperandrogenia.

Gli antiandrogeni agiscono bloccando i recettori ormonali presenti a livello cutaneo.

Il ciproterone acetato (CPA) può essere applicato a vari dosaggi. L'applicazione parenterale mensile di un bolo di CPA ha mostrato una buona efficacia accompagnata da minimi effetti collaterali. Altri antiandrogeni-spironolattone e cimetidina non convincono nel monotrattamento e dovrebbero essere utilizzati soltanto come coadiuvanti terapeutici nei casi più gravi. L'impianto dell'acetato di Medrossiprogesterone mostra buoni risultati dopo sei settimane sia se effettuato intramuscolo che sottocutaneo direttamente nelle zone affette, soprattutto nelle donne in menopausa.

Introduction

The clinical aspect of facial and body hair distribution shows broad individual variations due to racial, genetic and hormonal influences. hirsutism is the overgrowth of hair in sex hormone dependent areas of facial and body hair under increased androgenic influence. In the face the chin, the submental region, the cheeks and the upper lips are mainly involved. On the body of sites predilection are the presternal and circumareolar regions and the abdomen. The density of pubic hair is nearly always increased in hirsute women and the hair mostly extends to the inner parts of thighs.

Regulation of hair growth is modulated by complex interactions of multiple - also hormonal - influences on the different structures of the hair follicle and the dermal papilla. Hamilton (1) showed as early as 1942 that hair follicles are active target sites of testosterone. Plucked hair follicles were shown to metabolize testosterone. Fazekas and Sandor were the first to demonstrate androgen receptors in pilary roots (2). These observations confirmed the role of the hair follicles not only as endocrine targets but also as active sites of androgen metabolism. Androgens seem to interact with all of the compounds that are responsible for hair growth. By elongation of the growth phase the previous thin, medulla and pigment less vellus hair is transformed into the medullated, pigmented and thick terminal hair in androgen dependent areas, which is characteristic of hirsute aspect.

Although the stimulatory effects of androgens on androgen dependent hair roots are well described, the percentage of elevated androgen serum levels in hirsutism varies between 90% elevated (3, Kirschner & al) and normal range levels (4, Korenman & al.). Hirsutism in females with normal androgen levels is the so-called "idiopathic hirsutism". Determination of androgen receptors allows conclusions about the androgen stimulability of the target organ - the skin tissue.

Studies and results

In our studies of hirsutism in 36 females androgen receptors (AR) were determined by saturation analysis and found to be abnormally high in 26%. The mean AR level was 68 /fmol/mg protein and thus almost 8 times higher than in normal skin and 3 times higher than in acne (5, Schmidt & Spona, 1985). The endocrine profile showed elevations of Testosterone (T) in 63%, Dehydroepiandrosterone - sulfate (DHEA-S) in 50% and Androstenedione (A) in 37% of the patients. Moreover, the missing correlation between androgen serum levels and AR indicated an autonomous hormone metabolism at the receptor level.

These results show that both elevated androgens and increased AR binding may contribute to hirsutism. The most effective treatment thus aimed at both levels, the hormonal as well as the cellular.

If the androgen constellation indicates an ovarian source of hyperandrogenaemia, the extent of the androgen elevations (testosterone, androstenedione) determines further diagnostic or therapeutic steps. Of course, in severe cases polycystic ovary syndrome has to be excluded prior to any hormonal treatment. In the other cases antiandrogens can properly be used to suppress the increased hormone levels and the block the AR binding sites.

Of all available substances, cyproterone acetate is clinically the most promising substance. The low dose cyproterone acetate treatment (Diane: 2 mg CPA + 50 or 35 µg E²/pill) is a successful regimen for the treatment of moderate hirsutism, but has the disadvantage of late onset of the therapeutic effects. By additive application of 50 mg cyproterone acetate (Androcur) from day 5 to 15 of the menstrual cycle the effects are increased.

Recently, improved effects had been reported by a once monthly parenteral application of a bolus of 300 mg CPA (6, Moltz & al). In our study the

effects of 100 mg cyproterone acetate administered daily perorally for the first 10 days of menstrual cycle have been compared with those of a once monthly implant of 300 mg cyproterone acetate on the first day of each cycle. 10 patients with severe hirsutism were recruited for each treatment. Additionally, contraception was maintained with Diane in both groups.

