

Standards of statin usage in Poland in high-risk patients: 3ST-POL study results

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Abstract

Background: According to epidemiological studies, dyslipidaemia is the commonest risk factor of atherosclerosis in the Polish population. It is estimated that 18 million adult Poles are affected by dyslipidaemia.

Aim: The purpose of this study was to evaluate the quality of the statin therapy in high-risk Polish outpatients.

Methods: The 3ST-POL study involved 49,950 Polish outpatients. The enrolled patients met the following inclusion criteria: age between 40 and 85 years and a history of a minimum three months of statin therapy. A full lipid profile was screened in each patient; 72% of all subjects were high-risk patients.

Results: Among the patients in the 3ST-POL study, women represented 53%, and the mean age was 59.5 ± 10.8 years. Patients were treated by: general practitioners (GPs) 78.95%; diabetologists 5.02%; and cardiologists 16.03%. The most frequently used statins were atorvastatin and simvastatin. The most common dose was 20 mg/24 h. In the high-risk population, the lowest recommended total cholesterol (TC) concentration was achieved in 3.7% of treated subjects, whereas 5.6% of patients attained LDL < 80 mg/dL (2.0 mmol/L). 9.5% of patients did not exceed the upper limit of normal values for TC (155–175 mg/dL; 4.0–4.5 mmol/L) and 12.6% of patients reached LDL between 80–100 mg/dL (2.0–2.5 mmol/L). Subjects under the cardiologists' and diabetologists' care more often reached the recommended TC concentration (TC < 175 mg/dL; TC < 4.5 mmol/dL) and the difference was statistically important.

Conclusions: This partial efficacy in dyslipidaemia control is not satisfactory.

Key words: hypercholesterolaemia, statin, pharmacotherapy

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INTRODUCTION

Today, one in four deaths in high-income countries and one in ten deaths in low-income countries is caused by a cardiovascular disease. According to WHO (World Health Organisation) estimates [1], vascular events account for 11% of deaths in developing countries and 24.3% in developed countries. This makes cardiovascular diseases the leading cause of deaths in Europe, followed by different types of cancer. Major epidemiological studies demonstrate that dyslipidaemia is the commonest risk factor in the development of cardiovascular diseases in the population of Poland. According to the WOBASZ [2, 3], NATPOL PLUS [4] and NATPOL 2011 studies,

approximately 18 million Polish people have dyslipidaemia. Hypertension is the second leading, though less widespread, risk factor, found in around 9 million subjects.

The ESC (European Society of Cardiology)/EAS (European Atherosclerosis Society) guidelines of 2007 [5] and 2011 [6] stress the importance of reaching the defined levels of main cholesterol fractions, with a particular focus on achieving the target plasma low density lipoproteins (LDL) concentrations.

Over recent decades, hypolipaeamic treatment has been revolutionised by the introduction of statins which are a safe and inexpensive class of medication. However, American and European studies, which will be discussed in the applicable

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part of this paper, have shown that an insufficient proportion of patients treated with statins reach the recommended treatment targets for LDL and total cholesterol (TC).

The 3ST-POL study was designed to assess the extent to which Polish ambulatory patients treated with statins reach the target levels of particular cholesterol fractions [7].

The purpose of the study was to evaluate the quality of the statin therapy in high-risk Polish outpatients.

METHODS

3ST-POL is a cross-sectional cohort study conducted between June 2007 and June 2008 on a population of Polish ambulatory patients in different regions of Poland. The study included 49,950 patients who came for a routine check-up visit with their primary care doctor, cardiologist or diabetologist. Participants were included in the study if they met all of the following criteria: (1) patient's consent; (2) age between 40 and 85 years; and (3) statin therapy for more than three months.

Patients were excluded from the study if they did not meet any of the above criteria. The co-existence of other conditions and/or therapy with medications other than statins did not exclude patients from the study.

The visits consisted of taking the patients' medical history, a clinical examination, and a full lipid profile test. In order to prevent differences between readings from different laboratories, the tests were conducted in local laboratories. Based on these data and the patient's medical history, the doctor filled in questionnaires to be read by an optical character recognition scanner. Questionnaires were then scanned and the data was entered into a database.

