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CLINICAL RESEARCH

Application in general practice of treatment guidelines for patients with dyslipidaemia: The RESPECT study

Application des recommandations françaises de la prise en charge des dyslipidémies en médecine générale : étude RESPECT

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Summary

Background. — Screening for and management of dyslipidaemia are crucial in primary and secondary prevention of cardiovascular disease. The impact on general practitioners (GP) of the 2005 French guidelines for hypercholesterolaemia has not been evaluated.

Aims. — To compare GP's estimation of cardiovascular risk with that from a theoretical calculation; to analyse the consequences of cardiovascular-risk estimation on the threshold of therapeutic intervention and the target low-density lipoprotein cholesterol (LDL-C) concentration; and to analyse patients' awareness of their hypercholesterolaemia.

Methods. — The RESPECT study was a transverse, multicentre, observational survey conducted between March 2006 and February 2007 by 1797 GP in France. Inclusion criteria were adults with primary hypercholesterolaemia who had not taken lipid-lowering drugs within the previous 6 months.

Results. — Of the 5627 patients included (60.9% men; mean age ± standard deviation 58.2 ± 11.0 years; body mass index 27.2 ± 4.1 kg/m²; mean total cholesterol 2.68 ± 0.37 g/L; LDL-C 1.79 ± 0.35 g/L), 1963 (36.2%) had at least three cardiovascular risk factors. GP identified a high cardiovascular risk level in 40.8%, moderate risk in 45.8% and low risk in 13.4% of

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patients. These compared with calculated rates of 48, 23 and 29%, respectively (κ concordance 59.4%). For most patients (98.2%), GP defined the therapeutic target based on LDL-C concentration. The target LDL-C was significantly different when cardiovascular risk was estimated by GP versus that calculated theoretically. The higher the estimated risk level, the greater the rate of introduction of lipid-lowering drugs and the shorter the time to the next GP visit. Most patients considered themselves to be well or rather well informed about their cholesterol concentration (91.3%), the causes (64.3%) and consequences of cholesterol-induced diseases (83.7%), and the difference between 'good' and 'bad' cholesterol (57%). Most (81.5%) patients were aware of the benefits of lipid-lowering drugs on cardiovascular disease prevention; 95.8% considered adequate diet and compliance with pharmacological treatment to be very important.

Conclusion. – Recent French guidelines for hypercholesterolaemia are used widely by GP in practice. They enable correct assessment of overall cardiovascular risk level, have an impact on the therapeutic threshold of intervention by physicians and improve patients' awareness of the relevance of cholesterol concentration.

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MOTS CLÉS

Dyslipidémie ;
Hypercholestérolémie ;
Pathologies
cardiovasculaires ;
Cholestérol ;
Facteur de risque ;
Recommandations ;
Médecine générale ;
Prévention primaire

Résumé Le dépistage et la prise en charge des dyslipidémies sont des éléments majeurs de la prévention primaire et secondaire cardiovasculaire (CV). L'impact des recommandations françaises de 2005 pour la prise en charge des hypercholestérolémies par les médecins généralistes (MG) n'a pas été évalué.

Objectif. – Comparer l'estimation du niveau de risque CV par les MG à celui calculé par une méthode mathématique ; analyser les conséquences de cette estimation sur les mesures thérapeutiques et le niveau de LDL-cholestérol cible ; analyser les connaissances des patients sur leur hypercholestérolémie.

Méthodes. – L'étude RESPECT est une étude multicentrique, transversale, observationnelle, menée de mars 2006 à février 2007 auprès de 1797 MG. Les critères d'inclusion principaux étaient des patients adultes ayant une hypercholestérolémie primaire et n'ayant pas reçu de traitement hypolipémiant durant les six mois précédents l'étude.

