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Evaluation of antiperspirant preparations under normal conditions of use

M. W. STEED*

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Synopsis—A method of assessing the effectiveness of ANTIPERSPIRANT agents under normal or near normal conditions of use has been developed. SILICA GEL moisture absorbing tins strapped to the body side of the AXILLA are used for SWEAT collection, and the change in ratio of sweat produced between axillae for a subject, when only one axilla is treated, is taken as a measure of antiperspirant effect. The advantage of the ratio method is that it eliminates the need for controlled conditions.

Using three ALUMINIUM CHLORHYDRATE preparations, significant individual and group sweat reductions have been recorded.

It has also been observed that the individual response to these preparations varies considerably from one subject to another.

INTRODUCTION

The primary function of an antiperspirant preparation is to reduce the rate of perspiration flow in the axilla. Progress in developing effective antiperspirants is, however, limited by the lack of a reliable *in vivo* method of assessing their action under normal conditions of use. There has been much literature published on the measurement of perspiration flow, but many of the methods have practical drawbacks. Basically there are three

* Reckitt & Colman Toiletry Division.

types of published method, visual or colorimetric, continuous humidity assessment and gravimetric.

The basis of the colorimetric method is to apply an anhydrous indicator to the skin and to observe the extent of colour formation, when sweat is produced. A developer may also be used to produce the colour, which is usually in the form of individual dots, each dot corresponding to a sweat gland. The disadvantage of this type of method is that it is not readily quantitative, and that it is only applicable to flat, accessable areas of the body such as the back or fore-arm. Many workers have studied the colorimetric approach and Daley (1) has produced a quantitative method that has given good agreement with other methods. It did, however, require a large area of skin such as the back, and depended on a numerical count of dots, not taking into account their size or intensity.

The continuous humidity approach is almost the opposite to the gravimetric in that it is readily suited to axillary sweating measurement, and is fully quantitative. It depends on directly measuring the humidity of the air in a cell held in the axilla, and sophisticated adaptions produced by workers such as James (2) are capable of giving a direct print out on an x–y recorder of the sweating ratio between axillae. The objection to the method is that the subject is severely restricted in movement, and adaptation to normal conditions of use is not really feasible.

Most attention in recent years has been directed at gravimetric methods of assessing perspiration flow, as they are direct or absolute and reasonably convenient. Much of the early work in this field was conducted by Fredell and co-workers (3, 4). Their method was to use pre-weighed absorbent pads held in place in the axilla without a harness for a fixed period of time. The increase in weight of the pad was a measure of degree of perspiration. The daily variation of weight of sweat produced by individuals was found to be high, but the ratio of sweat produced from one axilla to the other for an individual was reasonably constant. If after a control period only one axilla was treated, the change in ratio was a measure of antiperspirant effect. It was necessary with this sweat collection technique, however, that the subjects were static, and a hot room to induce perspiration was required. This method is the basis of the procedure used by Hill Top Research Inc., and typical results obtained using this procedure have been published by Martin (5). The great advantage of using the change in ratio as a measure of antiperspirant effectiveness is that it is independent of the absolute weight of sweat collected, which can vary considerably even under fairly controlled conditions.

To adapt the gravimetric method to be suitable for assessing antiperspirant preparations under normal conditions of use, Wooding *et al.* (6) used silica gel drying tins of the type used in analytical balances. These were strapped to the backs of subjects and had the advantages of being easy to handle, reusable and efficient.

From consideration of the different types of procedure described above, it was clear that the gravimetric method was the most adaptable for assessment of antiperspirant effect under normal conditions of use, if the ratio technique was employed. As to the method of sweat collection, it was found, after experimentation, that the moisture absorbing tins of Wooding *et al.* could be strapped to the body side of the axilla with waterproof tape, without greatly inconveniencing the tester, and that they gave more reliable and accurate results than the various pad and cup arrangements tried. The experimental method described in this paper is, therefore, a gravimetric one, whereby silica gel moisture absorbing tins are used to collect axillary perspiration and the change in ratio of sweat production between axillae for an individual, when only one axilla is treated, is a measure of antiperspirant effect.