The treatment targets set out by the ESC in 2007, endorsed by the Polish Cardiac Society and then applicable, were used as a measure of the efficacy of hypolipaeamic treatment. The patients were also assessed according to the SCORE — fatal cardiovascular event risk estimation system [8].

The final analysis educed high-risk patients out of the overall population of the 3ST-POL study. Patients qualified to the high-risk group had confirmed ischaemic heart disease and/or type 2 diabetes or SCORE ≥ 5 . Furthermore, patients with diagnosed peripheral vascular disease and a history of stroke and/or transient ischaemic attacks were also included in the high-risk patients group.

Patients' characteristics

The 3ST-POL study population consisted of 53% women, 47% men, and the patients' mean age was 59.5 ± 10.3 years. Almost half of the population suffered from coronary artery disease, one in five patients had a history of myocardial infarction (MI) and one third of patients had diabetes mellitus type 2 [7]. Subpopulations treated by specialists (cardiologists and diabetologists) had been far more burdened (Table 1). High risk patients accounted for almost 72% of all patients.

Statistical analysis

The data gathered in the course of the study is presented by means of standard descriptive statistics: means and standard deviations, medians and quartiles for continuous data and frequency tables for discrete data.

The achievement of lipid profile levels consistent with the applicable ESC guidelines of 2007 was the defining point of effective treatment.

A multi-factor logit model was used for the analysis of the relationship between chosen factors and the occurrence of the analysed event. The tiered approach with 0.1 level was used, with statistically significant factors chosen at the level of 0.05. Due to a small group of patients who reached more restrictive limits of the levels of both TC and LDL, a multi-factor logit model was performed for those who reached LDL < 100 mg/dL (2.5 mmol/L) and TC < 175 mg/dL (4.5 mmol/L).

The correlation between significant factors and the occurrence of the analysed event was expressed via odds ratio (OR) and 95% confidence interval (CI).

The Hosmer-Lemeshow test was used for the assessment of goodness of fit for the models. The non-significant result of this test should be interpreted as correct calibration of the models.

The diagnostic value of the models was assessed by means of the area under curve (ROC). The diagnostic value of the model is to be understood as the model's ability to correctly identify the observation and, what follows, the event. The AUC value stands between 0.5 and 1. For a model of high diagnostic value, AUC approaches a value of 1. For a model of no diagnostic value, AUC approaches a value of 0.5.

A significance level of 0.05 was adopted for analysis, which was conducted using Stata v10 software (Stata Statistical Software, Release 10, Stata Corporation, College Station, TX, USA).

RESULTS

Statin treatment

The most commonly administered statin was atorvastatin (49%), followed by simvastatin (44.8%). Other statins were used to a marginal extent. The most commonly prescribed dosage was 20 mg for both most popular statins. Dyslipidaemia was diagnosed more than 12 months prior to the study in the majority of patients, with the treatment having started at least three months prior to the study. Treatment combining statins and fibrates was administered to 18% of patients (Table 2).

Achievement of treatment targets in high-risk patients

In high-risk patients (Table 3), mean TC (245.4 mg/dL) and LDL-C (142.9 mg/dL) concentrations were significantly lower than mean TC (252.4 mg/dL; $p < 0.01$) and LDL-C (147.8 mg/dL; $p < 0.01$) concentrations in low-risk patients.

The largest proportion of subjects with appropriate TC levels was found in patients treated by diabetologists. The group of patients treated by cardiologists had significantly

Table 1. Co-morbid diseases (TIA/stroke, atherosclerosis, MI and SCORE > 5; with regard to specialisation of attending physicians

