High monthly temperature as a possible risk factor of local vascular bleeding complications during percutaneous coronary interventions evaluated by ultrasonography – retrospective analysis

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Abstract

Background: Bleeding complications are a very important issue in the era of percutaneous coronary interventions (PCI). Effective antiplatelet therapy increases the rate of successful interventions but the risk of bleeding complications, among them local vascular complications, may be higher. Other factors may also be important in the development of local bleeding complications.

Aim: To examine the relationship between air temperature and local haemorrhagic complications.

Methods: The retrospective analysis of ultrasonographic examinations performed during the last 5 years (2003-2007) in 10 548 consecutive patients undergoing cardiac catheterisation due to acute coronary syndromes or elective coronary angiography was performed. The relationship between mean monthly temperature, other factors and the rate of local bleeding complications was examined.

Results: Mean number of treated patients was 2708 ± 377/year (2113-3089), of whom 1692 ± 362/year had coronary angiography and 1345 ± 281/year had PCI. Yearly rate of all femoral bleeding complications was 3.0 ± 0.5%. There were more haematomas than pseudoaneurysms: 2.2 ± 0.4 vs. 0.8 ± 0.1%, $p < 0.0001$. Higher mean monthly air temperatures were positively correlated with the number of complications ($r = 0.11$, $p < 0.05$), both in males and females ($r = 0.13$, $p < 0.05$). A positive correlation between number of haematomas and air temperature values was detected in women. Yearly rate of all vascular complications, haematomas and pseudoaneurysms was higher in women than in men 4.3 ± 0.9 vs. 2.3 ± 0.3% ($p < 0.0001$), 3.0 ± 0.7 vs. 1.7 ± 0.3% ($p < 0.0001$) and 1.3 ± 0.2 vs. 0.6 ± 0.1% ($p < 0.0005$) respectively. In spite of more aggressive antiplatelet therapy, higher clopidogrel loading doses and abciximab use introduced during the analysed period, the rate of local vascular bleeding complications did not increase.

Conclusions: High air temperature during the post-intervention period, besides female gender and advanced age, may be another risk factor for local bleeding complications. This risk remains low (3%), in spite of growing intensity of antiplatelet treatment.

Key words: coronary angiogram, percutaneous coronary interventions, local bleeding complications, retrospective analysis

Kardiol Pol 2009; 67: 753-759

Introduction

Rapid progress of interventional cardiology and a tendency for optimisation of treatment effects with the use of new antiplatelet and antithrombotic drugs have increased the efficacy of percutaneous coronary interventions (PCI). On the other hand, reduction of ischaemic complications and a tendency for maximal flow restoration in coronary arteries may result in an increase of local and systemic bleeding events. Their occurrence worsens prognosis, increases the length of hospitalisation and generates additional costs. Local bleeding complications are painful, less prone to rehabilitation, increase the risk of pulmonary embolism and require detailed diagnostic work-up before introduction of optimal treatment. Frequency of bleeding complications is estimated at 0.1-6.1% depending on the definition, type of procedure, antiplatelet or antithrombotic drugs used, the use of artery puncture closure devices, patients' age,

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Received: 10 September 2008. **Accepted:** 01 April 2009.

sex or concomitant diseases [1]. Our own clinical observations suggest a higher frequency of those complications in times of high air temperature, which encouraged us to assess the possible role of summer hot spells as an additional risk factor of local bleeding events.

The aim of the study was to analyse the effects of high air temperature and other risk factors on the frequency of local bleeding events after elective or urgent coronary angiography and/or PCI using femoral access.

Methods

This retrospective analysis included patients who underwent coronary angiography and/or PCI and ultrasonography of the site of puncture between 2003 and 2007. All catheterisation procedures were carried out in the cath lab and all ultrasonography examinations in the echo lab. Coronary angiography was performed using the Judkins technique with femoral artery puncture and 6 F vascular sheath [2]. The vascular sheath was removed immediately after the completion of coronary angiography and followed by manual pressure application on the artery above the puncture site for at least 10 min. After restoration of haemostasis patients received a compression dressing for 2 hours and were immobilised for 12 h. Patients undergoing PCI were given unfractionated heparin (70-100 IU/kg of body weight) or low-molecular-weight heparin (from January 2006) at the dose of 1 mg/kg of body weight. All patients referred for PCI received two antiplatelet drugs: aspirin and thienopyridine derivative. Ticlopidine was used more often than clopidogrel until December 2006. From September 2003 patients with acute coronary syndromes (ACS) selected for PCI received a 300 mg loading dose of clopidogrel, and from December 2005 – a 600 mg dose.

