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**A SURVEY ON LIFESTYLE AND AWARENESS OF THE USE OF STATINS
IN A SAMPLE OF CARDIOPATHIC PATIENTS**

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Abstract

Background: Current guidelines highlight the importance of lifestyle modification (i.e. improving diet and physical activity) in the treatment of hypercholesterolemia, in addition to lipid-lowering drugs. However, patients taking statins do not always follow physician's prescriptions on lifestyle change. No studies investigated the psychological aspects involved in the engagement in healthier lifestyle. The present research aims to understand which psychological characteristics could be associated with unhealthy lifestyle change/maintenance among patients treated with statins.

Methods: 58 cardiopathic patients taking statins were enrolled. The assessment included both observer- (clinical and psychosomatic distress) and self-rated (lifestyle, subclinical distress, well-being) measures. Ad-hoc items were included to evaluate self-perceived lifestyle changes and awareness about statins' effect.

Results: Among patients, 55.4% did not change their lifestyle since taking statins and felt less contented ($F=5.25$, $p<0.05$), whereas 10.7% **were** unaware of the effect of these drugs. Unaware patients reported significantly lower well-being (positive relations [$F=4.44$, $p<0.05$]; purpose in life [$F=9.52$, $p<0.001$]). Minor depression was the most frequent diagnosis (8.9%). All the patients with minor depression were aware of statins' effect and did not modify their lifestyle ($\chi^2=4.42$, $p<0.05$).

Conclusion: A high percentage of patients did not report a modification of their unhealthy lifestyle. Minor depression appears to be strictly linked with this failure. Moreover, low psychological well-being is related to a lack of awareness about the effect of pharmacological therapy. Minor depression and psychological well-being impairments should be assessed in patients taking statins in order to recognize potential psychological risk factors associated with unhealthy behaviors' maintenance.

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Introduction

The American College of Cardiology's guidelines highlighted the importance of lifestyle modification in the treatment of hypercholesterolemia both before and during the use of lipid-lowering drugs (Booth et al., 2016). Few studies (Litsy, Burell & Westerling, 2012; Kaestner et al., 2014; Johal et al., 2017) showed that patients taking statins had healthier behaviors than those who did not use the same medications. On the contrary, current studies in the literature have shown that patients taking statins do not always modify their lifestyle (Sugiyama, Tsugawa, Tseng, Kobayashi & Shapiro, 2014; Savolainen, Kautiainen, Niskanen & Mantyselka, 2015; Panza et al., 2016). These studies did not consider psychological factors as moderators of change in unhealthy behaviors. Among these factors, depression is linked via neuroendocrine, neurobiological, autonomic systems and behavioral aspects to unhealthy lifestyle (Rafanelli, Sirri, Grandi & Fava, 2013; Pogosova, et al., 2015) and can significantly reduce commitment to lifestyle changes (Feng et al., 2017).

It is thus necessary to further investigate patients' lifestyle and how they can change it after they start taking statins. The aims of the present study are to evaluate 1) self-perceived changes in lifestyle among cardiopathic patients taking statins; 2) the relationship between self-perceived lifestyle modification and specific psychological variables; 3) the relationship between awareness of statins' consumption/cholesterol-lowering effect and specific psychological variables.

Method

Sample

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The sample was recruited at the Cardiac Rehabilitation division of Bellaria Hospital in Bologna, from September 2017 to May 2018. All the participants who joined the study gave their informed consent for the treatment of personal data. The inclusion criterion was the use of statins. 58 patients were recruited but 2 of them did not complete the assessment.

Assessment

Two items were created in order to detect 1) patients' self-perceived changes in lifestyle after they started taking statins (“*Have you changed your lifestyle at the beginning of statin therapy?*” with YES/NO response) and 2) their awareness of both statins therapy and their lowering effect on cholesterol levels (“*Are you aware of the consumption of statins? If yes, are you aware of their effect on lowering cholesterol levels?*”, both with YES/NO response).

Lifestyle. The GOSPEL questionnaire (Giannuzzi et al., 2008) was chosen in order to assess diet, behavioral aspects related to food consumption, physical activity, and stress management.