Résultats. – Cinq mille six cent vingt-sept patients (77% d'hommes, âge moyen : $58,2 \pm 11$ ans ; IMC : $27,2 \pm 4,1$ kg/m²) ont été inclus. Le cholestérol total était à $2,68 \pm 0,37$ g/L, le cholestérol LDL à $1,9 \pm 0,35$ g/L et 1963 (36,2%) patients avaient au moins trois facteurs de risque CV. Les MG ont identifié un haut niveau de risque CV chez 40,8%, un risque modéré chez 45,8% et un faible risque chez 13,4% patients. Les valeurs respectives en utilisant la méthode de calcul théorique était de 48, 23 et 29% (concordance kappa, 59,4%). Pour la majorité des patients (98,2%), les MG ont défini une cible thérapeutique basée sur le niveau de cholestérol LDL. La cible de cholestérol LDL était significativement différente quand le niveau de risque CV était estimé par le MG que lorsqu'il était calculé de manière théorique. Il y avait une corrélation étroite entre le niveau estimé de risque CV et la prescription d'un traitement hypolipémiant, ainsi que le temps séparant la première consultation de la seconde. La plupart des patients se considéraient comme bien ou assez bien informé sur leur niveau de cholestérol (91,3%), les causes (63,4%) et les conséquences des maladies induites par une hypercholestérolémie (83,7%) et la différence entre le « bon » et « mauvais » cholestérol (57,2%). Les patients étaient informés des bénéfices attendus d'un traitement hypolipémiant dans la prévention des maladies CV (81,5%). Ils considéraient le plus souvent qu'une diététique adaptée et une bonne compliance au traitement pharmacologique ont une importance majeure (95,8%).

Conclusion. – Les récentes recommandations françaises de la prise en charge des hypercholestérolémies sont largement appliquées par les MG dans leur pratique quotidienne. Ces recommandations permettent d'avoir une estimation correcte du niveau de risque CV global. Elles ont un impact sur le niveau d'intervention thérapeutique utilisée par les praticiens et améliorent les connaissances sur les pathologies liées aux hypercholestérolémies par les patients.

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Abbreviations

AFSSAPS	French Health Products Safety Agency
ANAES	National Agency of Health Accreditation and Evaluation
CHD	Coronary heart disease
GP	General practitioner
LDL-C	Low-density lipoprotein cholesterol

Background

Dyslipidaemia is a major cardiovascular risk factor for the development of CHD, cerebrovascular disease and peripheral arterial disease. Elevated cholesterol concentrations have been estimated to induce 56% of CHD and 18% of cerebrovascular disease events [1]. Large clinical trials have shown that reduction of cholesterol concentration is associated with a significant decrease in cardiovascular morbidity and mortality [2–5]. Lowering LDL-C slows atherosclerotic plaque development and reduces the risk of CHD [6]. It is critically important that patients with lipid disorders are identified and treated appropriately to reduce morbidity and mortality associated with hypercholesterolaemia.

Several national and international guidelines have been established to determine the levels of risk associated with the presence of cardiovascular risk factors and the actions necessary to reduce the global burden of atherosclerosis. A patient's lipid status often presents a subclinical and asymptomatic aspect of their cardiovascular risk level, such as elevated LDL-C, a well-known major modifiable risk factor. Accurate measurement of LDL-C is now considered the best marker for determining the threshold of therapeutic intervention and assessing the efficacy of lipid-lowering drugs.

In France, hypercholesterolaemia is present in 20–30% of adult patients and has been identified as a major public health issue [7]. In 2000, the ANAES edited its recommendations on screening and biological diagnosis procedures for dyslipidaemia in primary prevention [8]. A few months later, the AFSSAPS edited their recommendations for the management of dyslipidemia [9]. In 2005, the AFFSAPS recommendations were revised to help physicians, particularly GP, determine the therapeutic threshold and target LDL-C concentration [9]. These current guidelines simplified the rules of screening through a simple laboratory assessment of lipids in all adults and redefined the methods of cardiovascular-risk assessment.

The aim of the RESPECT (Application of the recent French guidelines for the management of dyslipidemia in general practice) study was to analyse the extent of implementation by French GP of the updated AFSSAPS recommendations for the assessment and treatment of dyslipidaemia. The first goal was to compare GP's estimate of cardiovascular risk with that from a theoretical calculation. The second goal was to analyse the consequences of such cardiovascular-risk estimation on the threshold of therapeutic intervention and target LDL-C concentration. The third goal was to analyse patients' awareness of their hypercholesterolaemia and the relevance of targeted therapy.

Methods

The RESPECT study was a transverse, multicentre, observational survey conducted from March 2006 to February 2007 by 1797 GP, each of whom included the first four patients who met the inclusion criteria. Inclusion criteria were adults (≥ 18 years) with primary hypercholesterolaemia, a fasting laboratory assessment taken within the previous 3 months, who had not received any lipid-lowering therapy in the previous 6 months and had visited their GP for any reason. This survey was strictly observational and did not require changes in GP's usual management decisions.