The number of clinically important complications at the artery puncture site was assessed. Important local bleeding complications were defined as the presence of lividity at the puncture site area which required ultrasonographic examination for the presence of pseudoaneurysm. Colour Doppler ultrasonography examinations of the puncture site to assess the flow in the femoral artery were performed with the SONOS 5500 with 7.5 MHz H-P head and registered on video. The frequency of complications was compared in monthly and yearly intervals. Risk factors of these complications were sought with respect to the type of the procedure: PCI or coronary angiography.

Mean monthly temperatures were analysed on the basis of the clinical observation that the number of complications was higher during summer temperature highs. Because of the retrospective character of the study and the long duration of the analysis (5 years) mean monthly temperatures were based on the data from the Institute of Meteorology and Water Management (IMGW) [3]. Climatic conditions in Poland causing variations in the frequency of summer hot spells caused difficulties in standardisation. Based on the analysis of temperature distribution during the 5 years of the study and to obtain objective measurements the temperature threshold was set at 18°C. The catheterisation theatre, where all examinations were performed, was equipped with an air conditioner, however removal of the vascular sheath and application of pressure took place in the cardiological surveillance rooms and patient rooms which were not air conditioned. In these places the temperature was higher and dependant on the external conditions. During the study period all catheterisations were performed by a constant team of 5 operators each with more than 15 years of experience.

Statistical analysis

Statistical analysis was performed with the SAS 8.2 package. Results are presented as means and standard deviations. Student's t-test or Mann-Whitney rank sum test was used to compare the differences between means, where appropriate. Correlations between the registered temperature and the frequency of complications were analysed by the calculation of Pearson's correlation coefficient. Statistical significance was set at alpha ≤ 0.05. To assess the relationship between air temperature and the frequency of local bleeding complications a discrimination coefficient was calculated (R2). The determination coefficient is the square of the correlation coefficient and shows what percentage of variability in haematoma number (factor y) can be attributed to the variability in air temperature (factor x).

Results

Between 2003 and 2007 coronary angiography and/or PCI were performed in 10 548 patients, in 99.9% using femoral access, with a mean of 2708 ± 377 procedures per year (range 2113-3089). Mean number of coronary angiographies was 1692 ± 362 per year and PCIs 1345 ± 281 per year. Local bleeding complications were diagnosed in 3.0 ± 0.5% of patients. A higher mean monthly temperature was significantly associated with the number of complications, haematomas and pseudoaneurysms (adjusted for the number of admitted patients): determination coefficient $R^2 = 0.11$ ($p < 0.05$) (Figure 1). A significant correlation was also found between the frequency of local bleeding complications and the number of admitted patients and temperature values both in men and women: determination coefficient $R^2 = 0.13$ ($p < 0.05$) (Figure 2). A positive correlation between the frequency of haematomas and air temperature was confirmed in women (Table I), but not in men. There was no relationship between the frequency of pseudoaneurysms and temperature values in either men or women (Table I).

High air temperature increased the risk of local bleeding complications by about 15% as calculated by

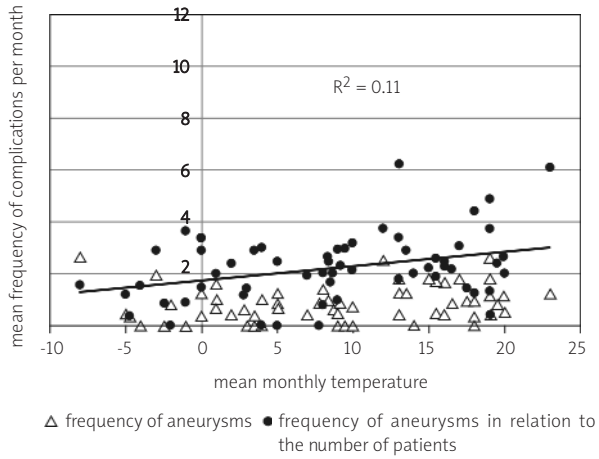

Figure 1. Correlation between the frequency of both types of complications, haematomas and pseudoaneurysms, and air temperature (number of complications adjusted for the number of admitted patients)

