Section 13.4 Dermatological medicines (topical) – Medicines affecting skin differentiation and proliferation

Coal tar

Review submitted by

The International League of Dermatology Societies.
Question raised by the 18th Expert Committee on Selection and Use of Essential medicines

Should adults and children with psoriasis be treated with coal tar solution compared to other topical preparations for psoriasis

Summary of the review

The ILDS working group recommends that this medicine be retained on the essential medicines list for both children and adults. However, some more effective medicines are currently available. Of these topical corticosteroids are already listed in EML. Coal tar has no efficacy and safety advantage over corticosteroids. However it is relatively cheap, easily available and easy and safe to use. The maximum concentration of coal tar preparations recommended should not exceed 5%. It is further recommended that this is kept under review as medicines with different modes of action could become more cost effective in the management of psoriasis in the future.

Public health relevance

Psoriasis is a common skin condition with an estimated prevalence of approximately 1.2% in the general population. The prevalence varies in different world populations with the condition being less common eg 0.5% in sub-saharan Africa and higher in northern Europe eg 1.5%. It is mainly seen in adults although it may occur in children.

Action of coal tar

Coal tar preparations, prepared from distilled coal tar have been used for over 100 years for the treatment of scaly skin condition including psoriasis. Despite this long term experience it is not clear how coal tar works although it is thought to reduce scaling. It is also active against some microorganisms such as Malassezia species although this is unlikely to influence its efficacy in psoriasis. It is available for the treatment of psoriasis in a variety of different formulations and can be used for lesions on the trunk and limbs as well as the scalp where tar containing shampoos are widely available. A number of additives such as polysorbate, triethanolamine, phenoxyethanol, phospholipids such as lecithin have been added to the distilled coal tar which provide the different formulations with slightly different properties such as emulsification.

Efficacy and safety

A systematic review of coal tar used in psoriasis in 2010 [1] concluded that 84% of the studies identified supported the use of coal tar as a treatment for psoriasis. The authors pointed out that only two studies were placebo controlled and that was a need for more work. The situation is complicated by the fact that there are a number of different products that use different excipients and the ideal strength is not well established. For instance the conventional strength used is 5% but a study comparing a 1% coal tar solution versus 5% showed a significant advantage in favour of the lower strength i.e. 1% [2]. The reasons for this are not clear and other studies
using similar formulation with and without the fatty acid additives showed no advantage in incorporating these additional substances [3].

A recent Cochrane systematic review of topical treatments for psoriasis examined 131 RCTs with some investigating coal tar against placebo or other alternative medicines; the two principle alternatives to coal tar are Vitamin D analogues and topical corticosteroids. Vitamin D analogues (e.g. Calcipotriol) were significantly more effective than placebo. Also with one exception, all corticosteroids performed better than placebo. Comparisons of Vitamin D against steroids, found no significant differences. Combined vitamin D and corticosteroids performed significantly better than either treatment alone. Corticosteroids are lesser likely to produce local side effects. Vitamin D performed better than coal tar and overall coal tar products showed no specific advantage over a variety of other alternatives such as calcipotriol [4]. But efficacy in psoriasis as other chronic inflammatory diseases also varies on the time point of analysis. A recent comparison of calcipotriol versus coal tar showed a significant difference in clinical response in favour of calcipotriol between the two sides at 4, 6 and 8 week time points with the percentage reduction in severity (ESI) score with calcipotriol being 65.7 +/- 12.2% compared with 45.8 +/- 16.6% with coal tar at 8 weeks (P < 0.01, t = 6.4). However, the difference in clinical response at 10 and 12 weeks between the two arms was not significant, with a mean reduction of 71.9 +/- 13.3% in ESI score on the calcipotriol-treated side compared with 69.4 +/- 15.4% with coal tar ointment (P > 0.05) [5].

There has been one cost effectiveness study comparing tar treatments for psoriasis with calcipotriol. The coal tar treatment produced greater improvement in severity (PASI) score (58.2%) at less cost ($0.92 per 1% improvement in PASI, or “PASI-1”) than calcipotriol treatment (36.5% at $35.42 per PASI-1) after 12 weeks of treatment. After treatment and 6 weeks of follow-up (at week 18), the cost of PASI-1 was $1.01 in the coal tar group and $58.11 in the calcipotriol group because the coal tar group maintained PASI improvement (52.5%), while PASI in the calcipotriol group significantly worsened (to 22.2%). Furthermore, the expected costs for achieving PASI-50 and PASI-75 with each therapy choice were also less for coal tar than for calcipotriol [6].

The main side effect of coal tar is skin irritancy although it may also be a photosensitiser.

There has been concern expressed over potential carcinogenicity of the application of tar – based products based on experimental animal studies. Coal tar products containing coal tar above a concentration of 5% are listed by the World Health Organisation as carcinogenic. Reviews of the literature have however been unable to uncover evidence of increased risk of cancer in those treated with medical formulations of coal tar [7, 8]. Studies of patients receiving long term treatment with coal tar have also not found evidence of an increased risk of cancer [9]. A recent in depth analysis of patients receiving tar based anti-psoriasis treatment [10] compared with alternative medications found no evidence of an increased risk of skin cancer associated with tar. Specifically the median exposure to coal tar ointments was 6 months (range 1–300 months). Coal tar did not increase the risk of non-skin malignancies (hazard ratio (HR) 0.92; 95% confidence interval (CI) 0.78–1.09), or the risk of skin cancer (HR 1.09; 95% CI 0.69–1.72).
Other considerations

EML already has alternative medication for the treatment of psoriasis e.g. topical corticosteroids, while newer medicines in common use in many parts of the world such as Calcipotriol are not listed. Topical corticosteroids also show efficacy in a variety of different dermatoses including eczema and psoriasis. Their use as described above is also supported by the clinical evidence [4]. Topical steroids are also often used in combination with agents such as coal tar [11]. Rotation of treatments is important as tachyphylaxis is experienced with corticosteroids and continuous treatment is also associated with adverse effects such as skin thinning. However coal tar remains the least expensive of treatments and can be used repeatedly and has relatively few local side effects. The ILDS group advise listing two agents for the topical treatment of psoriasis and their preference is for a corticosteroid and coal tar, thereby providing the advantage of cover for other diseases such as eczema with the former and the cost benefit in psoriasis with coal tar.

Newer medications such as calcipotriol are relatively expensive which makes their use in resource poor regions impractical. Hence no additions are requested this time. National guidelines continue to recommend the use of coal tar based treatments for psoriasis eg

UK (www.bad.org.uk/.../Guidelines/Clinical%20Guidelines/BAD-),

New Zealand (http://www.dermnetnz.org/scaly/psoriasis-treatment.html ),

Canada (http://www.dermatology.ca/wp-content/uploads/2012/01/cdnpsoriasisguidelines.pdf)

References