Test procedure

The particular moisture absorbing tins selected were Silica Gel Air Dryers*, size No. 2, 60 mm × 9 mm (*Fig. 1*). These are perforated disc-shaped containers of silica gel, which are capable of absorbing 8–9 g of moisture. They are supplied in aluminium outer containers. The rate of loss of moisture by evaporation, from a used tin, is negligible for a tin in its container left on the bench for half an hour. Thus, during the time that the tin is removed from the axilla, placed in its container and weighed, there is negligible evaporation of sweat. The waterproof tape used is a microporous, plastic, self-adhesive plaster, *Elastoplast Airstrip*†, which was supplied in rolls 1½ inch wide. The tins and containers were numbered, and were used randomly during a test.

At approximately 09.00 every working morning, the tins were weighed in their containers to the nearest milligram. Subjects were asked to dry their axillae with tissue paper, and the tins were removed from their

* Silica Gel Limited, London.

† T. J. Smith and Nephew Ltd, Hull and Welwyn Garden City.

containers and placed in position on the body side of the axilla, as close to the apex of the axilla as possible without causing discomfort. They were completely covered and held in position by three horizontal strips of plaster (*Fig. 2*). Three hours later the tins were removed, placed in their respective containers and re-weighed. The tins were dried in the afternoon in a vacuum oven at 80–90°C for about 2 h, when they returned virtually to their original weight each time.

Application of test materials was carried out by indivdual panelists at home. One arm of each subject was arbitrarily designated as the 'treatment arm' and the other as the 'untreated or control arm'. The ratio of the weight of sweat obtained from the treated arm to that obtained from the untreated arm, as explained above, was taken as a measure of the efficacy of the treatment and this had the advantage that such diverse factors, as air temperature, humidity and the activity of the subject, that affect the level of sweating, are automatically compensated for. In addition, the ratio is independent of the time for which the absorbing tins are in place, so any discrepancies in collecting time do not affect the results.

Mixed panels of approximately twelve subjects were used, and panel members were asked to shave the axillae a few days before the test. They were also requested to shave during the test when necessary. The panellists were asked to abstain from using an antiperspirant 2 weeks before the start of the test, and unperfumed soap was supplied for use during the test. The panellists were also supplied with a mild aerosol deodorant containing a very low level of cationic germicide, which they were allowed to use during control periods, if desired. The antiperspirant treatment was applied after washing in the morning and in the evening.

No attempt was made to control the quantity of application of the test product by the panellists, as:

(a) evaluation under normal conditions of usage was required;
(b) the surface area of one axilla to the next for different panellists varied very considerably;
(c) individual panellist accuracy in using aerosol products was very variable.

The experiment was divided into three phases; pre-treatment, during which neither arm received any treatment; treatment, during which the predesignated treatment arm received the specific treatment; and finally a post-treatment phase, during which no treatment was given. The inclusion of a post-treatment phase, was to observe the carry over effect of any of the

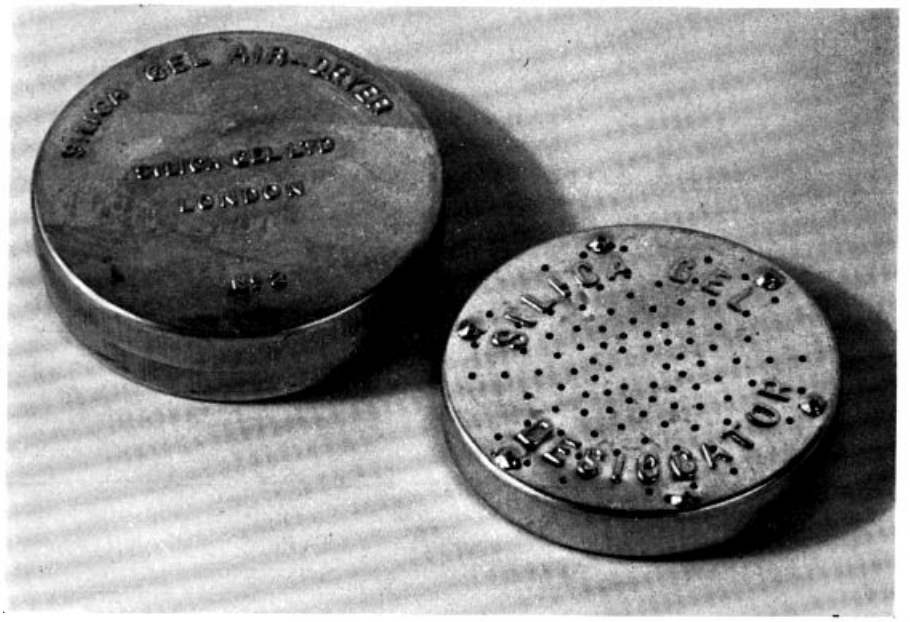

Figure 1. Moisture absorbing tin (Silica Gel Ltd).

