Short-term effects of thyroid hormone therapy on quality-of-life (QoL) evaluation by ThyPRO inventory in chronic autoimmune thyroiditis

Marilena Sidoti (1), Massimo Giusti (1, 2)
Centro Diagnostico "Priamar", Savona (1) and
Dipartimento di Medicina Interna (2), Università di Genova, Genoa, Italy

INTRODUCTION

ThyPRO is a new 13-scale questionnaire validated for QoL assessment in thyroid diseases. In chronic autoimmune thyroiditis, increased anti-thyroperoxidase antibody (TPOAb) levels have been found to be associated with impaired QoL. The aim of the study was to evaluate QoL by means of ThyPRO in women with positive TPOAb levels arriving at an independent medical centre for their first endocrinological examination

Table 1 some clinical data of subjects divivided in the 3 groups

			Gr 1 Observation	Gr 2 L-T4	Gr 3 L-T4+T3	Significance p
Subjects	number		21	21	20	NS
Age	years	mean± SD	46.5 ±12.0	46.4 ±12.8	46.6 ±11.2	NS
Obesity	%		19	14	10	NS
Hypertension	%		19	19	10	NS
Symptoms	%		48	71	75	NS
Thyroid volume	ml	mean ± SEM	10.9 ± 1.1	11.4 ± 1.4	13.8 ± 2.0	NS
f-T3	pg/ml	mean ± SEM	2.7 ± 0.1	2.9 ± 0.1	2.9 ± 0.1	NS
f-T4	pg/ml	mean ± SEM	9.4 ± 0.5	10.3 ± 0.6	10.2 ± 0.5	NS
TSH	mU/l	mean± SEM	5.6 ± 0.5	6.6 ± 0.6	6.5 ± 0.8	NS
TPOAb	mU/l	mean± SEM	1268 ± 322	1321 ± 472	1119 ± 199	NS

RESULTS

No differences among groups were noted with regard to age and clinical and laboratory parameters (Tab 1). At the baseline, sub-clinical hypothyroidism (TSH over 4.2 mIU/l) was found in 62%, 81% and 80% in Gr 1, Gr 2 and Gr 3 women, respectively (χ^2 test p=0.4, NS). No differences in overall symptoms or drug load were noted at the baseline among groups, but asthenia was more frequent in Gr 3 (45%) than in Gr 1 (24%) and Gr 2 (9%) (p=0.03). No difference in the incidence of psychological symptoms (Gr 1: 19%, Gr 2: 33%, Gr 3: 40%; p=0.3) or therapies (Gr 1-3: 1-2%) was found (Fig 1). The study was completed by 71%, 57% and 60% of Gr 1, Gr 2 and Gr 3 women, respectively (Tab 2). No difference was found in the groups in the causes of drop out. At the baseline, no difference in ThyPRO scores emerged among the groups on ANOVA. Among clinical data, only systolic BP was significantly (p=0.02) related to the mean ThyPRO score. As expected, a significant decrease in TSH levels was noted in the treated groups (Gr 2 p=0.001; Gr 3 p=0.01) (Fig 2). QoL improved in all groups between the baseline and the last examination. However, the decrease in mean ThyPRO scores (i.e. fewer symptoms or lower impact of disease) was only slightly significant in Gr 1 (18.1 ± 1.8 vs 15.7 ± 2.2; p=0.02), while it was highly significant (p=0.0005) in Gr 2 (30.1 ± 4.9 vs 20.3 ± 3.9) and Gr 3 (26.1 ± 3.5 vs. 16.7 ± 2.6). Significant improvement was observed in the Group 1 for the anxiety (p=0.001) and depressivity (p=0.01) scales; in the Group 2 for the goitre symptoms (p=0.01),   hypothyroid symptoms (p= 0.04), eye symptoms (p=0.01), anxiety (p=0.01), depressivity (p=0.03)and emotional susceptibility (p=0.02) scales ; in the Group 3 for the hypothyroid symptoms (p=0.02), hyperthyroid symptoms (p=0.03), tiredness (p=0.03) cognitive complaints (p=0.04) anxiety (p=0.04), depressivity (p=0.01) imparied social life(p=0.03) and cosmetic complaiants (p=0.03) (Fig 3). At the last examination, a significant difference was found in % of symptomatic patients among the groups (Gr 1: 33%, Gr 2: 42%, Gr 3: 83%; p=0.02) (Tab 3). At the baseline, the scale "Tiredness" displayed the lowest scores in all groups; at the last examination, an improvement was noted, but this was significant only in Gr 3 (p=0.03).