	Overall	GP	Cardiologist	Diabetologist
Ischaemic heart disease:				
N	47,556 (100%)	36,942 (100%)	7,537 (100%)	2,308 (100%)
Yes	22,234 (46.8%)	15,748 (42.6%)	4,987 (66.2%)	1,111 (48.1%)
History of MI:				
N	45,780 (100%)	35,554 (100%)	7,305 (100%)	2,195 (100%)
Yes	9,231 (20.16%)	5,802 (16.32%)	2,821 (38.62%)	439 (20%)
Stroke or TIA:				
N	45,392 (100%)	35,346 (100%)	7,152 (100%)	2,170 (100%)
Yes	4,475 (9.9%)	3,309 (9.4%)	839 (11.7%)	235 (10.8%)
Peripheral vascular disease:				
N	46,419 (100%)	36,131 (100%)	7,297 (100%)	2,244 (100%)
Yes	9,191 (19.8%)	7,095 (19.6%)	1,336 (18.3%)	610 (27.2%)
Type 2 diabetes mellitus:				
N	46,804 (100%)	36,327 (100%)	7,334 (100%)	2,400 (100%)
Yes	15,382 (32.9%)	10,763 (29.6%)	2,399 (32.7%)	1,984 (82.7%)
Co-morbid diseases:				
N	42,226 (100%)	32,874 (100%)	6,691 (100%)	2,022 (100%)
Yes	28,566 (67.7%)	20,792 (63.3%)	5,480 (81.9%)	1,865 (92.2%)
High SCORE risk > 5:				
N	26,441	20,453	4,282	1,246
Yes	10,311 (39%)	7,798 (38.1%)	1,866 (43.6%)	467 (37.5%)
Burden of CVD:				
			p < 0.01	
N	46,921 (100%)	36,468 (100%)	7,647 (100%)	2,038 (100%)
Yes	33,773 (72%)	26,884 (73.7%)	6,777 (88.6%)	1,898 (93.1%)

Arrows show comparison of the burden of CVD subpopulation treated respectively by GPs vs cardiologists and diabetologists; GP — general practitioner; TIA — transient ischaemic attack; MI — myocardial infarction; CVD — cardiovascular diseases

Table 2. Hypercholesterolaemia duration and duration of statin treatment

	Time from hypercholesterolaemia diagnosis (%)	Time from the start of statin treatment (%)
Last 6 months	13.8	24.6
6–12 months	18.1	19.4
1–3 years	25.6	23.6
3–5 years	19.2	17.4
Over 5 years	23.4	15.0

better controlled TC and LDL-C levels compared to patients treated by primary care doctors ($p < 0.05$). TC levels were best controlled in patients under the care of specialist doctors. As far as LDL-C was concerned, the group with the best treatment results was the one treated by cardiologists ($p < 0.001$).

A low proportion of high-risk patients were found to meet the strict 2007 ESC recommendations for cholesterol levels (TC < 155 mg/dL; TC < 4 mmol/L and LDL < 80 mg/dL; LDL < 2.0 mmol/L). As regards TC, the lowest recommended concentrations were reached by one in 25 patients, and LDL-C of < 80 mg/dL (2.0 mmol/L) was found in one in 20 subjects. Less than 10% of patients had TC concentrations close to the upper limit of the norm (155–175 mg/dL; 4.0–4.5 mmol/L), and one in eight reached LDL-C levels in the 80–100 mg/dL (2.0–2.5 mmol/L) range.

It is worth highlighting the fact that the mean atorvastatin and simvastatin doses did not differ significantly between the group of patients that reached the treatment targets and the group with elevated levels of TC and LDL-C. This constitutes evidence for the occurrence of clinical inertia.

Out of all specialists, cardiologists administered statistically higher doses of both atorvastatin and simvastatin compared to primary care doctors ($p < 0.05$) in the group

Table 3. Percentage of correctly controlled patients and applied statin dosages in high-risk patient population, divided according to specialisations of attending physicians

