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Clinical Evidence. Practical Advice

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Adherence Optimization in Acne Management

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Introduction

Acne is a common dermatological condition found in about 85% of adolescents and young adults.[1] Acne can have significant psychological, social or physical impacts. Many effective treatments are available to manage acne, but for best results, all therapeutic interventions require good patient adherence. Unfortunately, for a variety of reasons, the risk of poor adherence has been documented in around 50% of acne patients.[2]

Acne Overview

Acne is a chronic inflammatory skin disease characterized by four pathological processes, with treatments targeted at the various mechanisms felt to be responsible for its development:

1. Sebaceous hyper secretion - oral isotretinoin, antiandrogen oral contraceptives
2. Abnormal keratinization of the walls of the pilosebaceous unit - topical retinoids
3. Proliferation of *Propionibacterum acnes* - benzoyl peroxide, antibiotics
4. Inflammation - antibiotics, retinoids[2]

Measuring Acne Severity

- Severity of acne can be described objectively by the physician and subjectively by the patient.
- Mild acne is characterized by open and closed comedones (black and whiteheads, respectively) and few papulopustular lesions.
- Moderate acne includes papules, pustules, and no more than one nodule.
- Severe acne is widespread and includes all the lesions above. Even the presence of a few cysts or nodules can be indicative of severe acne.
- Acne on the trunk is more difficult to treat, thereby increasing the severity rating even if the lesion counts are modest.
- Scarring is very common and should be taken as an indication for aggressive therapy. Scarring may be produced even in mild acne.
- The objective severity of acne typically drives particular treatment rationales; although, the physician should include patient values and preferences to help guide therapeutic strategies.
- Furthermore, acne of any grade can be considered more severe if there is significant psychological upset.

Treatment Rationale

Acne treatment information usually starts at the patient's local pharmacy or, increasingly, online. Skin cleansers, skin wipes, and lifestyle changes, which will be discussed below, are usually the first considerations for patients with acne. Typically, when the patient feels their acne is not improving or when it has breached the patient's disease 'threshold' by becoming 'too severe', they might consult their family doctor or dermatologist. Many treatment options (Table 1) are

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available that target one or more of the pathological processes described above. However, because of its multifactorial pathogenesis, combination therapy is frequently prescribed. The purpose of treatment is to improve the quality of life for patients and to prevent long-term sequelae, particularly scarring and psychological distress.

Acne Severity	Therapy
Mild acne	• Skin care • Topical therapy*
Moderate acne	• Skin care • Topical* + systemic therapies
Severe acne	• Systemic therapy, especially isotretinoin

Table 1: Overview of treatment options for acne
*e.g., antibiotics, retinoids, or combination products (e.g., antibiotic + benzoyl peroxide or antibiotic + retinoid)

Optimizing Treatment Adherence

In acne, as in many other disorders, adherence to treatment is essential for successful therapeutic results as well as improving outcomes.[2]

- The reasons attributable to the high rate of poor adherence can be categorized into patient factors, physician factors, treatment-related issues, and disease characteristics.
- Unfortunately, acne has a few unavoidable characteristics that can be difficult for patients to accept:[2]
  1. Clinical improvement is usually seen 6-8 weeks after treatment is started.
  2. There may be an initial flare-up of inflammation.
  3. Relapses are frequent and cures are not, causing treatment fatigue that may contribute to adherence difficulties.
- Many factors have an effect on adherence in acne treatment (Table 2).

Negative Effect on Adherence	Positive Effect on Adherence
• Age (<15 years old) • At least one side-effect from treatment • Dissatisfaction with previous systemic treatment • Patient's lack of knowledge about acne and/or their treatment • Lack of improvement noted by the patient's treating physician • A consultation with a primary care physician	• Severe acne • Satisfaction with current treatment • Use of cleansers and moisturizers • Knowledge about acne and/or their treatment • Clinical improvement noted by the patient's treating physician • Topical therapy only or use of isotretinoin

Table 2: Factors associated with effects on adherence to acne treatment[2]

In order to optimize adherence to treatment, the physician first needs to quantify and measure compliance to therapy. Many methods are available to assess adherence, although one quick, effective, and validated tool that can be used in a clinical setting is called the ECOB (Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux) questionnaire (Table 3). In this mini-questionnaire, adherence is considered poor if at least one answer given is different from the answers expected. If a physician suspects poor adherence, it is important to gently investigate the reasons as to why adherence is suboptimal.

