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Effectiveness of skin protection creams as a preventive measure in occupational dermatitis: a critical update according to criteria of evidence-based medicine

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Abstract Objectives: This study attempts to assess the evidence of the generally recommended three-step programme of skin protection in the prevention of occupational skin disease. **Methods:** The following clinical questions, representative of critical appraisal of this preventive measurement, were generated: (1) Can a skincare regimen effectively reduce or eliminate work-related poor skin conditions? (2) Do protective creams prevent harmful substances from penetrating and adhering to the skin? (3) Is the differentiation between pre-exposure and post-exposure products justified by reliable data? Answers were generated according to the method used in evidence-based medicine by searching the literature, critically appraising the results and applying the results to the clinical questions. For our search we decided to use PubMed as the most convenient access to Medline and because, in contrast to other databases, this access is available free of charge. **Results:** To investigate the efficacy of barrier creams as pre-exposure skin protectors various in vitro and in vivo test methods have been developed. Over the past years the test techniques have been improved in order to adopt a real workplace situation. Efforts for standardisation of evaluation criteria have been made, too. Nevertheless, there is a lack of placebo-controlled, randomised clinical trials evaluating the benefit of these products in the prevention of occupational contact dermatitis under real workplace conditions. The literature data are conflicting; some publications report on the positive aspects of skin protection, whereas others stress the negative ones. **Conclusion:** Not enough data have been accumulated for one to prove the benefit of skin protection measures under real workplace condition. Up to now, it is almost unclear if the various in vitro and in vivo methods used are suit-

able to simulate real workplace conditions and if these test results can be related to real occupational exposure. For the evidence-based recommendation of skin protection, further studies, especially under daily working conditions evaluating the contribution of each single element of skincare programme (products, frequency of application and education programme) are needed.

Keywords Evidence-based medicine · Skincare programme · Barrier cream · Skin protection creams · Moisturiser · Prevention of occupational skin disease

Introduction

In the past decade evidence-based medicine has become a generally accepted method of linking the results of research to the practise of medicine. Evidence-based medicine uses the following five steps: (a) formulate a clear clinical question, (b) search the literature for relevant articles (systematic reviews, meta-analysis, randomised clinical trials, etc.), (c) assess (critically appraise) the evidence for its validity and usefulness, (d) implement useful findings in clinical practice, and (e) evaluate one's own performance [48, 49].

In the field of occupational medicine the use of evidence-based medicine has been advocated [9, 11, 13, 52], but up to now these methods have been applied to occupational health risks and intervention in only a very limited way, and there is considerable scope for wider use [11].

For many years the three-step programme of occupational skin protection, consisting of skin protection before work, cleaning, and skincare after work, has been introduced into practice. While protective creams are supposed to prevent skin damage due to irritant contact, skin cleansing should mildly remove aggressive substances from the skin, whereas post-exposure skincare is intended to enhance epidermal barrier regeneration. This three-step concept is strongly propagated and is

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one of the generally recommended measures to prevent occupational contact dermatitis. But in spite of intensive measurements for skincare and protection in Germany, the number of recorded occupational skin diseases according to BK 5101 did not decline over the past years (data of HVBG: general German employee liability insurance association). Occupational skin diseases are still the second most common type of occupational disease. In 1998 the annual costs for occupational skin disease reached 287.4 million DM [63].

Data compiled by the US Bureau of Labor Statistics (BLS) also indicate that occupational skin diseases are the second leading cause of occupational disease in the US. According to the National Institute of Occupational Health and Safety the estimated total annual costs, including workdays and loss of productivity associated with occupational skin diseases, can reach up to \$1 billion annually.