	Number of patients (% of overall population)	Mean cholesterol level	Number of patients in the correctly and incorrectly controlled group				Mean atorvastatin dosages [mg/24 h]				Mean simvastatin dosages [mg/24 h]				
			Overall	GP	Cardiologist	Diabetologist	Overall	GP	Cardiologist	Diabetologist	Overall	GP	Cardiologist	Diabetologist	
Total cholesterol	33,707	245.4	≥ 175 mg/dL				21.0	20.7	22.2	21.9	24.5	24.3	25.6	22.4	
			30,520	23,141	5,454	1,925									
			90.5%	91.8%	87.2%	86.2%									
			155–175 mg/dL				21.6	20.9	24.1	22.2	21.6	22.8	26.7	23.5	
			1,954	1,308	454.0	192.0									
			5.8%	5.2%	7.3%	8.6%									
LDL	2,2603	142.9	≥ 100 mg/dL				21.3	20.8	22.8	22.4	24.4	24.3	25.1	22.7	
			2,1229	1,5956	3,965	1,308									
			87.2%	88.66%	83.81%	81.50%									
			80–100 mg/dL				20.8	20.7	20.6	21.6	24.4	23.8	26.7	21.5	
			1,729	1,107	443	179									
			7.1%	6.2%	9.4%	11.2%									
			< 80 mg/dL				21.5	21.5	22.1	20.3	24.1	23.4	25.9	21.1	
			1,374	933	323	118									
			5.6%	5.2%	6.8%	7.4%									

GP — general practitioner

reaching normal TC levels. This correlated with significantly higher treatment efficacy.

High-risk patients under the care of cardiologists and diabetologists significantly more often reached the recommended TC concentration (TC < 175 mg/dL; 4.5 mmol/L); a similar correlation was observed in patients under statin-fibrate combination therapy, in patients who never smoked, and patients with correct waist circumference (Table 4). In the analysed group, a negative relation between education and desired levels of TC concentration was noticed.

Cardiologists were more effective than primary care doctors as regards attaining LDL levels < 100 mg/dL (2.5 mmol/L) in burdened patients (Table 5). The abovementioned objectives were significantly more often achieved in patients over 65 years of age, when compared to patients between 40 and 50 years of age. Smoking had a negative influence on the efficacy of hypolipaeic treatment. In the case of LDL < 100 mg/dL (2.5 mmol/L), low or average physical activity vs. no physical activity brought about a negative influence.

DISCUSSION

In the last ten years, intensive research has been performed in order to assess the efficacy of ambulatory hypolipaeic pharmacotherapy. In 2003–2004, such an assessment was completed in the population of Great Britain [9] based on a retrospective analysis of general practice research database. Almost 18,500 patients, both high-risk and low-risk, were covered by a year-long follow-up. After the one-year-long hypolipaeic treatment, in 34.7% of patients the treatment objectives for TC were not achieved; for LDL that figure was 27.4%. In the high-risk population alone, the values stood correspondingly at 27.2% and 21.6%. In the 3ST-POL study, in the burdened population, the recommended TC concentrations were achieved in 9.5% of the population and LDL concentrations in 12.5%. The difference between Polish and British populations as regards efficacy of treatment for therapeutic objectives for LDL and TC exceeds the level of 50%.

At the same time, the DETECT study was being conducted in Germany on more than 55,500 patients [10]. In the analysed population, and according to the then appli-

Table 4. Factors influencing the attainment of total cholesterol < 175 mg/dL in the high-risk patient population

	Odds ratio	95% CI	P
Cardiologist vs. GP	2.05	(1.707; 2.453)	< 0.001
Diabetologist vs. GP	1.66	(1.168; 2.355)	0.005
Statin and fibrate combination therapy	1.21	(1.036; 1.423)	0.016
Vocational vs. primary education	0.74	(0.580; 0.948)	0.017
Secondary vs. primary education	0.63	(0.496; 0.796)	< 0.001
Higher vs. primary education	0.74	(0.559; 0.968)	0.028
Smoking now vs. never smoked	0.44	(0.354; 0.553)	< 0.001
Smoked in the past vs. never smoked			> 0.1
Alcohol consumption vs. abstinence	0.85	(0.723; 0.993)	0.041
Waist circumference above norm*	0.83	(0.707; 0.986)	0.033

CI — confidence interval; GP — general practitioner; Factors: sex, age, body mass index, diet**, physical activity** were also incorporated in the model — $p > 0.1$; *desirable waist circumference for European men > 94 cm; women > 80 cm; **declarative data — patient's estimation

cable standards, LDL-C concentrations correctly controlled by pharmacotherapy were noted in 11.1% of cases. In the subsequent years, the German results of the DYSIS study were published [11], showing a 33.4% efficacy in achieving recommended therapeutic objectives for TC and 41.9% efficacy as regards LDL. When comparing the German DYSIS results to the abovementioned DETECT study, it is worth noting a major improvement in efficacy of hypolipaeamic treatment in patients undergoing the more recent therapy. Furthermore, higher efficacy was also observed in the Dutch results of DYSIS. In the Netherlands, the LDL plasma concentration level recommended by the ESC (2007) was not achieved in 33.3% of patients and TC concentration level in 35% of patients. The patients included in DYSIS were at the same time more often achieving their therapeutic objectives, both for TC and LDL, compared to the 3ST-POL study population.