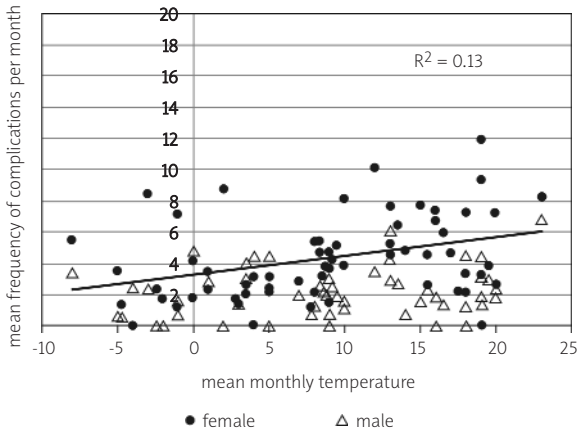

Figure 2. Correlation between the frequency of local bleeding complications (adjusted for the number of admitted patients) and air temperature in men and women

the determination coefficient. Obese or older patients were not more often admitted during the summer season (Figure 3). There was no difference in baseline characteristics of patients throughout the year or months. The same puncture technique was used for winter and summer months. Introduction of a standard 600 mg loading dose of clopidogrel for patients with ACS in 2005 did not influence the frequency of local bleeding complications. The frequency of abciximab administration in patients with ST-elevation myocardial infarction (STEMI) increased from 33% in 2003 to 42% in 2007 without apparent increase in the number of complications (NS) (Figure 4, Table II).

There were more haematomas of the groin than pseudoaneurysms of the femoral artery, respectively 2.22 ± 0.4 and 0.8 ± 0.1% of patients ($p < 0.0001$), both in women (3.0 ± 0.7 vs. 1.3 ± 0.2%, $p < 0.0001$) and in men (1.7 ± 0.3 vs. 0.6 ± 0.1%, $p < 0.0001$). Yearly frequency of all local vascular complications, haematomas and pseudoaneurysms was higher in women than in men, respectively 4.3 ± 0.9 vs. 2.3 ± 0.3% ($p < 0.0001$), 3.0 ± 0.7 vs. 1.7 ± 0.3% ($p < 0.0001$) and 1.3 ± 0.2 vs. 0.6 ± 0.1% ($p < 0.0005$) (Table III).

Women with haematomas were older than men, respectively: 67.3 ± 0.9 vs. 61.5 ± 1.0 years ($p < 0.0001$). Patients with pseudoaneurysms were also older: 67.3 ± 1.0 vs. 64.4 ± 0.7 years ($p = 0.023$). In women there was no significant age difference in the occurrence of pseudoaneurysms in relation to haematomas and in comparison to men with the same complications (NS) (Table IV).

Table I. Correlations between mean air temperature and local complications, age or BMI

Parameter	Male	Female	Both
Haematomas	0.12 (NS)	0.38 (p = 0.0017)	0.34 (p = 0.006)
Aneurysms	0.17 (NS)	0.08 (NS)	0.18 (NS)
All complications	0.18 (NS)	0.35 (p = 0.0038)	0.34 (p = 0.051)
Age	0.01 (NS)	0.06 (NS)	0.05 (NS)
BMI	0.11 (NS)	–0.01 (NS)	0.05 (NS)

Results are presented as correlation coefficients with p-value in brackets

Table II. Frequency of local bleeding complications in periods of lower (2003-2005) and higher (2006-2007) intensity of antiplatelet treatment

	All/year/no. of patients	Haematomas/year/no. of patients	Aneurysms/year/no. of patients
2003-2005	3.2 ± 0.6%	2.3 ± 0.5%	0.9 ± 0.1%
2006-2007	2.9 ± 0.4%	2.1 ± 0.3%	0.8 ± 0.2%