The clinical effects, consisting of reduced hair growth and thinning of hair, decrease of pigmentation and prolongation of the intervals between epilatory measures, were noted in both groups from 3 months of treatment onwards.

Side effects consisted mainly of breast tension, nausea and menstrual disturbances.

Clinically, parenteral administration of cyproterone acetate appeared slightly more effective than oral administration (7, Schmidt, Huber, Spona).

As well as the classical antiandrogen, cyproterone acetate, also antiandrogens such as spironolactone and cimetidine have also been claimed to provide beneficial effects in hirsutism. In our experience, spironolactone should be administered only in cases which show therapeutic resistance to other substances. Although the effects of treatment show rapid onset, they also diminish after few months. Regular controls of the electrolytes, which often are responsible for severe side effects are requested if treatment is performed in adequate dose (2x100 mg/d).

Cimetidine is the weakest antiandrogen and therefore should only be administered for moderate forms of hirsutism or as additional treatment, in a dosage of at least 3x400 mg/day. Another promising but less well-known substance is medroxyprogesterone acetate (MPO). The Depot-Gestagen acts by inhibition of the enzyme 5 α -reductase which converts T to DHT and by a decrease of serum androgens. For comparison of systemic and local effects of the substance 3 forms of application were carried out in a group of 26 females with moderate hirsutism

for a mean of 16 weeks: 150 mg MPO was administered as an intramuscular implant or as intralesional injections into hairy areas of the face in 6 weekly intervals. A third group of patients applied a 0.2% MPO containing ointment on the hairy sites of the face. As before, clinical changes were noted and hair measurements were made. The comparison of these parameters revealed that the best results were achieved by the intralesional application of MPO into the hairy areas where both the local and systemic effects of MPO contributes to the action. Next best was parenteral application where the systemic effects predominate. However, the local ointment also showed positive effects, thus confirming a peripheral action of MPO at the tissue level, as no decrease of serum androgens was shown. Side effects consisted mainly of menstrual disturbances (8, Schmidt & Spona, 1985). In menopausal hirsute women, especially MPO treatment is of great benefit, as it also displays beneficial effects on menopausal symptoms.

Discussion

A range of substances, broader than in former years, allows more specific and individual treatment of hirsutism than previously. Detailed determination of the hormone parameters should help to clarify the source of hyperandrogenemia and should precede the decision on hormonal treatment.

Adequate treatment may sometimes include a combination of various hormonal substances adapted to the individual hormone profile. New developments of merely topically active androgens could mainly amplify the endocrine treatment of hirsutism and permit effective therapy without side effects in cases in which serum androgens are normal.

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CO₂ LASER SURGERY OF THE LOWER GENITAL TRACT IN WOMEN: RESULTS OF POST-OPERATIVE TREATMENT WITH VITAMIN A + E GELATIN MIXTURE.

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Key words: Vitamin A; Vitamin E; Gelatin; Laser Treatment; H.P.V.; Laser Surgery; Condylomathosis Treatment; Genital Mucous Membrane;

Synopsis

The viral pathology of the lower genital tract has gained in importance because of the role of H.P.V. (papilloma/virus) in the genesis of carcinoma of the cervix.

Laser surgery seems to be the most effective treatment available for condylomatosis of lower genital tract in women.

Despite the benefits of laser surgery we deem it useful to reduce post-operative side effects and help the mucous re-epithelization. After laser treatments (108 patients) we administered a collagen activated vitamin A + E gelatin, with 3-4 daily applications for 3 weeks. The use of this gel helps healing and re-epithelization reducing any side-effects.

Riassunto

Il controllo della patologia dei bassi genitali ha assunto molta importanza dato il ruolo svolto dal papilloma virus (HPV) nella genesi del carcinoma della cervice.

La chirurgia laser sembra essere il migliore trattamento attualmente disponibile nelle condilomatosi del basso tratto genitale femminile. Per facilitare la riepitelizzazione delle mucose e ridurre gli effetti collaterali del trattamento laser è stato utilizzato un gel a base di vitamina A ed E che veniva applicato 3/4 volte al giorno per 3 settimane. I positivi risultati ottenuti su 108 pazienti incoraggiano l'uso di questa nuova terapia topica a completamento del normale trattamento laser.