These findings invite the question of how effective the actual recommended measures for prevention of occupational dermatitis, especially the use of skin protection creams, really are. Therefore, we raised the question as to what extent the three-step concept of skin protection—especially the use of skin protection creams—as a measure to prevent occupational skin disease, is really evidence-based. Our work is aimed to assess critically the evidence for the recommendation of skin protection creams in the prevention of occupational skin disease. The following three working hypotheses are to be proven or rejected:

1. Use of a skincare regimen can reduce or eliminate work-related minimal skin changes such as mild eczema or contact dermatitis.
2. The protective creams provide a layer that prevents harmful substances from penetrating and adhering to the skin, thus protecting skin integrity.
3. Employees using skin protection have a lower risk of systemic exposure to dangerous workplace hazards.

However, our search on Medline [43] using the phrases or subject headings “evidence-based medicine and skin protection cream”, “evidence-based medicine and barrier cream”, “evidence-based and barrier cream” or “skin protection and evidence-based” yielded no articles in August 2002.

Intensifying this search by using the database of the Cochrane Collaboration [12] gave us no further information, although the Cochrane Library is known as a unique source of reliable information on the effects and interventions in healthcare. Five out of seven separate databases of the Cochrane Library provide coverage of evidence-based medicine; the other two provide information on research methodology.

In contrast to other literature databases such as the Cochrane Library or Embase, only Medline [43] is available free of charge through the Internet with the search tool PubMed. Medline not only contains references to original studies, but also references to databases

of systematic reviews and is therefore comparable to those of the Cochrane Collaboration. Based on these reflections, we decided to use PubMed as the most convenient access to Medline at <http://www.ncbi.nlm.nih.gov/PubMed> for answering the following questions:

Is the use of barrier creams an effective measure to prevent or reduce occupational contact dermatitis?

Are barrier creams, due to skin integrity, protective against resorption of dangerous substances at the workplace?

The objective of this article is to solve the generated questions by means of methods used in evidence-based medicine.

Methods

Search strategy

Evidence-based medicine is a process of systematically finding, appraising and using up-to-date research findings as the basis for clinical decisions or preventive measurements. The success of a search strongly depends on the strategy used. By the use of search limits for Medline, such as a combination of different terms, or restriction to the English language, or to reviews, the right balance must be found between too few and too many articles. According to Allison et al. [2] the appropriate number of articles will be about 50 references.

The first search restricted to the main key terms failed. The only way to get more information was to modify the search strategy by generalising the search terms. Based on this we first searched for “skin protective cream” and “barrier cream”. The search for skin protective creams revealed 59 results, whereas the search for “barrier cream” produced 106 results. By screening the abstracts of the retrieved articles we noticed that this search was not precise enough. By using the search term “skin protection” we found that a huge number of articles were related to protection from UV radiation by sunscreens. In order to get a fast overview of the literature and to find the relevant articles we tried to specify the search by combining both terms with other aspects of our generated question (Table 1).

Critical appraisal

Abstracts of all search strategies giving fewer than 100 results were screened for their relevance to solve our generated questions. Different search strategies can lead to different results (Table 1); therefore we decided to screen all findings of fewer than 100 abstracts. Then, the full text articles of all relevant abstracts were provided and assessed for the best evidence. This method has the advantage that conclusions of abstracts can be critically appraised and the design of clinical studies can be proved.

Results

Test and evaluation methods

A huge number of *in vitro* and *in vivo* methods for evaluation of barrier creams have been described. *In vitro* methods include measurement of solvent permeability through a standardised cream layer, and permeability through excised murine or human skin [36, 37]. In animals, measurement of the blood concentration of a

Table 1 Results of the literature research on Medline, with PubMed being used to solve the generated questions: “Is the use of barrier creams an effective measure to prevent or reduce occupational contact dermatitis?” and “Are barrier creams, due to skin integrity, protective against resorption of dangerous substances at the workplace?”

