The Influence of the Regular Use of a Soap or an Acidic Syndet Bar on Pre-acne

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Summary: The role of regular skin cleansing with soap or syndet in pre-acne is ill-defined. The intention of this study was to assess the relative value of an acidic syndet bar and a conventional soap bar in the prevention of acne lesions in acne-prone patients. In a randomized, open, comparative trial the three months' application of either an acidic syndet bar or a conventional soap to facial skin for 1 min each in the morning and in the evening was compared in 120 adolescents and young adults with inflammatory acne grade I or II according to the Plewig and Kligman classification. It was a confirmatory trial with the number of inflammatory lesions being the prime parameter of concern. In addition, non-inflammatory acne lesions were analyzed as were parameters of safety such as itching, redness and scaling. While the number of inflammatory acne lesions, i.e., papulopustules, did not differ in the two trial groups composed of 57 evaluable cases each, this was the case from 4 weeks of application onward: in the group using soap the mean number of inflammatory lesions increased from 14.6 (± 5.3) to 15.3 (± 6.0), while it decreased in the other group from 13.4 (± 5.2) to 10.4 (± 5.8) (p < 0.0001). Symptoms or signs of irritation were seen in 40.4% of individuals belonging to the former and 1.8% belonging to the latter group. The number of papulopustules characteristic of inflammatory acne thus is clearly lower when a syndet bar of the acidic type is regularly used for cleansing the face as compared to a (necessarily alkaline) soap. Hence, acidic cleansers should be preferred for skin care in adolescents and young adults if there is no reason for a different decision. Better tolerability might add further to an increased benefit-to-risk ratio. Whether acne patients who apply an anti-acne drug would also profit from cleansing the skin with an acidic syndet bar still needs further investigation.

Introduction
As a rule acne vulgaris turns up in the second decade of life or even somewhat earlier and resolves during the fourth at the latest [1,2]. Prevalence peaks at the age of 14–17 in female subjects and of 16–19 in males, the rate of affected individuals amounting to 40 and 35% respectively [1]. Acne vulgaris, in fact, is so common that the entity has been termed “physiologic.” The face is the main site of manifestation [3].

The face as well as the hands also form the prime sites of application of bar type skin cleansers may they be soaps or syndets [4]. The link of facial acne vulgaris and the use of facial skin cleansers might not be a mere coincidence. Routine washing whether it be performed with soaps or syndets has long been considered a relevant adjunct to acne care [5]. This, however, is not reflected in most recent monographs and textbooks. If discussed at all, it is rather an adverse effect which is related to regular skin cleansing [3,6,7]. Plewig and Kligman [7] in particular note that there is “no evidence that lack of washing worsens acne or that frequent cleansing is helpful.” They do not see any particular advantage or drawback of a cleanser due to its principal nature, i.e., whether it is a soap or a syndet. Finally, they also do not put any “emphasis on such aspects as pH, mildness, natural...” This discrepancy between the more practical and the more academic approach to the subject might reflect the obvious lack of well-documented and published comparative trials [5]. As according to a not previously published trial discussed in a review article a “mild detergent-containing product” is able to reduce inflammatory lesions on the face markedly both in boys and girls [5], there is a rationale for a valid comparative trial comparing the influence of a soap and a syndet on the inflammatory lesions linked to acne. It appears appropriate to address mild acne in particular. Overt scars can evolve from inflammatory lesions, i.e., more severe acne. Therefore it would seem unethical to study scientifically unproven treatment in patients in whom this sequela is of real concern. On the other hand, the status of acne vulgaris as a “physiologic disease” implies that there are many borderline cases in which pharmacotherapy is not clearly indicated although probably efficacious. It is these cases which would profit most of all from the regular use of an optimum cleanser.

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Unfortunately, classification of acne still is considered difficult. In fact, even the “consensus conference on acne classification” held in Washington in 1990 was not able or willing to define borderline acne. The paper published as a report rather concentrates on severe than mild forms of acne. Here we therefore report on a comparative trial with soap and acidic syndet bar in patients belonging to the two low grade groups in four of the patients suffering from papulopustular acne according to the classification by Plewig and Kligman.