Over the last few years, the viral pathology of the lower genital tract has gained in importance because of the role of papillomavirus (H.P.V.) in the genesis of carcinoma of the cervix.

Gynecologists have therefore committed themselves to the early diagnosis of viral infection and injury.

The changes in sex habits and the improvements in colposcopic diagnostics has led to a steady increase in the incidence of the disease over the last few years.

Because of the young age of patients and the higher incidence of nulliparity, the choice of treatment is fundamental for healing as well as for full restitutio ad integrum of the anatomy and physiology of the tissues.

Laser surgery is the best treatment available, both for its therapeutic achievements and its few intra- and post-operative side effects. No specific anti-viral drugs yet exist.

In addition, compared with other methods of physical destructive therapy (DTC-cryotherapy), laser surgery seems to have less operative aftermath.

Despite the benefits of laser surgery, we deem it useful to resort to drugs to reduce post-operative side effects and help re-epithelization as much as possible. (1-5)

Materials and Methods

From May through September 1990, at the Laser Surgery Center of the Quisisana Clinic in Rome, 108 women with condylomatosis of the lower genital tract underwent CO₂ laser out-patient treatment.

Patients were aged 16 to 51, with the average of 31.5 years.

Our diagnostic standard envisaged exo- and endo-cervical cytology, colposcopy and a possible ad-hoc biopsy.

Surgery consisted of brushing at a depth of 1-2 mm inside the vagina and/or external genitalia. Anaesthesia was administered locally with 2% carbocain.

The best time for treatment is before menstruation, to give enough time for repair before the next menstruation.

In 23 patients (21.3%) injuries were detected only in the vagina, while 31 patients (28.7%) reported vulva injuries. In the remaining 54 (50%), injuries were vulvo-vaginal, mainly florid condylomatosis. (Fig. 1).

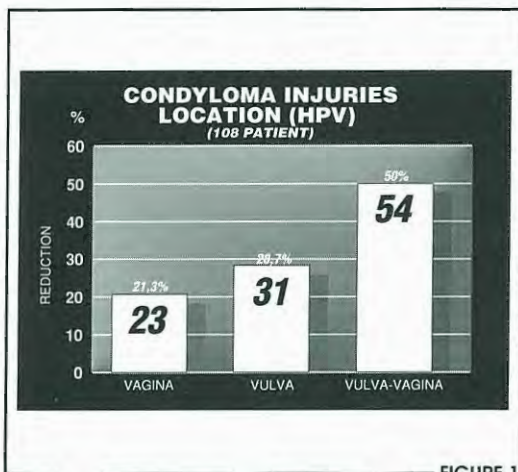


FIGURE 1

Fig. 1 Condyloma injuries location(HPV) (108 Patients)

After laser treatment, we administered a collagen activated Vitamin A + E mixture in a special highly penetrative gel vehicle (*) (Vitamin A Palmitate 0.25% - Vitamin E Acetate 0.4%, gel vehicle q.s.) Gel administration was local, with 3-4 daily applications for 3 weeks. The preparation was chosen for the fundamental role of vitamin in re-epithelization. This vitamin also plays a major role in differentiation of mucus-secreting and keratinizing epithelium. Vitamin A is known to stimulate mucus secretion in basal epithelial cells. (6-9-10)

Patients were followed-up monthly for three months, using the diagnostic procedures previously described. Repair was appraised a 1 to 3 score for fair-good-very good re-epithelization.

(*) Elageno A gel - Mavi Sud.

Results

Healing was appraised at the 1st control one month after vaginal and/or vulval laser treatment. The treatment period for the 108 patients ranged from May to September. For 89 patients (82.4%) at the 2nd control, the treatment period ranged from May to August. The 3rd control was made in the period from May to July over 69 patients (63.8%). (Fig. 2)

The complete follow-up is still under way for the remaining 39 (36%) patients and insists over a relatively recent period.