Search terms on Medline (August 2002)	Articles retrieved (<i>n</i>)
Barrier cream	109
Skin protective cream	59
Skin protective cream and barrier	17
Skin protective cream and effic* ^a	18
Barrier cream and effic* ^a	29
Skin protective cream and prevention of contact dermatitis	20
Barrier cream and prevention of contact dermatitis	26
Skin protective cream and prevention of occupational dermatitis	9
Barrier cream and prevention of occupational dermatitis	9
Barrier cream and clinical trial	3
Skin protective cream and clinical trial	1
Skin protective cream and benefit	1
Barrier cream and benefit	1
Skin protective cream and harm	0
Barrier cream and harm	0
Skin care	1555
Skin care products	168
Skin care and prevention	469
Skin care and prevention of work-related skin disease	4
Skin care and prevention of occupational contact dermatitis	26
Skin care programme	10
Skin care programme and prevention	6
Skin care programme and prevention of occupational* ^a	5
Barrier function and occupational skin disease	27
Barrier function and prevention of occupational contact dermatitis	10
Barrier function and prevention of irritant contact dermatitis	10
Skin care and evidence-based	53
Skin care and evidence-based prevention	22
Skin care and evidence-based prevention of contact dermatitis	0
Moisturizer	80
Moisturizer and prevention	16
Moisturizer and prevention of irritant dermatitis	2

^aIn the Medline research the asterisks were used to indicate all possible endings in order to enlarge the search

solvent after percutaneous absorption through a barrier cream has been used as a method for validation of barrier-cream efficacy [10]. Also, histological assessment of skin inflammation after skin irritation has been performed in mice for the same purpose [40]. Frosch et al. [21, 22] first used a guinea-pig model for performing the repetitive irritation test to evaluate the efficacy of barrier creams. Over a 2-week period cumulative irritation with standard irritants such as sodium lauryl sulphate, sodium hydroxide, lactic acid and toluene was performed. Irritation of pre-treated sites was compared with irritation of untreated control sites.

In vivo methods in humans are mostly based on assessment of the reduction either of a known contact sensitisation or of irritant and inflammatory changes in the skin when a barrier cream or moisturiser is used before application of the irritant [20, 26, 47, 50, 56] or allergen [28, 45] in relation to an area of skin that was not pre-treated. Over the past years, this irritation test was modified by duration [56, 57], concurrent application of two irritants instead of one [58], the use of a set of four standard irritants [19] or by change of the test area, e.g. using a hand model instead of the forearm, upper arm or back [31]. Recently, in order to be closer to real workplace situations, the tandem repeated irritation test was propagated. Here, the sequential application of two irritants is used to evaluate the efficacy of protective creams [59].

Zhai and Maibach [61] developed an in vivo method to measure the effectiveness of skin protection creams against two dye indicator solutions: methylene blue in water and oil red O in ethanol, representative of model hydrophilic and lipophilic compounds. Solutions of 5% methylene blue in water and 5% oil red O in ethanol were prepared and applied to untreated and protection-cream pre-treated skin with the aid of aluminium occlusive chambers for 0 h and 4 h, respectively. At the end of the application time the cream was removed and consecutive skin surface biopsies from one to four strips were taken. Barrier creams were assessed by measurement of the dye in cyano-acrylate strips of protected skin. The amount of stain in each strip was determined by colorimetry, with the cumulative amount representing the amount of permeation of each solution at each time point, and therefore, representing a marker for the efficacy of a barrier cream.

De Fine Olivarius et al. [15] introduced a method based on evaluation of colour intensities to prove the water protective effects of barrier creams. If the skin is pre-treated with a water-repellent cream, the penetration of an aqueous solution of crystal violet is impaired, leading to lesser binding to the keratin and a less intense colour. The relative efficacy of different creams may therefore be assessed visually by comparing the different colour intensities. Colour intensity was quantified by measurement of skin reflectance.