Methods

Subjects: A total of 120 volunteers were to be enrolled. The inclusion criteria were as follows: two to 20 inflammatory lesions of acne vulgaris, i.e., papulopustules, on each side of the face; age between 14 and 24 years, written informed consent after detailed explanation of the study protocol, with adolescents, in addition, written informed consent of the person responsible. Exclusion criteria were also defined: known intolerance or hypersensitivity to soaps and syndets; diseases influencing acne; other treatment for acne whether physical or pharmaceutical, in particular drug treatment within the last month before enrolment; drugs potentially influencing acne, in particular systemic or topical antibiotics, with the exception of oral contraceptives; change of the contraceptive during the last 2 months, moreover the volunteers were not to be put on contraceptive at the first time at the beginning of the trial, nor was the type of contraceptive to be changed within the trial period proper; use of anabolic cleansers; cosmetic habits during the study envisaged. Predictable causes for non-compliance such as absence from home; inability to conform to the rules laid down in the trial protocol; addiction to ethanol or drugs, psychiatric disorders; participation in a clinical trial within the last 30 days or concurrent participation in a different clinical trial.

The study population could be enrolled in the period from June 1992 to June 1993. In both groups, three subjects were not followed after the initial visit. The reasons were: (1) a patient who was lost to follow-up; (2) two patients who were not able to maintain the study protocol; (3) one patient who had to be withdrawn due to adverse effects. In both groups, five patients were excluded from the analysis, leaving 57 individuals per treatment group.

Experimental design: This was a mono-centric, randomized, open, parallel-controlled trial in a dermatological office. After a 2-week period of no treatment whatsoever (“wash-out period”; treatment was to be performed over a 12-week period. Study preparations: Two skin cleansers were to be compared: “Sebamed compact” an acidic bar syndet (pH in solution: 5.5 to 5.6) composed of sodium cocoyl isethionate, disodium sulfo succinate, wheat starch, paraffin, stearyl acid, glyceryl stearate, cetyl palmitate, cetaneth alcohol, water, lecithin, tocopheryl acetate, perfume, lactis acid, PEG-14, disodium EDTA, hydrogenated coca-glucide (and) tocopherol, urea phosphate, glycine, aspartic acid, alanine, pyridoxine hydrochloride, lysine, leucine, C177891, C147085, C161570, and a bar soap, i.e., “Lux” soap.

Unfortunately, the composition of this soap is not known. Yet it is generally considered as representative for conventional soaps. Moreover, it is considered to be free of disinfectants as is the syndet used. Both cleansers were offered in their usual packages as provided by the original manufacturer, i.e., Sebapharma, Boppard, and Lever, Hamburg, Germany, as true blind is not feasible without changing properties relevant in the trial situation. Stability under trial conditions amounted to 30 months.

Treatment: During the wash-out period the face was only to be cleaned with tap water. During the following 12-week treatment period either Sebamed compact or Lux soap was to be used as follows: facial skin was to be washed in the morning and in the evening for 1 min, thereafter thoroughly rinsed with plain water and dried with a towel.

Randomization: As blinding is not feasible with the types of preparation tested, treatment was assigned to the volunteers by an institution outside the trial center according to a random plan in written form via telegram on an individual basis.

Parameters of analysis: The main target parameter was defined as the number of inflammatory lesions, i.e., papulopustules in the face. In addition, the number of non-inflammatory lesions, i.e., closed and open comedones, was recorded as well tolerability and adverse events. The number of inflammatory and non-inflammatory lesions in the face was recorded separately per side.

Time course of investigations: All volunteers were investigated on the day of enrolment (date 0), a fortnight later (date 1) and at 4-week intervals three times thereafter (dates 2 to 4).

Monitoring: The trial center was visited by a study monitor before initiation of the trial, 2, 5, and 8 months after start of the trial and at the end of the trial. All documents were checked for completeness and plausibility. If needed, queries were made which had to be answered by the doctors in charge of the volunteers in written form. All data were entered into a computer by two separate individuals and cross-checked.

Statistical analysis: Study populations — The study was performed according to the intent-to-treat principle, i.e., all volunteers were considered treated the way assigned to them according to the trial plan. If a volunteer defaulted before the end of the trial period the last documented data were used for evaluation (“last observation carried forward”). With respect to the main target parameter, all cases were finally evaluated and, in addition to the initial visit and the inspection before the beginning of the trial period proper, at least one more inspection was performed and documented.