After a month of treatment, 5 (4.6%) of the 108 patients showed a fair re-epithelization, 22 patients (20.4%) a good re-epithelization, and 81 patients (75%) a very good repair process. At the 2nd control of 89 patients, 3 patients (3.4%) scored repair level 1, 7 patients (7.8%) scored 2 and 79 patients (88.8%) scored 3. The

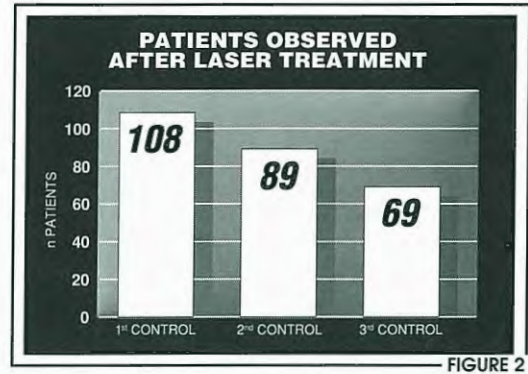


FIGURE 2

Fig. 2 Patients Observed After Laser Treatment

third-month control focused on 69 patients. One of them (1.5%) showed fair re-epithelization (score 1), 2 (2.9%) showed good re-epithelization (score 2) and 66 patients (95.6%) showed very good-epithelization with full restitutio ad integrum (score 3). (Fig. 3)

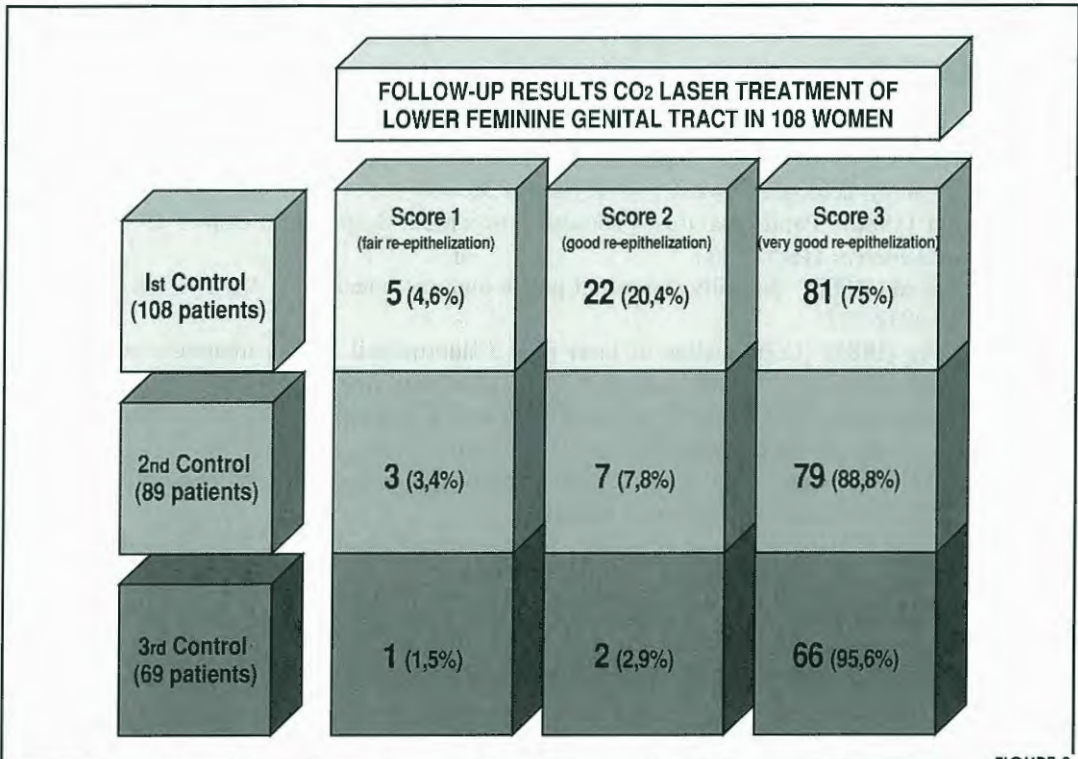


FIGURE 3

Fig. 3 Follow-up Results CO₂ Laser Treatment of Lower Feminine Genital

In summary good results at the 1st control were seen in 103 patients, that is 95%.