Oral Treatment	Topical Treatment
• Do you remember the name of the last drugs you took?* ***Yes*** • Have you used these drugs? ***Yes*** • Have you forgotten to take these drugs at any time during the treatment period? ***No*** • Have these drugs improved your acne? ***Yes***	• Do you remember the name of the last drugs you took?* ***Yes*** • Have you tolerated these drugs well? ***Yes*** • Have you ever stopped taking these drugs because you thought it would do more harm than good? ***No*** • Have these drugs been useful for you? ***Yes***
• *Colour of packaging was acceptable as a correct answer. • If at least one answer is different from the expected answers (written in blue above), the patient's adherence is considered to be poor. • The 'adherence scale' based on this selection can be considered as an aid to measure the risk of poor adherence, but it does not allow an exact determination.	

Table 3: ECOB questionnaire to assess the risk of poor adherence[2]

Tips to Improve Adherence[3]

- An open empathetic approach can help establish trust
- Dedicated appointments for acne counseling – either nurse or doctor led
- Patient education about etiology, prevalence, and myths associated with acne
- Provide written information (i.e., handouts/leaflets) or online resources on acne, and also on their specific treatments, including expectations
- Address nonadherence promptly
- If current treatment is unsatisfactory, be willing to modify
- Recommend simplified treatment and skin care regimes, including an appropriate moisturizer and mild, gentle cleanser, to suit the patients needs[2]

Non-drug Interventions and Recommendations

Dispel common acne myths:

- Acne is due to being dirty
  - Hourly washing does not make a difference
- Acne is due to 'hormonal imbalance'
  - Hormonal levels are normal in the majority of acne patients
- Acne is related to sexual behaviour
  - There is no proven association with the level of sexual activity[4]

Topical treatment considerations that can encourage adherence:

- Using medication on sites that are easily accessible (face and upper trunk)
- Keeping the regimen simple and quick to use
- Selecting therapies with cosmetic acceptability
- Minimizing factors that produce irritation of the skin; many anti-acne topicals are irritating
- Applying the topicals on the entire acne-prone area to prevent new acne lesions is fundamental, rather than on existing acne lesions only
- Using short contact application (e.g., cleaning off after a few minutes to a few hours is useful at the start of a new topical regiment); introducing longer contact time as tolerated
- Avoiding application just before bedtime may reduce the additive irritant occlusive effect of a pillow
- Using aqueous-based topicals, thereby avoiding irritants such as alcohol
- Explaining that visible improvement may take several weeks or months, and an initial flare of acne can occur

Moisturizers and Cleansers

An essential component of acne skin care management with positive effects on adherence is the appropriate selection and use of moisturizers and cleansers.[2] Physicians can provide information on key ingredients and suitable formulations to assist patients in making informed decisions.

- Recommend aqueous moisturizers that are noncomedogenic, with minimal allergenic ingredients (e.g., fragrance and preservatives), and compatible with the chosen therapeutic regimen.
- Regular use of mild cleansers is an important aspect of optimal acne management. Routine cleansing is not only an essential part of basic hygiene, but it also removes dirt, sweat, bacteria, and exfoliated cells, preparing the skin to receive topical medications and improving drug absorption.
- Routine cleansing may enhance antimicrobial activity and decrease the chances of infection.
- Care must be taken to minimize any further disruption of the skin barrier during cleansing. The use of improper techniques and unsuitable cleansing agents can irritate or exacerbate existing lesions.
  - The use of anionic detergents (i.e., soaps) can alter the pH of skin, resulting in increased skin sensitivity.
  - Cleansers containing the surfactant sodium lauryl sulfate (SLS) can be irritating and further disrupt the skin barrier.[5]
  - Avoid the use of soaps, foams, and mechanical cleansers (e.g., beads, brushes, and scrubs), which can inadvertently damage intercellular lipids, leading to further impairment of the barrier function and cause dry skin.
- Cleansers that are suitable for acne-prone skin are generally based on mild synthetic surfactants that minimize barrier disturbances.
  - Non-ionic surface-acting agents (e.g., silicone and polysorbate) are less likely to cause irritation and are formulated to the same pH as the skin (5.5).
  - Silicone surfactants (e.g., dimethicone) are effective at eliminating surface debris without completely stripping away protective oils.
- Emollients contained in cleansers can minimize barrier damage by emulsifying dirt and oil for easy removal, while at the same time replacing lipids that are lost during the washing.[6]
- With the use of a mild cleanser, washing should be done twice daily.