Data collection

Physicians completed a questionnaire for each patient that collected data on clinical and laboratory information, cardiovascular risk factors and medical history. Based on clinical and laboratory investigations, GP estimated each patient's cardiovascular risk level as being high, moderate or low, and then defined a therapeutic target for the LDL-C concentration. They decided whether a non-pharmacological approach and/or a medication for the hyperlipidaemia was useful.

The theoretical cardiovascular-risk level was determined according to the ANAES recommendations [10]: high-risk patients were defined as those with at least one personal history of cardiovascular disease (that is, CHD, cerebrovascular disease or peripheral arterial disease) or high-risk diabetes or a greater than 20% risk of a coronary event occurring in the next 10 years; moderate-risk patients were defined as the presence of two or more cardiovascular risk factors; all others were identified as low-risk patients. A family history of premature CHD was defined as a myocardial infarction or sudden death in a first-degree relative before the age of 55 years in men or 65 years in women.

Each patient completed a questionnaire that collected data on their sociodemographics and extent of knowledge about cholesterol-associated cardiovascular disorders, pharmacological and non-pharmacological treatment of hypercholesterolaemia and awareness of the importance of therapeutic compliance.

Statistical methods

Based on an expected 7% of patients with high cardiovascular risk [11], the number of patients needed in this group was estimated to be 554 to detect 10% of such individuals having a different therapeutic threshold compared with French guidelines. The total number of patients required to perform the study was estimated at 7914. Even though only 7069 patients were recruited into the study, the statistical power ($> 90\%$) of the sample size means that the final number of patients was satisfactory.

Descriptive statistics used for quantitative parameters were mean and standard deviation, median and range, and missing values. Those used for qualitative parameters were frequency and percentage. Concordance between the GP's estimate of cardiovascular risk and the theoretical calculation based on the ANAES method was evaluated using

weighted kappa (κ_w). To interpret the kappa ratings, the benchmarks suggested by Landis and Koch were used [12] (less than 0.8 representing almost perfect concordance; 0.6–0.8 good concordance; 0.4–0.6 moderate concordance; 0.2–0.4 fair concordance; 0–0.2 slight concordance; less than 0 poor concordance). All tests were bilateral with an α -risk equal to 0.05. Statistical analysis was performed using SAS® software, version 8.2 (SAS Institute Inc, Cary, NC, USA).

Results

A total of 1797 GP from all metropolitan areas in France participated in the RESPECT study. The GP's mean age was 50.5 ± 7.0 years (range 32–84) and 90% were men. The majority (63%) practised in towns with less than 20,000 inhabitants (36% in a town with less than 5000 inhabitants), 18% with 20,000 to 100,000, 6% with 100,000 to 200,000, 9% with 200,000 to two million, and 4% in the Paris area (less than two million).

Patient profile

Of the 7069 patients recruited, 1442 (20.4%) were excluded from the analysis due to major protocol deviations, including missing date of lipid assessment ($n=988$) or missing high-density lipoprotein cholesterol (HDL-C; $n=560$) and/or LDL-C ($n=261$) concentration. The main demographic and clinical baseline characteristics were not statistically different for excluded and included patients (data not shown).

The RESPECT study population comprised 5627 adults with hypercholesterolaemia. Their main clinical and laboratory characteristics are summarized in Table 1. Age was a cardiovascular risk factor for 77% of men (2596 out of 3391 were greater than 50 years) and for 55% of women (1195 out of 2177 were greater than 60 years). Laboratory assessment had been carried out within the past 28 ± 33 days (median 14 days), and included total cholesterol, LDL-C (calculated using the Friedewald formula when direct measurement was not available), HDL-C and triglyceride concentrations in 99% of cases and fasting glycaemia in 89%.