At the 2nd control, 86 (96.6%) patients scored repair levels 2 and 3.

Finally, at the 3rd control, the success rate was 98.5%, that is 68 out of 69 patients.

CO₂ laser surgery proved helpful in healing and for the full restitutio ad integrum of treated surfaces.

The administration of substances such as Vitamin A gel accelerated re-epithelization and thus significantly reduced side effects of treatment.

Conclusions

In the authors' opinion, CO₂ laser surgery is the most effective treatment available for condylomatosis of lower genital tract in women. Because of the young age of patients, the aim is to achieve healing in the shortest possible time with physiological recovery of the vaginal functions and minimal side effects. Laser surgery has only rarely intra- or post-operative complications. Not with standing these benefits, we deem it useful also to resort to additional preparations to help healing and re-epithelization and reduce any side-effects, however scarce. The use of this Vitamin A + E gel in the post operative period meets these requirements.

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A SCIENTIFIC MEETING TO SAVE THE SKIN

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Key words: *Cosmetic Dermatology; Oral Cosmesis; Cosmesis and Vitamins; EEC Cosmetic Labelling; EEC Cosmetic Regulations; Cosmetic Carriers; Preserved Cosmetics; Cosmetic Distribution;*



Opening remarks (Mr. P. Morganti, Sen. E. Marinucci, Mr. C. Jacobson, Mr. N. Loprieno)

“Progress in Cosmetic Dermatology: Science and Safety” was the topic of the IV World Meeting of the International Society of Cosmetic Dermatology (I.S.C.D.) - held in the marvellous Villa Miani in Rome on October 31 and November 2. The meeting was organized by

Dr. Pierfrancesco Morganti, I.S.C.D. Secretary General, and opened with the address of Sen. Marinucci, Under Secretary of State, and of Prof. Coleman Jacobson, famous U.S. dermatologist.

“Everlasting youth” is what is required of a cosmetic today.

Psychologists and sociologists have widely demonstrated that a nice appearance is a considerably positive asset in all human relationship: at school, in marriage, in the court, and on the labour market.

Today, many women work and wish to look as young as possible. Men are more and more aware of the importance of looking young within the labour market, as shown by the dramatic increase in the sale of cosmetics for men. In 30-45 minutes a skilled beauty specialist can bring about an extraordinarily change in a person's appearance.

This is achieved through cosmetic manipulation of hair (cut and colour), eye make-up (lines and shadows) and the skilful use of cosmetic products for face and body treatment. The quality and the appearance of the skin are improved: it appears younger.



During the brunch

The regular use of cosmetic products prevents damage caused by photoageing thanks to recent scientific progress.

This was affirmed at the opening of the meeting, which was sponsored by the UNIPRO group working in the pharmacy field, including GUIEU, LIERAC, MAVI, PSN, ROC, RYDELLE LAB and SCHIAPARELLI.

The positive results obtained were by the use of carefully selected active principles and appropriate carriers. Professors Gregoriades of London University, Menegatti of Ferrara University and Junginger of Leiden University in the Netherlands widely demonstrated the fundamental role played by the cosmetic carrier. The "Plurilayers" liposome cannot penetrate the skin structure because of its excessive size. After local application, the liposome or niosome was found in the second and third layer of corneocytes but it did not seem able to keep its micellar conformation.

Further studies are needed.

Alternative carriers such as nanospheres and collaspheres were in turn discussed by the French Caillon and Huc. They appear interesting as cosmetic carriers but further "in vivo" tests are required.



Speaking

Cosmetics are now safe products. This was affirmed by Prof. Nicola Loprieno of Pisa University and Chairman of the EC Scientific Commission for Cosmetics, who outlined the work carried out by the Commission. The ingredients included in the positive and negative lists were all carefully screened in terms of safety. Raw materials are continuously added to, or removed from products if scientific updates from the international literature deems them unsafe. So-called "Full labelling", i.e. the qualitative composition of the cosmetic product, will be required on the package by law. This is the EC legal view, as affirmed by Dr. Gagliardi of the Italian Higher Health Institute.

