EFFECT OF THE SWITCH FROM CONVENTIONAL GLUCOCORTICOIDS TO "DUAL RELEASE HYDROCORTISONE" IN ADULT PATIENTS WITH PRIMARY AND SECONDARY ADRENAL INSUFFICIENCY: A SIX-MONTHS MULTICENTER STUDY

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Background:

Adrenal Insufficiency (AI) requires life-long glucocorticoid (GC) treatment, which is associated with an increased risk of metabolic syndrome (MS), probably due to cortisol overexposure for multiple drug daily doses, together with an impairment of quality of life (QoL). Moreover, treatment compliance (TC) is reported to be suboptimal in AI patients.

Patients:

Thirty-five patients, treated with Cortisone Acetate (CA) or immediate-release hydrocortisone (HC), entered the study and were evaluated before and 6 months after the switch to DR-HC (Tab. 1)

TABLE 1 PATIENT CHARACTERISTICS		
CHARACTERISTICS	PAI	SAI
N° pts	12	23
F/M	7/5	9/14
Age (ys)	33~60	20~77
N° pts in CA CA Dose (mg/day)	8 37.5~75	15 18.75~37.5
N° pts in HC HC Dose (mg/day)	4 20~30	8 15-20
DR-HC Dose (mg/day)	20~60	20~40

Aim:

The current study aimed at investigating the impact of the switch from twice/thrice daily conventional GCs to once daily dual-release hydrocortisone (DR-HC) treatment on metabolic profile, QoL and TC in patients with primary AI (PAI) and secondary AI (SAI).

Methods:

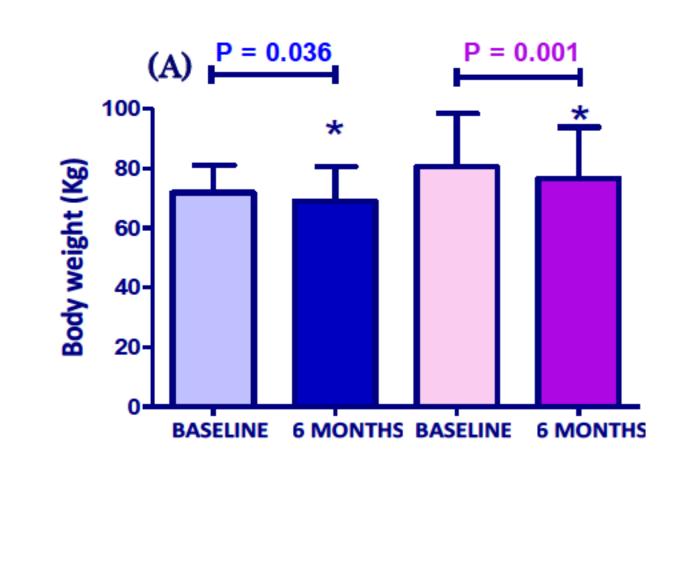
- Metabolic parameters were measured using routine assays. MS was defined according with IDF criteria, whereas Visceral adiposity index (VAI) was measured according to Amato et al.¹
- > QoL was evaluated using AddiQoL Questionnaire²
- > TC using Morisky 8-items medication Adherence Questionnaire³