Metods an materials

From January to December 2011, 62 women were invited to participate in the study. Inclusion criteria were: age over 18 years, TPOAb levels >100 mIU/l, no previous therapy for thyroid diseases, no current wish to become pregnant and availability of an E-mail address to return the ThyPRO inventories and communicate further data and any new medical problems. After giving oral consent, women were randomized to observation (Gr 1 n=21), L-T4 therapy (Gr 2 n=21; 50 μg/day) or L-T4 plus triiodothyronine (Gr 3 n=20; 37 μg plus 10.7 μg/day). Clinical parameters [BMI, blood pressure (BP), thyroid volume (TV) by sonography, subjective symptoms and current therapies] and laboratory parameters (f-T3, f-T4, TSH, TPOAb) were recorded at the baseline and after 6 months. One month after randomization, thyroid hormones were checked. Women were asked to compile and send in ThyPRO questionnaires at the baseline and 1 and 6 months after randomization.

Table 2 Causes of drop out from the protocol

	GROUP 1	GROUP 2	GROUP 3
Data Lost	1	1	0
Invalid E-mail	1	1	0
Informed consent withdrawal	2	3	3
Lost at follow-up	2	2	3
Drug change	-	1	2
Percentage of drop-out	29%	43%	40%

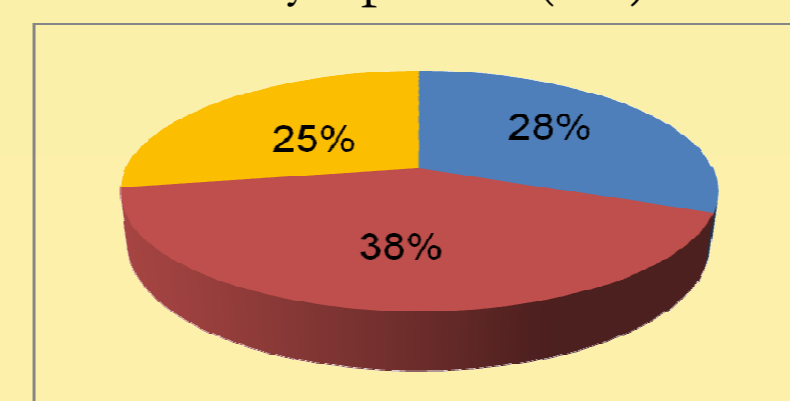Table 3 Patients without or with reported symptoms at the last examination

	GROUP 1	GROUP 2	GROUP 3
Without symptoms	10	7	2
With symptoms (%)	5 (33%)	5 (42%)	10 (83%)
Psycological	1	2	0
Asthenia	1	1	0
Others somatic (*)	3	2	10

(*) palpitation, headache, arthalgias, cramps, myalgias and neck discomfort

Gr 1 ■ Gr 2 ■ Gr 3 ■

Psychological symptoms (NS)
19% 33% 40%
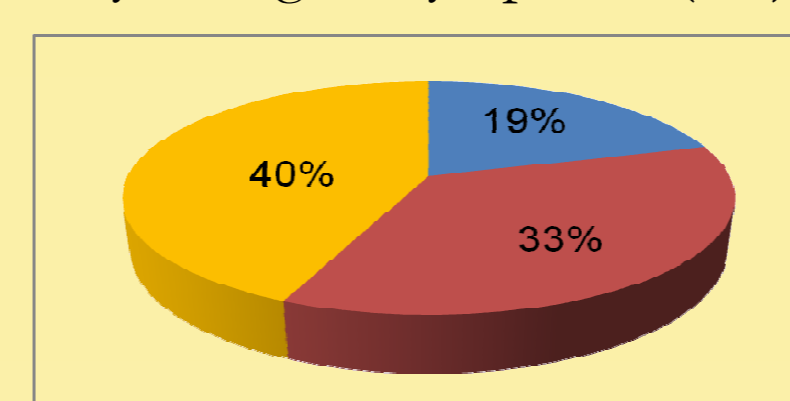
Somatic symptoms (NS)
28% 38% 25%