Conclusion

Achieving adherence in acne patients often represents an ongoing challenge. In order to realize therapeutic objectives, pharmacologic initiatives must be accompanied by patient education. Time devoted to counseling patients on avoiding aggravating factors, medication use, and the importance of maintaining proper skin care routines can contribute to increased adherence. Finally, efforts aimed at early detection and mitigation of poor treatment follow-through signs will improve the outcome of therapeutic strategies.

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Delivery Vehicle Advances in Dermatology

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Introduction

For decades, physicians have relied on conventional delivery vehicles, such as creams and ointments, for the topical treatment of cutaneous skin conditions. However, patient dissatisfaction with older topical therapy delivery methods can result in reduced patient compliance and ultimately poor control of their skin condition. As such, newer delivery vehicles in dermatology are being developed to improve clinical efficacy, reduce side-effects, and ultimately improve patient adherence. Newer vehicles include gel, foam, and spray preparations. The newer topical delivery agents have the potential to limit the progression of cutaneous disorders requiring oral systemic therapy, which can expose the patient to greater risk for adverse side-effects than topical therapy alone.

Vehicle Selection

In determining the most appropriate topical treatment regime for various skin disorders, physicians must undertake patient-specific assessments, including disease severity, patient preference, skin type, formulation availability, and delivery vehicle

Delivery Vehicle	Pros	Cons
Creams	• oil and water base makes it suitable for use on most skin areas • tend to be less irritating • emollient properties • most suitable for patients with dry or sensitive skin	• may result in an oily feel due to thicker consistency
Foams	• minimal residue after application • quick drying, ease of application, lack of fragrance • no difference in cost compared to cream/solution after controlling for body surface area (BSA) • spreads easily, especially helpful if treating larger BSA • leaves minimal residue on skin surface	• small number of application site reactions (e.g., burning, stinging, pruritus)
Gels	• contain high water content • cooling effect upon application • significant long-term efficacy compared to conventional treatments • fast onset of action, good safety profile, high patient satisfaction	• burning, itching, dryness, irritation, peeling, or redness of skin (<1% of patients)
Lotions	• can have either water or alcohol base • are the most versatile • can be used for all skin types • have a lighter feel, which patients prefer • preferred for treatment of large or hairy areas, or skin sites subject to chafing (e.g., axilla, foot, groin).	• can cause skin irritation (e.g., burning and dryness)
Ointments	• effective for patients with very dry skin • many are preservative-free • provides higher potency and greater drug penetration • effective on thickened skin lesions	• insoluble in water, so are difficult to wash off • can be perceived by patients as being greasy or messy to apply
Shampoos	• short contact application (about 15 minutes) • reduced side-effects • can be used for extended periods of time • high patient satisfaction, which may increase adherence and treatment efficacy	• small number of cases with burning, skin atrophy, and telangiectasia
Solutions	• easy to spread • leaves minimal residue	• usually contains an alcohol base that can cause stinging or exacerbate dryness and irritation
Sprays	• can treat large areas of affected skin (up to 15-20% BSA) • improved quality of life scores when compared with other formulations	• few cases of erythema, scaling, dryness, stinging/burning, and lack of smoothness

Table 1: Pros/cons of some newer and conventional topical delivery vehicles used in dermatology

considerations. Active agents are formulated in a variety of vehicles (Table 1) to address the possible combinations. In general, patients with drier skin may favour creams for their moisturizing effect, while those with oilier skin may prefer gels or solutions. In addition to ease of spreadability, the use of foams may be particularly well suited for application over larger areas and hair bearing sites.