In order to make the cosmetic composition readable and understandable at international level, the introduction of CTFA English classification is desirable so that the EC is harmonized with the USA, Canada and Japan.

The audience welcomed favourably the report of Prof. James from the U.S., which provided data on the oral use of gelatine-glycine for cosmetic purposes. This dietary supplement is rich in trace elements and vitamin C and contains vitamins of the B group. The study revealed that it is a moisturizer and is effective against free radicals therefore anti-aging. In addition "ORAL COSMESIS" and the moisturizing action of glycine were discussed.

The U.S. data were confirmed by Prof. Damiano Randazzo of Catania University who - together with Dr. Palombo of S; Eugenio Hospital of Rome - used gelatin-glycine in a cosmetic carrier. However, local application requires proper carriers, given the importance and the variability of skin lipids which change considerably with age -

as wonderfully described by the learned report of Prof. John Ebling. It is not possible to deal with carriers without speaking of ways of absorption. Absorption through skin and mucosae, in fact, is not so simple as it might appear to a non-expert.



Behind the scenes of the meeting



Organizing secretariat



A view of exhibition area



Mavi Sud



Rydelle



ROC



Lierac



Guieu

This was demonstrated by Professors Kerdel Vegas, famous Venezuelan dermatologist and current Ambassador in London, Prof. Schalla of Friburg, Prof. Randazzo of Catania and Prof. Jacobson of the U.S. Skin varies from birth to old age and it behaves differently with respect to absorption as its structure changes.

The biological features of skin layers also vary - as explained by Prof. Bruno Berra, outstanding biochemist of Milan University. Recent studies have demonstrated the importance of sphingolipids for transcutaneous absorption. These special intercell hydrophobic lipids - known also more generally as ceramides - regulate the passage of both lipophilic and hydrophilic substances, also adjusting the NMF content.

On the other hand, keratinocytes should no longer be considered simple passive targets of substances applied on their surface, but actual active cells which can transmit signals and messages to the dermal cells. Cosmesis is a science. But, the magic part of a cosmetic is not to be left aside, for - unlike a drug - a cosmetic treats "healthy skin". The cosmetic should not be only "active", but also pleasant and attractive in its packaging.

Antonio Tosti, Professor and Chairman of the Department of Dermatology of Palermo University, dealt with psychological and social implications related to ageing and his learned report underlined that pleasant looking people enjoy great social advantages. It is undeniable that "beautiful" is associated to "good", whereas "ugly" is always linked to "bad".

Prof. Brodie James of the U.S. and Prof. Jarret of London University, described changes in the oral mucosa as a result of ageing. Oral mucosae are controlled not only by hormones but also by vitamins such as vitamin A which can fight the ageing process and cause it to regress. Also the saliva plays an important role in the absorption of the active principles of mouthwashes and toothpastes. According to James, an example is given by odontoblanxina used against plaque.



PSN



Schiapparelli

The mucosae of the vagina, similarly to oral mucosae, are active sites for absorption of both drugs and cosmetics - as affirmed by Prof. Lanzone and Prof. Mancuso, Chairman of the II Department of Gynecology of Rome Catholic University.



Uniderm

sand billion Lire in Italy, employment for thousands of people, and investment in research.

The cosmetic market for treatment products is increasing in pharmacies and beauty centres. The user asks for service and qualified staff. Whereas qualified

The subject of cosmesis is far from what it may appear to a superficial observer.

Cosmetic Dermatology is not a problem affecting only women, and nor is it purely concerned with vanity.

On the contrary, it is a problem affecting everybody, men and women, with deep implications at social level, as Prof. Chiacchierini, Dean of Commodities Studies Faculty of Rome University and Prof. Ruggeri of Salerno University affirmed. Last, but not least, are the its implications at the economic level, a turnover of 9 thou-

sand billion Lire in Italy, employment for thousands of people, and investment in research. The cosmetic market for treatment products is increasing in pharmacies and beauty centres. The user asks for service and qualified staff. Whereas qualified can be found in both pharmacy and beauty centres, service is widespread and efficient only in beauty centres completely lacking in pharmacies. Pharmacies must therefore comply with the demands of the public if they do not want to lose this favourable opportunity.