In the Polish population, no tendency similar to the German one forming over the years has been observed. The Polish study POLKARD SPOK [12] was conducted between 2003 and 2005. In the high cardiac risk patients, the study shows 9.9% efficacy in achieving recommended concentration of TC and 11.61% of LDL. This is a small divergence from the later 3ST-POL study.

The low efficacy of hypolipaeamic treatment noted in the 3ST-POL study may be contested in the light of one of the

Table 5. Factors influencing the attainment of LDL cholesterol < 100 mg/dL in the high-risk patient population

	Odds ratio	95% CI	P
Cardiologist vs. GP	1.58	(1.324; 1.882)	< 0.001
Diabetologist vs. GP			> 0.1
Age: 50–55 vs. 40–50 years			> 0.1
Age: 55–60 vs. 40–50 years			> 0.1
Age: 60–65 vs. 40–50 years			> 0.1
Age: > 65 vs. 40–50 years	1.17	(0.997; 1.378)	0.054
Smoking now vs. never smoked	0.64	(0.530; 0.772)	< 0.001
Smoked in the past vs. never smoked			> 0.1
Physical activity low vs. none**	0.74	(0.558; 0.971)	0.030
Physical activity average vs. none**	0.76	(0.577; 1.002)	0.052
Physical activity high vs. none**			> 0.1

Factors: statin-fibrate combination therapy vs. statin therapy, sex, education, body mass index, alcohol consumption vs. abstinence, waist circumference above norm*, diet** were also incorporated in the model — $p > 0.1$; CI — confidence interval; GP — general practitioner; *desirable waist circumference for European men > 94 cm; women > 80 cm; **declarative data — patient's estimation

most extensive and multicentre research projects conducted on the European population — EUROASPIRE III [13]. This research was performed between 2006 and 2007 on the population of 22 European countries, including Poland. In patients undergoing pharmacotherapy, the recommended TC concentration was achieved in 70.8%. The lowest efficacy of the treatment occurred in the Lithuanian population (27.3%) and the highest in the Finnish population (75.3%). Results in the Polish arm of EUROASPIRE III thus present high European levels of efficacy of hypolipaeamic treatment. These results must be therefore analysed with regard to the fact that the study was conducted in a select population controlled by renowned clinical centres. When comparing results of the EUROASPIRE study to high-risk patients of the 3ST-POL study, a significant difference may be noticed. In the author's study, in the high-risk patients, almost 10% efficacy was achieved for therapeutic objectives regarding TC.

One of the many possible explanations for the low efficacy in attaining therapeutic objectives in the Polish ambulatory patients' population might be the fact that statins were applied in suboptimal doses [14]. However, this would not account for such significant differences between Poland and other European countries. Another reason for therapeutic failure may be the lack of patient adherence to the statin

therapy. As the Finnish [15] study shows, adherence to the statin therapy is a dynamic process and may change randomly over time. The discussed cohort study shows that almost 50% of patients discontinued statin treatment for at least six months within ten years of follow-up. Furthermore, only 52% of patients had a period of six years or more with a proper adherence to the therapy (proportion of days covered ≥ 0.80). Even though there is no data describing Polish outpatients' adherence to the statin therapy, it can be supposed that the adherence is similar.

The problem of insufficient statin treatment is not only limited to improper treatment of outpatients [16]. According to the results of the British study, statin prescription is often overlooked in secondary care. Despite indications, more than 30% of patients discharged from hospital were not prescribed a statin. It is vital to be aware of all advantages that may be gained by aggressive statin therapy, to improve quality of inpatient and outpatient treatment. This is necessary to decrease atherosclerotic events and reduce the need for coronary interventions.