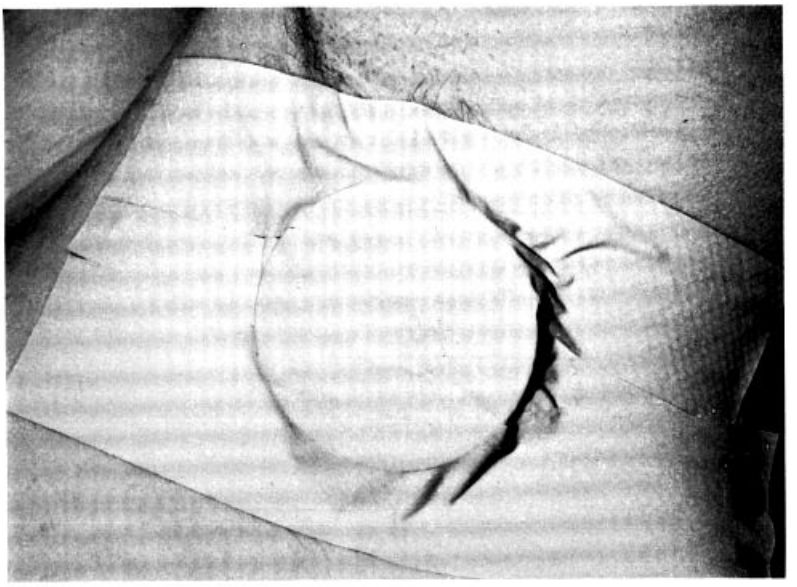

Figure 2. Moisture absorbing tin strapped to axilla.

(*Facing p. 20*)

treatments. (This effect was not quantitatively assessed owing to lack of post-treatment data.)

Test preparations

Although there are many potential antiperspirant agents available, aluminium chlorhydrate is the only one in widespread commercial use. It was decided, therefore, that at this stage only aluminium chlorhydrate would be evaluated, and its performance from different bases compared.

The following were the products tested.

Test 1

An aqueous solution containing by weight 25% aluminium chlorhydrate and 30% Industrial Methylated Spirit, which was thickened to an appropriate viscosity with hydroxyethyl cellulose. The product was dispensed from a bottle with a roll-ball applicator.

Test 2

An experimental aerosol preparation, where the concentrate was a W/O emulsion. The aqueous phase of the emulsion consisted of 50% aluminium chlorhydrate solution, and this was emulsified into light mineral oil. The phase ratio of the emulsion was 80 : 20 water/oil. The emulsion was dispersed in propellant 12/114 in an aerosol giving an overall concentration of 11.0% aluminium chlorhydrate and 5.5% mineral oil on can contents.

Unlike other aerosols the aluminium chlorhydrate in this product is deposited on the skin in aqueous solution.

Test 3

A leading brand of aerosol antiperspirant believed to contain 3.5% aluminium chlorhydrate powder, suspended in an emollient, and dispersed in aerosol propellant in conjunction with a silica suspending agent.

Statistical treatment of results

During the control period, ratios were calculated daily showing the relationship between the control arm output and the (untreated) treatment arm output. These ratios were then compared with the comparable daily ratios obtained when the designated arm was treated, in the treatment period. For each subject approximately 15 observations were obtained as control ratios and 10 as treatment ratios.

A standard (unpaired) *t*-test was used to compare the ratios (7). For each subject it was possible to state whether a statistically significant effect was observable at the conventional levels of significance (*P* 0.05, 0.01, 0.001).

For each subject a percentage inhibition was calculated, where

$$M = \frac{(P - T)}{P} \times 100$$

M = % inhibition;
P = mean pre-treatment ratio;
T = mean treatment ratio.

The calculations were conveniently carried out by using the logarithms of the perspiration outputs.