Cosmetic products need carriers with particular transcutaneous penetration properties to become "new active ingredients": Dr. Djerassi of Hoffmann-LaRoche Inc., underlined the different activities carried out, for example, by vitamin E as acetate; this vitamin is active against free radicals and, as linoleate, has basically a re-moistur-

ring action. Retinol or vitamin A seem also to have an interesting anti-ageing action with appropriate carriers, according to Prof. Decio Cerimele, Chairman of the Department of Dermatology of Rome Catholic University.



Rohm & Haas

The opportunity to regulate carriers was debated also by Prof. John Ebling, illustrious English researcher, Prof. Chimenti, Chairman of the Department of Dermatology of L'Aquila University and Prof. Carlesimo, Chairman of the I Department of Dermatology of Rome University, carriers should more resemble ceramides than phospholipids in order to obtain real transcutaneous absorption after local application.

In fact, epidermal cells transform phospholipids into ceramides as the basal cells become corneocytes. Thus, the skin course should be favoured. The cosmetic product is a very good "pabulum" for microorganisms and preservatives are therefore necessary. This was highlighted by Ms. Eilen Warwick, U.S. doctor of Rohm and Haas, and Mr. Dihel, German doctor of Schulke and Mayer. The alteration of a non-preserved cosmetic product can lead to toxic metabolites which are more dangerous to the skin than the preservatives themselves of greatest importance in the use of preservatives is strict compliance with the dosage recommended by the producing company. This was established with a number of tables and references by the English toxicologist Dr. Michael Wooder. The number of cases of Katon CG sensitization in Europe has considerably decreased in recent years thanks to the reduction of the "active principle" used. A similar claim was made by Mr. Rosen, U.S. doctor from Sutton Lab, who presented the last European and U.S. consumption data for Germall 115 and Germall II (Diazolidinil urea).

Prof. Klaus Andersen, Danish allergologist, together with Prof. Angelini, Professor of Dermatology of Bari University stated that both the negative and positive data emerging from recent literature should not be considered too superficially. In fact a critical re-examination of patch-test methods is needed to provide a final assessment of all currently used preservatives.



*Coffee break:
Mr. Grendene, Mr. Menegatti,
Mr. Morganti, Mr. Leopardi and
Mr. Marchetti.*



This interesting workshop continued with a careful investigation of some preservatives considered safe for use in food. A review of data for the last 50 years; reported by the English Mark Shawe of NIPA laboratories, demonstrated the preservatives parabens are among the sa-

fest products both for cosmetic and food. Mr. John Yablonski, U.S. biologist, went on to demonstrate the interesting bactericidal and fungicidal activity of a new category of preservatives: synthetic phospholipids.

These new physiological and non-toxic products are similar to cellular membranes, and could therefore become the safe preservatives of the future, especially if used together with natural fatty acids described by the Prof. Kabara of the U.S. In fact, among the number of fatty acids existing in nature, some proved to have not only an emul-

sifying action but also strong antimicrobial activity.

"Primum non nocere" is what Prof. Kemper, German toxicologist and member of the EC Scientific Commission for Cosmetics, emphasized many times to the audience with his learned report which closed the session. For these reasons, toxicological studies must become more frequent

and also focus on the development of alternative methods so to avoid the use of experimental animals. This target, nonetheless, is very far away. "In vitro" techniques cannot yet replace current methods. After the science and research topics were dealt with, a whole session of the meeting was dedicated to the legal aspects linked to the production and distribution of cosmetic products. As recalled by Dr. Florio Terenzi, General Director of UNIPRO, selective distribution of cosmetic products would be accepted by the EC Commission only if defined by very precise contra-

ctual conditions in compliance with European regulations on competition. While the guidelines have been defined for the model regulations for an exclusive channel in respect of perfumery, the EC Commission tends not to acknowledge any exclusivity for the sale of co-



*Relax on Villa Miani
(Mrs Kemper, Mr. Morganti,
Mr. Kemper, Mr. Shalla, Mr. Ebling)*



*Relax on the bus for Casamari
Abbey (Mr. and Mrs Valenzano
- Dermatologists)*

smetics in pharmacies. It is then necessary that the industries of the sector and FEDERFARMA cooperate at European level in order to reach the common goal of a closed and protected pharmacy network.