Confirmatory analysis: With respect to the main target parameter, inflammatory skin lesions in the face, the main question was whether there would be a difference in the inflammatory lesions in the face after a 3-month application of the syndet cleanser. A two-sided zero-hypothesis was formulated as follows: the change of the number of inflammatory lesions in the face after a 3-month application of the syndet cleanser does not differ from the one after the corresponding application of soap. The alternative hypothesis was: the change of the number of inflammatory lesions in the face after a 3-month application of the syndet cleanser differs from the one in the control group using soap. In case of falsification of the zero-hypothesis by a significant result of testing, it was possible to conclude that treatments were different.

As differences between the treatment groups were expected to be significant at the end of the application period, the change of the main target parameter after 3 months (date 4) was compared in the first test. The data obtained after 2 and 1 months were analyzed in a second and third test. Following this order and stopping the procedure with a non-significant result of a single test, this procedure conforms to the multiple level of 5%, every single test being judged on a significance level of 5%. This procedure also was to define the point of time when a possible difference between both treatment modalities turned up. The test to be used was the U-test by Mann-Whitney (two-sided).

Descriptive analysis: The other data collected were interpreted in a descriptive manner. The similarity of the treatment groups with
Results

Study Population

There was no major difference between the 57 individuals in each of the study groups in terms of sex and age. Thirty-five individuals in the soap group were male and 32 in the synthetic cleanser group. The ages were $19.4 \pm 3.2$ and $20.6 \pm 3.4$ years respectively. The corresponding figures for height (cm) and weight (kg) were as follows: $171.1 \pm 9.7$ vs. $171.3 \pm 9.0$ and $66.6 \pm 9.7$ vs. $67.6 \pm 9.3$. Fifteen patients in the first group were pretreated and 16 in the other. Seven (8) volunteers had suffered from pre-acne for 0 to 6 months previously, 10 (12) for 7 to 12 months, 27 (16) for 13 months to 5 years, 13 (21) for more than 5 years.

No major difference in the number of inflammatory skin lesions in the face was detected before the start of treatment: in the soap group the figure was 14.6, in the syndet group 13.4 ($p = 0.351$).

Five volunteers belonging to the soap group discontinued application of the cleanser before the end of the trial period. In four this was due to exacerbation of acne. In the syndet group all volunteers applied the trial preparation for the entire trial period. Six volunteers in the soap group did not conform to the trial protocol in full, in particular pretreatment with a drug was sometimes not discontinued in time. Another volunteer should have been given soap according to the random plan, but he obtained the syndet. In the syndet group five volunteers did not comply in full. In both groups about one-third started with the trial proper after a reduced wash-out period. These patients, however, had no pretreatment aimed at acne.

Influence of Inflammatory Lesions

In the group using soap the number of inflammatory lesions increased from 14.6 ($\pm 5.3$) to 15.3 ($\pm 6.0$), while in the other group it decreased from 13.4 ($\pm 5.2$) to 10.4 ($\pm 5.8$). The difference in the number of inflammatory lesions as compared to the start was markedly different under treatment at every point of time investigated, i.e., at the latest from 4 weeks' application onward (date 4: $p < 0.0001$, date 3: $p < 0.0001$, date 2: $p = 0.003$). The development of the number of inflammatory lesions in both groups over time is depicted in Figure 1.

In the group using soap the number of non-inflammatory lesions increased from 6.7 ($\pm 5.3$) to 8.8 ($\pm 6.0$), while it decreased in the other group from 6.8 ($\pm 5.0$) to 6.0 ($\pm 5.0$).

Tolerability

Symptoms or signs of irritation turned up in 23 volunteers of the soap group as compared to one in the other group; the corresponding per cent rates were 40.4% vs. 1.8%.

![Figure 1: Number of inflammatory acne lesions in the face upon regular application of soap or acidic syndet over time.](image)

Table 1: Tolerability of soap and syndet according to itching, redness and scaling.