Some Newer Therapeutics with Advanced Delivery

Foams for Dermatoses

- Steroid foam preparations are newer formulations that provide commonly prescribed topical steroids in a low residue vehicle[1] for the treatment of steroid-responsive dermatoses (e.g., allergic reactions, atopic dermatitis, and psoriasis).
- In Canada, desonide foam 0.05% is indicated for the treatment of mild to moderate atopic dermatitis in patients ≥1 year of age.
- Foam formulations of corticosteroids offer cosmetic advantages over traditional topical vehicles (ointments and creams), including quality of life variables such as minimal residue after application, quick drying, ease of application, and no odour.
- Other findings included that patients using foam preparations spent less time applying medication as compared with other forms of topicals, and that no significant difference in cost was found between foam and cream/solution after controlling for body surface area.[2]
- In preliminary studies, steroid foams have also been shown to be more efficacious treatment vehicles by demonstrating more rapid penetration and greater total absorption than conventional delivery modes (i.e., lotions and creams).[1]
- Additionally, foam formulations are also considered to have a better acceptability profile in patients, with a greater positive effect on quality of life, than traditional topical formulations.
- These advantages may lead to improved compliance and efficacy of treatment. The most frequently reported adverse events with steroid foam preparations are application-site reactions, such as burning, stinging, or itching.
- However, ethanol-free steroid foam formulations are also being developed to minimize side-effects.[2]

Gel for Acne

- Many new topical acne formulations have aqueous-based gel vehicle delivery systems that do not contain alcohol and are suitable for use in all skin types.
- A once-daily formulation of clindamycin 1% + benzoyl peroxide (BP) 5% in a gel vehicle improves absorption and cosmetic acceptability, and facilitates ease of use, especially over larger or hair-bearing areas.[3]
- Recent study findings demonstrate that this fix-dose combination not only has the potential to inhibit antimicrobial resistance,[4] but also to improve both treatment tolerability and safety.[5]
- The nonmedicinal constituents in this anti-acne compound include both glycerin (humectant) and dimethicone (emollient) to reduce both epidermal barrier impairment and cutaneous irritation, and increase hydration.

Gel for Scalp Psoriasis

- Calcipotriol 0.005% + betamethasone dipropionate 0.05% in a lipophilic gel is specially formulated for the treatment of scalp psoriasis.[6]
- A study comparing this two-compound gel with calcipotriol alone was conducted and the proportion of patients with 'clear' or 'minimal' disease at week 8 was significantly greater in the gel group (68.6%) as compared to the group receiving calcipotriol monotherapy (31.4%).[7] Additionally, the rate of improvement was more rapid and adverse events were less with the two-compound gel.
- The results further showed that the two-compound scalp formulation demonstrated significant efficacy after only a 1 week period, with a faster onset of effect than either of the individual components in the same vehicle.

Spray for Psoriasis

- All of the newer topical clobetasol propionate (CP) formulations produce clearing or near-clearing of psoriasis for a large proportion of patients within 2-4 weeks, with response, safety, and tolerability rates that are at least comparable to those observed with older topical CP ointments and creams.[8]
- CP spray is the only CP 0.05% formulation currently approved for treatment up to 4 weeks for those moderate-to-severe plaque psoriasis patients whose benefit/risk ratio supports the additional 2 weeks of treatment.
- Previous studies have indicated that the additional 2 weeks of therapy with CP spray greatly increased efficacy without adversely affecting the safety profile of the drug.[9]
- The CP spray may have an important role in the treatment of large areas of affected skin (up to 15-20% body surface area), expanding the range of topical treatment in psoriasis patients and improving quality of life scores at the end of treatment when compared with other formulations.[9]

Conclusion

Patient dissatisfaction with traditional topical modes of delivery in dermatology have led to the recent introduction of newer delivery vehicle formulations to improve clinical efficacy, reduce side-effects, and better address and promote patient adherence. Newer therapeutic options formulated as gels, foams, sprays, and shampoos have shown to be clinically efficacious, while exhibiting a high degree of patient satisfaction associated with their use. The newer topical delivery agents will also likely reduce the number of patients prematurely progressing to oral systemic therapies to control their cutaneous conditions, which can pose a more adverse side-effect profile than topical therapy alone.