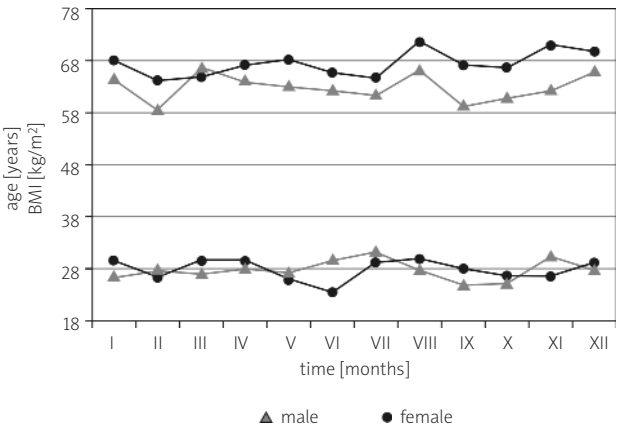

Figure 3. Mean age (in years) and body mass index (BMI, kg/m^2) of patients referred for diagnostic and therapeutic percutaneous procedures in respective months according to gender

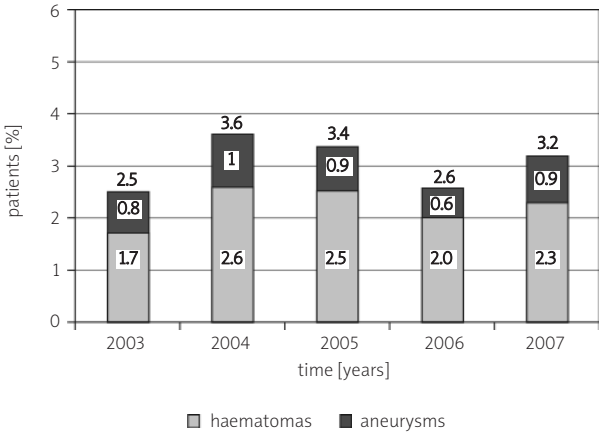

Figure 4. Frequency of local bleeding complications (haematomas and aneurysms) in respective years, with inclusion of periods of changes in antiplatelet treatment (2003-2005 vs. 2006-2007, NS)

In the analysed period there was one case of retroperitoneal bleeding (the patient underwent surgery) and no arteriovenous fistulas.

Discussion

The analysed group of patients had angiographic studies and procedures performed using femoral access. This technique increases the risk of local bleeding complications: haematomas, pseudoaneurysms and less frequently arteriovenous fistulas or retroperitoneal bleeding. Transradial procedures were performed in our centre only in the case of femoral access failure. According to data from various centres the frequency of bleeding complications after angioplasty procedures was 0.8 to 6.6% even before the era of intensive antiplatelet treatment [4-10]. The frequency of local bleeding complications at the level of 3.1 ± 0.5% of all diagnostic and therapeutic studies requiring femoral artery puncture seems to be low taking into account the dynamic progress in interventional cardiology and development of methods aimed at optimisation of coronary interventions.

Identified risk factors of the aforementioned complications were divided into procedure-dependent and patient-dependent. Procedure-dependent risk factors included vascular sheath diameter, puncture site or the type and intensity of antiplatelet and antithrombotic treatment [11]. Duration of puncture site compression was considered as one of the major risk factors by some authors [12]. Patient-dependent factors included advanced age, peripheral artery disease, hypertension and obesity [13-15]. Some studies suggested an increased risk of complications in women [6, 13, 15, 16]. Anatomical abnormalities may also predispose to bleeding. It has been postulated that a puncture site located too high or

Table III. Cumulative mean number of complications per year and frequency of complications per month in relation to the number of patients

Group	All	Haematomas	Aneurysms	p (haematomas vs. aneurysms)
Mean number of complications per year				
All [%]	83.2 ± 18.3	60.0 ± 13.0	23.2 ± 5.9	0.0006
Female [%]	43.6 ± 12.0	30.4 ± 8.7	13.2 ± 3.6	0.0024
Male [%]	39.6 ± 7.7	29.6 ± 5.1	10.0 ± 3.4	0.0004
Frequency of complications (no. of complications per month/no. of patients admitted per month)				
All [%]	3.0 ± 0.5	2.2 ± 0.4	0.8 ± 0.1	< 0.0001
Female [%]	4.3 ± 0.9	3.0 ± 0.7	1.3 ± 0.2	< 0.0001
Male [%]	2.3 ± 0.3	1.7 ± 0.3	0.6 ± 0.1	< 0.0001
p	< 0.0001	< 0.0001	< 0.0005	-

administration of compressive dressing below the puncture site may facilitate the occurrence of pseudoaneurysms of the femoral artery.