Asthenia (p=0.03)
24% 9% 45%

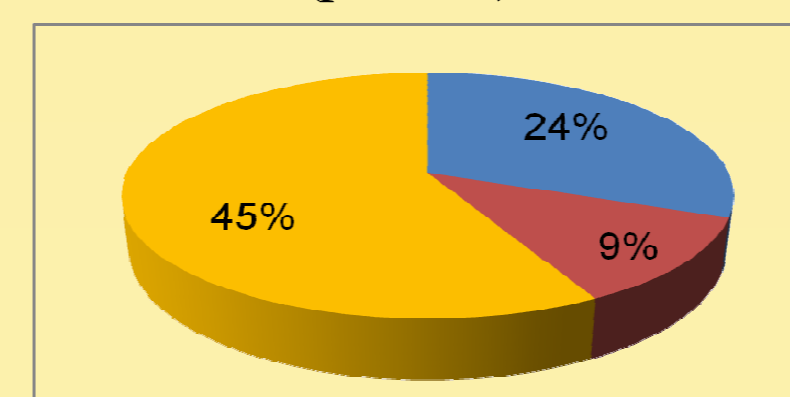Fig 1
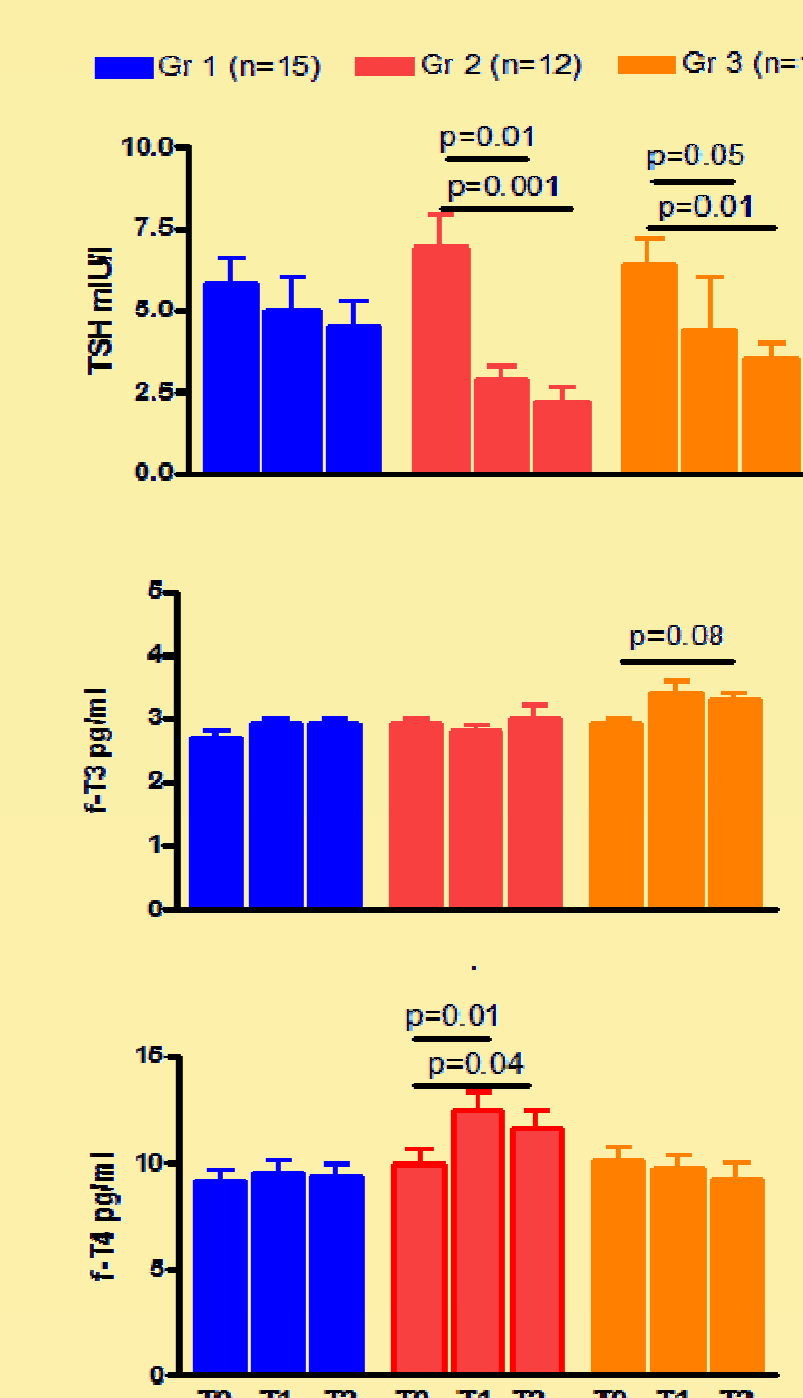Differences in some symptoms at the baseline among groups