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Management of Unwanted Facial Hair

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Introduction

Unwanted facial hair is a common, frustrating condition that affects up to 25% of women. For many individuals, it significantly impacts their quality of life. Treatment options include physical methods such as shaving, waxing, threading, bleaching, electrolysis, and laser therapy. Pharmacologic methods include chemical depilatories, oral hormonal therapy (i.e., spironolactone and contraceptive pills), and topical enzyme blockade (eflornithine).

Overview of Hirsutism

Hirsutism is defined as excessive growth of terminal hair in women in androgen-sensitive areas of the body (face, neck, chest, etc.).[1] This is to be differentiated from hypertrichosis, which is generalized excessive hair growth. The primary androgen responsible for hair growth is dihydrotestosterone (DHT), which is synthesized from testosterone by the activity of 5-alpha-reductase type 2. Hirsute females have increased 5-alpha-reductase activity in the hair follicles.[2]

Unwanted facial hair is a common, chronic, life-affecting problem for many women. A European study of female college students showed that up to 26% of women had facial hair growth and in 9% it was markedly noticeable.[3] Self-esteem and quality of life can be significantly altered by excessive facial hair.[4] Hirsutism can often be accounted for by ethnicity or genetics, but in a small percentage of people it can be a sign of underlying disease.

Signs of Androgen Excess [5,6]

- Hirsutism
- Acne
- Seborrhea
- Menstrual irregularities or infertility
- Alopecia

Causes of Androgen Excess and Hirsutism [5]

- Polycystic ovarian syndrome (1-4% of all females of reproductive age)
- Androgen-producing tumours (ovarian or adrenal)
- Congenital adrenal hyperplasia
- Cushing's disease
- Exogenous steroid use or other drugs

Clinical Considerations

- To determine if a patient needs a work-up for her hirsutism, clinical assessment in the form of a thorough history and physical exam are the most important tools.
- If hirsutism is associated with significant acne, menstrual irregularities or signs of androgenization, such as deepening of the voice, clitoromegaly or other, hormonal work-up is warranted.

Blood-work to Assess for Androgen Excess [6,7]

- Total and free testosterone
- Dehydroepiandrosterone sulfate (DHEA-S)
- +/- 17 hydroxy-progesterone
- +/- prolactin
- +/- 24-hour urine cortisol

Psychological Sequelae

- Studies have shown that women with unwanted facial hair can exhibit significant levels of emotional distress.[4,8]
- The dissatisfaction with their appearance and persistent pattern of hair removal practices can become obsessive and intrusive on the daily lives of affected individuals, resulting in substantial psychosocial burden.
- The social and emotional impacts of hirsutism, especially among women, are commonly overlooked. Hence, assessment for such disturbances is helpful in guiding therapeutic recommendations.

Treatment Overview

Once underlying pathology causing the hirsutism is ruled out, many women will want to pursue removal of their unwanted facial hair. While there is still no permanent method of hair removal, any one or a combination of the following treatment options can be used to improve the cosmetic outcome. The more common hair removal modalities include:

- Physical removal (e.g., shaving, waxing, plucking, electrolysis)
- Bleaching agents
- Chemical depilatories
- Laser assisted removal
- Oral hormonal blockade
- Topical enzyme blockade

Treatment Options for Unwanted Facial Hair

Physical Removal

Physical removal methods are common, inexpensive, and often home administered, excepting electrolysis. Drawbacks to physical removal include discomfort, resultant folliculitis, rapid regrowth, and the possibility of scarring or hyperpigmentation.

- Only electrolysis is potentially permanent.[5]
- Bleaching is effective for lightening the hair shaft, but it does not affect hair length or growth. Irritant dermatitis is a common drawback.
- Chemical depilatories use thioglycolic acid to dissolve the hair shaft. This is effective at removing both the surface hair as well as hair just below the skin surface, but not down to the depth of the follicle. Irritant dermatitis is again a common side-effect.[6]
- Pseudofolliculitis barbae is a common chronic inflammatory skin condition that is caused by the habitual removal of unwanted hair through physical means. This persistent practice can contribute to a foreign-body reaction surrounding the ingrown hair, which can produce papules and pustules that result in hyperpigmentation and keloidal scars.