There was a correlation between the frequency of local bleeding complications and high air temperature, especially during summer hot spells. At the same time there was no excess of admissions of obese or older patients during summer months. There was no difference in relation to baseline characteristics of patients throughout the year or consecutive months. The same puncture technique was used in summer and winter months. For that reason we assumed that all these factors did not play a role in the development of bleeding complications. Therefore, the relation between factors which might have been considered as confounding and the analysed factor is very unlikely.

Which possible factors predispose to the occurrence of those complications in the analysed periods? They may include the inability to obtain a stable body position after the procedure, excessive sweating and the potential influence of high temperature on blood haemostasis. These may explain the relation between high air temperature and the frequency of superficial haematomas but not pseudoaneurysms. Fast onset of haematoma naturally prevents the development of femoral artery pseudoaneurysm. More frequent occurrence of haematomas in women may be related to higher amount of fat tissue in the thighs, predisposing to this complication. Higher air temperature and immobilisation lead to distention of the vascular bed and blood congestion at the peripheries.

An important factor leading to decrease of bleeding from the injured artery is its contraction. At the same time, it is known that high air temperature results in relaxation of the vascular bed, which can transport up to 8 litres of blood per minute. It is caused by a reduction of the peripheral resistance and an increase of blood flow through the peripheral arteries in response to strong stimulation of sympathetic activity, which increases blood flow in the skin vasculature [17]. Superficial body temperature similar to internal temperature leads to an increase of blood flow through the femoral artery [18]. It may be speculated that these phenomena impair the automatic contraction of vascular wall smooth muscle cells after removal of the vascular sheath and facilitate a flow increase through the relaxed iliac arteries. Artery compression used after removal of the vascular sheath causes accumulation of metabolites in the peripheral parts of the extremity and reactive congestion, which is also related to vasodilatation and increased blood flow through the artery. Both processes counteract the automatic contraction of the injured femoral artery and may stimulate the extravasation of blood to the surrounding tissues. The influence of high air temperature was significant because of the southerly orientation of windows and the lack of air conditioning after the procedure. This analysis is limited by the short periods of heat characteristic for our climate, while the study was based on the mean monthly temperature. Correlations calculated for better defined and shorter periods of high temperature during summer hot spells might have been even higher in comparison to the monthly interval periods.

Table IV. Age of patients with local bleeding complications

	Haematomas	Aneurysms	p
All	64.4 ± 0.7	67.3 ± 1.0	0.0230
Male	61.5 ± 1.0	65.8 ± 1.6	0.0241
Female	67.3 ± 0.9	68.4 ± 1.3	NS
p	< 0.0001	NS	

It can be suspected that aggressive antiplatelet treatment (aspirin, loading doses of clopidogrel, abciximab) used in recent years together with antithrombotic treatment (unfractionated heparin, low-molecular-weight heparin) may facilitate the occurrence of those complications, especially haematomas and pseudoaneurysms. Our own observations do not support this hypothesis: introduction of 600 mg loading doses of clopidogrel as a standard of care in ACS in 2005 and increase of the number of procedures did not influence the frequency of local bleeding complications.

Study limitations

The study was limited by the fact that temperature assessment was based on objective, specialised measures of external air temperature. On one hand it is a limitation, but on the other hand the study parameters are objectively standardised, taking into account the fact that after the procedure patients were placed on different floors and in different rooms, such as the intensive care unit or general ward, where temperatures may be different but still higher. The presented analysis included the number and results of ultrasonography examinations. We have not analysed the efficacy of methods used for treatment of complications, such as physical activity limitation using local compression, direct, longer compression with means of the ultrasonographic beam, or, in the case of larger pseudoaneurysms and good anatomical conditions, USG-guided thrombin injection into the aneurysmal cavity. Another limitation of the study was its retrospective nature.