Clinical Distress. The Structured Clinical Interview for the Diagnostic and Statistical Manual of the Mental Disorders - 5th edition (First, Williams, Karg & Spitzer, 2015) was used to evaluate the presence of major depressive disorder and persistent depressive disorder. The assessment of minor depression, based on the diagnostic criteria described in the DSM-IV Appendix (APA, 2000), was also included since minor depression constitutes a potential risk factor for cardiac events (Rafanelli, Roncuzzi & Milaneschi, 2006; Rafanelli et al., 2009).

Subclinical Distress. The Symptom Questionnaire (SQ, Kellner, 1987) is a 92-item self-report measure to assess subclinical symptoms of depression, anxiety, hostility and somatization.

Psychological Well-Being. The Psychological Well-Being Scales (PWB, Ryff, 1989) are a self-rated instrument used to evaluate psychological well-being. It consists of 84 items divided into 6

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scales, which refer to the 6 dimensions of psychological well-being conceptualized by Ryff: self-acceptance, positive relationships, autonomy, environmental mastery, purpose in life and personal growth.

Allostatic overload. The Psychosocial Index (PSI, Sonino & Fava, 1998) is a questionnaire that allowed us to evaluate the presence of allostatic load (Fava, Guidi, Semprini, Tomba & Sonino, 2010).

Psychosomatic syndromes. The Structured Interview based on the revised version of the Diagnostic Criteria for Psychosomatic Research (DCPR, Fava, Cosci & Sonino, 2017) was used to investigate psychosomatic syndromes.

Statistical analyses

Results of the psychological interviews and the self-rated questionnaires were examined, respectively, as dichotomous or continuous variables. Comparisons between subgroups of patients' scores and diagnoses were carried out with two-tailed analysis of variance, by means of General Linear Model and χ^2 test, as appropriate. Data were analyzed using SPSS, version 20.0.

Results

55.4% of the patients reported that they did not change their lifestyle overall. Of the total sample, 10.7% **were** not aware of taking statins, whereas 83.9% **were** aware and knew the effect of these medications on lowering cholesterol's level, and 5.4% **were** aware but did not know the effect. By comparing self-perceived lifestyle modification and awareness of statins' intake, we found a significant difference within the sample ($\chi^2=8.64$, $p=0.013$): all the patients who were not aware of taking statins reported that they did not change their lifestyle overall (Table 2). Supporting the self-

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perception of general lifestyle's modification, Gospel questionnaire highlighted that patients who self-perceived to have modified their lifestyle attained higher scores on both "physical activity" (6.56 ± 0.55 versus 4.06 ± 0.50 ; $F=11.13$, $p=0.002$) and "Mediterranean diet" (18.84 ± 0.64 versus 16.74 ± 0.57 ; $F=5.88$, $p=0.019$) scales compared with those who did not refer the same lifestyle improvement (Table 3). In addition, we found a significant difference between self-perceived changes in lifestyle and **time since patients started to take** statins ($\chi^2=23.14$, $p<0.001$). Indeed, 45.2% of patients who did not modify their lifestyle had been taking statins for more than 5 years (Table 4).

Concerning psychological distress, patients who reported to have modified their lifestyle showed impaired levels of "contentment" ($F=5.25$, $p=0.026$), as assessed by SQ, compared to those who did not engage in lifestyle modification after starting statins' consumption (Table 3). The most frequent psychiatric diagnosis was minor depression (8.9%), followed by major depression (3.6%). All the patients affected by minor depression were aware of their pharmacotherapy, as well as its effect on cholesterol's reduction, and **reported** that they did not change their lifestyle since they had started taking statins ($\chi^2=4.42$, $p=0.035$) (Table 5). The same significant association was not found among patients with major depression ($\chi^2=0.025$, $p=0.877$).

Finally, the comparison between the variable "awareness versus unawareness" of statins' consumption/effects and PSI dimensions showed a significant difference regarding the level of psychological distress, with the "unaware" patients showing higher scores of distress (14.00 ± 2.22 versus 6.79 ± 0.79 , respectively; $p=0.004$) (Table 6). Concerning PWB dimensions, the scores revealed a significant difference **regarding** positive relationships ($F=4.44$, $p=0.016$) and purpose in life ($F=9.52$, $p<0.001$), with the "aware" patients showing significantly higher scores of psychological well-being (Table 6).