Limitations of the study

For the proper interpretation of the research results, both limitations resulting from methodology as well as from respondent-dependent factors must be discussed.

The study was limited due to its questionnaire nature, i.e. some of the data obtained must be regarded as declarative.

Both patients and doctors participating in the study were chosen randomly.

The 3ST-POL study covered patients who asked for a routine check-up at primary care doctors, cardiologists and diabetologists. Therefore, the study does not cover patients with already diagnosed dyslipidaemia, patients who do not undergo routine check-ups, or patients with dyslipidaemia which is not yet diagnosed. The presented results are an 'impression' of how therapeutic objectives are achieved via statin treatment, in the population of patients motivated to treatment.

The results concerning applied pharmacotherapy may be overestimated because they present the state of pharmacotherapy as recommended by the attending physicians. The study did not consider the percentage of prescriptions purchased or recommendations followed.

The behavioural treatment results were based on the medical inquiry. Patients' actual lifestyle may differ from the one they presented to their attending physician.

A significant percentage of the female population of the study was in the pre-menopausal age group. The 3ST-POL study did not take into consideration hormone-dependent lipid concentration fluctuations.

The 3ST-POL study project did not include follow-up. Hence there was no possibility of long-term observation or modification of diagnostics and therapy.

The study was undertaken before the widespread use of a statin new to the Polish market — rosuvastatin, so the present data of efficacy of hypolipaeamic treatment in Poland might be underestimated nowadays.

CONCLUSIONS

An analysis of the 3ST-POL study against the last ten years of research in Europe suggests much lower efficacy of statin treatment. In patients treated with hypolipaeamic preparations, efficacy in achieving therapeutic objectives for TC and LDL was similar to the efficacy of obtainable European research. The 50% level reached was a considerable divergence from the efficacy shown in the Polish population. This partial efficacy in dyslipidaemia control is not fully satisfactory.

Conflict of interest: Krka, Poland partly granted the study.

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Standardy stosowania statyn w Polsce u pacjentów wysokiego ryzyka na tle wyników badania 3ST-POL

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Streszczenie

Wstęp: Według badań epidemiologicznych dyslipidemia jest najczęściej występującym czynnikiem ryzyka choroby niedokrwiennej serca w polskiej populacji. Szacuje się, że na dyslipidemię choruje 18 mln dorosłych Polaków.

Cel: Celem pracy była ocena jakości leczenia statynami w populacji polskich pacjentów leczonych ambulatoryjnie.

Metody: Badanie 3 ST-POL objęło 49 950 osób leczonych ambulatoryjnie. Pacjenci włączeni do badania spełniali następujące kryteria: wiek 40–85 lat i minimum 3 miesiące leczenia statynami. U wszystkich chorych wykonano pełny lipidogram. 72% badanej populacji to pacjenci z grupy wysokiego ryzyka.

Wyniki: W populacji badania kobiety stanowiły 53%; średni wiek wynosił $59,5 \pm 10,8$ roku. Pacjenci byli objęci opieką: lekarzy POZ — 78,95%, diabetologów — 5,02%, kardiologów — 16,03%. Najczęściej stosowanymi statynami były atorwastatyna i simwastatyna, a najczęściej stosowaną dawką statyny — 20 mg/24 h. W populacji pacjentów wysokiego ryzyka zalecane stężenia cholesterolu całkowitego (TC) osiągnięto u 3,7% badanych, 5,6% pacjentów osiągało stężenia LDL < 80 mg/dl (2,0 mmol/l). Wartość TC u 9,5% osób mieściła się w przedziale 155–175 mg/dl (4,0–4,5 mmol/l), a 12,6% pacjentów osiągało LDL w przedziale 80–100 mg/dl (2,0–2,5 mmol/l). Chorzy pod opieką lekarzy specjalistów istotnie statystycznie częściej osiągnęli zalecane stężenia TC (< 175 mg/dl; < 4,5 mmol/dl).

Wnioski: Osiągnięcie celów terapeutycznych w zakresie leczenia dyslipidemii jest niewystarczające.

Słowa kluczowe: dyslipidemia, statyny, farmakoterapia

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