Not only did test methods vary, but also the evaluation methods varied, between visual scoring system, histological findings, bioengineering methods or a combination of all. To date, however, no generally accepted standardised procedure for the evaluation of skincare products exists [39]. To find a standardised, reproducible test procedure for the evaluation of skin protection products, a multicentre study was performed, evaluating a multiple repeated short-time occlusive irritation method [51]. Efforts for standardisation of evaluation methods have been made, as well [8, 23, 46]. Nevertheless, in spite of improvement in test and evaluation methods, it is unclear if all these different test models are reliable for simulating real workplace conditions. Therefore, an evidence-based clinical decision does

not seem possible, related to these *in vitro* and *in vivo* models.

Clinical trials

Clinical trials related to the subject of skin protection can be divided into three main groups. The first group comprises studies supposing the validity of skin protection. These studies are aimed to prove either acceptance of skin protection creams [4] or the right application of skincare products [54, 55].

The second group consists of several clinical studies confirming the efficacy of skin protection measures [3, 6, 14, 16, 17, 18, 25, 30, 34, 35, 38, 41, 44, 60], whereas the third group is related to studies reporting even negative effects of skin protection [5, 29, 32, 33].

In order to answer our initially generated questions concerning the efficacy of the generally recommended skincare programme, we focussed on the clinical studies that reported either benefit or harm from this prevention.

Perrenoud et al. [44] compared the protective action of Excipial Protect (Spirig Pharma AG, Egerkingen, Switzerland) containing aluminium chlorohydrate 5% as active ingredient, against its vehicle alone. Twenty-one apprentice hairdressers at the beginning of their 2nd year of studies were recruited; 16 of these were able to be followed up to the end of the study. The study was designed as a double-blind cross-over study, applying first the vehicle and then the verum over 2 weeks, and vice versa. The efficacy of the creams was evaluated according to clinical scores and bioengineering parameters and assessed by subjective opinions of the subjects. No statistically significant difference in efficacy was observed between the protective cream and its vehicle. In a randomised double-blind study Berndt et al. [6] compared Excipial Protect with its vehicle, too. Fifty hospital nurses with mild signs of compromised skin on their hands, such as roughness or slight erythema, were included in the study population. Half of the test population received the commercial product, whereas the other half had to use the vehicle for a month. Effects of both types of preparation were studied weekly by clinical examination and instrumental assessment of bioengineering parameters. Results showed no significant differences between barrier cream and vehicle. Even the vehicle alone was capable of positively influencing the skin status.

Critical points of these two very similar studies are: (1) the small study population, (2) the lack of a real control group (without any cream application) and (3) the short observation time. Furthermore, the study by Berendt et al. included only subjects with already impaired skin conditions (roughness or slight erythema), and therefore the study is qualified only for evaluating the therapeutic, not the preventive, properties of skin protection.

In a double-blind randomised trial [41] an oil-containing lotion was compared with a novel barrier cream

in 54 healthcare workers with severe hand irritation, over a 4-week period. Subjects in both groups experienced marked improvement. Due to inclusion criteria (impaired skin condition) this trial, as well as four others [6, 14, 17, 18], is qualified to prove only the therapeutic effects of skin protection creams; conclusions related to the preventive aspects could not be drawn.

If we summarise the results of these clinical trials, the following questions are left unanswered:

1. Do we need, if the vehicle or an oil-containing lotion is as effective as the verum, special skin protective creams?
2. Are the persons who use a vehicle a suitable control-group, because of the well-known hydrating or greasing effects of this substance? Would "no intervention" not better fit as a control?

Duca et al. [16] followed 657 workers in 13 dyeing and printing factories in North Italy over 1 year. The study was aimed to assess the efficacy of two different barrier creams in comparison with non-treatment in practical circumstances. Unfortunately only the abstract of this article is available in English, the original paper being published in Italian. The formulation used for recruitment of subjects: "A total of 942 workers of 13 dyeing and printing factories in the area of Como were examined in order to detect skin complaints on the hand and forearms" suggests that impaired skin condition was a criterion for inclusion. Based on this suggestion, this study also focuses on the therapeutic aspects of skin protection. Additionally, the evaluation methods are missing in the English abstract; for these reasons the critical appraisal of this trial might be difficult or even impossible.