The present trend of the pharmacy skin cosmetic market was discussed by Dr. Leopardi, Chairman of F.O.F.I. (Federation Order Italian Pharmacists) and Dr.

Grendene, vice Chairman of Federfarma who underlined the importance of the professionalism of the pharmacist in his role of "advisor" for the health and well-being of the customer. Lively attention was paid to the reports of Doctor in Law David Morganti, teacher of Luis University, of Prof. Angelini Rota, legal medicine doctor of Rome University and of Prof. Marchetti of Milan University, which were focused on the product liability of the manufacturer, of the doctor as prescriber and of the pharmacist as distributor of cosmetics.

Stress was paid on the new EC regulation and how it tends to link liability to the educational level of the subject who introduces the user to the purchase. Thus the dermatologist as specialist, shall be more liable than a regular doctor and similarly, the pharmacist more liable than a market or perfumery sale-attendant. It was also underlined that the doctor, for example, is also liable for any negative effect of a service performed for the customer by third parties as a result of the doctor's specific recommendation. Similarly, the pharmacist is liable for the conduct of his sales-assistant.

In fact, the user goes to the dermatologist or the pharmacist in order to have a specialist service. After a lively debate, in which a number of dermatologists made their intervention, including Professor Nini, Chairman of the II Department of Dermatology of Rome University, Pierluigi Amerio, Professor and Chairman of Department of Dermatology of Chieti University, and Pietro Santoianni, Professor and Chairman of Dermatology of Naples University, some other technical problems were dealt with. Issues related to cellulite were presented in an experimental



The Casamari Abbey



The entrance of the Abbey

study by Prof. Melli of Florence University and Dr. Nastruzzi of Ferrara University. Mr. Wickett, U.S. doctor of Rydelle Lab. outlined the interactions which can occur at cutaneous level when using alkaline soaps or acid syndets. The use of some cosmetic detergents may in-

crease the skin pH, but this remains stable after using special body lotions. Dr. Teresa de Monte, stressed the need to give better information to ski-school staff about the damage provoked by the sun to exposed skin and about the cosmetics which can be used to reduce photo-ageing. Prof. Fabrizi and finally Dr. Cardillo of the Dermatology Hospital of Rome Catholic University demonstrated that it is possible and simple to verify the effectiveness of the local action of cosmetic or pharmaceutical products by checking the changes induced on the superficial sebum, the temperature or skin hydration through the use of 3C SYSTEM DERMOTECH, a completely computerized and rapid system.

The meeting closed with the comments of Prof. Coleman Jacobson and Dr. Pierfrancesco Morganti who, satisfied with the high scientific level reached by the IVth I.S.C.D. International Meeting, reaffirmed the need of multidisciplinary exchanges about the fascinating subject of Cosmetological Dermatology. After thanking all speakers, the announcement was made that the Vth Meeting will be held in New York in October 1993 with the title "PROGRESS IN COSMETIC DERMATOLOGY EEC EUROPE AND INTERNATIONAL RELATIONS: SCIENCE, MARKET, REGULATIONS.



A particular of atrium

Mr. Coleman Jacobson in the Abbey garden

Going to the church



During the speaking of the monk



The visit to the Pharmacy



Dr. Morganti and Dr. Valenzano after the drink offered from the monks into the pharmacy



In prayer



During the concert



The monks are singing



An interview from television



During the cocktail party



At Morganti's house



Mr. and Mrs. Kerdel Vegas, Venezuela Ambassador, Mr. Morganti, ISCD Secretary General and Mr. James, ISCD Program Director

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The Cosmetic Connection

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Edited By: P. Morganti, F.J.G. Ebling

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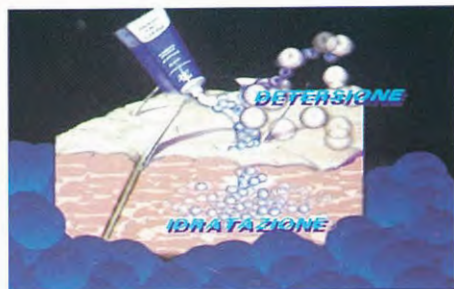
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