95% confidence intervals for M may be derived by the use of Fieller's Theorem (8). An acceptable approximation can also be obtained by applying the usual procedures for deriving confidence intervals after a *t*-test to the difference between the means of the logarithms of the two ratios.

Results

The tests were organized such that approximately 15 control readings (3 weeks) and ten treatment readings (2 weeks) were taken per person, and as far as was possible the same panellists were used on each test. The results (ratios) for each panellist were recorded on individual running charts, and a typical example of one is illustrated in *Fig. 3*.

The overall results for the three tests are given in *Tables I–III*. In these tables the individual panellists are referred to by code letters, A–Q, and pre-treatment and treatment ratio means, the significance of the change in

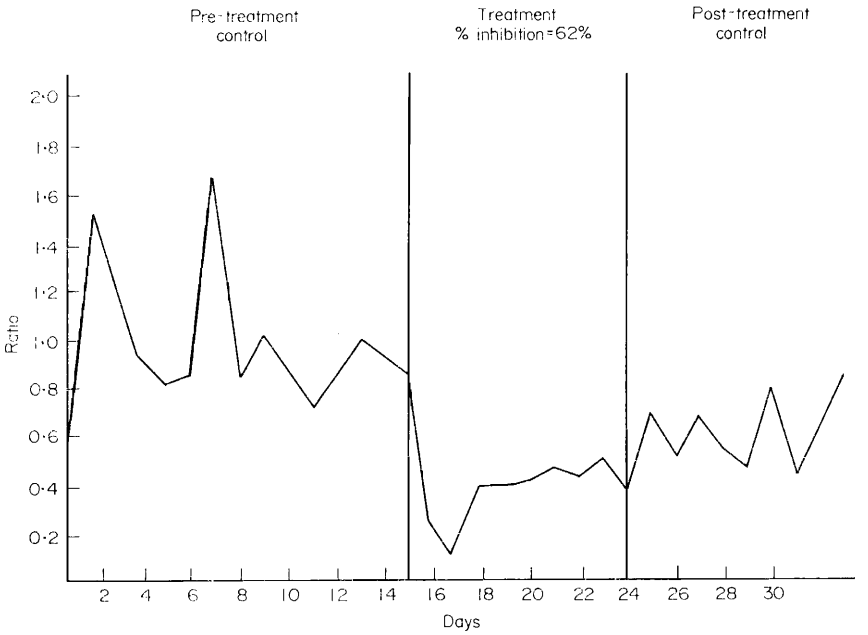

Figure 3. Subject A, Test 1.

ratio mean, the percentage inhibition in sweating caused by the treatment, and the 95% confidence of this figure are given. A combined, overall set of results is also given for each test.

The results, in general, confirm that aluminium chlorhydrate functions as an antiperspirant agent, but that the response from individuals is rather variable. Certain subjects such as panellists A, D and H show a consistently high degree of response, usually in the region of 40% or higher, whereas other panellists such as B, C and L, show only minimal response, often insignificant under the conditions of the test. This suggests that the overall results given for each test have only a very limited meaning, in that they predict an overall situation, but give very little indication of the likely response of an individual subject to a treatment. Such combined figures, therefore, should be used with caution. In this case, however, where the panels were basically similar and the pattern of response in each case was similar, it can be concluded that there was an order of response to the three preparations as follows:

$$\text{Treatment II} > \text{Treatment I} > \text{Treatment III}$$

Table I. Test 1

Subject	Sex	Ratio	Pre-treatment mean	Treatment mean	Change	% inhibition	95% confidence limits
A	M	R : L	0.97	0.37	× × ×	62	41 to 87
B	M	L : R	1.05	0.80	NS	23	−2 to 49
C	M	L : R	0.64	0.52	NS	18	−10 to 48
D	M	R : L	1.91	1.38	× ×	28	13 to 43
E	M	L : R	0.64	0.77	NS	−19	−108 to 69
F	F	R : L	1.56	1.79	NS	−14	−52 to 23
G	F	R : L	0.97	0.63	× × ×	35	20 to 52
H	F	L : R	1.16	0.61	× × ×	47	33 to 62
J	F	R : L	1.25	0.81	× × ×	35	26 to 45
K	F	L : R	1.03	0.66	× × ×	36	24 to 48
Overall			1.12	0.83	× × ×	26	13 to 39

× × × Significant reduction after treatment at 0.1% level.
× × Significant reduction after treatment at 1% level.
× Significant reduction after treatment at 5% level.
NS No significant difference.

