

PROJECT REVIEW

“The detection of the misuse of testosterone gel.”

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According to the WADA-list of prohibited substances, the use of testosterone is prohibited in sports. In 2000 a new testosterone preparation, a testosterone gel, was approved by the Food and Drug Administration of the USA for the testosterone replacement therapy in men for conditions associated with low testosterone. Since 2003 testosterone gel is also admitted to the European market. Several investigations have shown, that the application of testosterone gel leads to performance enhancing physiological effects like significant increase of the lean body mass, muscle strength and hemoglobin concentration.

First studies with urine samples from patients, who were treated several weeks with testosterone gel have shown, that with the present methods for the detection of testosterone doping it is difficult or even not possible to prove the transdermal use of testosterone gel. These methods are the evaluation of the testosterone/epitestosterone ratio followed by longitudinal or endocrinological studies or Carbon Isotope Ratio Mass Spectrometry.

The aim of the study is to develop a method to prove the misuse of testosterone gel i.e the search for a parameter or several parameters with the strongest discriminative power. These parameters are steroid profile parameters, pituitary gland hormones carbon isotope ratios and hydrogen isotope ratios of steroids or combinations of these parameters.

Preliminary results have shown that multivariate analysis combining carbon isotope and hydrogen isotope ratios and steroid profile parameters deliver promising results. For the investigation urine samples of male patients treated with testosterone gel will be used.

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Results and Conclusions

The aim of the study was to develop a method for the detection of the misuse of testosterone gel (T-gel) i.e the search for one or more parameters with the strongest discriminating power.

Therefore 18 healthy male volunteers were treated for six weeks continuously and intermittently with T-gel. Blood and urine samples were collected before, during and after the application of T-gel. The following results were obtained. The treatment with T-gel leads to an increase of serum testosterone and a decrease of LH. The most discriminating parameters of the urinary steroid profile for the detection of the misuse of T-gel are the ratios testosterone/epitestosterone, 5 α -androstane-3 α ,17 β -diol/epitestosterone and androsterone/epitestosterone. Individual reference ranges of the parameters have a much stronger discriminating power for the detection of the misuse of T-gel than population-based reference ranges. For the GC/C/IRMS analysis, most suitable target compounds for the detection of T-gel misuse are testosterone and 5 α -androstane-3 α ,17 β -diol. Therefore a comprehensive GC/C/IRMS for several testosterone metabolites has been developed and validated. Additionally reference limits for all relevant steroidal Δ - values (differences between the $\delta^{13}\text{C}$ values of target compounds (testosterone metabolites) and endogenous reference compounds) have been established.

Based on these reference limits and on the improved methods, GC/C/IRMS analyses allow the detection of T-gel use. It can be concluded that the misuse of T-gel in sports can be detected via deviations from individual reference ranges of urinary steroid profile parameters and via GC/C/IRMS.