Goh and Gan [25] compared the point prevalence of cutting fluid dermatitis and trans-epidermal water-vapour loss changes in groups of new machinists who (a) used a barrier cream (Arretil, Stockhausen, Germany; $n = 17$), (b) used an after-work emollient cream (Keri lotion, Westwood Pharmaceuticals, Buffalo, USA; $n = 14$), and (c) did not use any cream (control group: $n = 23$) over a 6-month period. In this prospective study, there was no significant difference in the prevalence of cutting fluid dermatitis in the three groups throughout the study period. Only the group of machinists using after-work emollient cream showed approximately 50% fewer cases of cutting fluid dermatitis than controls. However, the difference was not statistically significant. A larger study cohort might be necessary to attain statistical significance for this trend.

Last year an intervention study [34] showing promising results from the use of a skincare educational programme was published. The study was designed to investigate the potential of an educational programme in preventing work-related skin problems on the hands of student auxiliary nurses. One-hundred and seven student auxiliary nurses (61 in the intervention group, 46 in the control group) were followed during the first 10 weeks of their initial practical training in country hospitals. The

intervention group was given an educational programme before the practical training started. The investigators observed a significantly lower use of hand disinfectants in the intervention group than in the control group. A significant increase of trans-epidermal water loss (TEWL) was detected in the control group, but not in the intervention group after 10 weeks of practical training, and 48% of the intervention group and 58% of the control group experienced aggravation of skin problems during practical training. Recently, the same authors published a second study to assess the effect of implementation of an evidence-based skincare programme in wet-work employees [35]. A total of 375 wet-work employees were included in this prospective randomised, controlled trial and were allocated either to intervention ($n=207$) or control ($n=168$). The intervention group was exposed to a skincare programme during the 5-month study period. The intervention was successful with respect to information level, behaviour and clinical symptoms. Although annual differences are neglected, due to the 5-month duration of the study period, this study fulfils the most essential criteria for a valuable contribution to the solution of our generated problem.

Prevention of allergic contact dermatitis, as well as decrease of allergic reaction, is also related to the use of barrier creams. Thus, barrier creams containing chelating agents such as diethylenetriaminepenta-acetic acid are reported to prevent contact allergic reactions to metals [60]. A decrease in positive skin responses in tests on glove-wearing, natural rubber sensitised patients was observed after application of a commercially available protective cream [3]. These protective properties of a barrier cream in natural rubber sensitised patients are contradictory to the findings of Baur et al. [5], suggesting that skin protection creams may favour allergic reactions by increasing uptake of allergens from the gloves.

Some studies give evidence that moisturisers prevent the skin from irritant dermatitis [30, 38], whereas others [29, 32, 33] observed that some moisturisers, when used on normal skin, increased skin susceptibility to irritants or allergens.

Conclusions

A clear answer to the provocative title “Do barrier creams and gloves prevent or provoke contact dermatitis?” of a paper, which had already been published 4 years ago [53], is almost impossible. Beyond doubt is the fact that many barrier creams facilitate the removal of sticky oils, greases, and resins from the skin, thus decreasing the need to wash with potentially irritating abrasives and waterless cleansers [42]. With regard to aspects of safety, allergic reactions to contents of skin protective creams, such as preservatives, might also play a role [27], but it is unclear if the various *in vitro* and *in vivo* methods [10, 15, 19, 20, 21, 22, 26, 28, 31, 36, 37, 39, 40, 45, 47, 50, 51, 56, 57, 58, 59, 61] used are suitable to

simulate real workplace conditions and whether these test results can be related to a real occupational exposure.