Table II. Test 2

Subject	Sex	Ratio	Pre-treatment mean	Treatment mean	Change	% inhibition	95% confidence limits
A	M	R : L	1.16	0.66	× ×	44	15 to 75
B	M	L : R	1.18	0.93	NS	21	−6 to 51
C	M	L : R	0.88	0.65	NS	26	−15 to 73
D	M	R : L	1.81	0.97	× × ×	46	33 to 61
E	M	L : R	0.94	0.63	× × ×	34	20 to 49
F	F	R : L	1.74	0.67	× × ×	62	41 to 95
G	F	R : L	1.08	0.70	× × ×	35	17 to 55
H	F	L : R	1.16	0.64	× × ×	45	24 to 67
K	F	L : R	0.96	0.85	NS	11	−12 to 34
L	M	L : R	1.00	0.94	NS	6	−18 to 30
M	F	L : R	1.07	0.90	NS	16	−35 to 68
N	F	R : L	1.75	0.80	× × ×	54	29 to 82
Overall			1.22	0.78	× × ×	36	28 to 44

× × × Significant reduction after treatment at 0.1% level.
× × Significant reduction after treatment at 1% level.
× Significant reduction after treatment at 5% level.
NS No significant difference.

Table III. Test 3

Subject	Sex	Ratio	Pre-treatment mean	Treatment mean	Change	% inhibition	95% confidence limits
A	M	R : L	0.92	0.46	×××	50	34 to 68
B	M	L : R	1.13	0.87	××	23	9 to 38
D	M	R : L	1.65	1.00	×××	39	27 to 32
E	M	L : R	0.92	0.80	××	14	6 to 21
F	F	R : L	1.96	1.54	×	21	2 to 41
G	F	R : L	1.03	0.72	×××	30	15 to 46
H	F	L : R	1.13	0.84	××	26	11 to 42
K	F	L : R	0.92	0.75	×	18	2 to 35
L	M	L : R	0.93	1.14	NS	−23	−52 to 4
M	F	L : R	1.02	0.79	××	23	8 to 39
P	M	R : L	1.11	1.23	NS	−11	−34 to 10
Q	F	R : L	1.35	1.39	NS	−3	−24 to 18
Overall			1.17	0.96	×××	18	10 to 26

××× Significant reduction after treatment at 0.1% level.
×× Significant reduction after treatment at 1% level.
× Significant reduction after treatment at 5% level.
NS No significant difference.

It is likely that this order is a dosage effect, and that the effect of the vehicle is minimal.

The actual sweating rates for panellists were, as anticipated, very variable, but it was noted that certain panellists, noteably E and F, sweated consistently at a much greater rate, an average of 20–30 times greater, than many of the others. In a normal 3 h sweat collection period up to 5 g of sweat could be collected from one axilla in the case of these subjects, whereas some of the other panellists rarely gave more than 0.2 g. There was no indication that initial rate of sweating influenced the response to aluminium chlorhydrate treatment. It is also of interest to note that, whereas the majority of panellists have a ratio approaching unity, certain individuals, notably panellists D and F, sweat also twice as much on one arm as on the other. As there was only one left-handed panellist, whose ratio was close to unity, the effect of right- or left-handedness of an individual sweating ratio could not be assessed.

Conclusions

A test method has been developed whereby it has been possible to assess the effectiveness of antiperspirant preparations under normal or near normal conditions of use. Three preparations containing aluminium chlorhydrate have been tested on panels of 11–12 subjects who used the preparations twice daily, and significant (1 in 1000) overall sweat reductions were obtained of a magnitude varying from 18 to 36%. These results agree with other workers (6, 9).

The most important single result appears to be that the response of individuals to the various aluminium chlorhydrate preparations is very varied. Some subjects responded significantly with a reduction in sweating as high as 60%, and in the region of 40% for all three preparations, whereas others consistently gave nil or marginal results. It is, therefore, misleading to quote overall panel sweat reduction figures obtained under normal conditions of use, unless they are qualified by giving the range of individual responses, which in this case was from insignificant responses, usually within $\pm 20\%$, to very high significant responses in the region of 40–60%.

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