

Short Communication

Multicentre patch test studies: are they worth the effort?

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When are they needed?

Multicentre studies are required when 1 centre cannot collect enough patients to draw valid conclusions from a study. If a multicentre study is necessary, several problems arise. All participating centres need to adhere to the same protocol, or results become of dubious value, however large the total numbers. Inadequate and unclear communication between participating investigators is a common cause of variability (1). Further, few dermatologists participate wholeheartedly in a multicentre study unless they can influence the protocol, decide on trial conduct and analysis, and receive recognition.

Patch test clinics

Diagnostic patch testing is carried out in such centres several hundred times a year. The standard series and supplementary patch test materials are included, according to clinical picture, exposure history and occupation of the patient. This provides much patch test data that can be compiled and analyzed in various ways. Is it generally useful to gather data from a large number of clinics and present them in 1 publication? It may only be worthwhile if indications for patch testing, patch test performance, evaluation, and analysis is highly standardized.

The experience

The International Contact Dermatitis Research Group concluded in one of their 1st multicentre patch test studies that comparison of test results from different clinics was difficult (2). The patients tested in the participating clinics differed as to sex, duration and sites of dermatitis. The classification of dermatitis varied from clinic to clinic, suggesting differences in patient material as well as in organization of the various departments. Even the material within one clinic may be so different from one time to another that comparison between results is impossible unless several factors are considered (3).

Standardization and data handling

Standardization of the patch test technique is a prerequisite. The same patch test materials and the same

sources of allergens must be used in all centres during the study. Therefore, multicentre studies should preferably be done prospectively, when such matters can be arranged in advance. Further, most patch tests still use manually filled systems, allowing considerable variation in amount of allergen applied. Fischer & Maibach (4) found such variation to be at least 6-fold. In experimental situations, the variation in filling of Finn Chambers can be reduced to around 10% (5). Manufacturer-loaded systems, such as the TRUE Test™, permit purity, stability, bioavailability, and accurate dosing (6). However, they are available for only a limited number of allergens.

The patch test application time should be the same in all centres. Most use a 2-day application time but some use a 1-day application time, though prolonging exposure time seems to increase the rate of questionable or weak reactions (7, 8).

Reading of test reactions is another source of variation. Who performs the reading and when? Scoring may be left to experienced technicians or may be the responsibility of the doctors. There have been few studies of inter-observer variation. Experienced and highly dedicated contact dermatologists in Sweden recently compared their "blinded" recording of readings and found a concordance around 80% (9). Dermatologists use various reading scales, which may also introduce variation.

Difference in reading time may also cause variation between centres. Some read only once after 3 days. A minimum of 2 readings is strongly recommended and readings on days 4 and 7 may be more reliable than those on days 2 and 4 (10). The relevance of a reaction is the most difficult part of the patch test procedure (11). There is no generally accepted definition of the 'relevance' of a reaction, and its evaluation is made differently by different investigators, depending on their experience, knowledge and curiosity. Lachapelle (12) recently suggested a scoring system based on ranked grades of current and past relevance.

The last point is the composition of the patient material. This differs considerably from clinic to clinic, even within the same geographical area, due to special industries in a certain area, variation in referral patterns, indications for patch testing, etc. One way to

make comparisons between clinics more valid is the so-called MOAHL index (13), which gives the frequency of male patients, occupational contact dermatitis, atopic dermatitis, hand eczema and leg ulcers at each centre. The MOAHL index should be used more in multicentre patch test studies and allows for stratification of the material and multivariate statistical analysis (14, 15).

Following all these considerations, the answer to the question remains: it depends

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