Very few data [6, 16, 34, 35, 41, 44] have been accumulated that prove the benefit of skin protective measures under real workplace conditions. Appraising each study design we detected several points of criticism, such as the omission of a real control group (without recommendation for the use of skin protection measures), a small study population, or an extremely short study period. Due to inclusion criteria such as impaired skin condition, many clinical trials were designed to assess the therapeutic, rather than the preventive, properties of skin protection creams [6, 16, 17, 18, 41]. Based on these arguments only two recently published studies [34, 35] fulfilled all criteria of a reliable study concept to answer our question concerning the preventive properties of skin protection. Both studies, published by the same authors, support the thesis that an educational skincare regimen prevents or even reduces contact dermatitis. An alternative explanation for this result could also be that people being educated on skincare regimens have a more careful behaviour than people not being trained. These two studies gave evidence for the complete programme of skincare protection; a differentiation between the effectiveness of each single element of the three-step skincare programme (such as skin protection before work, cleansing, and skincare after work) or education was not made.

However, the effectiveness of a skincare programme is based on three factors: first, the effectiveness of the products used, then the frequency and elaborateness of the application of skincare products, and finally, the effectiveness of the education (reduction of exposure to skin-damaging substances).

Recently, Zhai and Maibach [62] reviewed the controlled study data related to the prevention of irritant contact dermatitis by the use of moisturisers. They concluded that further controlled experimental trials, under typical-use situations with a broader selection on irritants, have to be performed before one can generalise on the preliminary experimental results.

Therefore, for an evidence-based recommendation of skin protection, further studies, especially assessment of the contribution of each single element of skin protection (products used, level of application, education in reducing exposure to skin damaging activities) under daily working conditions, are needed.

In relation to the question “Are barrier creams, due to skin integrity, protective against resorption of dangerous substances at the workplace?” our Medline research gives controversial results. Uptake of allergens might be increased [5] as well as decreased [3]; skin susceptibility to irritants might be increased [29, 32, 33] as well as decreased [38] by skin protection products. Recently Korinath et al. [36] gave evidence that *in vitro* barrier creams were not effective in the protection of the skin from penetration with solvents. The percutaneous absorption of all solvents in 50% dilution was even increased by the use of barrier creams, in comparison

with untreated human skin. Furthermore, skin barrier creams enhance the penetration rates of solvents from complex mixtures compared with single solvents.

When we took into account publications other than those listed by Medline the findings remain contradictory, as well. Data from a field study gave evidence that skin protection enhances the skin's resorption of polycyclic aromatic hydrocarbons [1]. In a prospective study Funke et al. [24] identified risk groups for work-related hand eczema by examining 2,100 apprentices at Audi AG in Ingolstadt and Neckarsulm, before the start, after the first year, and at the end of their apprenticeships. The authors observed that hand eczema itself seemed to be the most important reason for the use of barrier creams. Therefore, their assessment of the effectiveness of barrier creams in the prevention of hand eczema could not be analysed in this epidemiological study. Initially, we overlooked another prospective study that analysed risk factors for hand eczema in metalworker trainees [7], although this publication is listed in Medline. We omitted to use the search term "skin-care products", and for this reason this publication escaped us. In that study there was no significant difference between the average skincare behaviour of the affected and the control group, up to the occurrence of skin disease.

In summary, all available data concerning harm or benefit of skin protection measures have remained controversial up to now. Results showing no significant difference between barrier cream and vehicle raise the question as to whether a strict distinction between skincare and skin protection products is necessary, or even justified. If it were supposed that a simple bland emollient had the same effects as a highly elaborate skin protection cream, then costs could be enormously reduced. For an evidence-based recommendation of the use of the three-step concept of skin protection, further studies, especially evaluating the contribution of the single elements of skin protection under daily working conditions, are needed. Furthermore, an educational concept can also reduce the burden of exposure to harmful substances. People being educated on skincare regimens might have a more careful behaviour than those not being trained. Therefore, not only the capability of bearing the exposure to skin-damaging working conditions, but also the reduced burden of exposure by an education plan, might play an important role in the field of skin protection.

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