Discussion

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More than half of the participants reported that they had not changed their lifestyle (such as engaging in healthier diet and physical activity) since they started to take statins. The findings of the present research highlighted some differences between patients who reported a change in their lifestyle and those who did not. Patients who did not report an overall improvement of their lifestyle showed statistically lower mean scores of both physical activity and Mediterranean diet. 44.6% of the patients who referred not having modified their lifestyle affirmed that they had been taking statins for more than 5 years. As adherence to lifestyle recommendations tends to fall over time (McAleer et al., 2016), it is hypothesized that at the beginning of the pharmacotherapy people are more likely to adhere to a healthy lifestyle, whereas a prolonged intake (beyond 5 years) could be linked to a worsening in both lifestyle and compliance.

Within the whole sample, patients diagnosed with minor depression were all aware of taking statins and knew the effect of these medications on lowering cholesterol levels. However, they did not change their lifestyle since they started to take statins. It could be hypothesized that minor depression represents a risk factor for the missing compliance. In literature, some studies showed that minor depression constitutes a potential risk factor for cardiac events (Rafanelli, et al., 2006; Rafanelli et al., 2009) and that subclinical distress can be associated with a worse prognosis in cardiac patients (Gostoli, Roncuzzi, Urbinati & Rafanelli, 2017). In addition, the current study highlighted how the patients that had not changed their lifestyles were more prone to report less contentment-related symptoms (i.e. not feeling cheerful, happy, well, contented, enjoying themselves). On the same vein, as far as psychological well-being is concerned, we found that patients who were unaware of taking statins self-reported worse levels of “purpose in life” and “positive relations”. It seems that these psychological well-being dimensions play an important role in the awareness of drug therapy consumption.

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Limits of this research include its small sample size, cross-sectional design, the absence of a control group and the use of brief self-report measures only, which however represent the most suitable assessment method in busy clinical settings. Despite these, the present study is the first investigating self-perceived changes in lifestyle and the awareness on pharmacotherapy in a sample of patients taking statins, evaluating their relationship with specific psychological characteristics found to be risk factors for cardiac outcomes (Rafanelli et al. 2006; Rafanelli et al., 2009). In conclusion, our findings show that lifestyle remains essentially unchanged for many patients after they started to take statins, with some of them even being unaware of their consumption. Since minor depression could be linked to the maintenance of a risky lifestyle by means of bi-directional relationships (Pinto-Pereira, Geoffroy & Power, 2014), the inclusion of this psychological condition in the assessment of cardiac patients appears to be relevant.

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Table 1

Socio-demographic and clinical variables of the sample

	N(%)	Mean± SD
Age		69.3 ± 8.63
Gender		
Male	40 (69%)	
Female	18 (31%)	
Weight (kg)		77.74 ± 15.44
Height (cm)		169.07 ± 8.75
Cardiovascular risk factors		
Diabetes	15 (26.3%)	
Previous habit of smoking	28 (50.9%)	
Hypercholesterolemia	29 (52.7%)	
Hypertension	40 (72.7%)	
Dyslipidemia	11 (20%)	
Familiarity	15 (27.3%)	
Obesity	12 (21.8%)	
Smoker	5 (9.1%)	
Glucose intolerance	3 (5.6%)	
Medical procedure		
Bypass-aortocoronary surgery	26 (45.6%)	
Aortic valve replacement	19 (34.5%)	
Mitral valve replacement	6 (10.9%)	
Stent implant	8 (14.5%)	
Cardiac insufficiency	1 (1.8%)	
Anterior pericardiectomy	1 (1.8%)	
Aortic dissection	1 (1.8%)	
Angina pectoris	1 (1.8%)	
Mitraclip	1 (1.8%)	
Atrial flutter	1 (1.8%)	
Statins' consumption time		
Not aware of taking statins	7 (12.5%)	
1 day < x < 1 month	6 (10.7%)	
1 month < x < 6 months	9 (16.1%)	
6 months < x < 1 year	4 (7.1%)	
1 year < x < 5 years	11 (19.6%)	
x > 5 years	19 (33.9%)	
Self-perceived changes in lifestyle		
No	31 (55.4%)	
Yes	25 (44.6%)	
Awareness of taking statins and their effect		
Not aware of taking statins	6 (10.7%)	
Aware of taking statins but not of their effect	3 (5.4%)	
Aware of taking statins and their effect	47 (83.9%)	
DSM		

