Lack of regulation for herbal medicines and supplements is concerning

Dear bpac,

Thank you for your reasoned and patient replies to the correspondence on Red Yeast Rice (BPJ 32, Nov 2010). Indeed the Becker study comparing simvastatin plus written diet and exercise advice, against red yeast rice tablets, plus fish oil supplements, plus a 12 week supervised and coached exercise programme, plus counselling from a dietician, is one of the best examples of the worst way to do a clinical trial, from which, no scientific conclusions can be drawn. A correct scientific study would have been comparing simvastatin, plus written diet and exercise advice, against red yeast rice tablets, plus the same written diet and exercise advice. In my opinion it is amazing that this study was even published.

A further matter for consideration is that to my knowledge, herbal medicines/supplements are not subject to any mandatory regulatory requirement for safety or toxicity testing prior to being launched on the unsuspecting public. Thus we doctors often may advocate to our patients herbal or nutritional supplement products which have no safety testing whatsoever.

Medicines such as simvastatin are required to conform to safety and toxicity testing including single dose toxicity lethal dose, repeat or ongoing dose toxicity, carcinogenicity, genotoxicity or mutagenicity and embryotoxicity or reproduction toxicity. If the regulators believe that a medicine is safe in all of these areas and the proposed medicine dosage for humans is significantly less than the dosages which could cause potential problems in animals, then the product is allowed to be safety tested on volunteer humans. Further clinical studies in efficacy and comparison with other therapies continue.

As well as this progressive safety hierarchy of medicine testing, we currently have post-marketing studies and intensive adverse drug reaction reporting to give us more data on any unexpected positive or negative effects once a medicine is registered and in use. Indeed, we usually think in terms of unexpected new negative effects showing up. However, the recent large scale study reported in the Lancet showing use of statins causing a significant 12% reduction in the incidence of bowel cancer, shows that such surveillance can bring up further positive effects that the initial pharmaceutical manufacturers and investigators never envisaged.

I know of no such safety procedures with any of the myriad of herbal and nutritional supplements, vitamins and "natural" remedies that I see marketed at present. If we GPs are going to follow the dictum "Primum Non Nocere", how can we confidently say to our patients it's safe just because it's natural? We may easily blame the pharmaceutical industry for withholding data, poor study design or investigations being done by people with vested interests. However, registered medicines that I use still have a markedly better basic consumer safety system than our "feel good natural products industry".

Dr Steve Culpan, GP
Auckland

Pityriasis versicolor

Dear bpac,

I often see patients present with pityriasis versicolor (especially at the end of summer when they have tanned skin). However I am never quite sure which treatment is most effective or evidence-based (and ideally funded). Can you help me with any guidance on treatment of this condition?

***GP**, Dunedin*

Pityriasis versicolor (also known as tinea versicolor) is a superficial infection of the skin caused by the yeast *Pityrosporum ovale*. This yeast can transform into a pathogenic form and turn off melanin-producing cells in the skin, producing asymptomatic flaky patches on the trunk, neck or arms. These patches appear pink or coppery on pale skin and pale brown on tanned skin.[1] A number of conditions can trigger conversion of *P. Ovale*, including hot and humid weather, use of oils, hyperhidrosis (excessive sweating) and immunosuppression.[2]

Topical antifungal medicines are the treatment of choice for pityriasis versicolor.[3] Two studies that compared topical therapy with systemic therapy, found that topical regimens were either equivalent to (clotrimazole cream for three weeks vs. fluconazole 300 mg/week for two weeks) or superior to (selenium sulfide shampoo for one week vs. itraconazole 200 mg/day for five days) oral therapy.[3]

Optimal treatment regimens have not yet been fully established, however, treatment for between one to four weeks is most common. Ketoconazole 2% shampoo (partly subsidised) or selenium sulphide shampoo (not subsidised) can be applied to affected areas, left on for at least ten minutes and then washed off. Treatment is ideally repeated daily for one to four weeks. Alternatively, imidazole creams such as clotrimazole 1% or miconazole 2% (both fully funded) can be applied once or twice daily, for one to four weeks.[2]

Systemic treatments for pityriasis versicolor include oral ketaconazole or itraconazole. Liver function must be monitored in patients receiving oral ketoconazole for more than one week or in patients prescribed oral itraconazole for any length of time.[4]

Recurrences of infection after successful treatment are common. To help prevent relapse, continued intermittent use of topical therapies can be useful.