<table>
<thead>
<tr>
<th>Symptom or sign</th>
<th>Soap group</th>
<th>Syndet group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itching</td>
<td>12 (21.1%)</td>
<td>—</td>
</tr>
<tr>
<td>Redness</td>
<td>15 (26.3%)</td>
<td>1 (1.8%)</td>
</tr>
<tr>
<td>Scaling</td>
<td>12 (21.1%)</td>
<td>1 (1.8%)</td>
</tr>
</tbody>
</table>

Symptoms and signs in general were mild. Table 1 gives details with respect to itching, redness and scaling.

Discussion

Upon the regular use of an acidic syndet the number of inflammatory acne lesions in acne-prone patients is lower as compared to the regular use of a soap. This can be demonstrated as early as 4 weeks after start of the regular application of either skin cleanser and remains that way for at least another 2 months. As the observation period did not comprise more than 12 weeks, we can only speculate about the final degree of difference in inflammatory acne lesions upon extended regular application, i.e., for more than 3 months. Yet it is remarkable that the number of inflammatory lesions under the acidic syndet decreased steadily, which implies that the endpoint might not yet have been reached. Even at date 4, i.e., after 12 weeks' application of either preparation the number of inflammatory lesions in volunteers using the soap was higher by about 50% as compared to the number in the other group. Hence it appears justified to state that the difference observed is not only statistically significant but also relevant.

In fact, it seems advisable to use an acidic syndet when it comes to cleansing facial skin in individuals suffering from pre-acne. It might be argued that this term is ill-defined. Whatever the most appropriate scientific term may be, it is, however, remarkable that a cosmetic can influence mild acne as defined by grades one and two of severity of in-
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Inflammatory acne vulgaris according to Plewig and Kligman [9].

The present trial cannot finally answer the question if pre-acne should only be treated by a skin cleanser. Yet it clearly shows that the choice of the type of skin cleanser is crucial. Just by the choice of the skin cleanser according to the criterion of its influence on pre-acne, in the absence of other important criteria, an acne-prone individual can improve his clinical state to a remarkable extent.

Skin cleansers have also been recommended in the past as a “basic concomitant” to other therapeutic regimens such as topical drugs [5]. As in the present trial the skin cleansers were evaluated in the absence of an anti-acne drug of any type, we cannot answer the question as to a possible additional benefit for those individuals using a drug anyhow. This has to be determined in another combined trial.

Yet currently there is no reason to believe that the effect of an acidic syndet should not be at least as good as of soap under these circumstances.

Initially, it might be difficult to see a rationale for the superiority of the acidic syndet in pre-acne. At a second glance, however, the clinical results demonstrated here correspond well to previous findings concerning the influence of skin cleansers of different types on skin surface pH, and consecutively a major component of the human skin flora, the propionibacteria. It has been demonstrated that the skin surface pH is higher by about 0.3 units upon the regular application of soap as compared to an acidic syndet, which in other words means that three times as many protons are available upon the regular application of an acidic cleanser. It has also been demonstrated that the skin surface pH is closely linked to the number of propionibacteria but not staphylococci on the skin [10]. Further, it has been demonstrated that the substitution of an alkaline syndet for the alkaline soap in principle does not matter: again both pH and bacterial flora of the skin were influenced the same way [11]. Consequently, it is rather the pH of the cleanser which matters than its chemical composition. In this context it might have been of particular interest to know if the syndet used by Parrish also was acidic when he found a beneficial effect on moderate acne [5].

The hypothesis that the pH of the skin surface itself influenced by the cleanser used is relevant to the bacterial skin flora has also been confirmed by in vitro studies. In discontinuous culture the specific growth rate of Propionibacterium acnes is critically higher at pH 6.0 as compared to pH 5.5, while this is not the case with coagulase-negative staphylococci [12]. These findings were corroborated in continuous culture using a chemostat [13,14]. Although the presence of propionibacteria is considered important in the context of inflammatory acne lesions, it has not yet been possible to demonstrate a close link between absolute numbers of propionibacteria on the skin and the severity of inflammatory acne [15,16]. More important than the influence of the pH on the absolute number of propionibacteria might be the influence on the metabolic capacity of propionibacteria, especially in the sense of the liberation of active substances linked to inflammation [17,18].

