SL07 Phytoequivalence of botanical derivatives: new perspectives

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The possibility to standardize extracts is nowadays a feasible task due to the combination of strict conditions of plants cultivation and/or harvesting (GAP) and rigorous industrial procedures for the extraction until the final product (GMP).

By using this approach it is now possible to prepare very well characterized and reproducible extracts that can be submitted to rigorous preclinical and clinical investigations according to pharmaceutical guidelines of western countries. In several countries, such as USA, UK, Canada, Italy and others, standardized extracts are also commercialized in non-pharmaceutical channels and they are commonly considered "dietary supplements" or "nutraceuticals".

Differently from the pharmaceutical market, where proprietary rights are considered a pivotal aspects and consequently protected by specific rules, in these parallel fields, the correspondence between the documentation and the composition of the products on the shelf is not a strict issue. This aspect is crucial causing a double damage respectively to the consumers which are not guaranteed for safety and efficacy and to the producers of standardized and well-documented products which have serious disadvantages in term of protection.

In this perspective, the problem of "phytoequivalence" is becoming more and more a strategic issue. Nowadays, the utilization of sophisticated analytical techniques allows to recognize differences in composition of extracts not only related to specific components but also to the unknown part.

The combination of specific HPLC analysis with semiquantitative ^{1}H- and/or ^{13}C-NMR or NIR (Near Infra Red) Spectroscopy represents a good approach to answer to the problem of phytoequivalence.

According to this combination of techniques, several products have been compared for their equivalence; in the specific instances of *Ginkgo biloba, Hypericum perforatum* and grape seeds standardized extracts prepared by different producers, it was possible to verify striking differences in term of composition profiles.

SL08 Transaminase and alkaline phosphatase activity in the serum of burn patients treated with highly purified tannic acid

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The use of tannic acid in the treatment of burns has a long and successful history (1). In the early nineties, preliminary experimental and clinical studies confirmed these positive reports from the past and indicated that highly purified tannic acid (HPTA) might be of interest as a valuable additional therapeutic regimen to improve long-term wound-healing characterisitics after thermal injury (2,3). However, prior to introduction of HPTA on a broader scale, previous publications on alleged hepatotoxic effects (1) must be negated. This necessitates further establishment of the effects of HPTA on the liver, as well as to prove its general non-toxicity. As a first step in such a safety evaluation, we report here on the results of a retrospective study into the serum transaminase and alkaline phosphatase activity of burn patients already treated with HPTA (3). Temporary elevations in the activity of gamma-glutamyl transferase, aspartate aminotransferase, alanine aminotransferase and alkaline phosphatase were observed in both HPTA-treated patients and their matched controls. No statistically significant difference (Student's *t*-test and multiple linear regression) was found between the two patient groups with respect to the mean enzyme activities, calculated as the areas under the curve between five and 15 days post-burn. These results seem to indicate that HPTA is not hepatotoxic, at least when applied to a burned area corresponding to approximately ten percent of the total body surface. This is in agreement with the widespread and frequent use of HPTA in the food, cosmetic and pharmaceutical industries.

Acknowledgement: The work described here is financially supported by Stichting Achmea Slachtoffer en Samenleving, Zeist, The Netherlands. Dr. M. Rubens is acknowledged for interpretation and discussion of the clinical chemical data. Dr. H. J. A. Wijnne is thanked for his helpful suggestions and assistance with the statistical analysis.

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