

nificant difference among groups was found (data not shown).

We also included some questions intended to evaluate the potential occurrence of treatment-dependent clinical anomalies regarding hormonal, physiological or metabolic disorders. We found no significant difference after final vs. initial records' comparison (data not shown).

7. No detectable β -hCG plasmatic levels in all tested groups.

On treatment days 0, 15 and 30 we have tested all volunteers, screening for the presence of plasmatic p-hCG. Concentrations were undetectable in all cases (data not shown).

Discussion

Concerning hCG and its utility for the management of obesity, this study introduces two new aspects, and adds new data for a third:

- I. This is the first report assessing variables not included in previous reports;^{38,51,68,89}
- II. We report a new administration route for hCG management of obesity, the oral approach, which has never been reported before;
- III. We have detected mood changes in hCG treated patients, regarding a better confrontation of daily emotionally conflicting situations.

I) Skinfold thickness (SKF) and Tetrapolar Bioelectric Impedance (TBI) records.

Both approaches have been extensively discussed in the literature. It was shown that the correlation between the values obtained with the two methods to be linear and highly significant for both sexes.^{42,81,27}

There is general agreement that skinfolds calipers are particularly useful in the clinical setting,^{56,82,16,76,10,65,9,15,75} particularly in view of the fact that measurement of subcutaneous body fat at different body sites is becoming increasingly important for the characterization of risk of certain disease states.⁵⁵

When comparing skinfold assessments to body circumference estimates, some data suggests that the latter approach appears to be more sensitive in the determination of subcutaneous body fat,⁵³ this procedure is in our opinion subjected to clinical variables (bloating syndrome after a meal, premenstrual water retention, etc.) that may affect negatively on the final estimate's re-

sults. Also, when comparing SKF to body contour assessments, some data suggest that the pattern of fat thickness body distribution measured over several specific sites by one method of measurement is unlikely to be duplicated by of the other method on the same individual.^{40,41}

Adipose tissue patterns show great variability, showing the importance of using skinfold caliper readings from a variety of different anatomic sites including upper limbs, lower limbs and trunk.^{30,65}

According to the above conclusions from several authors,^{72,13,60,25,73,62} we would like to suggest that former studies on hCG and obesity lacked of sufficient data to estimate accurately the modifications of adipose tissue distribution in tested volunteers. Consequently we designed the study to assess as many variables as possible .

As far as our study concerns, we subjected each volunteer enrolled in the trial to four bioelectrical impedance, eight anthropometrical plus nine SKF evaluations. Performing this multiple site determinations, our results show that specific SKF are highly responsive to hCG pharmacological intervention (upper and lower umbilical). The greater response was obtained in those regions where the corresponding circumference assessments resulted in nearly significant or significant decreases through the trial period (see waist and abdomen records in Fig. 2 and the above detailed description of statistical results for the effect of the interaction).

II) Oral hCG is an valuable alternative administration route.

No data appear on the scientific literature regarding an oral administration of hCG in humans. But results from this study suggests hCG may be used by the sublingual-enteral route. Despite plasmatic, β -hCG remained undetectable both in Placebo and hCG groups throughout the study, an oral administration of hCG proved to possess therapeutic activity.

Since commercial preparations of hCG contains β -endorphin, it may be tempting to hypothesize that this pentapeptide might account for the pharmacological activity observed on mood stability during the Protocol.

III) Volunteers treated with hCG coped better with daily irritating situations.

As can be seen on Figure 5, hCG-treated groups
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