Fig 2

Behaviour of TSH and free-thyroid hormone (mean ± standard error of mean) in control group (group 1) patients and patients under L-T4 (group 2) or L-T4 + T3 (group 3) therapy who completed the study protocol.
The baseline (T1) and month 1 (T1) and month 6 (T2) data are reported. No significant differences at baseline among groups are observed by ANOVA. Significance from baseline in each group by Wilcoxon test is reported.
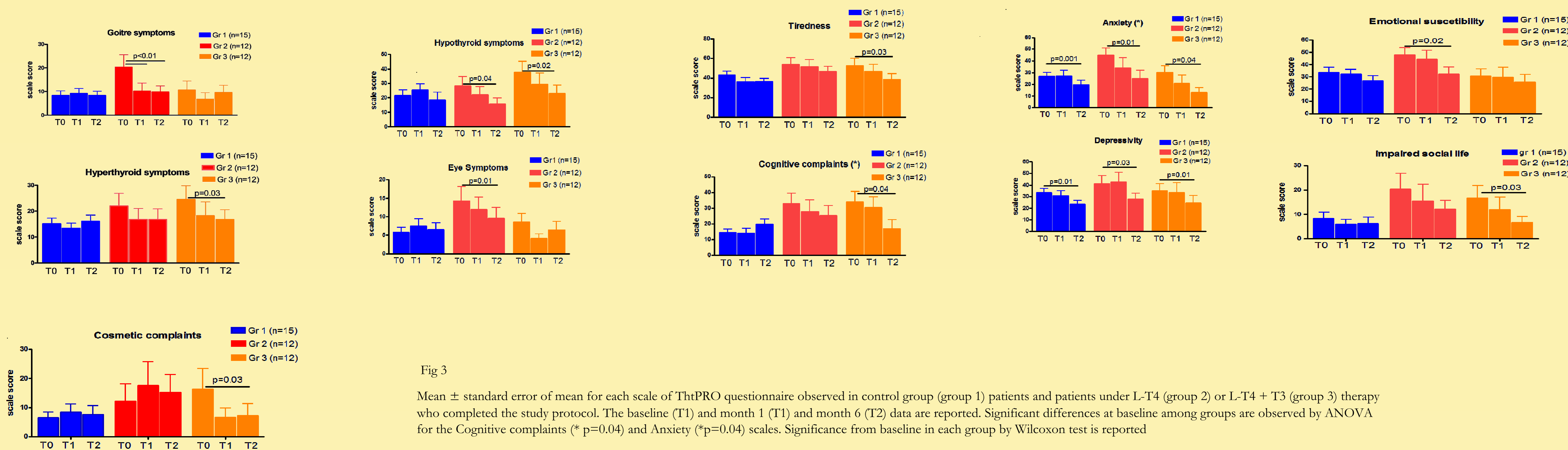

Fig 3
Mean ± standard error of mean for each scale of ThtPRO questionnaire observed in control group (group 1) patients and patients under L-T4 (group 2) or L-T4 + T3 (group 3) therapy who completed the study protocol. The baseline (T1) and month 1 (T1) and month 6 (T2) data are reported. Significant differences at baseline among groups are observed by ANOVA for the Cognitive complaints (* p=0.04) and Anxiety (*p=0.04) scales. Significance from baseline in each group by Wilcoxon test is reported

CONCLUSIONS

Although further studies in larger populations are needed, our data do not confirm a correlation between QoL and TPOAb levels in autoimmune thyroiditis. However, a significant improvement in QoL was seen during therapy; this was more significant under thyroid hormone supplementation. This   is more evident for L-T4 plus triiodothyronine but with slight adverse effects observed.The differences between L-T4 therapy and L-T4 plus triiodothyronine therapy proved slight.