Estimate of cardiovascular risk

The distribution of the main cardiovascular risk factors is shown in Fig. 1. In this population of patients with primary hypercholesterolaemia, the most frequent cardiovascular risk factors were older age (68%), hypertension (55%, treated in 95%), current or recent smoking (40%), family history of premature CHD (36.5%), diabetes (19.5%, type 2 in 89%) and personal cardiovascular history (19%). HDL-C concentration (<0.40 g/L) was a cardiovascular risk factor for 15.2% of patients, while it was protective (≥ 0.60 g/L) for 31%. The distribution of cardiovascular risk factors showed that 1963 (36.2%) patients had at least three cardiovascular risk factors, 1547 (28.5%) had two cardiovascular risk factors and 1913 (35.3%) had one or no cardiovascular risk factors (1215 and 698, respectively). The 'no cardiovascular risk factor' feature was possible when HDL-C concentration was protective (that is, ≥ 0.60 g/L), enabling one cardiovascular risk

Table 1 Patients' main characteristics ($n=5627$).

Characteristic	n (%) or mean (S.D.)	n^a
Age, years	58.2 ± 11.0	5627
Men, n (%)	3391 (60.9)	5568
Men ≥ 50 years, n (%)	2596 (46.6)	5568
Women ≥ 60 years, n (%)	1195 (21.5)	
Weight, kg	78.0 ± 13.9	5602
Height, cm	169.0 ± 8.2	5579
Body mass index, kg/m^2	27.2 ± 4.1	5568
Systolic blood pressure, mmHg	137.1 ± 13.0	5513
Diastolic blood pressure, mmHg	80.3 ± 9.0	5509
Total cholesterol, g/L	2.68 ± 0.37	5570
LDL-C ^b , g/L	1.79 ± 0.35	5627
HDL-C, g/L	0.54 ± 0.17	5627
Triglycerides, g/L	1.63 ± 0.85	5504
Glycaemia, g/L	1.09 ± 0.30	4287
Patients with diabetes, n (%)	1089 (19.5)	5591
Glycosylated haemoglobin, n (%)	6.92 (1.29)	1088
Creatininemia, $\mu\text{M}/\text{L}$	85.5 ± 18.1	4187

HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; S.D.: standard deviation.

^a Number of patients with available data.

^b Calculated using the Friedewald formula when direct measurement was not available.

factor to be subtracted from the total number of risk factors.

Kappa concordance between cardiovascular-risk level estimated by the GP and that calculated theoretically was 59.4% ($\kappa_w = 0.471$). High and moderate risk levels were well estimated, with 69.0 and 68.9% concordance rates, respectively (Table 2). Conversely, patients with a low calculated risk level were correctly estimated in only 550 out of 1544

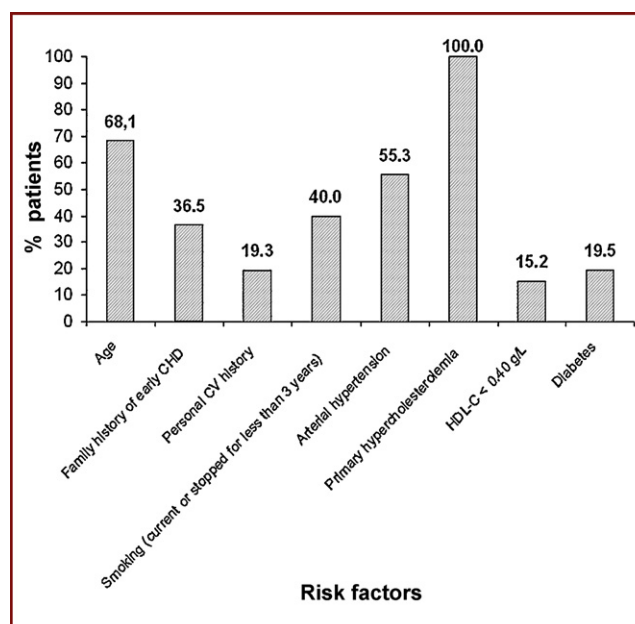


Figure 1. Distribution of the main cardiovascular risk factors.

Table 2 Concordance between GP estimate of cardiovascular risk and theoretical risk.

Theoretical risk	Total	GP estimate of risk		
		Low	Moderate <i>n</i> (%)	High
Low	1544	55 (35.6)	853 (55.2)	141 (9.1)
Moderate	1248	96 (7.7)	860 (68.9)	292 (23.4)
High	2603	64 (2.5)	744 (28.6)	179 (69.0)
Overall population	5395	71 (13.2)	245 (45.5)	222 (41.3)

GP: general practitioner.

(35.6%) patients. Investigators frequently overestimated the cardiovascular risk level in this group, as they considered 55.2% of patients to have a moderate cardiovascular risk level, or even to be at high risk in 9.1% of patients.