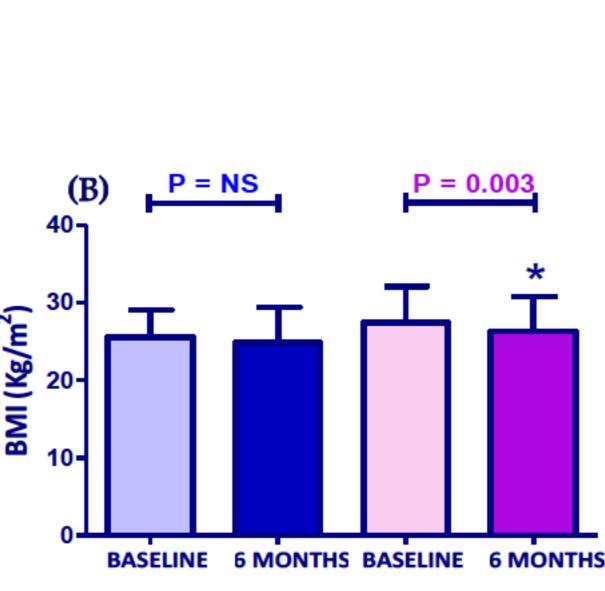
Results: Metabolic profile

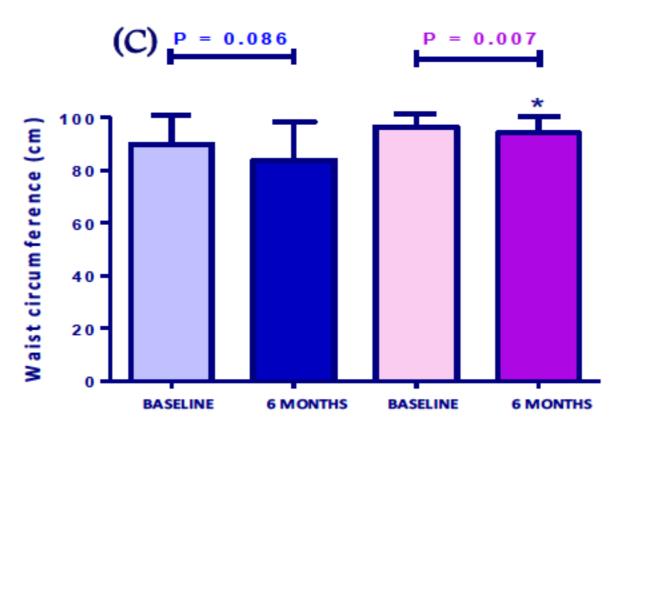
At 6-month-follow-up, different metabolic parameters improved: in particular body weight (BW) (PAI: p=0.036; SAI: p=0.001) (Fig.1A), BMI (PAI: p=NS; SAI: p=0.003) (Fig.1B) and waist circumference (WC) (PAI: p=0.086; SAI: p=0.007) (Fig.1C).

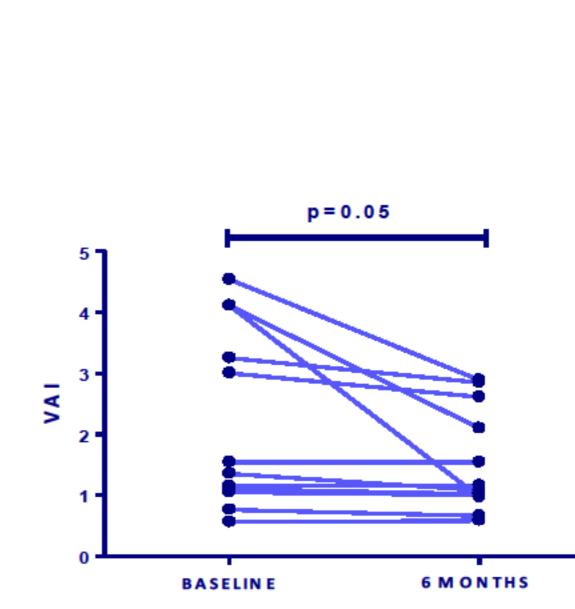
A clear diagnosis of MS, performed in 2 PAI patients (17%) at baseline, was not confirmed after 6 months. Similarly, a diagnosis of MS performed in 7 SAI patients (30%) at baseline, was confirmed only in 4 patients (17%) after 6 months.

In a subgroup of 12 pts, a significant improvement was observed in VAI (p=0.05) (Fig.2), an indicator of adipose function and distribution, which seems to indirectly express the cardiometabolic risk, and in insulin Sensitivity Index (ISI 120) (p=0.05) (Fig.3).









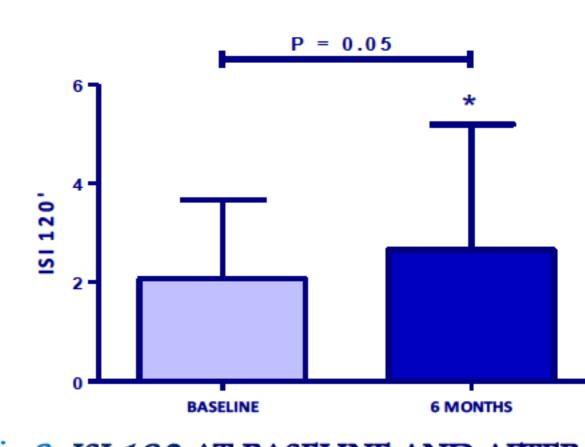


Fig.3 ISI 120 AT BASELINE AND AFTER 6 MONTHS OF DR-HC

Fig. 1 BODY WEIGHT (A), BMI (B) AND WAIST CIRCUMFERENCE (C) IN PAI AND SAI PATIENTS

Fig.2 VAI AT BASELINE AND AFTER 6 MONTHS OF DR~HC

Results: Quality of life and compliance

In a subgroup of 10 pts considered for the evaluation of QoL working ability ameliorated in 6 pts (60%), vitality in 5 pts (50%), general health perception and depression in 3 pts (30%), body pain perception in 2 pts (20 %).