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Major depression	2 (3.6%)
Minor depression	5 (8.9%)
Persistent depressive disorder	-
Diagnostic Criteria for Psychosomatic Research	
Type A behavior	4 (8.7%)
Illness denial	3 (8.8%)
Demoralization	4 (8.7%)
Irritable mood	3 (6.5%)
Alexithymia	-
Statins	
Atorvastatin	38 (66.7%)
Simvastatin	14 (24.6%)
Rosuvastatin	5 (8.8%)
Pravastatin	1 (1.8%)

Table 2

Comparison between the awareness of taking statins and their effect and self-perceived changes in lifestyle

	Unaware	Aware of taking statins but not of their effect	Aware of taking statins and their effect	χ^2	p
Self-perceived changes in lifestyle	N(%)	N(%)	N(%)	8.648	0.013
Yes	0	3(100%)	22(46.8%)		
No	6(100%)	0	25(53.2%)		

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Table 3

Differences on mean scores of self-rated questionnaires (Gospel Questionnaire, Symptom Questionnaire, Psychological Well-Being scale and Psychosocial Index) between patients who self-reported a change in lifestyle and those who did not.

	Self-perceived changes in lifestyle		F	p
	Yes	No		
Gospel Questionnaire	Mean ± SD	Mean ± SD		
Physical activity	6.56 ± 0.556	4.06 ± 0.500	11.133	0.002
Mediterranean diet	18.84 ± 0.664	16.74 ± 0.578	5.882	0.019
Behavioural aspects related to food consumption	5.96 ± 2.477	5.80 ± 1.990	0.065	0.800
Total diet	24.88 ± 0.919	22.64 ± 0.825	3.275	0.076
Stress management	13.70 ± 3.522	12.73 ± 2.876	1.199	0.279
Symptom Questionnaire				
Anxiety	3.78 ± 0.988	4.79 ± 0.88	0.579	0.450
anxiety symptoms	2.68 ± 0.740	3.61 ± 0.664	0.880	0.352
relaxation	1.10 ± 0.306	1.17 ± 0.275	0.035	0.851
Depression	3.68 ± 0.773	4.98 ± 0.69	1.575	0.215
depressive symptoms	2.40 ± 0.577	2.59 ± 0.519	0.064	0.801
contentment	1.28 ± 0.359	2.39 ± 0.323	5.252	0.026
Somatization	8.30 ± 0.860	7.78 ± 0.958	0.167	0.684
somatic symptoms	4.42 ± 0.734	4.46 ± 0.659	0.002	0.962
somatic well-being	3.36 ± 0.365	3.84 ± 0.328	0.952	0.334
Hostility	3.67 ± 0.679	3.20 ± 0.756	0.221	0.640
anger-hostility symptoms	1.96 ± 0.675	2.71 ± 0.606	0.683	0.412
friendliness	1.24 ± 0.192	0.97 ± 0.17	1.118	0.295
Psychological Well-Being scale				
Autonomy	36.34 ± 0.964	35.00 ± 0.866	1.070	0.306
Environmental mastery	33.88 ± 1.222	34.13 ± 1.097	0.023	0.880
Personal growth	35.52 ± 1.075	31.71 ± 0.966	1.569	0.216
Positive relationships	35.22 ± 1.052	35.95 ± 0.944	0.268	0.607
Purpose in life	30.72 ± 1.250	28.84 ± 1.122	1.254	0.268
Self-acceptance	33.66 ± 1.137	32.29 ± 1.021	0.804	0.374
Psychosocial Index				
Psychological distress	8.04 ± 5.950	8.10 ± 6.048	0.001	0.973
Abnormal illness behavior	0.87 ± 1.359	0.57 ± 1.135	0.781	0.381
Stress	1.74 ± 1.514	1.87 ± 1.167	0.120	0.730

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Well-being	7.30 ± 1.663	7.60 ± 1.329	0.518	0.475
Global well-being	5.96 ± 1.147	5.87 ± 0.973	0.095	0.759

Table 4

Comparison between the periods since statins' consumption started and self-perceived changes in lifestyle.