References

1. Dermnet nz. Pityriasis versicolor. Dermatological Society of New Zealand. Available from: http://dermnetnz.org/doctors/fungal-infections/pityriasis-versicolor.html (Accessed Jan, 2011).
2. Faergemann J. Pityriasis versicolor. Semin Dermatol 1993;12(4):276-9.
3. Hu S, Bigby M. Pityriasis versicolor. A systematic review of interventions. Arch Dermatol 2010; 146(10):1132-40.
4. Stratman E. Failure to use available evidence to guide Tinea Versicolor treatment. Arch Dermatol 2010; 146(10):1140.

Is aqueous cream an appropriate leave-on emollient?

Dear bpac

An article was published recently in the British Journal of Dermatology which suggested that emollient creams worsen eczema rather than improving it. Have we been giving the wrong advice on the use of aqueous cream as a moisturiser?

Pharmacist, Auckland

Emollients are commonly used first-line for the treatment of eczema as they help to maintain the skin's barrier function, keeping moisture in and irritants, allergens and pathogens out. They should be applied liberally, frequently and continuously, therefore it is important that they are acceptable to the patient.

Aqueous cream is one of the most commonly prescribed and used emollients, however recent evidence suggests that it may not be appropriate for all people.

A recent study involving six people found that aqueous cream applied twice daily, to healthy skin on the forearm, for four weeks, reduced the stratum corneum thickness and increased the permeability to water loss (i.e. caused dry skin).[1] The aqueous cream used in this study contained 1% sodium lauryl sulphate which is a surfactant with soap like properties and a known skin irritant. The authors

suggested that sodium lauryl sulphate was a likely cause of the adverse effects on the skin and stated the following: "The fact that sodium lauryl sulphate is able to reduce the stratum corneum thickness of normal skin significantly following repeated, yet rather brief, application suggests an even more damaging action on diseased skin, the barrier function of which may already be compromised".[1]

An audit of 100 children attending a paediatric dermatology clinic found that an immediate cutaneous reaction (which included burning, stinging, itching or redness) was reported after use of aqueous cream in 56% of exposures in comparison with 18% of exposures to other emollients.[2] The authors noted that aqueous cream was not originally designed as a leave-on emollient, rather it was designed as a wash product, with brief skin contact only.[2]

These small studies suggest that aqueous cream may not be an appropriate choice as a leave-on emollient for some people. Aqueous cream is still a suitable option as a soap substitute because in this situation, the cream is washed off and is only in contact with the skin for a short time. What is clear is that it is important to allow patients to choose the emollient and soap substitute that suits them best because this will increase compliance.

In New Zealand, funded emollients include; aqueous cream, fatty cream (healthE fatty cream), emulsifying ointment and cetomacrogol cream. Partially funded options include; oily cream, glycerol with paraffin and cetyl alcohol (QV lotion) and wool fat with mineral oil (Alpha-Keri, Hydroderm BK and DP lotions). Urea cream (Nutraplus) is very effective at moisturising dry skin, but may sting if there is active eczema.

"Adverse reactions to currently available aqueous creams are rare in New Zealand but occasionally people complain about its greasiness. I have rarely considered it an irritant – except many years ago when there was a bad batch. The emulsifying wax contains very small amounts of sodium lauryl sulphate which allows it to act as a cleanser. But I agree, our patients need to be given options with a variety of soap replacements and emollients".

–Dr Amanda Oakley, Dermatologist

For further information, see BPJ 23 "Managing eczema"

References

1. Tsang M, Guy R. Effect of aqueous cream BP on human stratum corneum in vivo. Br J Dermatol 2010:954-8.

2. Cork M, Timmins J, Holden C, et al. An audit of adverse drug reactions to aqueous cream in children with atopic eczema. Pharm J 2003;271:747-8.

We value your feedback. Write to us at: Correspondence, PO Box 6032, Dunedin or email: editor@bpac.org.nz