In a subgroup of 10 pts considered for the evaluation of TC, 9 (90%) improved TC (Fig.4).

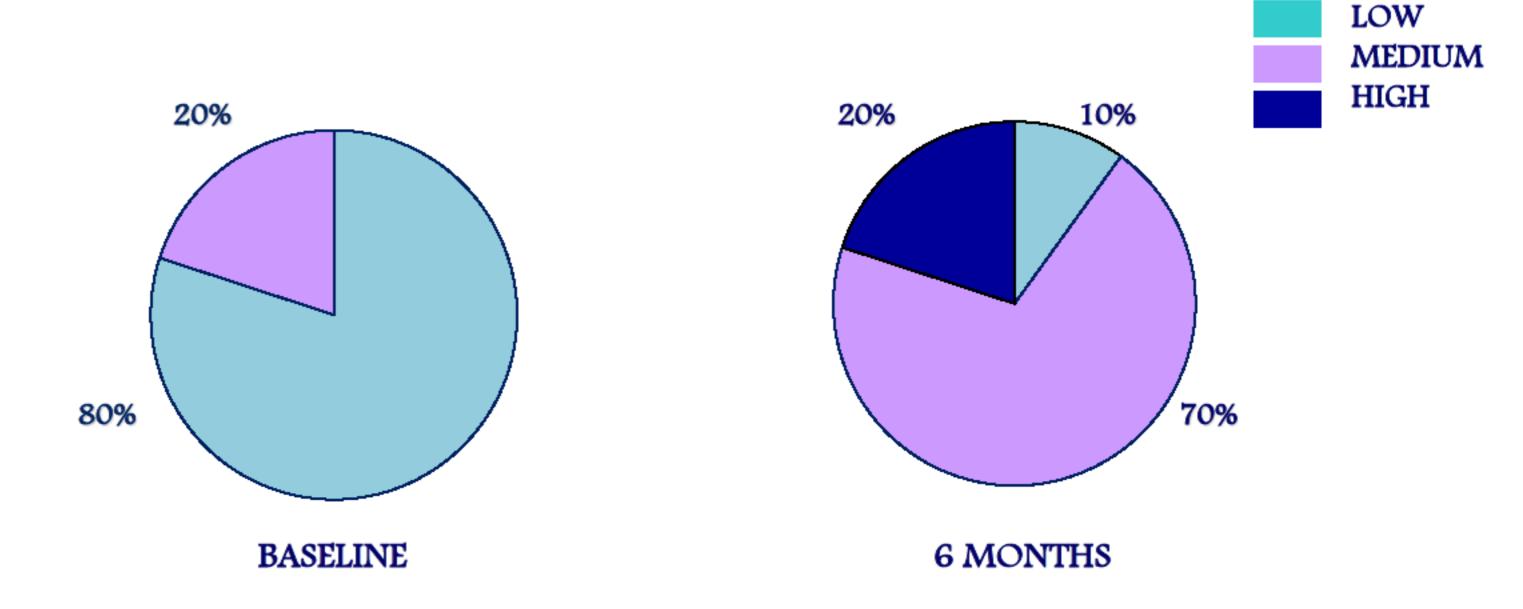


Fig.4 TREATMENT COMPLIANCE AT BASELINE AND AFTER DR~HC

Conclusions:

The switch from conventional GCs to once daily DR-HC in patients with primary and secondary adrenal insufficiency improved metabolic parameters, particularly body weight, body mass index, waist circumference, prevalence of metabolic syndrome, glucose tolerance and insulin sensitivity, together with quality of life and treatment compliance.

References:

- 1. Amato MC. et al. Visceral Adiposity Index: a reliable indicator of visceral fat function associated with cardiometabolic risk. Diabetes Care. 2010; 33(4):920-2;
- 2. Øksnes M. et al. Quality of life in European patients with Addison's disease: validity of the disease-specific questionnaire AddiQol. JCEM 2012; 97(2):568-76;
- 3. Morisky DE. et al. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care 1986; 24: 67-74.