Target LDL-C and therapeutic management

For most (98.2%) patients, GP defined the therapeutic target based on the LDL-C concentration, that is, less than 1.60 g/L for 22.9% patients, less than 1.30 g/L for 35.2% and less than 1.00 g/L for 32.6% (Table 3). The target LDL-C concentration was different when the cardiovascular risk was estimated by the GP and then calculated. For example, 95.3% of GP-estimated high-risk patients had a LDL-C target less than 1.30 g/L versus 87.8% when calculated using the ANAES method.

GP started lipid-lowering medications in 5158 out of 5627 (91.7%) patients. Use of these therapies rose with increasing estimated cardiovascular risk, being prescribed in 98.5% of

high-risk, 93.5% of moderate-risk patients and 78.2% of low-risk patients. Statins were prescribed in 5045 out of 5158 (97.8%) patients; the rate increased to 98.7% in patients with a high estimated cardiovascular risk.

GP planned a control visit within 3 months of the initial visit in 74% of patients. The higher the estimated cardiovascular risk, the shorter the time to the next visit: 1–3 months for 74.3% of patients estimated at low risk, 86.2% at moderate risk and 92.5% at high risk. Of the high-risk patients, 17.3% were scheduled to have an even earlier control visit, within 1 month. Overall, 88.7% of all patients, and 90.8% of those who had been prescribed cholesterol-lowering treatment, had previously received lifestyle recommendations within the past 9 ± 13 months. These recommendations were given by either the GP (89.6%) or a dietician (1.3%) or both (5.6%). A laboratory control test was planned over the next 1–3 months in 93.7% of patients (that is, 90.5% of patients at high risk versus 75.6% of those at low risk).

Patient's perception of hypercholesterolaemia

Data from the patient self-questionnaire showed that the patient's LDL-C concentration was frequently reported to them by their GP (89.1%). Although only 53.6% of patients could remember this figure, the majority (89.1%) had memorized the target LDL-C concentration.

A high cholesterol concentration was considered to be a cardiovascular risk factor by 65.2% of patients, as a disease by 26.2% and as an insignificant laboratory abnormality by 9.4%. Most patients considered themselves to be either well or rather well informed about their cholesterol concentration (91.3%), about the causes (64.3%) and the consequences of cholesterol-induced diseases (83.7%), and the difference between 'good' and 'bad' cholesterol (57.2%).

Over four-fifths (81.5%) of patients were aware of the benefits of lipid-lowering treatment on CHD prevention, and most (95.8%) considered adequate diet and compliance with pharmacological treatment to be very important. Some patients thought that lowering cholesterol would lead to weight loss (12.9%), enable eating without restriction (9.7%) or provide no benefits (0.3%). In fact, 80.9% had previously been given dietary advice, although 59.5% considered it difficult to adhere to dietary rules. The self-questionnaire highlighted poor knowledge concerning the duration of drug therapy, although 95.8% of patients were aware of the

Table 3 Therapeutic target for LDL-C concentration according to level of cardiovascular risk.

	GP estimate of risk		
	Low <i>n</i> (%)	Moderate	High
LDL-C (g/L)	<i>n</i> = 684	<i>n</i> = 2457	<i>n</i> = 2232
< 2.20	88 (12.9)	27 (1.1)	6 (0.3)
< 1.90	190 (27.8)	168 (6.8)	18 (0.8)
< 1.60	270 (39.5)	873 (35.5)	81 (3.6)
< 1.30	127 (18.6)	1206 (49.1)	557 (25.0)
< 1.00	9 (1.3)	183 (7.4)	1570 (70.3)
	Theoretical cardiovascular risk		
	Low ^a	Moderate ^b <i>n</i> (%)	High
LDL-C (g/L)	<i>n</i> = 1493	<i>n</i> = 1240	<i>n</i> = 2592
< 2.20	101 (6.8)	9 (0.7)	9 (0.3)
< 1.90	296 (19.8)	37 (3.0)	41 (1.6)
< 1.60	525 (35.2)	415 (33.5)	266 (10.3)
< 1.30	478 (32.0)	634 (51.1)	758 (29.2)
< 1.00	93 (6.2)	145 (11.7)	1518 (58.6)

LDL-C: low-density lipoprotein cholesterol.
^a Zero or one cardiovascular factor.
^b Two or greater or equal to three cardiovascular risk factors.

importance of complying with the therapy prescribed by their GP.