Conclusions

The frequency of local bleeding complications after cardiological interventional procedures using femoral access is relatively low and approximates 3%. High air temperature in the periprocedural period, together with older age and female gender, may be important risk factors of local complications. Intensification of antiplatelet treatment did not significantly influence their frequency.

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Wysoka temperatura otoczenia jako jeden z czynników ryzyka miejscowych powikłań krwotocznych badań koronarograficznych i zabiegów angioplastyki ocenianych ultrasonograficznie – analiza retrospektywna

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Streszczenie

Wstęp: Problem powikłań krwotocznych jest istotny w dobie licznych interwencji wieńcowych oraz stosowania coraz skuteczniejszych leków przeciwpłytkowych i przeciwzakrzepowych.

Cel: Ocena częstości występowania miejscowych powikłań badań koronarogarficznych i zabiegów angioplastyki wieńcowej: krwiaków i tętniaków rzekomych, oraz wpływu innych czynników na ryzyko ich wystąpienia.

Metody: Retrospektywną analizą objęto badania ultrasonograficzne wykonane w ciągu ostatnich 5 lat (2003–2007) u 10 548 chorych poddawanych interwencjom wieńcowym w trybie pilnym i planowym oraz badaniom koronarograficznym. Badania USG okolic miejsca wkłucia z oceną przepływu w tętnicy udowej metodą kolorowego doplera wykonywano aparatem SONOS 5500 z głowicą 7,5 MHz H-P. Analizowano średnie temperatury miesięczne powietrza wg danych IMiGW w związku z obserwacjami klinicznymi, że w okresach wysokich temperatur, w miesiącach letnich liczba powikłań była wyższa.

Wyniki: Średnia liczba hospitalizowanych pacjentów wynosiła 2708 ± 377 na rok (2113–3089), z tego u 1692 ± 362 wykonywano badanie koronarograficzne. Średnia liczba zabiegów angioplastyki wynosiła 1345 ± 281 na rok. Powikłania krwotoczne wystąpiły u 3,0 ± 0,5% chorych, więcej było krwiaków powłok uda niż tętniaków rzekomych: 2,2 ± 0,4 *vs* 0,8 ± 0,1%, $p < 0,0001$. Analiza średnich temperatur miesięcznych powietrza na podstawie danych IMiGW wykazała zależność liczby powikłań: krwiaków i tętniaków rzekomych, od wyższych średnich temperatur miesięcznych, współczynnik determinacji $R^2 = 0,11$ ($p < 0,05$). Wykazano także istnienie znamiennej korelacji między odsetkiem miejscowych powikłań naczyniowych a liczbą przyjętych pacjentów i wysokością temperatury zarówno u kobiet, jak i u mężczyzn, współczynnik determinacji $R^2 = 0,13$ ($p < 0,05$). Istnienie dodatniej korelacji między odsetkiem krwiaków a wysokością temperatury otoczenia stwierdzono u kobiet. Roczny odsetek wszystkich miejscowych powikłań naczyniowych, krwiaków i tętniaków rzekomych, był wyższy u kobiet niż u mężczyzn, odpowiednio: 4,3 ± 0,9 *vs* 2,3 ± 0,3% ($p < 0,0001$), 3,0 ± 0,7 *vs* 1,7 ± 0,3% ($p < 0,0001$) i 1,3 ± 0,2 *vs* 0,6 ± 0,1% ($p < 0,0005$). W analizowanym okresie liczba powikłań krwotocznych nie zwiększała się pomimo wzrostu intensywności terapii przeciwpłytkowej klopidogrelem i abciksimabem.

Wnioski: Wysoka temperatura otoczenia w okresie interwencji, obok zaawansowanego wieku i płci żeńskiej, może być istotnym czynnikiem ryzyka miejscowych powikłań. Częstość występowania miejscowych powikłań krwotocznych po kardiologicznych zabiegach interwencyjnych z dostępu od tętnicy udowej jest stosunkowo niska i wynosi średnio 3%. Intensyfikacja leczenia przeciwpłytkowego nie wpłynęła istotnie na wzrost ich liczby.

Słowa kluczowe: koronarografia, angioplastyka, miejscowe powikłania krwotoczne, analiza retrospektywna

Kardiol Pol 2009; 67: 753-759

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Praca wpłynęła: 10.09.2008. **Zaakceptowana do druku:** 01.04.2009.