Laser Hair Removal

- Laser light uses selective thermolysis to cause thermal uptake by the pigmented hair shaft. The heat absorbed by the hair shaft will cause disruption or destruction of the hair follicle.[9,10]
- Various lasers and light sources (e.g., intense pulsed light, alexandrite, diode, Nd:YAG)[9,10] have been used for this treatment and results vary depending on the skin type of the patient, the colour of the hair (i.e., it is ineffective on light-coloured hair), the growth phase of the hair, and the operator.
- Complications can include burning, edema, blistering, hyperpigmentation, scarring, and paradoxical hypertrichosis (~1-4%).[9-11]
- The possibility of permanent hair reduction can be attained through laser therapy.

Oral Hormonal Blockade

- Anti-androgen therapy using oral contraceptives can suppress adrenal and ovarian androgen production and increase sex-hormone binding globulin to reduce circulating testosterone.
- Cyproterone acetate (50-100mg on days 1-10 of the menstrual cycle) alone or in lower doses in Diane-35® inhibit 5-alpha reductase, preventing the transformation of testosterone to DHT, which is required for hair growth.[12]
- Spironolactone (100-200mg/day) acts as an androgen receptor blocker, again preventing the interaction of DHT in the hair follicle.[6]
- Side-effects may include menstrual irregularities, breast tenderness, weight gain, and with spironolactone, hyperkalemia and feminization of a male fetus.[6]
- Rare side-effects of contraceptive pills include cerebrovascular events, heart attack, or venous thromboembolism.[6]
- Much less commonly used oral therapies include flutamide and finasteride, as they have more potential toxic effects.

Topical Enzyme Blockade

- Eflornithine hydrochloride (HCl) cream 13.9% (Vaniqa®) is a novel product that is commercially available by prescription only.
- Eflornithine is an irreversible inhibitor of ornithine decarboxylase.
- It does not remove hair, but rather inhibits cell division and other cellular functions, thus slowing, but not stopping, hair growth, and shortens both the length and mass of hair.[13]
- Topical eflornithine HCl is effective against all causes of excessive facial hair, regardless of hair colour.
- Pivotal trials showed twice daily application for up to 24 weeks is effective at reducing hair growth in 58% of women, with 32% being considered a "clincial success"; improvement was seen as early as 8 weeks.[13]
- Side-effects include a potential for irritant contact dermatitis[14]
- Unlike lasers, it can be used to treat lighter vellus hairs.
- Topical eflornithine is effective alone or can serve as a useful adjunct to other hair removal techniques.
  - Studies have shown that it increases the efficacy of laser hair removal.[15] A randomized bilateral vehicle-controlled study of women with facial hirsutism comparing eflornithine HCl cream + laser treatment with laser alone demonstrated topical eflornithine provided an additive effect in enhancing the rate and degree of hair reduction on the upper lip.[15]
  - Eflornithine improved the reduction in unwanted facial hair until the sufficient number of laser treatments (due to a lag in response time) produced the desired long-term effects.
  - The study medication was well tolerated and no device/drug interactions were observed.

Conclusion

Facial hair can be a distressing, chronic problem for many women. Assessment for underlying abnormalities should be guided by clinical findings. Treatment options are varied in effectiveness, side-effects, and costs. Combination therapy with multiple modalities of treatment may afford the most effective results.

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Clindoxyl®, Duofilm®, Impruv®, PanOxyl®, Revaléskin®, Stieprox®, Uremol®, Uremol® HC, and Verdeso®

Tribute Pharma Canada Inc.
Soriatane®

Triton Pharma Inc.
Dermaflex-20, Dermaflex HC 1%, Neo-HC 1%, Topactin, and Vaniqa®

Valeant Canada Limited
Dermatix™ Ultra, Efudex®, Glyquin® XM, and Ultravate®