Statins' consumption time	Self-perceived changes in lifestyle		x ²	p
	Yes N(%)	No N(%)		
Not aware of taking statins	0(0%)	7(22.6%)	23.149	<0.001
1 day < x < 1 month	6(24%)	0(0%)		
1 month < x < 6 months	8(32%)	1(3.2%)		
6 months < x < 1 year	2(8%)	1(3.2%)		
1 year < x < 5 years	4(16%)	7(22.6%)		
x > 5 years	5(20%)	14(45.2%)		

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Table 5

Prevalence of DSM diagnoses and psychosomatic syndromes between patients who reported a change in lifestyle and those who did not

	Self-perceived changes in lifestyle		x ²	p.
	Yes	No		
DSM	N(%)	N(%)		
Major depression	1(4.0%)	1(3.2%)	0.025	0.877
Persistent depressive disorder	-	-		
Minor depression	0	5(16.1%)	4.428	0.035
DCPR				
Illness denial	0	3(14.3%)	2.037	0.154
Type A Behavior	1(5.3%)	3(11.1%)	0.480	0.488
Irritable mood	1(5.3%)	2(7.4%)	0.084	0.772
Demoralization	2(10.5%)	2(7.4%)	0.137	0.712
Alexithymia	-	-		
Allostatic overload	6(24%)	5(16.1%)	0.543	0.461

Note: DSM, Diagnostic and Statistical Manual for Mental Disorders; DCPR, Diagnostic Criteria for Psychosomatic Research.

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Table 6

Differences on mean scores of self-rated questionnaires (Gospel Questionnaire, Symptom Questionnaire, Psychological Well-Being scale and Psychosocial Index) between patients who are aware of taking statins and their effect, patients who are aware of taking them but do not know their effect, and patients who are unaware of taking statins.

	Awareness of taking statins and their effect			F	p
	Unaware	Aware of taking statins but not of their effect	Aware of taking statins and their effect		
Psychological Well-Being scales	Mean ± SD	Mean ± SD	Mean ± SD		
Autonomy	35.67 ± 2.005	35.33 ± 2.836	35.61 ± 0.717	0.005	0.995
Environmental mastery	30.33 ± 2.458	33.33 ± 3.477	34.53 ± 0.878	1.314	0.277
Personal growth	29.83 ± 2.185	29.33 ± 3.090	33.06 ± 0.781	1.530	0.226
Positive relationships	30.33 ± 2.010	33.33 ± 2.843	36.45 ± 0.718	4.444	0.016
Purpose in life	20.83 ± 2.235	27.00 ± 3.160	30.98 ± 0.798	9.520	>0.001
Self-acceptance	29.67 ± 2.292	36.33 ± 3.242	33.10 ± 0.819	1.584	0.215
Symptom Questionnaire					
Anxiety	6.60 ± 2.44	4.00 ± 3.15	4.34 ± 0.94	0.393	0.678
Depression	6.30 ± 1.89	4.33 ± 2.44	4.62 ± 0.724	0.366	0.696
Somatization	11.30 ± 2.25	8.33 ± 2.90	7.59 ± 0.863	1.190	0.315
Hostility	4.80 ± 1.85	3.00 ± 2.38	3.68 ± 0.708	0.217	0.806
Psychosocial Index					
Psychological distress	14.00 ± 2.229	11.67 ± 3.153	6.79 ± 0.797	5.427	0.004
Abnormal illness behavior	0.33 ± 0.499	-	0.79 ± 0.178	0.881	0.420
Stress	2.17 ± 0.530	1.00 ± 0.749	1.77 ± 0.189	0.809	0.451
Well-Being	7.50 ± 0.608	6.67 ± 0.860	7.57 ± 0.217	0.524	0.595
Global well-being	5.83 ± 0.439	5.67 ± 0.621	5.96 ± 0.157	0.129	0.879

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