In general, the benefit-to-risk ratio of a cosmetic is a critical issue as primarily the benefit to be expected is considered limited. Therefore it is of interest that the use of soap irritated facial skin in acne-prone individuals much more often than the use of an acidic Syndet. Although safety was not the prime parameter of this trial, this finding provides a good basis for another pertinent trial that should be able to prove the superiority of the acidic cleanser, not only in terms of efficacy but also in terms of safety, indicating a clear increase in the all-over benefit-to-risk ratio. The safety of the acidic syndet used here looks even more important, as in the recent literature the term detergent in the context of acne is almost exclusively used in connection with an unwanted effect. Mills and Kligman [19] have even introduced the term acne detergents. They, however, did not focus on the exact type of skin cleanser used.

In fact, it could be argued that the different irritation potential might influence follicular hydration via compromising the follicular permeability barrier and thus the density of propionibacteria [20]. To us, this possible explanation of the clinical findings looks less probable.

Strictly speaking, the clinical findings described here can only be attributed to the two particular cleansers used. Further trials will have to demonstrate finally if corresponding findings are related to the use of different types of acidic syndets and alkaline soaps. Taking the hypothesis concerning the mode of action for granted, however, it is tempting to speculate that general effects of the two different classes of skin cleansers have been demonstrated.

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Zusammenfassung: Einfluß der regelmäßigen Anwendung ei-
ner Seife oder eines sauren Syndetwaschstücks auf die Prä-
Akne. Über die Bedeutung einer regelmäßigen Hautreinigung
mit Seife oder Syndet bei Prä-Akne ist wenig bekannt. Es war
deshalb beabsichtigt, die relative Bedeutung eines sauren Synd-
etests bei einer konventionellen Seife für die Vorbeugung von
Akneerscheinungen bei Akne-empfindlichen Patienten auf-
zuziehen. In einer randomisierten offenen Vergleichsstudie
wurde die dreimonatige Anwendung von entweder einem sa-
ren Syndet-Waschstück oder einem konventionellen Seifen-
stück an der Gesichtshaut für eine Minute morgens und
abends verglichen bei jungen Erwachsenen mit entzündlicher
Akne vom Grad I oder II. Zufolge der Klassifikation von
Plet-
wig und Kligman. Im Rahmen des konfirmatorischen Ansatzes
wurde die Anzahl entzündlicher Erscheinungen als Haupt-
parameter festgelegt. Darüber hinaus wurden die Zahl der
nicht entzündlichen Akneerscheinungen als weiterer Parameter
untersucht, ebenso wie als Parameter der Verträglichkeit
Juckreiz, Rötung und Schuppend. Während die Zahl entzünd-
llicher Akneerscheinungen, d.h. von Papulopusteln, sich zu Be-
ginn in den beiden Behandlungsgruppen mit jeweils 57 aus-
wertbaren Individuen nicht unterschied, war dies vier Wochen
nach Behandlungsbeginn sowie später der Fall: In der Seife be-
nutzenden Gruppe stieg die Anzahl entzündlicher Erschein-
ungen von 14,6 (± 5,3) auf 15,3 (± 6,0), während sie in der an-
deren Gruppe von 13,4 (± 5,2) auf 10,4 (± 5,8) zurückging (p <
0,001). Subjektive oder objektive Symptome der Irritation
wurden bei 40,4% der Individuen in der ersten und 18,8% in
der letzten beobachtet. Die Zahl von für entzündliche Akne
charakteristischen Papulopusteln ist somit deutlich niedriger,
als ein Syndet vom sauren Typ regelmäßig zur Reinigung
der Gesichtshaut verwendet wird, verglichen mit der Anwen-
dung von (nichtwirkungsfähiger alkalischer) Seife. Von daher
sollen saure Hautreiniger zur Hautreinigung bevorzugt wer-
den bei Jugendlichen und jungen Erwachsenen, wenn es kei-
nen Gegengrund gibt. Eine bessere Verträglichkeit mag die
Nutzung/Risiko-Relation weiter verbessern. Ob Aknepatienten,
die ein arzneimittelähnliches Aknemedikament anwenden, auch
daus der Hautreinigung mit einem sauren Syndet Nutzen ziehen wür-
den, bedarf der weiteren Untersuchung.

References