Discussion

The aim of the RESPECT study was to describe the current care of hypercholesterolaemic patients by French primary care physicians. Estimating a patient's risk of cardiovascular events is of major importance, particularly in the field of hypercholesterolaemia where most algorithm guidelines are based on individualized risk. In the present study, moderate and high levels of cardiovascular risk were estimated accurately, but GP overestimated risk in those at low risk. While this approach might lead to better follow-up and closer management, it could also result in unnecessary healthcare expenditure. The level of cardiovascular risk also influences the threshold for therapeutic intervention. The data from the present study suggest that GP were more likely to treat hypercholesterolaemia aggressively when they perceived that patients were at higher risk. In France, many studies have reported the undertreatment of high-risk and the overtreatment of low-risk dyslipidaemic patients [7,13]. The present survey confirms the widespread use of statins for initiating cholesterol-lowering pharmacological therapy, in line with AFSSAPS guidelines, although they were started later than recommended (at a mean of 9 months after giving lifestyle advice versus within 3 months as recommended in guidelines).

The target LDL-C compared with the cardiovascular risk level estimated by GP, and showed that patients at high cardiovascular risk were better screened, given a more appropriate target LDL-C concentration and a closer follow-up schedule than low-risk patients. Compared with a previous survey assessing adherence in primary care to the NCEP ATP II guidelines [14] or the recent PRAGMA study [15], these results showed an improvement in determining patients' overall risk. This finding highlights the need for simple scales of cardiovascular risk factors and therapeutic decision-making in order to facilitate determination of a patient's therapeutic threshold and target LDL-C.

The higher the estimated cardiovascular risk, the greater was the rate of prescription of lipid-lowering therapy, most of which were statins. Large clinical studies [16–18] have demonstrated the clinical efficacy of a dramatic reduction in LDL-C in patients at moderate or high risk. Recently, the Study of Practice versus Objectives of Treatment (SPOT) study showed that cardiovascular prevention with lipid-lowering drugs, used according to the AFSSAPS guidelines, has improved in France. In primary prevention and in low-risk patients, the recommended objectives were achieved in 95% of cases; conversely, patients at high risk were less likely to achieve them [7]. In the EUROASPIRE study, which concerned secondary prevention of CAD [19], major benefits were obtained with the widespread use of practice guidelines. Some difficulties were encountered, however, in maintaining sufficient compliance with these recommendations by physicians and patients [20]. A French study (Paris Cardiovascular Risk Factor Prevention Trial) highlighted the threat of failure to implement guidelines [21], mainly in the moderate-risk population. Conversely, the intervention had a favourable effect in high-risk patients.

Numerous guidelines (AFSSAPS, NCEP) have been published [9,10,22], identifying elevated LDL-C as the primary target of cholesterol-lowering therapy. North American, European and French guidelines have highlighted the need to integrate screening and management of the moderate-risk population in daily general practice [6,8,9,22].

In the present study, patients were aware of the benefits of lipid-lowering treatment on CHD prevention, with most believing that adequate diet and compliance with pharmacological treatment was of great importance. These data suggest that awareness has improved recently in both physicians and patients, when compared with the results of an earlier study conducted in France and Northern Ireland [23]. This awareness needs to be increased further, through reinforcement of physicians' skills and availability of information on cholesterol dosage and hypercholesterolaemia. Patient compliance is essential in order to reach and maintain the recommended therapeutic targets for their particular level of cardiovascular risk [24].

Study limitations

This was a transverse observational study, which, by its nature, did not take into account patient follow-up; management and control of cardiovascular risk factors is a long process from which cardiovascular benefit can be assessed only after a long interval. Further observational trials conducted over a longer period may confirm the positive trend towards this major public health objective.

Conclusions

Recent French guidelines for the management of hypercholesterolaemia are used widely by GP in daily practice. These guidelines have an impact on the therapeutic threshold of intervention used by GP, and increase patients' awareness of the importance of cholesterol concentrations. Screening and management of adult patients with hypercholesterolaemia appears to be widely in line with revised AFSSAPS guidelines. Ongoing educational efforts targeting both physicians and patients are warranted, particularly for high-risk patients who could be treated more aggressively, whereas low-risk patients are often misclassified by risk overestimation.

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